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Subject: **81st Annual General Session of the OIE - May 2013**

Dear Director General,

Please find attached, for your informal information, annexes indicating the intended positions of the European Union (EU) on the reports of the Terrestrial and Aquatic Animal Health Standards Commissions to be raised and drafts proposed for adoption at the 81st General Session in May 2013 in Paris.

We take this opportunity to inform you that the EU supports the adoption of the draft revised chapters of the OIE *Terrestrial Manual* to be proposed for adoption in May.

We trust you will find this useful and we thank you for your continued cooperation.

Yours sincerely,

Dr Martin Blake Chief Veterinary Officer and OIE Delegate Ireland	Dr Bernard Van Goethem Director for Veterinary and International affairs European Commission, DG Health and Consumers

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Annexes: 2

Copy: All Directors / Chief Veterinary Officers of the EU 27 and Croatia, Iceland, Liechtenstein, Norway, Switzerland and Turkey.

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ANNEX 1

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February 2013

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

Paris, 19–28 February 2013

EU comments

The EU would like to commend the OIE for its work and thank in particular the Code Commission for having taken into consideration EU comments on the Terrestrial Code submitted previously.

A number of general comments on this report of the February 2013 meeting of the Code Commission as well as the intended positions of the EU on the draft Terrestrial Code chapters proposed for adoption at the 81st OIE General Session are inserted in the text below, while specific comments are inserted in the text to the respective annexes of the report.

The EU would like to stress again its continued commitment to participate in the work of the OIE and to offer all technical support needed by the Code Commission and its *ad hoc* groups for future work on the Terrestrial Code.

The OIE Terrestrial Animal Health Standards Commission (the Code Commission) met at the OIE Headquarters in Paris from 19 to 28 February 2013. The list of participants is attached as Annex I.

The Code Commission thanked the following Member Countries for providing written comments: Argentina, Australia, Canada, Chile, Chinese Taipei, the European Union (EU), Guatemala, Japan, Mexico, New Zealand, Norway, South Africa, Switzerland, Thailand and the United States of America (USA). Comments were also received from the Food and Agriculture Organization of the United Nations (FAO) and African Union – Interafrican Bureau for Animal Resources (AU-IBAR). In addition, the International Embryo Transfer Society (IETS), International Poultry Council (IPC) and the International Coalition for Farm Animal Welfare (ICFAW) submitted written comments.

The Code Commission reviewed comments that Member Countries had submitted by 18 January 2013 and amended texts in the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) where appropriate. The amendments are shown in the usual manner by 'double underline' and '~~strikethrough~~' and may be found in the Annexes to the report. The amendments made at the February 2013 meeting are highlighted with a coloured background in order to distinguish them from those made at the September 2012 meeting.

All Member Countries' comments were considered by the Code Commission. However, because of the very large volume of work, the Commission was not able to prepare a detailed explanation of the reasons for accepting or not every proposal received. Member Countries are reminded that if comments are resubmitted without modification or new justification, the Commission will not, as a rule, repeat previous explanations for decisions. The Commission encourages Member Countries to refer to previous reports when preparing comments on longstanding issues. The Commission also draws the attention of Member Countries to those instances where the Scientific Commission for Animal Diseases (the Scientific Commission) has addressed Member Countries' comments and proposed amendments

in several chapters. In such cases the rationale for such amendments are described in their report and the Code Commission encourages Member Countries to review this report together with the report of the Scientific Commission.

Member Countries should note that texts in Part A of this report are proposed for adoption at the 81st General Session in May 2013. Texts in Part B are presented for comment by Member Countries and all comments received will be addressed during the Commission's meeting in September 2013. The reports of meetings (Working Groups and *ad hoc* Groups) are also attached in Part B of this report for information.

The Commission strongly encourages Member Countries to participate in the development of the OIE's international standards by submitting comments on this report. Comments should be submitted as specific proposed text changes, supported by a scientific rationale. Proposed deletions should be indicated in '~~strikethrough~~' and proposed additions with 'double underline'. Member Countries should not use the automatic 'track-changes' function provided by word processing software as such changes are lost in the process of collating Member Countries' submissions into the Commission's working documents.

Comments on this report must reach OIE Headquarters by 16 August 2013 to be considered at the September 2013 meeting of the Code Commission. However, considering that Member Countries' comments on Chapters 7.5 and 7.6. (Annex XXXVI) as well as new draft chapter on animal welfare and dairy cattle production systems (Annex XXXVII) should be reviewed by the Working Group on Animal Welfare prior to the next Code Commission meeting, Member Countries are kindly requested to submit their comments on these chapters by 3 June 2013.

All comments should be sent to the OIE International Trade Department at: trade.dept@oie.int.

A. MEETING WITH THE DIRECTOR GENERAL

The Code Commission met Dr Bernard Vallat, the Director General of the OIE, on 25 February 2013 to discuss several key topics as follows. Dr Karim Ben Jebara (Head of OIE Animal Health Information Department) and Dr Manuel Sanchez (Deputy Head of OIE Animal Health Information Department) joined the discussion on point 3 below.

1. Coordination among Specialist Commissions

Dr Alejandro Thiermann (President of the Code Commission) noted that a Member Country had requested better coordination between Specialist Commissions to harmonise the use of terminology in the *Terrestrial Code* and the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *Terrestrial Manual*). He suggested this could be achieved by nominating a Commission responsible for initiating specific areas of work and inviting the other Commissions align with once adopted (see Part D Item 1). Dr Vallat agreed with the approach.

2. User's guide

Dr Thiermann commended Dr Etienne Bonbon's initiative in revising the current User's Guide of the *Terrestrial Code* with a view to clarify the role, scope and correct use of the *Terrestrial Code* as requested by Member Countries. He informed Dr Vallat that both the Scientific Commission and the Code Commission reviewed the revised User's Guide and it would be circulated for Member Country comments.

3. Notification of emerging diseases

Dr Ben Jebara explained that there was an urgent need to clarify the definition of 'emerging disease' and notification requirement for them. Thus an internal task force in the OIE Headquarters reviewed the definition of emerging disease in the Glossary and Chapter 1.1. of the *Terrestrial Code* and proposed revised texts to the Scientific Commission and the Code Commission for their consideration. While acknowledging the initiative of the task force to address this important issue, Dr Thiermann noted that both Commissions were of the view that this issue would need a careful consideration and undertook to discuss this issue jointly at the next meeting in September 2013.

Dr Ben Jebara also noted the difficulty in notifying OIE listed disease in wildlife due to the ambiguity of the case definition of some diseases. He suggested applying standard case definitions to all OIE listed diseases. Dr Thiermann replied that the notification obligations for domestic and wildlife species are based in the recommendations of each disease specific chapter. The wildlife issue would be progressively addressed jointly by the Scientific Commission and the Code Commission on a chapter by chapter basis, clarifying each case definition by including epidemiologically important species including wildlife. He highlighted that the Scientific Commission had already taken that approach in reviewing some disease chapters, including that for foot and mouth disease.

4. Review of the OIE listed diseases

Dr Thiermann noted that the Code Commission decided to propose to delist swine vesicular disease, vesicular stomatitis and infection with equid herpes virus 4 on the grounds that Member Countries had not based their opposition to the deletion of these diseases on the listing criteria in Chapter 1.2.

In light of the significant number of Member Countries' comments on the report of the *ad hoc* Group on Notification of Animal Diseases and Pathogenic Agents, the Code Commission suggested that the Director General convene an *ad hoc* group to re-examine the other diseases proposed for delisting using a structured, scientifically-rigorous method, and allow more time for experts to adequately review the relevant literature, apply the criteria of Article 1.2.2., and consistently document the justification for their recommendations.

5. Definition of 'veterinarian' in the Glossary

Dr Vallat noted the need to ensure sufficient education for a veterinarian to be considered suitably and asked the Code Commission the outcome of their consideration of a proposed revision of the definition of 'veterinarian'. Dr Thiermann explained that the Code Commission had revised the definition of 'veterinarian' to incorporate education factors while recognising that OIE's recommendations for 'Day 1 competencies' of veterinarians had been already referred to in Chapter 3.2. (Evaluation of Veterinary Services).

6. Foot and mouth disease

Dr Thiermann informed Dr Vallat that the Code Commission agreed with the total revision of the chapter made by the Scientific Commission and an *ad hoc* Group and decided to present it with additional changes for Member Countries' comment.

7. Disease specific chapters proposed for adoption

Dr Thiermann noted that with close collaboration between the Scientific Commission and the Code Commission, several important disease chapters had been updated in terms of both scientific content and clarity of text, and these are proposed for adoption in May 2013. Such chapters include classical swine fever, peste des petits ruminants, rabies and African horse sickness.

B. ADOPTION OF THE AGENDA

Adopted agenda of the meeting is attached as Annex II.

C. REPORT ON JOINT MEETING OF THE PRESIDENT OF THE CODE COMMISSION AND THE SCIENTIFIC COMMISSION (4th and 8th February)

The President and the Vice-president of the Code Commission met the Scientific Commission on 4th and 8th February to discuss various issues of mutual interest. The minutes of this joint meeting are attached as Annex III.

D. EXAMINATION OF MEMBER COUNTRY COMMENTS AND WORK OF RELEVANT EXPERT GROUPS

Item 1. General comments of OIE Member Countries

Comments were received from Canada, Chile, the EU, Japan, New Zealand, South Africa, African Union – Interafrican Bureau of Animal Resources (AU-IBAR).

A Member Country's comment on the need for better coordination between the OIE Specialist Commissions was noted. The need for harmonised use of terminology (host species taxonomy, 'index screening test') in the *Terrestrial Code* and *Terrestrial Manual* were referred to the Biological Standards Commission (the Laboratories Commission).

In addition, the Code Commission suggested that OIE should nominate a Commission responsible for initiating specific categories of work and invite the other Commissions to align with it once adopted by the OIE Member Countries. The Commission proposed as follows:

- Scientific Commission for Animal Diseases (the Scientific Commission): scientific information (e.g. taxonomy, new scientific evidence for certain animal diseases)

- Terrestrial Animal Health Standards Commission (the Code Commission): case definitions, trade related recommendations for terrestrial animals
- Biological standards Commission (the Laboratories Commission): diagnostic tests, vaccines and other issues related to laboratory
- Aquatic Animal Health Standards Commission (the Aquatic Animals Commission): case definitions, trade related recommendations, diagnostic tests for aquatic animals.

Rather than duplicating texts from the lead Commission, other Commissions should restrict their own texts to making cross-references. An example was noted of an extensive quote in the *Terrestrial Manual* from an old edition of the *Terrestrial Code*. Case definitions of diseases should be deleted from the *Terrestrial Manual* and reference should be made to the *Terrestrial Code*, as the *Terrestrial Code* does with the diagnostic and vaccines recommendations in the *Terrestrial Manual*.

EU comment

The EU strongly supports the suggestion of the Code Commission. Indeed, case definitions and trade related recommendations should be defined by the Code Commission and the Aquatics Animals Commission, and only be included in the relevant chapters of the Terrestrial and Aquatic Codes, with systematic cross-reference in the Codes to the Manuals at the beginning of a given chapter and vice-versa. This is vital for consistency and to avoid contradictions between different OIE standards, as shown by the example on Newcastle Disease. Reference is made to the EU's comment on the work programme of the Code Commission (cf. item 30 of this report).

The Commission noted repeated requests from Member Countries for expanded explanations for accepting or rejecting Member Countries' comments. While undertaking to give more explanation, Dr Thiermann noted that a considerable amount of information was already provided in the Scientific Commission reports and associated *ad hoc* Group reports and invited Member Countries to consult those reports together with the Code Commission reports. In this regard, the Code Commission highlighted again the desirability of providing reports of the Scientific Commission to the OIE Delegates in MS Word format to facilitate the review of texts by national experts, as is currently done for the Code Commission and the Laboratories Commission reports.

A Member Country's comment on the use of the WAHIS was referred to the OIE Information Department.

In response to a Member Country's comment on the need to review Chapters 7.2. to 7.6. on animal welfare, the Code Commission noted that this was already on the agenda of the Working Group on Animal Welfare (AWWG).

In response to a comment from a regional organisation requesting the OIE to address the issue of the interface between wildlife and livestock in a consistent manner, it was noted that this is being addressed by both the Scientific Commission and the Code Commission on disease by disease basis, as existing chapters are reviewed and new ones drafted.

Item 2 Horizontal issues

a) User's Guide

Dr Thiermann appreciated the initiative taken by Dr Etienne Bonbon to revise the User's Guide with a view to address Member Countries' request for clarification on the role, scope and correct use of the *Terrestrial Code*. It was noted that the draft was reviewed by both the Scientific Commission and the OIE Headquarters. The Code Commission closely reviewed the document and made amendments as appropriate.

The revised User's Guide is presented as Annex XXXII for Member Country comments.

EU comment

The EU thanks the OIE once more for having considered its request and for having provided this draft revised User's Guide for Member Country comments. The EU strongly supports the revision of the User's Guide to clarify the role, scope and correct use of the Terrestrial Code and very much looks forward to it being submitted for adoption by the World Assembly at a

future OIE General Session. Indeed, the EU would support adopting the User's Guide as a "standard", so as to give it the appropriate standing.

b) 'Standards' versus 'guidelines' and 'recommendations'

Dr Thiermann noted that there had been confusion among Member Countries regarding the terms 'standards', 'guidelines' and 'recommendations'. While recognising that the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization does not make a legal distinction between these terms, the Commission considered that there should be clear differentiation when they are used in the OIE texts: 'standards' means any texts which have been subjected to the official procedure of the OIE for adoption by the World Assembly of Delegates, and thus are found in Codes and Manuals, while 'guidelines' and 'recommendations' are used for other texts published officially by the OIE Headquarters.

EU comment

The EU supports the views of the Code Commission on the differentiation of the terms "standards", "guidelines" and "recommendations" when used in the context of the OIE.

Item 3 Glossary

Comments were received from Australia, Canada, Chile, the EU, New Zealand, Switzerland, the USA, AU-IBAR and the Federation of Veterinarians of Europe.

In response to a Member Country's request for inclusion of reptiles in the definition of '*animal'*, the Code Commission invites the Member Country to first submit a request for the addition of reptile diseases to the work programme of the Code Commission. Such a request would be addressed by the OIE Council and eventually the World Assembly of Delegates.

In response to a Member Country's comment on the improvement in translation from English to other OIE official languages, Dr Thiermann noted that the OIE continues its efforts towards the improvement of the quality of translations.

In response to Member Countries' comments on the definition of 'good manufacturing practices', the Code Commission agreed to include 'recognised by the Competent Authority' in order to avoid an arbitrary definition of 'good manufacturing practices'. However, the Commission did not accept the text 'developed by the public or private sector concerned' because it was not considered necessary to specify who had developed the practices.

In response to a Member Country's comment on the definition of 'veterinary medicinal product' suggesting replacing 'protective' with 'preventative' the Code Commission considered 'prophylactic' would be more suitable to cover vaccines in the definition.

The Code Commission disagreed with a regional organisation's comment on the definition of 'veterinary statutory body' because the proposed text is sufficiently explanatory without giving a synonym for 'statutory'.

The Code Commission reviewed a definition of 'veterinarian' received from a regional organisation of veterinarians. The Commission agreed to include a reference to education to recognise its importance in the qualification of a veterinarian.

The revised Glossary is attached as Annex IV for adoption at the 81st General Session in May 2013.

EU position

The EU thanks the OIE and supports the adoption of the modified Glossary.

Item 4 Notification of diseases, infections, infestations and epidemiological information

a) Notification of diseases and epidemiological information (Chapter 1.1.)

Comments were received from Australia, Canada, South Africa, Switzerland, the EU and AU-IBAR.

To align with other *Terrestrial Code* Chapters, the construct "and/or" was replaced by "or" or 'and' throughout the chapter, as appropriate, and the words "or infestation" were added after "infection" throughout Article 1.1.3.

EU comment

The EU thanks the OIE and suggests that, for reasons of consistency, the words "or infestation" should gradually also be added in other relevant parts of the Terrestrial Code (e.g. in the glossary, in the definition of "*Notification*" and others, as relevant).

The Code Commission accepted Member Countries' suggestions to insert "and their aetiological agents" after diseases where appropriate throughout Chapter 1.1.

They also accepted Member Countries' suggestions to improve the clarity and precision of the language of point 4 of Article 1.1.2., and points 1 and 2 of Article 1.1.3.

A Member Country's comment to clarify WAHIS procedures was referred to the OIE Headquarters.

In response to Member Countries' suggestions to clarify reporting expectations for animal health events of epidemiological significance that are not listed or emerging diseases, a new clause was added to the end of Article 1.1.3.

The Code Commission accepted Member Countries' suggestions to remove the words "or compartment" from points 2 and 4 of Article 1.1.4.

The Code Commission also accepted a Member Country's suggestion to reinstate Article 1.1.5., and updated the text to align it with the other articles of Chapter 1.1., and current reporting practice.

b) Notification of 'emerging disease'

With respect to Member Countries' suggestions to clarify the definition and reporting expectations for emerging diseases, the Code Commission noted that a task force in the OIE Headquarters had drafted a proposal to amend the definition of 'emerging disease' in the Glossary, and this had been presented to the Scientific Commission. In line with the Scientific Commission's views (see the minutes of Joint meeting as attached in Annex III) the Code Commission considered this issue needs more thorough examination, and this will be done by the two Commissions during the joint meeting in September 2013.

EU comment

As regards the clarification of the definition and reporting obligations for emerging diseases, the EU supports the procedure described above and looks forward to the outcome of the discussions between the Code Commission and the Scientific Commission scheduled for September 2013. The EU would be eager to contribute to this discussion and to participate with its experts should any *ad hoc* group meeting be organised on the subject.

The revised Chapter 1.1. is attached as Annex V for adoption at the 81st General Session in May 2013.

EU position

The EU thanks the OIE and in general supports the adoption of this modified chapter. Comments are inserted in the Annex V.

Item 5 Criteria for listing diseases

a) Criteria for listing diseases (Chapter 1.2.)

A comment was received from Australia.

In response to the Member Country's comment to improve the numbering of Article 1.2.2., the Code Commission considered this should be best dealt with by the decision tree diagram proposed as new Article 1.2.2. bis.

b) Report of the *ad hoc* Group on Notification of Animal Diseases and Pathogenic Agents and report of an electronic *ad hoc* Group on the Listing of Porcine Cysticercosis (*Taenia solium*)

Comments were received from Australia, Argentina, Canada, Chile, Guatemala, Japan, New Zealand, Norway, South Africa, Switzerland and the EU. The Code Commission also reviewed the report of an electronic *ad hoc* Group on the Listing of Porcine Cysticercosis (*Taenia solium*).

The Code Commission noted a Member Country's comment suggesting greater clarity was needed for the term 'significant morbidity and mortality'. The Code Commission considered that the structured process of listing diseases, first by an expert group whose conclusions are circulated for Member Countries' review and comment then consideration by the World Assembly of Delegates before final adoption, is sufficiently rigorous and transparent.

The Code Commission also noted that the placement of the reference to emerging diseases in Article 1.1.3. (point e)) will be considered along with the definition of emerging disease in the joint meeting with the Scientific Commission in September 2013.

Proposal to delist diseases:

The Code Commission noted extensive comments and concerns from many Member Countries on the proposal to delist 16 diseases. Many comments questioned the procedures used, the application of the listing criteria, and inconsistencies in the documentation of justification, and thus challenged the arguments for delisting.

Recalling that the Code Commission asked Member Countries to justify arguments for or against the proposed for delisting in September 2012, the Commission proposed delisting the following diseases on the basis that no Member Countries presented arguments against delisting based on the listing criteria in Chapter 1.2.:

- Swine vesicular disease
- Vesicular stomatitis
- Equine rhinopneumonitis (EHV-4).

On the same basis, the Code Commission recommends amending the listing of equine rhinopneumonitis to 'infection with equid herpes virus 1 (EHV-1)'.

In response to a Member Country's detailed justification for listing of chronic wasting disease of cervids (CWD) against the criteria of Article 1.2.2., the Code Commission recommended this disease be reconsidered for listing.

The Code Commission recommended that in the future the OIE limit the number of diseases to be examined at any one *ad hoc* Group meeting and allow more time for experts to adequately review the relevant literature, apply the criteria of Article 1.2.2., and consistently document justification for their recommendations to list and delist diseases.

In response to Member Countries' comments on the proposed delisting of some diseases on the basis that vector transmission was not included among the factors for international spread, the Code Commission proposed adding "vector" to point 1 of Article 1.2.2.

The revised Chapter 1.2. is attached as Annex VI for adoption at the 81st General Session in May 2013. In accordance with the proposed delisting mentioned above, the Code Commission proposed to delete Chapters 8.15. (Vesicular stomatitis) and 15.4. (Swine vesicular disease), as attached in Annex VI, for adoption at the 81st General Session in May 2013.

EU position

The EU would like to thank the OIE for having taken into consideration its comments as regards the delisting of certain diseases proposed by the *ad hoc* group on notification of animal diseases and pathogenic agents. The EU would like to continue supporting the work of the OIE in this area by offering participation of its experts in future *ad hoc* groups, and by providing relevant data on certain diseases, including on Enzootic Bovine Leucosis and Paratuberculosis.

The EU can in general support the adoption of this modified chapter. However, comments are inserted in the text of Annex VI, some of which should be taken into account before adoption.

The report of the electronic *ad hoc* Group on the Listing of Porcine Cysticercosis (*Taenia solium*) is attached as Annex XXXIII for Member Countries' information.

Item 6 Support for Veterinary Services

a) Evaluation of Veterinary Services (Chapter 3.2.)

Comments were received from Australia, Canada, the EU, New Zealand and Switzerland.

In response to a Member Country's general comment requesting a close editing of this chapter, the Code Commission suggested that the OIE forward the chapter to the *ad hoc* Group on Evaluation of Veterinary Services for formatting.

A Member Country's comment on the reference to a National Reference Laboratory in point 3 b) of Article 3.2.6. was not accepted because the use of the word 'may' means that the sentence does not imply that the existence of a National Reference Laboratory would necessarily result in higher standards.

Point 1 c) of Article 3.2.12. was amended based on a Member Country's suggestion for improved clarity.

As far as point 2 c) of Article 3.2.12. is concerned, the Code Commission accepted a Member Country's suggestion to add the words "and competence" to this clause. By this amendment, another Member Country's comment was addressed as the revised text became more neutral than the previous text.

The title of point 4 of Article 3.2.12. was revised in response to a Member Country's comment for improved clarity.

As far as point 7 of Article 3.2.12. is concerned, the Code Commission noted a Member Country's comment requesting further clarification of this clause, but decided to leave the new text unchanged as it incorporates the key points of the previous text more concisely.

The revised Chapter 3.2. is presented as attached in Annex VII for adoption at the 81st General Session in May 2013.

EU position

The EU supports the adoption of this modified chapter.

b) Veterinary legislation (Chapter 3.4.)

Comments were received from the EU and FAO.

The Code Commission noted that the *ad hoc* Group on Veterinary Legislation had reviewed comments from Member Countries and the international organisation. The Code Commission endorsed the *ad hoc* Group's review with additional amendments as follows:

The Code Commission noted that the *ad hoc* Group had sought the Commission's advice on the definition of veterinary legislation. The Code Commission deleted the definition of 'veterinary legislation' in the chapter because the term is already defined in the glossary.

The Code Commission noted that the *ad hoc* Group on Veterinary Legislation reviewed comments received from an international organisation, which had suggested that Article 3.2.7. be moved or combined with relevant Articles in Chapter 3.4. The Code Commission agreed with the *ad hoc* Group's suggestion that this comment should be dealt with by experts on evaluation of Veterinary Services so as not to undermine the integrity and narrative style of the current Chapter 3.2. The Code Commission suggested the OIE forward this comment to the *ad hoc* Group on Evaluation of Veterinary Services for consideration.

The revised Chapter 3.4. is presented as attached in Annex VIII for adoption at the 81st General Session in May 2013.

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

c) Report of the *ad hoc* Group on Veterinary Legislation

The Code Commission reviewed and approved the report of the meeting of the *ad hoc* Group in September 2012. The report is attached as Annex XXXIV for Member Countries' information.

d) Update on OIE's work for strengthening Veterinary Services

Dr Dietrich Rassow (OIE International Trade Department) updated the Code Commission on the OIE's work for strengthening Veterinary Services including the workshop held in Kazakhstan in November 2012 and forthcoming OIE Global Conference on Veterinary Education in Brazil in December 2013.

Item 7 Semen and embryos

a) Collection and processing of bovine, small ruminant and porcine semen (Chapter 4.6.)

Comments were received from Argentina, Canada, the EU, Norway and Switzerland.

A Member Country's comment on point 3 of Article 4.6.7. requesting to add 'frozen' before 'semen' in the title was accepted for clarity.

A Member Country's comment on point 4 of Article 4.6.7. requesting to delete the requirement for permanent identification was not accepted because the identification of straws containing sex-sorted sperm was required to ensure sanitary conditions are met, given that a straw might contain seminal plasma from more than one animal.

b) Collection and processing of *in vivo* derived embryos from livestock and equids (Chapter 4.7.)

Comments were received from Australia, Canada, the EU, Norway and International Embryo Transfer Society (IETS).

Regarding a Member Country's comment on point 2 of Article 4.7.5. requesting to revert the Note as a new sub-point e) was accepted for consistency.

A comment from the IETS on point 3b) of Article 4.7.14. suggesting to add atypical scrapie as a category 3 disease was accepted in line with the decision to reflect the IETS decisions on the safety of embryos in this article.

The revised Chapters 4.6. and 4.7. are attached as Annex IX for adoption at the 81st General Session in May 2013.

EU position

The EU thanks the OIE and supports the adoption of these modified chapters.

Item 8 Biosecurity procedures in poultry production (Chapter 6.4.)

Comments were received from Canada, Chile, the EU, Norway and Switzerland.

The Commission decided to keep for future consideration Member Countries' comments on texts other than those on point 1 f) of Article 6.4.5., which was the only new text proposed at the Code Commission meeting in September 2012. In response to Member Countries' comments on point 1 f) of Article 6.4.5., the Commission agreed to delete the reference to Chapter 6.11., as this article does not address the topic.

The revised Chapter 6.4. is attached as Annex X for adoption at the 81st General Session in May 2013.

EU position

The EU supports the adoption of this modified chapter.

Item 9 Antimicrobial resistance

a) Introduction to the recommendations for controlling antimicrobial resistance (Chapter 6.6.)

b) Harmonisation of national antimicrobial resistance surveillance and monitoring programmes (6.7.)

Comments were received from Canada, Chile, the EU and Switzerland on Chapter 6.6. and from Australia, Canada, the EU, Switzerland and the USA on Chapter 6.7.

The Code Commission decided to defer the review of these comments due to lack of time.

c) Responsible and prudent use of antimicrobial agents in veterinary medicine (Chapter 6.9.)

Comments were received from: Australia, Canada, Chile, Chinese Taipei, the EU, South Africa, Switzerland, USA and AU-IBAR.

The Code Commission noted the *ad hoc* Group on Antimicrobial Resistance had reviewed the Member Countries' comments and amended the text as appropriate and the Scientific Commission had endorsed the changes.

Points 1 through 4 of Article 6.9.3. were combined into a single point in response to Member Countries' requests for improving the clarity of the text and a reference to adulterated products was added to the first paragraph of new point 1.

A Member Country's previous comment suggesting to delete the reference to broadening the spectrum of activity in point 2 b) of Article 6.9.6. was not accepted as there are situations in which it can be demonstrated scientifically to be correct.

Point 1 of Article 6.9.8. was amended following a Member Country's suggestion to put primary focus on prescription by a veterinarian.

Elsewhere throughout the chapter the Code Commission accepted a number of Member Countries' suggestions to improve clarity and avoid ambiguity. Several suggestions to include declarative statements were rejected as inappropriate for inclusion in a standard. Several Member Countries' suggestions to make minor text changes without supporting rationale were rejected because the Code Commission did not see how the suggestions would improve the text.

The Code Commission rejected specific mention of WHO's list of critical antimicrobial agents because the OIE's own list is regularly updated and takes into consideration the WHO's list.

The revised Chapter 6.9. is attached as Annex XI for adoption at the 81st General Session in May 2013.

EU position

The EU is of the opinion that the OIE Terrestrial Code chapters on Antimicrobial resistance should be further reviewed considerably and would therefore appreciate a deep reflection and further work in this area in the future.

While this proposed modified chapter has somewhat improved and is a step in the right direction, the EU would wish to go further.

The EU understands that most of its important comments submitted further to the September 2012 report of the Code Commission have not been considered by the OIE. These comments are therefore reiterated in the text below, along with some general comments, for consideration by the OIE *ad hoc* group on Antimicrobial Resistance at its next meeting.

Given the outcomes of the recent first global OIE conference on the Responsible and Prudent Use of Antimicrobial Agents for Animals, the EU encourages the OIE to continue work to further improve Chapter 6.9. in the near future. To this effect, the EU would like to offer technical support to the OIE for future work on the *Terrestrial Code* chapters related to AMR by participation of EU experts in the relevant *ad hoc* groups.

Considering the above, the EU can in general support the adoption of this modified chapter at the 81st OIE General Session.

d) Risk assessment for antimicrobial resistance arising from the use of antimicrobial agents in animals (Chapter 6.10.)

Member Countries' comments were examined by the *ad hoc* Group on Antimicrobial Resistance and reviewed by the Scientific Commission, and the Code Commission decided to circulate the revised chapter for Member Countries' comment.

The revised Chapter 6.10. is presented as Annex XXXV for Member Countries' comments.

Item 10 Zoonoses transmissible from non-human primates (Chapter 6.11.)

Comments were received from Australia, Canada, the EU, the USA and Switzerland.

A Member Country's comment seeking the follow-up of its intervention at the 80th General Session regarding the list of tests in the chapter was referred to the Laboratories Commission.

Member Countries' comments suggesting to clarify the testing method for other bacterial pathogens in the table after Article 6.11.4. was not accepted as the Code Commission was of the view that current text is sufficient to complement what is described in the *Terrestrial Manual*.

The revised Chapter 6.11. is attached as Annex XII for adoption at the 81st General Session in May 2013.

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Item 11 Animal welfare

a) Draft new chapter on animal welfare and broiler chicken production systems (Chapter 7.X.)

Comments were received from Australia, Argentina, Chinese Taipei, the EU, Japan, Mexico, New Zealand, Norway, Switzerland, Thailand, the USA, International Poultry Council (IPC), International Coalition for Animal Welfare (ICFAW) and an Animal Welfare Working Group expert

Many comments were received on this chapter, and all were reviewed by the Code Commission. Numerous amendments are proposed on the basis of those comments.

However, comments with inadequate or no supporting rationale were rejected. Suggestions to add new text already covered elsewhere in the chapter were also rejected.

Throughout the chapter, the Code Commission accepted Member Countries' suggestions to improve clarity and to consistently use the terms 'completely outdoors systems', 'humanely killed' '*day-old bird(s)*' and 'broilers'.

As this text is now presented for adoption, all citations have been removed.

Article 7.X.1. Definitions

Point 1 Completely housed system

The Code Commission accepted a Member Country's suggestion to remove the reference to stocking density as an unnecessary detail in the definition.

Article 7.X.3. Criteria or measurables for the welfare of broilers

The Code Commission accepted a Member Country's suggestion to align this text with that used in Article 7.9.4. (beef cattle).

Point 1 Mortality (dead and culled) and morbidity

The Code Commission accepted a Member Country's suggestion to amend the text to distinguish culling from mortality.

Point 3 Contact dermatitis

The Code Commission accepted Member Countries' suggestions to add the word "wet" before the words "litter" and "flooring" to improve clarity; and the addition of the words "for use in a *slaughterhouse/abattoir*" to give specificity to the second clause.

Point 4 Feather condition

The Code Commission accepted a Member Country's suggestion to expand explanations for plumage dirtiness and insert text indicating times when assessments of plumage dirtiness can be made.

Point 6 Behaviour

The Code Commission accepted a Member Country's suggestion to include text that "validated methods have been developed for evaluating fearfulness."

Subpoint c) Panting and wing spreading

The Code Commission re-instated "high levels of ammonia" at the end of the first sentence on the basis of the reference supplied. It also accepted an organisation's suggestion to add the word "excessive" to the beginning of the second sentence.

Point 12 Vocalisation

The Code Commission added text suggested by an organisation to expand the context of this clause.

Article 7.X.4. Recommendations

Point 1 Biosecurity and animal health

In response to a Member Country's comment, the Code Commission aligned this text with existing text in Chapter 7.9.

The Code Commission also accepted a Member Country's suggestion to delete duplicative text, to use the generic term 'veterinarian' rather than 'poultry veterinarian' or 'qualified veterinarian', and to add gait to the list of outcome based measurables.

Point 2. Environment and management

Subpoint a) Thermal environment:

In response to a Member Country's suggestion, the Code Commission changed 'Thermal Heat Index' to 'heat index', which is a more commonly used term.

The Code Commission accepted an expert's suggestion to revise the wording of the text on unacceptable environmental conditions to a recommendation, and they accepted advice that ventilation does not control relative humidity and therefore deleted the clause.

The Code Commission also accepted a Member Country's comment for outcome based rather than prescriptive language, and revised the relevant clause accordingly.

Subpoint b) Lighting

The Code Commission was unable to reconcile several Member Countries' comments for greater specificity in a variety of circumstances, and concluded that the current text adequately describes the outcome required for all situations.

The Code Commission agreed to a Member Country's suggestion to delete the second sentence, which was inconsistent with established Code format.

The Code Commission accepted a Member Country's comment to generalise the reference to light intensity, by deleting the words: "in the first few days".

Based on scientific references provided, the Code Commission accepted an NGO's suggestions to reinstate eye conditions in the list of relevant outcome based measurables, and also expanded the text on eye conditions in point 10 of Article 7.X.3 to include abnormal eye development associated with low light intensity. The scientific references provided are:

Deep A., Schwean-Lardner K., Crowe T.G., Fancher B.I., and Classen H.L. 2010. Effect of light intensity on broiler production, processing characteristics, and welfare. Poult Science 89(11):2326-2333.

Prescott NB, Kristensen HH, and Wathes CM. 2004. Light. In: Weeks CA and Butterworth A (eds.), Measuring and Auditing Broiler Welfare (Wallingford, U.K.: CAB International).

Subpoint d) Noise

The Code Commission accepted Member Countries' suggestions to align text with the adopted Chapter 7.9.

Subpoint e) Nutrition

The Code Commission accepted a Member Country's suggestion to add the words "and welfare" to the end of the first clause.

The Code Commission accepted Member Countries' suggestions to replace the word 'palatable' with 'acceptable', given the subjectivity of assessing palatability, and amended the text on contaminants to make it more specific.

In response to a Member Country's suggestion, the Code Commission added the text: "Broilers physically unable to access food or water should be humanely killed as soon as possible".

Subpoint f) Flooring

The Code Commission accepted an organisation's suggestion for additional text on factors that may cause poor litter quality. The Code Commission amended text in response to Member Countries' comments with respect to slatted floors, and to align it as closely as possible with the language of Chapter 7.9.

Subpoint k) Genetic selection

The Code Commission accepted Member Countries' comments to change 'genetic selection' to 'choice of broiler strain' and expanded the text and measurable list.

Subpoint l) Painful interventions

In response to Member Countries' suggestions, the Code Commission added text noting that feather pecking and cannibalism are rarely a problem in broilers because of their young age, and revised and expanded the outcome based measurable list.

Subpoint m) Handling and inspection

In response to Member Countries' suggestions the Code Commission revised "inspection frequency" to "at least daily" to provide flexibility.

A Member Country's suggestion to include environmental enrichment in this chapter was referred to the AWWG for further consideration.

The revised draft chapter 7.X. as attached in Annex XIII is proposed for adoption at the 81st General Session in May 2013.

EU position

The EU thanks the OIE and in general supports the adoption of this modified chapter. The EU does however have some comments as indicated in the text of Annex XIII and would ask the OIE to take these into consideration at a future revision.

b) Member Country comments on existing Chapters 7.1., 7.3., 7.5., 7.6., 7.8. and 7.9.

Due to time constraints, the Code Commission decided to focus on reviewing Member Countries' comments on the amended text proposed at its meeting in September 2012 and deferred review of other chapters to its meeting in September 2013.

Introduction to the recommendations for animal welfare (Chapter 7.1.)

Comments were received from Australia, Canada, the EU, Mexico, the USA and Switzerland.

Point 2 of Article 7.1.4.

In response to Member Countries' suggestions the Code Commission deleted "successfully" from this clause.

Other suggestions for additional text were rejected as being irrelevant or beyond the scope of this chapter.

The revised Chapter 7.1. as attached in Annex XIV is proposed for adoption at the 81st General Session in May 2013.

EU position

The EU supports the adoption of this modified chapter.

Animal welfare and beef cattle production systems (Chapter 7.9.)

Comments were received from Australia, the EU, Japan, Mexico, Switzerland, the USA and ICFAW.

In response to Member Countries' comments, the Code Commission amended the text:

in the section on animal health management, to include the avoidance of dragging of non-ambulatory cattle;

in the section on environment, the addition of reduction of stocking density as a measure of managing heat stress;

in the section on management, conditions for tethering were modified to improve clarity.

The revised Chapter 7.9. as attached in Annex XV is proposed for adoption at the 81st General Session in May 2013.

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Chapter 7.8. Laboratory animal welfare

The Code Commission rejected a Member Country's suggestion to delete the proposed text in Article 7.8.10. as this text had been requested by Member Countries during the 80th General Session in 2012.

The revised Chapter 7.8. as attached in Annex XVI is proposed for adoption at the 81st General Session in May 2013.

EU position

The EU supports the adoption of this modified chapter.

c) Update of existing chapters (Chapters 7.5. and 7.6.)

The Code Commission endorsed the work of an expert in restructuring these chapters by removing tables and figures as requested by Member Countries.

The draft text is attached in Annex XXXVI for Member Country comments.

EU comments

The EU does not support the proposed removal of the tables from these chapters. The justification is given in the text of Annex XXXVI.

d) Report of the meeting of the *ad hoc* Group on Animal Welfare and Dairy Cattle Production System (January 2013)

The Code Commission reviewed and approved the draft report of the *ad hoc* Group.

The Code Commission endorsed the draft chapter prepared by the *ad hoc* Group and presents it for Member Country comments as attached in Annex XXXVII together with the report of the ad hoc Group for Member Country information.

EU comments

The EU thanks the OIE for its work on this new chapter which in general is based on the adopted chapter on beef cattle. However, some changes have been proposed for the beef cattle and these should also be proposed here. The EU has several comments as indicated in the text of Annex XXXVII.

e) Work programme of the Working Group on Animal Welfare

The Code Commission reviewed and approved the work programme of the Working Group on Animal welfare with amendment.

The amended work programme, for information and comment of Member Countries, is at Annex XXXVIII.

Item 12 Bluetongue (Chapter 8.3.)

Comments were received from Australia, Canada, Chile, the EU, New Zealand, Switzerland and AU-IBAR.

The Code Commission noted that an *ad hoc* Group on Harmonisation of African horse sickness, bluetongue and epizootic hemorrhagic disease would be convened under the auspices of the Scientific Commission. The Code Commission deferred the review of Member Country comments on this chapter to the next meeting in September 2013 until the outcome of this *ad hoc* Group's meeting is available.

Item 13 Zoonotic parasites

a) Infection with *Echinococcus granulosus* (revised Chapter 8.4.)

Comments were received from Canada, Chile, the EU, New Zealand, Norway, Switzerland and the USA.

The Code Commission reviewed Member Countries' comments and made several modifications to the draft text accordingly. The Code Commission noted that this chapter had been circulated for Member Countries' comments on three occasions and that in the course of revision, several parts of the text had previously been inserted or deleted. For this reason, the Code Commission made amendments only to those parts where the proposed text modifications significantly improved clarity.

The Code Commission inserted the word 'livestock' in the first sentence of Article 8.4.2. on 'Safe commodities' to clarify that the listed commodities applied to all livestock.

The Code Commission retained the reference to "Veterinary Authority or other Competent Authority" throughout the text, in order to stress the importance of the role of the Veterinary Authority in the prevention and control of *E. granulosus* but also to acknowledge that another Competent Authority may also be involved.

In response to Member Countries' comments, the Code Commission amended the treatment time for animals prior to embarkation from between 48 to 72 hours, to between 24 and 72 hours (Article 8.4.5.), noting that point 2 requires precautions to avoid reinfection between treatment and embarkation.

b) Infection with *Echinococcus multilocularis* (new Chapter X.X.)

Comments were received from Canada, Chile, the EU, New Zealand, Norway and the USA.

The Code Commission reviewed Member Countries' comments and made several modifications to the draft text accordingly. Bearing in mind the modifications made to Chapter 8.4., the Code Commission reviewed these amendments to ensure alignment between the two chapters, where appropriate.

The Code Commission noted that this chapter had also been circulated for Member Countries comments on three occasions and that in the course of revision, several parts of the text had previously been inserted or deleted. For this reason, the Code Commission made amendments only to those parts where the proposed text modifications significantly improved clarity.

In order to align this chapter with other *Terrestrial Code* chapters, the Code Commission added a new article on 'Safe commodities'.

The revised Chapter 8.4. and the revised draft Chapter X.X. are attached as Annex_XVII for adoption at the 81st General Session in May 2013.

EU position

The EU thanks the OIE and in general supports the adoption of these modified chapters. Two previous comments on point 2b) of Article 8.4.3, which the EU thinks would further improve the text, are reiterated in the text of Annex XVII for consideration by the Code Commission at its next meeting.

c) Infection with *Trichinella* spp. (Chapter 8.13.)

Comments were received from Argentina, Australia, Chile, the EU, Japan, Mexico, New Zealand, Norway, Switzerland, Thailand and the USA.

Dr Gillian Mylrea (Deputy Head, OIE International Trade Department) informed the Code Commission of the discussion held at the 44th Session of the Codex Committee on Food Hygiene (CCFH), in November 2012, on the development of the Proposed Draft Guidelines for Control of Specific Zoonotic Parasites in Meat. She noted that the CCFH had proposed an alternative pathway to achieving a negligible risk compartment for Infection with *Trichinella* spp. to that described in the revised Chapter 8.13. This proposed pathway would rely less on on-going verification of farms but would provide for on-going monitoring of a representative sample of slaughtered pigs to confirm the status of the compartment. The CCFH had noted that for this alternative pathway to become operational, it required including additional provisions in Chapter 8.13.

The Code Commission agreed with Member Countries which commented on the importance of the OIE continuing to work in close collaboration with the Codex Alimentarius Commission.

The Code Commission reiterated that this chapter does not address requirements for establishing an article on 'negligible risk country' because of the general lack of clear and objective means to achieve such a status, notably in terms of biosecurity and surveillance for pigs not kept under controlled management conditions. The Code Commission noted that the absence of such an article in the chapter does not exclude the possibility of a Member Country negotiating with trading partners on the basis of a bilaterally recognised negligible risk country status.

In response to several Member Countries' comments regarding point 2 in Article 8.13.3. and the need for more flexibility in how the Veterinary Authority verifies that a herd is in compliance with the requirements given in point 1, the Code Commission made amendments to points b) and c).

The Code Commission noted that the points listed in Article 8.13.4. regarding the establishment of a negligible risk compartment may not be relevant in all situations, hence the inclusion of the words 'as applicable'. The Commission agreed to delete point 5 as this is not a prerequisite for establishing a negligible risk compartment. The Code Commission did not agree to delete point 6 on surveillance as the management and verification of the compartment will be influenced by the *Trichinella* status outside of the compartment. The Commission did not add more details on the design of the surveillance programme as this would vary from country to country depending on local conditions.

In response to Member Countries' comments, the Code Commission revised point 3 of Article 8.13.5. to allow countries with already established herd programmes and current and historical information to demonstrate negligible risk.

The revised Chapter 8.13. as attached in Annex XVIII is presented for adoption at the 81st General Session in May 2013.

EU position

The EU thanks the OIE and in general supports the adoption of this modified chapter. Some comments are inserted in the text below.

Item 14 Foot and mouth disease (Chapter 8.5.)

Dr Laure Weber-Vintzel (OIE Scientific and Technical Department) joined the Code Commission meeting. The Code Commission supported the amendments proposed by the *ad hoc* Group and endorsed by the Scientific Commission and made minor amendments to Article 8.5.1. to align with established *Terrestrial Code* format.

The Code Commission also reviewed Articles 8.5.8. and 8.5.9. and amended them for consistency with the text on containment zones in other chapters.

The revised chapter 8.5. as attached in Annex XXXIX is presented for Member Countries' comments. Member Countries are invited to read this revised chapter in conjunction with the Scientific Commission and *ad hoc* group reports.

Item 15 Infection with rabies virus (Chapter 8.10.)

The Code Commission noted that following joint work on a Global Strategy for rabies control in dogs in collaboration with other key partners, a new article on the control of rabies in dogs in Chapter 8.10. was needed. Dr Thiermann clarified that the purpose of this article is to encourage countries whose dog population is currently infected with rabies to implement a structured control strategy with a view to achieve eventual eradication of canine rabies. The Code Commission thus introduced draft Article 8.10.1. bis taking into consideration the comments made by the Scientific Commission. Consequently, a requirement for a stray dog population control programme with reference to Chapter 7.7. was added to Article 8.10.2.

The revised Chapter 8.10. is attached as Annex XIX for adoption at the 81st General Session in May 2013.

EU position

The EU acknowledges the wish of the OIE to encourage countries whose dog population is currently infected with rabies to implement a structured control strategy with a view to achieve eventual eradication of canine rabies and would therefore support the newly proposed article 8.10.1bis. However, the EU can support the adoption of this modified chapter only if its important comment, inserted in the text below, is taken into account.

Item 16 Rinderpest (Chapter 8.12.)

Comments were received from Argentina, Canada, Chile, the EU, New Zealand and Switzerland.

The Code Commission noted that the Scientific Commission had reviewed Member Countries' comments at their meeting in February 2013.

Based on a Member Countries' comment, the title of this chapter was amended to 'Infection with rinderpest virus'.

A Member Countries' general comment suggesting delaying the adoption of this chapter until the international contingency plan has been developed was not accepted because of the urgency of advancing this post global eradication text and the fact that the Scientific Commission had not agreed either.

In response to Member Countries' comments:

Article 8.12.5. was closely examined and amended for improved clarity.

Point 1 of Article 8.12.5. was amended to clearly explain that rinderpest should be suspected in the case of detection of stomatitis-enteritis syndrome and that differential diagnosis should be conducted systematically;

Points 2 and 4 of Article 8.12.5. were amended with a view to clarifying the required actions step by step in accordance with the correct sequence of events (detection of a suspected case → follow-up of suspicion → confirmation of rinderpest case → follow-up of confirmation → suspension of the global freedom). In point 2, the second sentence of the first paragraph was moved to the beginning of point 4, as this referred to actions upon confirmation of rinderpest. The second paragraph of point 2 was amended too, for better sequence of events.

Point 5 of Article 8.12.5. was also amended to specify the relevant articles for legal certainty.

The last sentence of the first paragraph of Article 8.12.6. was relocated for better logical flow.

A new point 7 was added to Article 8.12.7. as the Scientific Commission had agreed with it.

'Country' in the first sentence of Article 8.12.8. was replaced by 'Member Country' to avoid the confusion that this article would apply only to a free 'country' and not a free 'zone'.

The Code Commission did not accept a Member Country's suggestion to move Article 8.12.8. after Article 8.12.6. because it was of the view that this should be the correct order.

In response to a Member Country's comment seeking clarification on the coverage of 'all populations of rinderpest susceptible species' in point 1 of Article 8.12.8., the Code Commission agreed with the Scientific Commission that all susceptible species including wildlife should be covered.

In response to a Member Country's comment, Article 8.12.9. was amended to accommodate Member Countries which host more than one institution.

In relation to Article 8.12.9., a Member Country's comment seeking the rationale for submitting the report to the OIE by the end of November, the Code Commission noted that the Scientific Commission had clarified that this provision was in line with the OIE's existing policy.

In response to a Member Country's comment, the Model annual report on RPV-containing material was amended to specify the biosecurity level of each individual facility holding RPV-containing material because one institution might have more than one facility holding RPV-containing material.

A Member Country's suggestion to add a footnote to clarify 'other potential infectious material' by giving examples was not accepted although the Scientific Commission had agreed with it, because the Code Commission considered that such examples could not be exhaustive and might lead to overlooking of some important materials which should be reported.

The revised Chapter 8.12. is attached as Annex XX for adoption at the 81st General Session in May 2013.

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Item 17 Review of chapters on bee diseases

Dr François Diaz (OIE Scientific and Technical Department) joined the Code Commission for the review of chapters on bee diseases. The Code Commission commended the high quality work done by the Scientific Commission and the *ad hoc* Group on this issue.

a) Official health control of bee diseases (Chapter 4.14.)

Comments were received from Canada, the EU and Switzerland.

The Code Commission thanked the supporting comments from Member Countries.

The revised Chapter 4.14. as attached in Annex XXI is proposed for adoption at the 81st General Session in May 2013.

EU position

The EU supports the adoption of this modified chapter.

b) Bee diseases (Chapters 9.1. to 9.6. inclusive)

In response to Member Countries' comments, where relevant throughout the bee disease chapters, the Code Commission agreed to:

- use the phrase "which is widely distributed" as used elsewhere in the *Terrestrial Code* in place of "and occurs in most countries where such bees are kept";
- change "apiary" to "apiaries";
- change 'is' to "has been"; and
- include more specific text on the requirements for strained honey.

In response to Member Countries' questions on the irradiation requirements used throughout the chapters, the Code Commission recalled that these requirements are taken from the IPPC standard which recommends specific, different irradiation doses for killing of mites and beetles (IPPC standard, ISPM No.18 2003).

EU comment

The EU thanks the OIE for this important clarification.

c) Infestation of honey bees with *Acarapis woodi* (Chapter 9.1.)

Comments were received from Argentina, the EU, Japan and Norway.

Although the Code Commission agreed with a Member Country's comment that it is difficult to conduct surveillance of wild bees or feral bees, it considered that it is necessary to recognise the possibility of establishment of a pest or disease free status.

The Code Commission noted for future consideration a Member Country's comment that the host is not normally included in the title of *Terrestrial Code* chapters.

EU comment

The EU agrees with the Code Commission and would support deleting the reference to host species ("of honey bees") in the titles of the bee disease chapters (and in the list in point 8 of Article 1.2.3.), for consistency with other *Terrestrial Code* chapters.

d) Infection of honey bees with *Paenibacillus larvae* (American foulbrood) (Chapter 9.2.)

Comments were received from Argentina, the EU, Japan, Norway and Switzerland.

Article 9.2.1. General provisions

The Code Commission agreed with a Member Country's comment to reinstate the sentence "However subclinical infections are common and require laboratory diagnosis" for clarity, because it fits the logic and standard format of the *Terrestrial Code*.

Article 9.2.2.

The suggestion from Member Countries to remove eggs from the list of safe commodities without providing new scientific evidence was rejected. The Code Commission noted that the earlier decision to include eggs was supported by a peer reviewed risk analysis.

e) Infection of honey bees with *Melissococcus plutonius* (European foulbrood) (Chapter 9.3.)

Comments were received from Argentina, Canada, EU, Japan, Norway and Switzerland.

The Code Commission supported the *ad hoc* Group on Bee diseases and the Scientific Commission's assessments and suggested amendments throughout the chapter.

Article 9.3.2.

The Code Commission agreed with the *ad hoc* Group's recommendation to delete eggs from the list of safe commodities, as there is no supporting evidence for their safety with respect to this disease. As a consequence, eggs are proposed to be reinserted into Article 9.3.6.

f) Infestation with *Aethina tumida* (Chapter 9.4.)

Comments were received from the EU and Norway.

The Code Commission accepted a Member Country's comment to include "(small hive beetle)" in the title for improved clarity.

g) Infestation of honey bees with *Tropilaelaps* spp. (Chapter 9.5.)

Comments were received from Argentina, the EU, Japan and Norway.

The Code Commission made necessary changes as described above for improved clarity.

h) Infestation of honey bees with *Varroa* spp. (Chapter 9.6.)

Comments were received from Argentina, the EU, Japan, New Zealand and Norway.

The Code Commission agreed to Member Countries' suggestions to expand the title to include (Varroosis) and agreed with the suggestion of the *ad hoc* Group for referencing viruses associated with *Varroa.*

Article 9.6.2.

The Code Commission noted the *ad hoc* Group acknowledgement that the inclusion of pollen and propolis in the list of safe commodities was a result of a transcription error.

Article 9.6.5.

The Code Commission rejected a Member Country's suggestion to include the words "or a suitable biocide product" as unnecessary duplication of existing text.

The revised Chapters 9.1. to 9.6. as attached in Annex XXII are proposed for adoption at the 81st General Session in May 2013.

EU position

The EU thanks the OIE and supports the adoption of these modified chapters.

Item 18 Avian influenza (Chapter 10.4.)

Comments were received from Argentina, Australia, Canada, the EU, New Zealand and Switzerland.

In response to comments from several Member Countries, the Code Commission proposed to review the terminology used in the chapter with the aim of improving clarity, with the least change. They agreed not to change the scientific content of the chapter and its focus on poultry, and to continue to require notification of high pathogenicity influenza A viruses in all birds, including wild birds.

To simplify the chapter the term "avian influenza" was redefined, and the term "notifiable avian influenza" was removed. The listing name in point 6 of Article 1.2.3. was also amended to incorporate the revised definition of avian influenza. All previous abbreviations denoting pathogenicity and notifiability of avian influenza were removed and replaced by the complete words. The title of the chapter was amended accordingly.

The Code Commission did not agree with a Member Country's proposal to change the definition of poultry, which is a defined term in the Glossary.

A Member Country's request to include testing requirements for import of day-old live poultry from a free country, zone or compartment was rejected as unjustified.

The Code Commission considered a Member Country's comment challenging the fact that the *Terrestrial Code* does not recommend sanitary measures be applied to eggs for human consumption from countries with low pathogenicity avian influenza viruses. The Code Commission recalled that this principle had been previously considered and adopted by Member Countries, that no new justification was brought to change it and so did not modify the text.

A Member Country's suggestion to add text on surveillance in species other than poultry to Article 10.4.27. was rejected as unnecessary, given this point is already covered in several existing articles.

The Code Commission also revised Figures 1 and 2 of Article 10.4.33. for improved clarity.

The revised Chapter 10.4. is attached as Annex XXIII for adoption at the 81st General Session in May 2013.

EU position

The EU thanks the OIE and supports the adoption of this modified chapter. Reference is made to the EU comment on point 6 of Article 1.2.3., inserted in the text of Annex VI.

Item 19 Newcastle disease (Chapter 10.9.)

Comments were received from Australia.

In response to the Member Country's comments, the Code Commission examined the definition of Newcastle disease in the *Manual* and noted that it did not refer appropriately the definition in the *Terrestrial Code*. The Code Commission asked the Laboratories Commission to remove the outdated definition and ensure that the *Manual* refers unambiguously to the *Terrestrial Code.*

Moreover, point 7 of Article 10.9.1. was aligned with the comparable clause in Chapter 10.4. for consistency with notification obligations.

The revised Chapter 10.9. is attached as Annex XXIV for adoption at the 81st General Session in May 2013.

EU position

The EU in general supports the adoption of this modified chapter. A comment is inserted in the text of Annex XXIV.

Item 20 Infection with *Brucella abortus, melitensis* and *suis* (Chapter 11.3)

The Code Commission supported the amendments proposed by the *ad hoc* Group and endorsed by the Scientific Commission and made minor amendments to Article 11.3.1. to align with established *Terrestrial Code* format. The Code Commission invited Member Countries to consult the report of the Scientific Commission for rationales.

The revised Chapter as attached in Annex XL for Member Countries' comments.

Item 21 Bovine spongiform encephalopathy (Chapters 11.5. and 1.6.)

Comments on Chapter 1.6. (Procedures for self declaration and for official recognition by the OIE) were received from the EU and Switzerland and on Chapter 11.5. (Bovine spongiform encephalopathy [BSE]) from Chinese Taipei, the EU and Switzerland.

The Code Commission noted that the Scientific Commission and the *ad hoc* Group on BSE risk status evaluation of Member Countries had reviewed Article 11.5.22. in response to Member Countries' comments seeking advice on surveillance points required for risk status recognition of countries with small population of cattle.

The Code Commission agreed with the Scientific Commission to delete all references to 'compartment' in Article 1.6.3.

A Member Country's request to revise certain aspects of BSE surveillance, taking into consideration of existence of atypical BSE, particularly in the subpopulations of older cattle, was referred to the Scientific Commission.

The Code Commission presented the revised Chapters 1.6. and 11.5. as attached in Annex XXV for adoption at the 81st General Session in May 2013.

EU position

The EU supports the adoption of these modified chapters.

Item 22 Contagious bovine pleuropneumonia (Chapter 11.8.)

Comments were received from Canada, Chile, the EU and Switzerland.

The Code Commission accepted a Member Country's suggestion to amend the title of the chapter to harmonise with the new naming of diseases.

The Code Commission did not accept a Member Country's suggestion to replace the word 'bilateral' with alternate text in Article 11.8.5. bis, because the current text was used consistently in reference to free compartments throughout the *Terrestrial Code*, and accurately reflected how compartments might be recognised.

The Code Commission presented the revised Chapter 11.8. as attached in Annex XXVI for adoption at the General Session in May 2013.

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Item 23 Equine diseases

a) African horse sickness (Chapter 12.1.)

The Code Commission supported the amendments proposed by the *ad hoc* Group on the Evaluation of African horse sickness status of Member Countries and endorsed by the Scientific Commission, and made further amendments to the text to align with the established *Terrestrial Code* chapter format.

The revised chapter as attached in Annex XXVII is proposed for adoption at the 81st General Session in May 2013.

EU position

The EU in general supports the adoption of this modified chapter. However, an important comment is inserted in the text of Annex XXVII for consideration by the Code Commission at its next meeting.

b) Equine viral arteritis (Chapter 12.9.)

Comments were received from the USA and IETS.

The Code Commission supported the rejection of a Member Country's comment by the Scientific Commission on the basis of expert advice, which can be found in the report of the Scientific Commission in February 2013.

The Code Commission accepted the insertion of an article of recommendation for importation of embryos proposed by IETS in response to a Member Country's request.

The revised Chapter 12.9. as attached in Annex XXVIII is proposed for adoption at the 81st General Session in May 2013.

EU position

The EU in general supports the adoption of this modified chapter. Comments are inserted in the Annex XXVIII.

c) Update on international movement of competition horses

Dr Susanne Munstermann (OIE Scientific and Technical Department) joined the Code Commission meeting to give a brief explanation of the joint work with the Fédération Equestre Internationale (FEI) under the recently signed official agreement between OIE and FEI. Dr Munstermann noted that the international movement of competition horses had been often hampered by the complex quarantine protocols which importing countries implement to prevent the introduction of multiple OIE listed and other diseases of equids, despite the fact that such horses are maintained under enhanced biosecurity control and that their international movements are on a short term basis. She explained that an *ad hoc* Group of experts would be established to define, as the first step of the joint work, a subpopulation of horses which can be differentiated from other horse populations in terms of international trade. The Code Commission thanked Dr Munstermann for the briefing and asked to be kept updated on this issue.

Item 24 Infection with *Chlamydophila abortus* (Chapter 14.5.)

Comments from Australia, Canada, the EU, New Zealand, Switzerland and IETS.

The Code Commission rejected a Member Country's suggestion to change the title of this chapter as the current title is consistent with the *Manual*.

In Article 14.5.4., the Code Commission acknowledged a Member Country's comment that absence of clinical signs provided little assurance of freedom from *Chlamydophila abortus*, but retained this language on the basis that it is a generic requirement.

In Articles 14.5.4. and 14.5.5., the Code Commission accepted a Member Country's suggestion to reference specified timeframes to the day of collection and they accepted the suggestion to add "goats" where relevant throughout the chapter.

The Code Commission did not accept the text proposed by the IETS for Article 14.5.5. as the current text was based on a rigorous peer-reviewed import risk analysis.

The revised Chapter 14.5. is presented as attached in Annex XXIX for adoption at the 81st General Session in May 2013.

EU position

The EU supports the adoption of this modified chapter.

Item 25 Peste des petits ruminants (Chapters 14.8. and 1.6.)

The Code Commission reviewed the revised text received from the Scientific Commission and amended it to align with established *Terrestrial Code* format. The Code Commission invited Member Countries to consult the report of the Scientific Commission for rationales.

The revised Chapters 14.8. and 1.6. are attached as Annex XXX for adoption at the 81st General Session in May 2013.

EU position

The EU cannot support the adoption of the modified chapter 14.8., unless its important comments inserted in the Annex XXX are taken into account.

Furthermore, while in principle supporting the addition of this disease to the list of diseases for which the OIE officially recognises the disease status of Member Countries, the EU acknowledges and wishes to emphasise the significant increase in workload this represents for the OIE Headquarters and the Scientific Commission for the years to come. Therefore, the EU will be very interested in the implementation of the official status recognition procedure for the newly added diseases, which should be consolidated successfully before the addition of further diseases can be considered in the future.

The EU in general supports the adoption of the modified chapter 1.6.

Item 26 Classical swine fever

a) Classical swine fever (Chapter 15.2.)

b) Questionnaire (Chapter 1.6.)

The Code Commission reviewed the revised text received from the Scientific Commission and amended it to align with established *Terrestrial Code* format. The Code Commission invited Member Countries to consult the report of the Scientific Commission for rationales.

Reference to uncertainties in the use of molecular tests was deleted from the draft text and this issue was referred to the Laboratories Commission to ensure it is addressed in the *Manual*.

The revised Chapters 15.2. and 1.6. are attached as Annex XXXI for adoption at the 81st General Session in May 2013.

EU position

The EU thanks the OIE and in general supports the adoption of the modified chapter 15.2. However, comments are inserted in the Annex XXXI, one of which is important and needs to be considered before adoption.

In addition, the EU would like to ask the OIE for clarification of how this chapter will be implemented after adoption as regards the official disease status recognition and ensuring that surveillance requirements in free countries are proportionate to the risk. In particular, what will the proposed procedure be in the first 12 months following May 2013?

Furthermore, while in principle supporting the addition of this disease to the list of diseases for which the OIE officially recognises the disease status of Member Countries, the EU acknowledges and wishes to emphasise the significant increase in workload this represents for the OIE Headquarters and the Scientific Commission for the years to come. Therefore, the EU will be very interested in the implementation of the official status recognition procedure for the newly added diseases, which should be consolidated successfully before the addition of further diseases can be considered in the future.

The EU supports the adoption of the modified chapter 1.6.

c) Animal health surveillance (Chapter 1.4.)

In response to a comment formulated by the Scientific Commission that there was an inconsistency between Article 15.2.3. and points 1 a) vi) and b) v) of Article 1.4.6. with respect to the requirements for disease freedom of a country or zone, where infection is established in wildlife, the Code Commission concluded that this subject needed further detailed discussion with the Scientific Commission to determine how best this inconsistency may be addressed.

Item 27 Draft new chapter on epizootic hemorrhagic disease (Chapter X.X.)

The Code Commission supported the amendments proposed by the *ad hoc* Group on Epizootic Hemorrhagic Disease (EHD) and endorsed by the Scientific Commission, and made minor amendments to align the text with established *Code* chapter format, and improve clarity.

They also deleted Article X.X.4., the last sentence of Article X.X.5., Articles X.X.7., X.X.10. and X.X.13., and reference to 'seasonally free' in Article X.X.16., all for consistency with the Scientific Commission's proposal to delete the 'seasonal freedom' concept from Chapter 12.1.

The revised draft chapter as attached in Annex XLI is presented for Member Countries' comments.

Item 28 Draft new horizontal chapter on disease control (Chapter X.X.)

The Code Commission supported the draft horizontal chapter on disease control proposed by the *ad hoc* Group on Epidemiology and endorsed by the Scientific Commission.

The draft text was attached in Annex XLII for Member Countries' comments.

Item 29 Report of the Working Group on Animal Production and Food Safety

Dr Gillian Mylrea, Deputy Head of the International Trade Department, explained the major outcomes of the meeting of the Working Group on Animal Production and Food Safety (APFSWG) in November 2012. She highlighted that the Codex Committee on General Principles (CCGP) had decided to establish an electronic working group with a view to further collaboration between the OIE and Codex Alimentarius Commission (CAC) in the development of standards of mutual interest.

Dr Gillian Mylrea also explained that the priority work areas of the CAC include parasites in food, such as *Taenia solium*, *Echinococcus multilocularis*, *Toxoplasma gondii*.

The report of the meeting of APFSWG in November 2012 is attached as Annex XLIII for information.

Item 30 Update of the Code Commission work programme

The Code Commission reviewed and updated its work programme. The revised work programme is attached as Annex XLIV for Member Countries' comments.

EU comments

The EU thanks the Code Commission for providing its updated and detailed work programme, which it supports.

The EU would like to suggest reviewing Chapter 12.8. "Equine rhinopneumonitis" in light of the proposed delisting of EHV-4 and the amendment to the listing of this disease, in case these changes are adopted at the 81st General Session.

Furthermore, as scrapie is not being proposed for delisting, the EU would like to reiterate its comments as to this disease submitted on the work programme of the Code Commission attached to the February 2012 meeting report (cf. http://ec.europa.eu/food/international/organisations/docs/annex%201_eu%20position_052012_en.pdf, p. 297).

In addition, in Chapter 5.2. "Certification procedures", more specifically Article 5.2.4. "Electronic certification", the EU suggests including a reference to the use of international standards for data exchange, as is the case in the relevant standards of IPPC and Codex. A text proposal to that effect is attached (see appendix to this Annex).

Finally, the EU notes the proposal by the Biological Standards Commission to include a case definition for dourine in Chapter 2.5.3. of the Terrestrial Manual. While this is acceptable for now as there currently is no case definition in the Terrestrial Code chapter on this disease, the EU is of the opinion that it would be preferable to have a clear case definition in the disease specific chapters of the Terrestrial Code, as this is important in view of notification obligations of members and for reasons of international trade. Consequently, case definitions in the Terrestrial Manual should in future be replaced by references to the Terrestrial Code, so as to avoid contradictions (reference is made to the EU's comment under item 1 of this report). Therefore, the EU invites the Code Commission to review Chapter 12.3. "Dourine" of the Terrestrial Code by adding a case definition in Article 12.3.1.

Item 31 Review of applications for recognition as OIE collaborating centre

a) Application from the Institute for Laboratory Animal Research (ILAR) for recognition as an OIE Collaborating Centre on Laboratory Animal Welfare and Science

The Code Commission reviewed the dossier submitted by the applicant and endorsed to recommend the adoption at the 81st General Session in May 2013, considering that the AWWG had supported the application.

b) Other applications

The Code Commission noted that several applications for recognition as OIE Collaborating Centre were to be reviewed pending submission of complete application dossier in accordance with the established procedure.

Item 32 Inactivation of pathogens in casings

The Code Commission noted that a regional industry association had proposed new articles on inactivation of the pathogen in casings be inserted to several chapters. Scientific evidence was submitted and considered by the Code Commission and the Scientific Commission. New articles are proposed in Chapters 8.5., 11.3., 14.8. and 15.2.

Item 33 Expert's advice on the diagnostic test for lumpy skin disease (Chapter 11.12.)

The Code Commission noted that an OIE reference laboratory expert had reviewed and provided his opinion on a previous Member Country's comment with respect to a diagnostic test for lumpy skin disease. The Code Commission invited the Laboratories Commission to take the advice into consideration for updating the *Manual*, as appropriate.

Item 34 Other issues referred to from the Scientific Commission

The Code Commission noted that the Scientific Commission proposed to convene an *ad hoc* Group on Tuberculosis and agreed with the Scientific Commission to include a representative of the Code Commission as an observer in this *ad hoc* Group.

Item 35 Proposed dates for the meeting in February 2014

The next meeting in September 2013 and the following meeting in February 2014 are scheduled on 17–26 September 2013 and 11–20 February 2014.

.../Annexes

Annex IV

GLOSSARY

EU position

The EU thanks the OIE and supports the adoption of the modified Glossary.

For the purposes of the *Terrestrial Code*:

Emerging disease

means a new *infection* or *infestation* resulting from the evolution or change of an existing pathogenic agent, a known *infection* or *infestation* spreading to a new geographic area or *population*, or a previously unrecognised pathogenic agent or *disease* diagnosed for the first time and which has a significant impact on animal or public health.

Good manufacturing practice

means a production and testing practice ~~that helps~~ recognised by the *Competent Authority* to ensure ~~a~~ the quality of a product.

Surveillance

means the systematic ongoing collection, collation, and analysis of information related to animal health and the timely dissemination of information ~~to those who need to know~~ so that action can be taken.

Veterinarian

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

Veterinary medicinal product

means any product with approved claim(s) to having a prophylactic ~~protective,~~ therapeutic or diagnostic effect or to alter physiological functions when administered or applied to an *animal*.

Veterinary statutory body

means an autonomous regulatory body for ~~authority regulating~~ *veterinarians* and *veterinary para-professionals*.

— Text deleted.

Annex V

CHAPTER 1.1.

NOTIFICATION OF DISEASES, INFECTIONS, INFESTATIONS AND EPIDEMIOLOGICAL INFORMATION

EU position

The EU thanks the OIE and in general supports the adoption of this modified chapter. Comments are inserted in the text below.

Article 1.1.1.

For the purposes of the *Terrestrial Code* and in terms of Articles 5, 9 and 10 of the OIE Organic Statutes, OIE Members shall recognise the right of the *Headquarters* to communicate directly with the *Veterinary Authority* of its territory or territories.

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

Article 1.1.2.

1) Members shall make available to other Members, through the OIE, whatever information is necessary to minimise the spread of important animal *diseases*, and their aetiological agents, and to assist in achieving better worldwide control of these *diseases*.

2) To achieve this, Members shall comply with the *notification* requirements specified in Article 1.1.3.

3) To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the official OIE *disease* reporting format.

4) Recognising that scientific knowledge concerning the relationship between ~~disease agents and~~ *diseases* and their aetiological agents is constantly developing and that the presence of an ~~infectious~~ aetiological agent does not necessarily imply the presence of a *disease*, Members shall ensure through their reports that they comply with the spirit and intention of point 1 above. This means that the ~~presence~~ detection of the aetiological agent of a *listed disease* in an *animal* ~~an infectious agent, even in the absence of clinical *disease*,~~ should be reported, even in the absence of clinical *disease*.

5) In addition to notifying new findings in accordance with Article 1.1.3., Members shall also provide information on the measures taken to prevent the spread of *diseases*, *infection* and *infestation*; including quarantine measures and restrictions on the movement of *animals*, animal products, ~~and~~ biological products and other miscellaneous objects which could by their nature be responsible for transmission of *disease*, *infection* and *infestation*. In the case of *diseases* transmitted by *vectors*, the measures taken against such *vectors* shall also be specified.

Article 1.1.3.

Veterinary Authorities shall, under the responsibility of the Delegate, send to the *Headquarters*:

1) in accordance with relevant provisions in the *disease* specific chapters, ~~immediate~~ *notification* through the World Animal Health Information System (WAHIS) or by fax or e-mail, within 24 hours, of any of the following events:

   a) first occurrence of a *listed disease* ~~and/or,~~ *infection* or *infestation* in a country, a *zone* or a *compartment*;

   b) re-occurrence of a *listed disease* ~~and/or,~~ *infection* or *infestation* in a country, a *zone* or a *compartment* following a report declared the *outbreak* ended;

   c) first occurrence of a new strain of a pathogen of a *listed disease*, *infection* or *infestation* in a country, a *zone* or a *compartment*;

   d) a sudden and unexpected increase in the distribution, incidence, morbidity or mortality of a *listed disease*, *infection* or *infestation* prevalent within a country, a *zone* or a *compartment*;

   e) an *emerging disease* with significant morbidity or mortality, or zoonotic potential;

f) evidence of change in the epidemiology of a *listed disease*, *infection* or *infestation* (including host range, pathogenicity, strain) in particular if there is a zoonotic impact;

2) weekly reports ~~by fax or e-mail~~ subsequent to a *notification* under point 1 above, to provide further information on the evolution of ~~an~~ the event ~~incident~~ which justified ~~urgent~~ ~~immediate~~ the *notification*;. ~~these~~ These reports should continue until ~~the situation has been resolved through either~~ the *disease*, *infection* or *infestation* has been ~~being~~ eradicated or the situation has become sufficiently stable ~~it becoming endemic~~ so that six-monthly reporting under point 3 will satisfy the obligation of the Member to the OIE; in any case, a final report on the event ~~incident~~ should be submitted;

3) ~~a~~ six-monthly reports on the absence or presence, and evolution of *listed diseases*, *infections* or *infestations* and information of epidemiological significance to other Members;

4) ~~an~~ annual reports concerning any other information of significance to other Members.

Although Members are only required to notify *listed diseases*, *infections* and *infestations* and *emerging diseases* according to points 1 to 4 above, they are encouraged to inform the OIE of other animal health events of epidemiological significance.

EU comment

The EU strongly supports this additional sentence, which is in line with its previous general comment on the need to clearly differentiate between the mandatory notification of listed or emerging diseases, and information on other animal health events provided to the OIE on a voluntary basis. Such a clear distinction that would be based as far as listed diseases are concerned on the case definitions of the disease specific chapters of the Terrestrial Code where they already exist also needs to be made in WAHID, including in its disease maps. This would ultimately increase Member Countries' willingness to share such voluntary information with the OIE.

Article 1.1.4.

1) The *Veterinary Authority* of a country ~~territory~~ in which an *infected zone* ~~or compartment~~ was located shall inform the *Headquarters* when this zone is free from the *disease*, *infection* or *infestation*.

2) An *infected zone* ~~or compartment~~ for a particular *disease*, *infection* or *infestation* shall be considered as such until a period exceeding the *infective period* specified in the *Terrestrial Code* has elapsed after the last reported *case*, and when full prophylactic and appropriate animal health measures have been applied to prevent possible reappearance or spread of the *disease*. These measures will be found in detail in the various chapters of Volume II of the *Terrestrial Code*.

3) A Member may be considered to regain freedom from a specific *disease*, *infection* or *infestation* when all conditions given in the relevant chapters of the *Terrestrial Code* have been fulfilled.

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

EU comment

The words "or *compartments*" in the first line of point 4 above should be deleted, for reasons of consistency with the rest of the text.

~~Article 1.1.5.~~ Article 1.1.5.

~~1)~~ ~~The *Headquarters* shall~~ The *Headquarters* shall communicate ~~send~~ by ~~fax,e-mail or~~ e-mail or World Animal Health Information Database ~~*Disease Information* to~~ to ~~the *Veterinary Authorities*~~ *Veterinary Authorities* ~~concerned,all notifications received as provided in Article 1.1.2.to 1.1.4.~~ all *notifications* received as provided in Articles 1.1.2. to 1.1.4. and other relevant information.

EU comment

The EU supports the amendments proposed in Article 1.1.5., including the proposed new text on "other relevant information", understanding the OIE will make a clear distinction between mandatory notification and voluntary information when communicating to Veterinary Authorities (cf. EU comment above).

2) The *Headquarters* shall dispatch to the Delegates information on new *outbreaks* of *listed diseases*.

3) The *Headquarters*, on the basis of information received and of any official communication, shall prepare an annual report concerning the application of the *Terrestrial Code* and its effects on *international trade*.

Article 1.1.6.

Faxes sent by *Veterinary Authorities* in pursuance of Articles 1.1.3. and 1.1.5. shall receive priority in accordance with the circumstances. Communications by telephone or fax, sent in the case of exceptional urgency when there is danger of spread of a notifiable epizootic *disease*, shall be given the highest priority accorded to these communications by the International Arrangements of Telecommunications.

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— Text deleted.

Annex VI

CHAPTER 1.2.

CRITERIA FOR THE INCLUSION OF DISEASES, INFECTIONS AND INFESTATIONS ON THE OIE LIST

EU position

The EU would like to thank the OIE for having taken into consideration its comments as regards the delisting of certain diseases proposed by the *ad hoc* group on notification of animal diseases and pathogenic agents. The EU would like to continue supporting the work of the OIE in this area by offering participation of its experts in future *ad hoc* groups, and by providing relevant data on certain diseases, including on Enzootic Bovine Leucosis and paratuberculosis.

The EU can in general support the adoption of this modified chapter. However, comments are inserted in the text below, some of which should be taken into account before adoption.

Article 1.2.1.

Introduction

The aim of this chapter is to describe the criteria for the inclusion of *diseases*, *infections* and *infestations* on the OIE List. The objective of listing is to support Members' efforts to prevent the transboundary spread of important animal *diseases*, including *zoonoses*, through transparent and consistent reporting. Each listed *disease* normally has a corresponding chapter to assist Member Countries in the harmonisation of *disease* detection, prevention and control. Requirements for notification are detailed in Chapter 1.1. and notifications are to be made through WAHIS or, if not possible, by fax or e-mail as described in Article 1.1.3.

Article 1.2.2.

The criteria for the inclusion of a *disease*, *infection* or *infestation* in the OIE List are as follows:

1) International spread of the agent (via live via live *animals* or, their products, *vectors* or fomites) has been proven.

AND

2) At least one country has demonstrated freedom or impending freedom from the *disease*, *infection* or *infestation* in populations of susceptible *animals*, based on the animal health surveillance provisions of the *Terrestrial Code*, in particular those contained in Chapter 1.4.

AND

3)

a) Natural transmission to humans has been proven, and human infection is associated with severe consequences.

OR

b) The *disease* has been shown to cause significant morbidity or mortality in domestic *animals* at the level of a country or a *zone*.

OR

c) The *disease* has been shown to, or scientific evidence indicates that it would, cause significant morbidity or mortality in *wild animal* populations.

AND

4) A reliable means of detection and diagnosis exists and a precise *case* definition is available to clearly identify *cases* and allow them to be distinguished from other *diseases*, *infections* and *infestations*.

OR

5) The *disease* or *infection* is an *emerging disease* with evidence of zoonotic properties, rapid spread, or significant morbidity or mortality and a *case* definition is available to clearly identify *cases* and allow them to be distinguished from other *diseases* or *infections*.

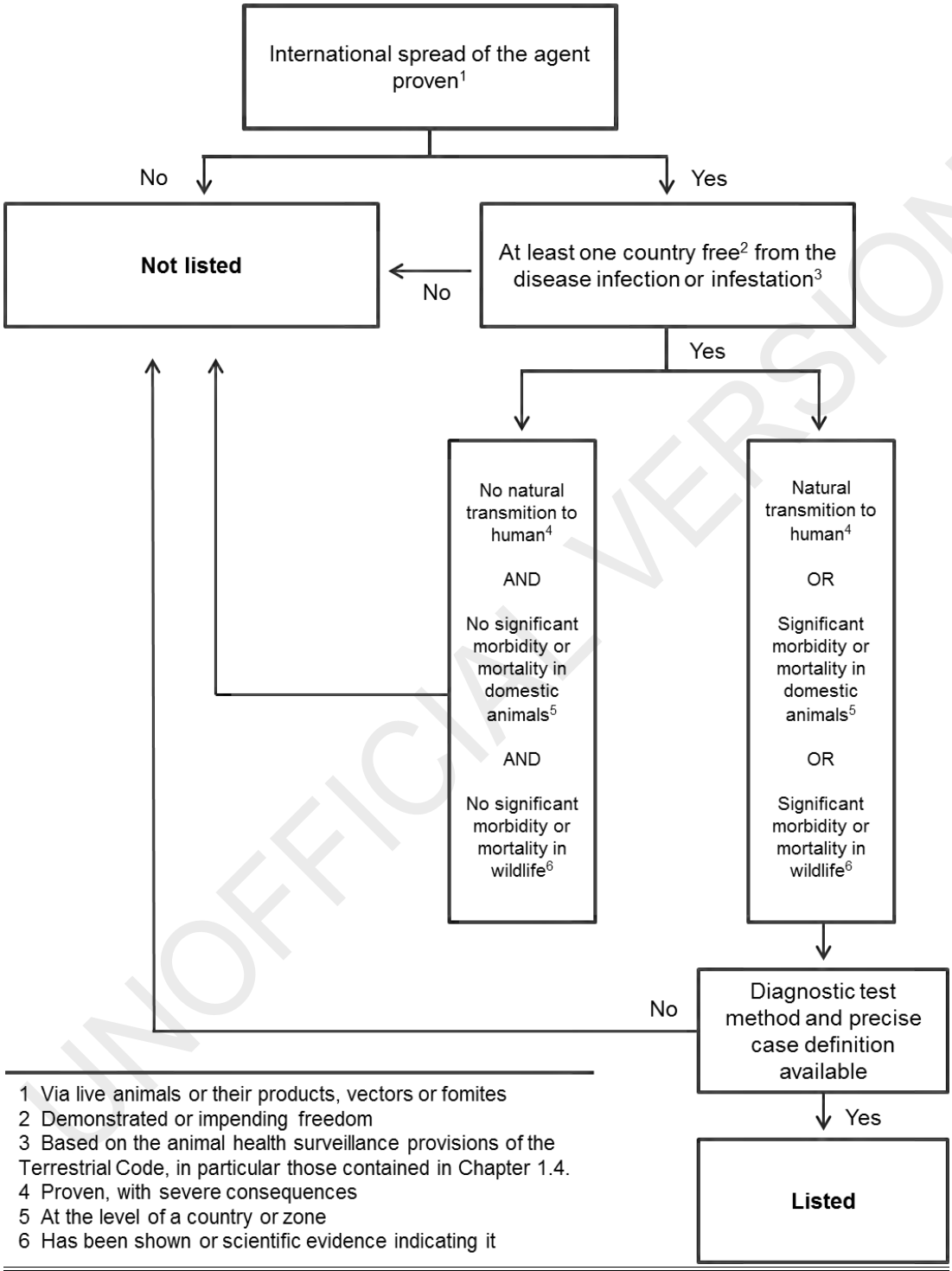
EU comment

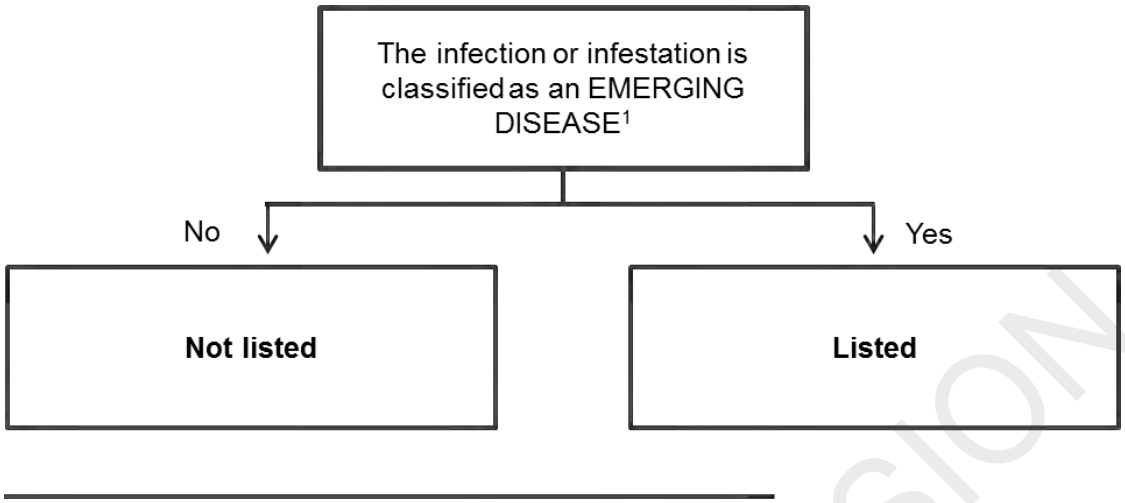
The EU is of the opinion that the point 5 above is not necessary and should be removed in the framework of the on-going review by the Code Commission and the Scientific Commission in September of the concept of emerging diseases. Indeed, Member Countries are already obliged to notify an emerging disease as per Article 1.1.3. point 1 e), thus making the listing of emerging diseases complying only with the criteria in the current point 5 above superfluous. Only diseases meeting the criteria of point 1 to 4 above should be listed on the OIE list. The EU would be eager to contribute to this discussion and to participate with its experts should any *ad hoc* group meeting be organised on the subject.

Article 1.2.2. bis

Flowchart of decision-making

The criteria in Article 1.2.2. above are applied according to the decision-making model shown below.





EU comments
The EU strongly opposes the inclusion of the above flowcharts in this chapter. Indeed, the flowcharts not only are not necessary, but may even lead to more confusion. The new criteria in Article 1.2.2. that were adopted in May 2012 are drafted in standalone text form, in contrast to the previous version of the criteria (2011 edition of the *Terrestrial Code*) where a decision-making model was necessary to complement the table containing the basic criteria and the parameters. Therefore, the above flowcharts are an unnecessary duplication which creates uncertainty. Especially the use of footnotes in the flowcharts is a source of confusion. Therefore, rather than adding flowcharts, the numbering of text of Article 1.2.2. should be improved to remove any ambiguity, if at all necessary.

Article 1.2.3.

The following *diseases*, *infections* and *infestations* are included in the OIE List.

In case of modifications of this list of animal *diseases*, *infections* and *infestations* adopted by the World Assembly, the new list comes into force on 1 January of the following year.

1) The following are included within the category of multiple species *diseases*, *infections* and *infestations*:

– Anthrax

– Infection with Aujeszky's disease virus

– Bluetongue

– Brucellosis (*Brucella abortus*)

– Brucellosis (*Brucella melitensis*)

– Brucellosis (*Brucella suis*)

– Crimean Congo haemorrhagic fever

- ~~Echinococcosis/Hydatidosis~~ Infection with *Echinococcus granulosus*
- Infection with *Echinococcus multilocularis*
- Epizootic haemorrhagic disease
- Equine encephalomyelitis (Eastern)
- Foot and mouth disease
- Heartwater
- Japanese encephalitis
- New World screwworm (*Cochliomyia hominivorax*)
- Old World screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Infection with Rabies virus
- Rift Valley fever
- Infection with Rinderpest virus
- Surra (*Trypanosoma evansi*)
- ~~Trichinellosis~~ Infection with *Trichinella* spp.
- Tularemia
- ~~Vesicular stomatitis~~
- West Nile fever.

2) The following are included within the category of cattle *diseases* and *infections*:

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- Bovine tuberculosis
- Bovine viral diarrhoea
- Infection with *Mycoplasma mycoides* subsp. *mycoides* sc (Contagious bovine pleuropneumonia)
- Enzootic bovine leukosis
- Haemorrhagic septicaemia
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Lumpy skin disease
- Theileriosis
- Trichomonosis
- Trypanosomosis (tsetse-transmitted).

3) The following are included within the category of sheep and goat *diseases* and *infections*:

- Caprine arthritis/encephalitis
- Contagious agalactia
- Contagious caprine pleuropneumonia
- Infection with *Chlamydophila abortus* (Enzootic abortion of ewes, (ovine chlamydiosis)
- Maedi–visna
- Nairobi sheep disease
- Ovine epididymitis (*Brucella ovis*)
- Infection with peste des petits ruminants virus
- Salmonellosis (*S.* abortusovis)
- Scrapie
- Sheep pox and goat pox.

4) The following are included within the category of equine *diseases* and *infections*:

- Infection with African horse sickness virus
- Contagious equine metritis
- Dourine
- Equine encephalomyelitis (Western)
- Equine infectious anaemia
- Equine influenza
- Equine piroplasmosis
- ~~Equine rhinopneumonitis~~ Infection with equid herpesvirus-1 (EHV-1)

EU comment

The EU supports this amendment. However, the EU suggests reviewing Chapter 12.8. of the Terrestrial Code in the near future so as to align it with this modified listing, and by adding a case definition in the new format that has been used in recent years.

- Infection with equine ~~viral~~ arteritis virus
- Glanders
- Venezuelan equine encephalomyelitis.

5) The following are included within the category of swine *diseases* and *infections*:

- African swine fever
- Infection with classical swine fever virus
- Nipah virus encephalitis
- Porcine cysticercosis
- Porcine reproductive and respiratory syndrome

– ~~Swine vesicular disease~~

– Transmissible gastroenteritis.

6) The following are included within the category of avian *diseases* and *infections*:

– Avian chlamydiosis

– Avian infectious bronchitis

– Avian infectious laryngotracheitis

– Avian mycoplasmosis (*Mycoplasma gallisepticum*)

– Avian mycoplasmosis (*Mycoplasma synoviae*)

– Duck virus hepatitis

– Fowl typhoid

– Infection with avian influenza viruses and infection with influenza A viruses of high pathogenicity in birds other than poultry ~~Highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in *poultry* as defined in Chapter 10.4.~~

EU comment

The EU supports the amendment above on Avian Influenza. However, in order to avoid any possible ambiguity, the wording should be consistent with point 9 of Article 10.4.1. Therefore, the EU strongly suggests adding the words ", including wild birds" at the end of the point above.

– Infectious bursal disease (Gumboro disease)

– Newcastle disease

EU comment

As for reasons of consistency the EU suggests changing the title of Chapter 10.9. to "Infection with Newcastle Disease viruses" (see EU comment inserted in Annex XXIV), the EU would also suggest changing the disease name accordingly in the OIE list, for it to read as follows:

"– Infection with Newcastle Disease viruses".

– Pullorum disease

– Turkey rhinotracheitis.

7) The following are included within the category of lagomorph *diseases* and *infections*:

– Myxomatosis

– Rabbit haemorrhagic disease.

8) The following are included within the category of bee *diseases*, *infections* and *infestations*:

– ~~Acarapisosis~~ Infestation of honey bees with *Acarapis woodi*

– ~~American foulbrood~~ Infection of honey bees with *Paenibacillus larvae* (American foulbrood)

– ~~European foulbrood~~ Infection of honey bees with *Melissococcus plutonius* (European foulbrood)

– ~~Small hive beetle (~~Infestation with *Aethina tumida* (small hive beetle)

– ~~*Tropilaelaps* ~~Infestation of honey bees with *Tropilaelaps* spp.

– ~~Varroosis~~ Infestation of honey bees with *Varroa* spp.(varroosis).

EU comment

For consideration by the Code Commission at its September meeting, the EU would suggest deleting the reference to the host species ("of honey bees") in point 8 above, and also in the title of the respective chapters, for reasons of consistency. Indeed, host species are not mentioned for other diseases in the Terrestrial Code.

9) The following are included within the category of other *diseases* and *infections*:

– Camelpox

– Leishmaniosis.

_____

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— Text deleted.

CHAPTER 8.15.

VESICULAR STOMATITIS

Article 8.15.1.

General provisions and safe commodities

For the purposes of the *Terrestrial Code*, the *incubation period* for vesicular stomatitis (VS) shall be 21 days.

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

When authorising the import or transit of the following *commodities* and any products made from these *commodities*, *Veterinary Authorities* should not require any VS related conditions, regardless of the VS status of the *exporting country*:

1) *milk* and *milk products*;

2) hides and skins;

3) *meat* and *meat products*;

4) tallow;

5) gelatine and collagen.

Article 8.15.2.

VS free country

A country may be considered free from VS when:

1) VS is notifiable in the country;

2) no clinical, epidemiological or other evidence of VS has been found during the past two years.

Article 8.15.3.

Trade in commodities

Veterinary Authorities of countries shall consider whether there is a risk with regard to VS in accepting importation or transit through their territory, from other countries, of ruminants, swine, Equidae, and their semen and embryos.

Article 8.15.4.

Recommendations for importation from VS free countries

For domestic cattle, sheep, goats, pigs and horses

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

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

2) were kept in a VS free country since birth or for at least the past 21 days.

Annex VI (contd)

Article 8.15.5.

Recommendations for importation from VS free countries

For wild bovine, ovine, caprine, porcine and equine animals and deer

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

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

2) come from a VS free country;

if the country of origin has a common border with a country considered infected with VS:

3) were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;

4) were protected from insect vectors during quarantine and transportation to the *place of shipment*.

Article 8.15.6.

Recommendations for importation from countries considered infected with VS

For domestic cattle, sheep, goats, pigs and horses

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

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

2) were kept, since birth or for the past 21 days, in an *establishment* where no *case* of VS was officially reported during that period;

3) were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;

4) were protected from insect vectors during quarantine and transportation to the *place of shipment*.

Article 8.15.7.

Recommendations for importation from countries considered infected with VS

For wild bovine, ovine, caprine, porcine and equine animals and deer

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

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

2) were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;

3) were protected from insect *vectors* during quarantine and transportation to the *place of shipment*.

Article 8.15.8.

Recommendations for importation from VS free countries or zones

~~For in vivo derived embryos of ruminants, swine and horses~~

~~*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 VS free country or *zone* at the time of collection;~~

~~2)~~ ~~the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.~~

~~Article 8.15.9.~~

~~**Recommendations for importation from countries or zones considered infected with VS**~~

~~For *in vivo* derived embryos of ruminants, swine and horses~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:~~

~~1)~~ ~~the donor females:~~

~~a)~~ ~~were kept for the 21 days prior to, and during, collection in an *establishment* where no *case* of VS was reported during that period;~~

~~b)~~ ~~were subjected to a diagnostic test for VS, with negative results, within the 21 days prior to embryo collection;~~

~~2)~~ ~~the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.~~

— Text deleted.

Annex VI (contd)

CHAPTER 15.4.

SWINE VESICULAR DISEASE

Article 15.4.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for swine vesicular disease (SVD) shall be 28 days.

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

Article 15.4.2.

SVD free country

A country may be considered free from SVD when it has been shown that SVD has not been present for at least the past two years.

This period may be nine months for countries in which a *stamping-out policy* is practised.

Article 15.4.3.

SVD infected zone

A *zone* shall be considered as infected with SVD until:

1) at least 60 days have elapsed after the confirmation of the last *case* and the completion of a *stamping-out policy* and *disinfection* procedures, or

2) 12 months have elapsed after the clinical recovery or *death* of the last affected *animal* if a *stamping-out policy* was not practised.

Article 15.4.4.

Trade in commodities

Veterinary Authorities of SVD free countries may prohibit importation or transit through their territory, from countries considered infected with SVD, of the following *commodities*:

1) domestic and wild pigs;

2) semen of 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 the SVD virus;

5) products of animal origin (from pigs) intended for use in animal feeding or for agricultural or industrial use which have not been processed to ensure the destruction of the SVD virus;

6) products of animal origin (from pigs) intended for pharmaceutical or surgical use which have not been processed to ensure the destruction of the SVD virus;

7) *pathological material* and biological products (from pigs) which have not been processed to ensure the destruction of the SVD virus.

Article 15.4.5.

Recommendations for importation from SVD free countries

For domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

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

2) were kept in an SVD free country since birth or for at least the past six weeks.

Article 15.4.6.

Recommendations for importation from SVD free countries

For wild pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

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

2) come from an SVD free country;

if the country of origin has a common border with a country considered infected with SVD:

3) were kept in a *quarantine station* for the six weeks prior to shipment.

Article 15.4.7.

Recommendations for importation from countries considered infected with SVD

For domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

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

2) were kept since birth, or for the past six weeks, in an *establishment* where no *case* of SVD was officially reported during that period, and that the *establishment* was not situated in an SVD *infected zone*;

3) were kept in a *quarantine station* for the 28 days prior to shipment, and were subjected to the virus neutralisation test for SVD with negative results during that period.

Article 15.4.8.

Recommendations for importation from countries considered infected with SVD

For wild pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

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

2) were kept in a *quarantine station* for the 28 days prior to shipment, and were subjected to the virus neutralisation test for SVD with negative results during that period.

Annex VI (contd)

Article 15.4.9.

Recommendations for importation from SVD free countries

For semen of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) showed no clinical sign of SVD on the day of collection of the semen;

   b) were kept in an SVD free country for not less than six weeks prior to collection;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 15.4.10.

Recommendations for importation from countries considered infected with SVD

For semen of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) showed no clinical sign of SVD on the day of collection of the semen, and were subjected to the virus neutralisation test for SVD with negative results;

   b) were kept in the *exporting country* for the 28 days prior to collection, in an *establishment* or *artificial insemination centre* where no *case* of SVD was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated in an SVD *infected zone*;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 15.4.11.

Recommendations for importation from SVD free countries

For fresh meat of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *animals* which:

1) have been kept in an SVD free country since birth or for at least the past 28 days;

2) have been slaughtered in an approved *abattoir*, and have been subjected to ante- and post-mortem inspections for SVD with favourable results.

Article 15.4.12.

Recommendations for importation from countries considered infected with SVD

For fresh meat of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *animals* which:

1) have not been kept in an SVD *infected zone*;

2) have been slaughtered in an approved *abattoir* not situated in an SVD *infected zone*, and have been subjected to ante- and post-mortem inspections for SVD with favourable results.

Article 15.4.13.

Recommendations for importation from countries considered infected with SVD

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- and post-mortem inspections for SVD with favourable results;

2) the *meat products* have been processed to ensure the destruction of the SVD virus;

3) the necessary precautions were taken after processing to avoid contact of the *meat* with any source of SVD virus.

Article 15.4.14.

Recommendations for importation from SVD 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 an SVD free country since birth or for at least the past 6 weeks.

Article 15.4.15.

Recommendations for importation from SVD free countries

For products of animal origin (from pigs) intended for pharmaceutical or surgical use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which:

1) have been kept in an SVD free country since birth or for at least the past six weeks;

2) have been slaughtered in an approved *abattoir*, and have been subjected to ante- and post-mortem inspections for SVD with favourable results.

Article 15.4.16.

Recommendations for importation from countries considered infected with SVD

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 to ensure the destruction of the SVD virus.

Article 15.4.17.

Recommendations for importation from countries considered infected with SVD

For bristles (from pigs)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the SVD virus, in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.

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Article 15.4.18.

Recommendations for importation from countries considered infected with SVD

For fertilisers of animal origin (from pigs)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products:

1) do not come from an SVD *infected zone*; or

2) have been processed to ensure the destruction of the SVD virus.

Article 15.4.19.

Recommendations for importation from countries considered infected with SVD

For products of animal origin (from pigs) intended for pharmaceutical or surgical use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products:

1) have been processed to ensure the destruction of the SVD virus;

2) come from *animals* which have not been kept in an SVD *infected zone*;

3) come from *animals* which have been slaughtered in an approved *abattoir* and have been subjected to ante and post-mortem inspections for SVD with favourable results.

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— Text deleted.

Annex VII

CHAPTER 3.2.

EVALUATION OF VETERINARY SERVICES

EU position

The EU supports the adoption of this modified chapter.

Article 3.2.1.

General considerations

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

   Any evaluation should be carried out with due regard for Chapter 3.1.

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

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

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

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

5) Good governance is the key to competence, integrity and confidence in organisations. Mutual confidence between relevant official *Veterinary Services* of trading partner countries contributes fundamentally to stability in *international trade* in *animals* and animal-related products. In this situation, scrutiny is directed more at the *exporting country* than at the *importing country*.

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

7) An *importing country* has a right of assurance that information on sanitary or zoosanitary situations provided by the *Veterinary Services* of an *exporting country* is objective, meaningful and correct.

   Furthermore, the *Veterinary Services* of the *importing country* are entitled to expect validity in the veterinary certification of export.

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

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

Article 3.2.2.

Scope

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

   – organisation, structure and authority of the *Veterinary Services*;
   – human resources;
   – material (including financial) resources;
   – *veterinary legislation*, regulatory frameworks and functional capabilities;
   – animal health, *animal welfare* and veterinary public health controls;
   – formal quality systems including quality policy;
   – performance assessment and audit programmes;
   – participation in OIE activities and compliance with OIE Members' obligations.

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

3) Article 3.2.14. outlines appropriate information requirements for:

   – self-evaluation by the *Veterinary Authority* which perceives a need to prepare information for national or international purposes;
   – evaluation by a prospective or actual *importing country* of the *Veterinary Services* of a prospective or actual *exporting country*;
   – verification or re-verification of an evaluation in the course of a visit to the *exporting country* by the *importing country*;
   – evaluation by third parties such as OIE PVS experts or regional organisations.

Article 3.2.3.

Evaluation criteria for the organisational structure of the Veterinary Services

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

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

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

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

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

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

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

Article 3.2.4.

Evaluation criteria for quality systems

1) The *Veterinary Services* should demonstrate a commitment to the quality of the processes and outputs of their services. Where services or components of services are delivered under a formal quality systems programme which is based on OIE recommended standards or, especially in the case of laboratory components of *Veterinary Services* other internationally recognised quality standards, the *Veterinary Services* undergoing evaluation should make available evidence of accreditation, details of the documented quality processes and documented outcomes of all relevant audits undertaken.

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

Article 3.2.5.

Evaluation criteria for human resources

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

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

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

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

Article 3.2.6.

Evaluation criteria for material resources

1. Financial

Actual yearly budgetary information regarding the *Veterinary Services* should be available and should include the details set out in the model questionnaire outlined in Article 3.2.14. Information is required on conditions of service for veterinary staff (including salaries and incentives), and should provide a comparison with the private sector and perhaps with other professionals. Information should also be available on non-government sources of revenue available to *veterinarians* in their official responsibilities.

2. Administrative

a) Accommodation

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

b) Communications

The *Veterinary Services* should be able to demonstrate that they have reliable access to effective communications systems, especially for animal health surveillance and control programmes.

Inadequate communications systems within the field services components of these programmes or between outlying offices and headquarters, or between the *Veterinary Services* and other relevant administrative and professional services, signify an inherent weakness in these programmes. Adequate communications systems between laboratories and between field and laboratory components of the *Veterinary Services* should also be demonstrated.

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

c) Transport systems

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

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

3. Technical

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

a) Cold chain for laboratory samples and veterinary medicines

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

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b) Diagnostic laboratories

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

In countries where there is more than one diagnostic laboratory for a given pathogen, the designation of a National Reference Laboratory for that pathogen may contribute to the quality of analysis performed by the diagnostic laboratories.

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

c) Research

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

Article 3.2.7.

Legislation and functional capabilities

1. Animal health, animal welfare and veterinary public health

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

2. Export and import inspection

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

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

Annex VII (contd)

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

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

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

The *Veterinary Services* should demonstrate that they are capable of providing accurate and valid certification for exports of *animals* and animal products, based on Chapters 5.1. and 5.2. of the *Terrestrial Code*. They should have appropriately organised procedures which ensure that sanitary or animal health certificates are issued by efficient and secure methods. The documentation control system should be able to correlate reliably the certification details with the relevant export consignments and with any inspections to which the consignments were subjected.

Security in the export certification process, including electronic documentation transfer, is important.

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

Article 3.2.8.

Animal health controls

1. Animal health status

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

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

2. Animal health control

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

3. National animal disease reporting systems

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

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

Article 3.2.9.

Veterinary public health controls

1. Food hygiene

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

2. Zoonoses

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

3. Chemical residue testing programmes

Adequacy of controls over chemical residues in exported *animals*, animal products and feedstuffs should be demonstrated. Statistically-based *surveillance* and monitoring programmes for environmental and other chemical contaminants in *animals*, in animal-derived foodstuffs and in animal feedstuffs should be favourably noted. These programmes should be coordinated nationwide.

Correlated results should be freely available on request to existing and prospective trading partner countries. Analytical methods and result reporting should be consistent with internationally recognised standards. If official responsibility for these programmes does not rest with the *Veterinary Services*, there should be appropriate provision to ensure that the results of such programmes are made available to the *Veterinary Services* for assessment. This process should be consistent with the standards set by the Codex Alimentarius Commission or with alternative requirements set by the *importing country* where the latter are scientifically justified.

4. Veterinary medicines

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

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

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

Annex VII (contd)

5. Integration between animal health controls and veterinary public health

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

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

Article 3.2.10.

Performance assessment and audit programmes

1. Strategic plans

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

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

2. Performance assessment

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

3. Compliance

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

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

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

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

4. Veterinary Services administration

a) Annual reports

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

b) Reports of government review bodies

The reports of any periodic or ad hoc government reviews of *Veterinary Services* or of particular functions or roles of the *Veterinary Services* should be considered in the evaluation process.

Details of action taken as a consequence of the review should also be accessible.

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

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

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

e) Publications

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

f) Formal linkages with sources of independent scientific expertise

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

g) Trade performance history

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

Article 3.2.11.

Participation in OIE activities

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

Article 3.2.12.

Evaluation of the veterinary statutory body

1. Scope

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

a) objectives and functions;

b) legislative basis for ~~the function of~~ the *veterinary statutory body*, including autonomy and functional capacity;

c) the composition ~~and representation~~ of the *veterinary statutory body's* ~~membership~~ ~~and~~ including the organisations represented in it ~~representativeness of its governing organs~~;

d) accountability and transparency of decision-making;

Annex VII (contd)

e) sources and management of funding;

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

2. Evaluation of objectives and functions

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

The policy and objectives of the *veterinary statutory body*, including details of its powers and functions, should be defined, notably with regard to:

a) ~~to regulate *veterinarians* and *veterinary para-professionals* through~~ the licensing or registration of *veterinarians* and *veterinary para-professionals* to perform the activities of veterinary medicine/science ~~such persons~~;

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

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

3. Evaluation of legislative basis, autonomy and functional capacity

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

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

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

4. Evaluation of the composition ~~membership representation~~ of ~~the governing organs of~~ the veterinary statutory body

Detailed descriptions of the composition, rules and conditions for membership, including duration of appointment, and representation of interested third parties, public and private, should be available. ~~in respect of the membership of the *veterinary statutory body* and the method and duration of appointment of members. Such information includes:~~

~~a) *veterinarians* designated by the *Veterinary Authority*;~~

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

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

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

~~e) representative(s) of veterinary academia;~~

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

~~g) election procedures and duration of appointment;~~

~~h) qualification requirements for members.~~

5. Evaluation of accountability and transparency of decision-making

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

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

6. Evaluation of financial sources and financial management

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

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

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

Documentary evidence should be available to demonstrate compliance with initial and continuing education requirements, including with OIE recommendations.

8. Evaluation of mechanisms for coordination between Veterinary Authority and veterinary statutory body

The exact mechanisms will vary according to the national governance systems.

Article 3.2.13.

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

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

3) In the case of evaluation for the purposes of *international trade*, the authorities of an *importing country* should use the principles elaborated above as the basis for the evaluation and should attempt to acquire information according to the model questionnaire outlined in Article 3.2.14. The *Veterinary Services* of the *importing country* are responsible for the analysis of details and for determining the outcome of the evaluation after taking into account all the relevant information. The relative ranking of importance ascribed, in the evaluation, to the criteria described in this chapter will necessarily vary according to case-by-case circumstances. This ranking should be established in an objective and justifiable way. Analysis of the information obtained in the course of an evaluation study should be performed in as objective a manner as possible. The validity of the information should be established and reasonableness should be employed in its application. The assessing country should be willing to defend any position taken on the basis of this type of information, if challenged by the other party.

Article 3.2.14.

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

Annex VII (contd)

1. Organisation and structure of Veterinary Services

   a) National Veterinary Authority

      Organisational chart including numbers, positions and numbers of vacancies.

   b) Sub-national components of the Veterinary Authority

      Organisational charts including numbers, positions and number of vacancies.

   c) Other providers of veterinary services

      Description of any linkage with other providers of veterinary services.

2. National information on human resources

   a) Veterinarians

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

      ii) Numbers of:

         – full time government *veterinarians*: national and sub-national;

         – part time government *veterinarians*: national and sub-national;

         – private *veterinarians* authorised by the *Veterinary Services* to perform official veterinary functions *[Describe accreditation standards, responsibilities and limitations applying tothese private veterinarians.]*;

         – other *veterinarians*.

      iii) Animal health:

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

         – full time government *veterinarians*: national and sub-national;

         – part time government *veterinarians*: national and sub-national;

         – other *veterinarians*.

      iv) Veterinary public health:

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

         – full time government *veterinarians*: national and sub-national;

         – part time government *veterinarians*: national and sub-national;

         – other *veterinarians*.

      v) Numbers of veterinarians relative to certain national indices:

         – per total human population;

         – per farm livestock population, by geographical area;

         – per livestock farming unit, by geographical area.

vi) Veterinary education:

– number of veterinary schools;

– length of veterinary course (years);

– curriculum addressing the minimum competencies of day 1 veterinary graduates and the post-graduate and continuing education topics to assure the delivery of quality veterinary services, as described in the relevant chapter(s) of the *Terrestrial Code*;

– international recognition of veterinary degree.

vii) Veterinary professional associations.

b) Graduate personnel (non-veterinary)

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

c) Veterinary para-professionals employed by the Veterinary Services

i) Animal health:

– Categories and numbers involved with farm livestock on a majority time basis:

• by geographical area;

• proportional to numbers of field Veterinary Officers in the Veterinary Services, by geographical area.

– Education or training details.

ii) Veterinary public health:

– Categories and numbers involved in food inspection on a majority time basis:

• *meat* inspection: export *meat* establishments with an export function and domestic *meat* establishments (no export function);

• dairy inspection;

• other foods.

– Numbers in import and export inspection.

– Education or training details.

d) Support personnel

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

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

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

g) Additional information or comments.

Annex VII (contd)

3. Financial management information

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

i) for the national Veterinary Authority;

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

iii) for other relevant government-funded institutions.

b) Sources of the budgetary allocations and amount:

i) government budget;

ii) sub-national authorities;

iii) taxes and fines;

iv) grants;

v) private services.

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

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

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

4. Administration details

a) Accommodation

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

b) Communications

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

c) Transport

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

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

5. Laboratory services

a) Diagnostic laboratories (laboratories engaged primarily in diagnosis)

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

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

– government operated laboratories;

– private laboratories authorised by *Veterinary Authority* for the purposes of supporting officialor officially-endorsed animal health control or public health testing and monitoring programmes and import and export testing.

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

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

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

vi) List of related National Reference Laboratories, if any.

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

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

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

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

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

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

b) Research laboratories (laboratories engaged primarily in research)

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

– government operated *laboratories*;

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

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

iii) Published programmes of future government sponsored veterinary research.

iv) Annual reports of the government research *laboratories*.

6. Veterinary legislation, regulations and functional capabilities

a) Animal health and veterinary public health

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

– animal and veterinary public health controls at national frontiers;

– control of endemic animal diseases, including *zoonoses*;

Annex VII (contd)

- emergency powers for control of exotic disease outbreaks, including *zoonoses*;
- inspection and registration of facilities;
- animal feeding;
- veterinary public health controls of the production, processing, storage and marketing of *meat* for domestic consumption;
- veterinary public health controls of the production, processing, storage and marketing of fish, dairy products and other foods of animal origin for domestic consumption;
- registration and use of veterinary pharmaceutical products including vaccines;
- *animal welfare*.

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

b) Export and import inspection

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

- veterinary public health controls of the production, processing, storage and transportation of *meat* for export;
- veterinary public health controls of production, processing, storage and marketing of fish, dairy products and other foods of animal origin for export;
- animal health and veterinary public health controls of the export and import of *animals*, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;
- animal health controls of the importation, use and bio-containment of organisms which are aetiological agents of animal diseases, and of pathological material;
- animal health controls of importation of veterinary biological products including vaccines;
- administrative powers available to *Veterinary Services* for inspection and registration of facilities for veterinary control purposes (if not included under other legislation mentioned above);
- documentation and compliance.

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

7. Animal health and veterinary public health controls

a) Animal health

i) Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services*.

ii) Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services*.

iii) Description and relevant data of current official control programmes including:

– epidemiological surveillance or monitoring programmes;

– officially approved industry administered control or eradication programmes for specific *diseases*.

iv) Description and relevant details of animal disease emergency preparedness and response plans.

v) Recent history of animal disease status:

– animal *diseases* eradicated nationally or from defined sub-national zones in the last ten years;

– animal *diseases* of which the prevalence has been controlled to a low level in the last ten years;

– animal *diseases* introduced to the country or to previously free sub national regions in the last ten years;

– *emerging diseases* in the last ten years;

– animal *diseases* of which the prevalence has increased in the last ten years.

b) Veterinary public health

i) Food hygiene

– Annual national *slaughter* statistics for the past three years according to official data by species of *animals* (bovine, ovine, porcine, caprine, *poultry*, farmed game, wild game, equine, other).

– Estimate of total annual slaughterings which occur but are not recorded under official statistics.

– Proportion of total national *slaughter* which occurs in registered export establishments, by category of *animal*.

– Proportion of total national *slaughter* which occurs under veterinary control, by category of *animal*.

– Numbers of commercial *fresh meat* establishments in the country which are registered for export by the *Veterinary Authority*:

• *slaughterhouses* (indicate species of *animals*);

• cutting or packing plants (indicate *meat* type);

• *meat* processing establishments (indicate *meat* type);

• cold stores.

– Numbers of commercial *fresh meat* establishments in the country approved by other *importing countries* which operate international assessment inspection programmes associated with approval procedures.

– Numbers of commercial *fresh meat* establishments under direct public health control of the *Veterinary Services* (including details of category and numbers of inspection staff associated with these premises).

– Description of the veterinary public health programme related to production and processing of animal products for human consumption (including *fresh meat*, *poultry meat*, *meat products*, game *meat*, dairy products, fish, fishery products, molluscs and crustaceans and other foods of animal origin) especially including details applying to exports of these *commodities*.

Annex VII (contd)

– Descriptive summary of the roles and relationships of other official organisations in public health programmes for the products listed above if the *Veterinary Authority* does not have responsibility for those programmes which apply to national production destined to domestic consumption or exports of the *commodities* concerned.

ii) Zoonoses

– Descriptive summary of the numbers and functions of staff of the *Veterinary Authority* involved primarily with monitoring and control of zoonotic diseases.

– Descriptive summary of the role and relationships of other official organisations involved in monitoring and control of *zoonoses* to be provided if the *Veterinary Authority* does not have these responsibilities.

iii) Chemical residue testing programmes

– Descriptive summary of national surveillance and monitoring programmes for environmental and chemical residues and contaminants applied to animal-derived foodstuffs, *animals* and animal feedstuffs.

– Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.

– Descriptive summary of the analytical methodologies used and their consistency with internationally recognised standards.

iv) Veterinary medicines

– Descriptive summary of the administrative and technical controls involving registration, supply and use of veterinary pharmaceutical products especially including biological products. This summary should include a focus on veterinary public health considerations relating to the use of these products in food-producing animals.

– Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.

8. Quality systems

a) Accreditation

Details and evidence of any current, formal accreditation by external agencies of the *Veterinary Services* of any components thereof.

b) Quality manuals

Documented details of the quality manuals and standards which describe the accredited quality systems of the *Veterinary Services*.

c) Audit

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

9. Performance assessment and audit programmes

a) Strategic plans and review

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

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

b) Compliance

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

c) Annual reports of the Veterinary Authority

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

d) Other reports

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

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

e) Training

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

ii) Summary descriptions of training courses and duration.

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

f) Publications

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

g) Sources of independent scientific expertise

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

10. Membership of the OIE

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

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— Text deleted.

Annex VIII

CHAPTER 3.4.

VETERINARY LEGISLATION

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Article 3.4.1.

Introduction and objective

Good governance is a recognised global public good and is of critical importance to OIE Members. Legislation is a key element in achieving good governance.

Veterinary legislation should, at a minimum, provide a basis for *Competent Authorities* to meet their obligations as defined in the *Terrestrial Code* and the relevant recommendations of the Codex Alimentarius Commission. In addition, there is an obligation for World Trade Organization (WTO) Members under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) to notify the WTO of changes in sanitary measures, including changes in legislation that affect trade, and provide relevant information.

For the purposes of the *Terrestrial Code*, *veterinary legislation* comprises all legal instruments necessary for the governance of the veterinary domain.

The objective of this chapter is to provide advice and assistance to OIE Members when formulating or modernising *veterinary legislation* so as to comply with OIE standards, thus ensuring good governance of the entire veterinary domain.

Article 3.4.2.

Definitions

For the purposes of this chapter the following definitions apply:

Hierarchy of legislation: means the ranking of the legal instruments as prescribed under the fundamental law (e.g. the constitution) of a country. Respect for the hierarchy means that each legal instrument must comply with higher order legal instruments.

~~**Legal certainty:** means the situation in which the legislation is clear, coherent, stable and transparent, and protects citizens against adverse side effects of legal instruments.~~

Legal instrument: means the legally binding rule that is issued by a body with the required legal authority to issue the instrument.

Primary legislation: means the legal instruments issued by the legislative body of a Member.

~~**Quality of legislation:** means the technical relevance, acceptability to society, sustainability in technical, financial and administrative terms and provision of a basis for effective implementation of laws.~~

Secondary legislation: means the legal instruments issued by the executive body of a Member under the authority of primary legislation.

Stakeholder: means a person, group, or organisation that can affect or be affected by the impacts of *veterinary legislation*.

Veterinary domain: means all the activities that are directly or indirectly related to *animals*, their products and by-products, which help to protect, maintain and improve the health and welfare of humans, including by means of the protection of animal health and welfare, and food safety.

~~**Veterinary legislation:** means the collection of specific legal instruments (primary and secondary legislation) required for the governance of the veterinary domain.~~

Annex VIII (contd)

Article 3.4.3.

General principles

1) Respect for the hierarchy of legislation

Veterinary legislation should scrupulously respect the hierarchy between primary legislation and secondary legislation.

2) Legal basis

Competent Authorities should have available the primary legislation and secondary legislation necessary to carry out their activities at all administrative and geographic levels.

Veterinary legislation should be consistent with national and international law, as appropriate, including civil, penal and administrative laws.

3) Transparency

Veterinary legislation should be inventoried and be readily accessible and intelligible for use, updating and modification, as appropriate.

Competent Authorities should ensure communication of *veterinary legislation* and related documentation to stakeholders.

4) Consultation

The drafting of new and revised legislation relevant to the veterinary domain should be a consultative process involving *Competent Authorities* and legal experts to ensure that the resulting legislation is scientifically, technically and legally sound.

To facilitate implementation of the *veterinary legislation*, *Competent Authorities* should establish relationships with stakeholders, including taking steps to ensure that they participate in the development of significant legislation and required follow-up.

5) Quality of legislation and legal certainty

Veterinary legislation should be clear, coherent, stable and transparent and protect citizens against unintended adverse side effects of legal instruments. It should be technically relevant, acceptable to society, able to be effectively implemented and sustainable in technical, financial and administrative terms. A high quality of legislation is essential for achieving legal certainty.

Article 3.4.4.

The drafting of veterinary legislation

Veterinary legislation should:

a) be drafted in a manner that establishes clear rights, responsibilities and obligations (i.e. 'normative');

b) be unambiguous, with clear and consistent syntax and vocabulary;

c) be precise, ~~and~~ accurate and consistent in the repeated use of the terminology ~~even if this results in repetition and a cumbersome style~~;

d) contain no definitions that create any conflict or ambiguity;

e) include a clear statement of scope and objectives;

f) provide for the application of penalties and sanctions, either criminal or administrative, as appropriate to the situation; and

g) make provision for the financing needed for the execution of all activities of *Competent Authorities*; the financing should be ensured in accordance with the national funding system.

Article 3.4.5.

Competent Authorities

Competent Authorities should be legally mandated, capacitated and organised to ensure that all necessary actions are taken quickly and coherently to address animal health, ~~and~~ public health and *animal welfare* emergencies effectively.

Veterinary legislation should provide for a chain of command that is as effective as possible (i.e. short, with all responsibilities clearly defined). For this purpose, the responsibilities and powers of *Competent Authorities*, from the central level to those responsible for the implementation of legislation in the field, should be clearly defined. Where more than one *Competent Authority* is involved such as in relation to environmental, food safety or other public health matters a reliable system of coordination and cooperation should be in place.

Competent Authorities should appoint technically qualified officials to take any actions needed for implementation or verification of compliance with the *veterinary legislation*, respecting the principles of independence and impartiality prescribed in Article 3.1.2.

1) Necessary powers of the Competent Authority

The *veterinary legislation* should also ensure that:

a) officials have the legal authority to intervene in accordance with the legislation and the penal procedures in force;

b) while executing their legal mandate, officials are protected against legal action and physical harm for actions carried out in good faith;

c) the powers and functions of officials are explicitly and thoroughly listed to protect the rights of stakeholders and the general public against any abuse of authority. This includes respecting confidentiality, as appropriate; and

d) at least the following powers are available through the primary legislation:

i) access to premises and vehicles for carrying out inspections;

ii) access to documents;

iii) taking samples;

iv) retention (setting aside) of *animals* and goods, pending a decision on final disposition;

v) seizure of *animals*, products and food of animal origin;

vi) suspension of one or more activities of an inspected establishment;

vii) temporary, partial or complete closure of inspected establishments; and

viii) suspension or withdrawal of authorisations or approvals.

These essential powers must be identified as they can result in actions that may conflict with individual rights ascribed in fundamental laws.

2) Delegation of powers by the Competent Authority

The *veterinary legislation* should provide the possibility for *Competent Authorities* to delegate specific tasks related to official activities. The specific tasks delegated, the body(ies) to which the tasks are delegated and the conditions of supervision by the *Competent Authority* should be defined.

For this purpose, the *veterinary legislation* should:

a) define the field of activities and the specific tasks covered by the delegation;

b) provide for the control, supervision and, when appropriate, financing of the delegation;

Annex VIII (contd)

c) define the procedures for making delegation;

d) define the competencies to be held by persons receiving delegation; and

e) define the conditions of withdrawals of delegations.

Article 3.4.6.

Veterinarians and veterinary para-professionals

1) Veterinary medicine/science

In order to ensure quality in the conduct of veterinary medicine/science, the *veterinary legislation* should ~~provide a definition of veterinary medicine/science sufficient to address the following~~:

a) define the prerogatives of *veterinarians* and of the various categories of *veterinary para-professionals* that are recognised by the Member Country;

b) define the minimum initial and continuous educational requirements and competencies for *veterinarians* and *veterinary para-professionals*;

c) prescribe the conditions for recognition of the qualifications for *veterinarians* and *veterinary para-professionals*;

d) define the conditions to perform the activities of veterinary medicine/science; and

e) identify the exceptional situations, such as epizootics, under which persons other than *veterinarians* can undertake activities that are normally carried out by *veterinarians*.

2) The control of veterinarians and veterinary para-professionals

Veterinary legislation should provide a basis for regulation of *veterinarians* and *veterinary para-professionals* in the public interest. To that end, the legislation should:

a) describe the general system of control in terms of the political, administrative and geographic configuration of the country;

b) describe the various categories of *veterinary para-professionals* recognised by the Member Country according to its needs, notably in animal health and food safety, and for each category, prescribe its training, qualifications, tasks and extent of supervision;

c) prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to *veterinarians* and veterinary para-professionals;

d) provide for the possibility of delegation of powers to a professional organisation such as a *veterinary statutory body*; and

e) where powers have been so delegated, describe the prerogatives, the functioning and responsibilities of the mandated professional organisation.

Article 3.4.7.

Laboratories in the veterinary domain

1) Facilities

Veterinary legislation should define the role, responsibilities, obligations and quality requirements for:

a) reference *laboratories*, which are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods;

b) *laboratories* designated by the *Competent Authority* for carrying out the analysis of official samples; and

c) *laboratories* recognised by the *Competent Authority* to conduct analyses required under the legislation e.g. for the purposes of quality control.

The *veterinary legislation* should define the conditions for the classification, approval, operations and supervision of *laboratories* at each level.

2) Reagents

Veterinary legislation should provide a basis for actions to address the elements listed below:

a) procedures for authorising reagents that are used to perform official analyses;

b) quality assurance by manufacturers of reagents used in official analyses; and

c) surveillance of marketing of reagents, where these can affect the quality of analyses required by the *veterinary legislation*.

Article 3.4.8.

Health provisions relating to animal production

1) Identification and traceability

Veterinary legislation should provide a basis for actions to address all the elements in Article 4.2.3., point 6.

2) Animal markets and other gatherings

Veterinary legislation should address, for animal markets and other commercially or epidemiologically significant animal gatherings, the following elements:

a) registration of animal markets and other animal gatherings;

b) health measures to prevent *disease* transmission, including procedures for cleaning and *disinfection*, and *animal welfare* measures; and

c) provision for veterinary checks.

3) Animal reproduction

Veterinary legislation should provide a basis for actions to address the health regulation of animal reproduction as appropriate. Health regulations may be implemented at the level of *animals*, genetic material, establishments or operators.

4) Animal feed

Veterinary legislation should provide a basis for actions to address the elements listed below:

a) standards for the production, composition and quality control of animal feed;

b) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and

c) recall from the market of any product likely to present a *hazard* to human health or animal health.

5) Animal by-products

Veterinary legislation should provide a basis for actions to address the elements listed below:

a) definition of the animal by-products subject to the legislation;

b) rules for collection, processing, use and disposal of animal by-products;

c) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and

d) rules to be followed by animal owners.

6) Disinfection

Veterinary legislation should provide a basis for actions to address the regulation and use of products and methods of *disinfection* relating to the prevention and control of *animal diseases*.

Article 3.4.9.

Animal diseases

Veterinary legislation should provide a basis for the *Competent Authority* to manage *diseases* of importance to the country and to list those *diseases*, guided by the recommendations in Chapters 1.1. and 1.2.

1) Surveillance

Veterinary legislation should provide a basis for the collection, transmission and utilisation of epidemiological data relevant to *diseases* listed by the *Competent Authority*.

2) Disease prevention and control

a) *Veterinary legislation* should include general animal health measures applicable to all *diseases* and, if necessary, additional or specific measures such as *surveillance*, establishment of a regulatory programme or emergency response for particular *diseases* listed in the country.

b) The legislation should also provide a basis for contingency plans to include the following for use in *disease* responses:

i) administrative and logistic organisation;

ii) exceptional powers of the *Competent Authority*; and

iii) special and temporary measures to address all identified *risks* to human or animal health.

c) *Veterinary legislation* should provide for the financing of animal disease control measures, such as operational expenses and, as appropriate, owners' compensation in the event of *killing* or *slaughtering* of *animals* and seizure or destruction of carcasses, *meat*, animal feed or other things.

3) Emerging diseases

Veterinary legislation should provide for measures to investigate and respond to *emerging diseases*.

Article 3.4.10.

Animal welfare

1) General provisions

Veterinary legislation should provide a basis for actions to address the *animal welfare* related requirements in Section 7 ~~of the *Terrestrial Code*~~.

To this end, the legislation should contain, as a minimum, a legal definition of cruelty as an offence, and provisions for direct intervention of the *Competent Authority* in the case of neglect by animal keepers.

2) Stray dogs and other free-roaming animals

Veterinary legislation should provide a basis for actions to address the requirements in Chapter 7.7. and, as appropriate, prohibition of the abandonment of *animals*, and management of abandoned *animals*, including transfer of ownership, veterinary interventions and *euthanasia*.

Article 3.4.11.

Veterinary medicines and biologicals

Veterinary legislation should provide a basis for assuring the quality of veterinary medicines and biologicals and minimising the *risk* to human, animal and environmental health associated with their use.

1) General measures

Veterinary legislation should provide a basis for actions to address the elements listed below:

a) definition of veterinary medicines and biologicals, including any specific exclusions; and

b) regulation of the importation, manufacture, distribution and usage of, and commerce in, veterinary medicines and biologicals.

2) Raw materials for use in veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the elements listed below:

a) quality standards for raw materials used in the manufacture or composition of veterinary medicines and biologicals and arrangements for checking quality;

b) establishment of the withdrawal periods and maximum residue limits for veterinary medicines and biologicals, as appropriate; and

c) requirements for substances in veterinary medicines and biologicals that may, through their effects, interfere with the conduct of veterinary checks.

3) Authorisation of veterinary medicines and biologicals

a) *Veterinary legislation* should ensure that only authorised veterinary medicines and biologicals may be placed on the market.

b) Special provisions should be made for:

i) medicated feed;

ii) products prepared by authorised *veterinarians* or authorised pharmacists; and

iii) emergencies and temporary situations.

c) *Veterinary legislation* should address the technical, administrative and financial conditions associated with the granting, renewal, refusal and withdrawal of authorisations.

d) In defining the procedures for seeking and granting authorisations, the legislation should:

i) describe the role of the relevant *Competent Authoritiesy*; and

ii) establish rules providing for the transparency in decision making.

e) *Veterinary legislation* may provide for the possibility of recognition of the equivalence of authorisations made by other countries.

4) Quality of veterinary medicines and biologicals

Veterinary legislation should address the following elements:

a) the conduct of clinical and non-clinical trials to verify all claims made by the manufacturer;

b) conditions for the conduct of trials;

Annex VIII (contd)

c) qualifications of experts involved in trials; and

d) surveillance for adverse effects arising from the use of veterinary medicines and biologicals.

5) Establishments producing, storing and wholesaling veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the following elements:

a) registration or authorisation of all operators manufacturing importing, storing, processing, wholesaling or otherwise distributing veterinary medicines and biologicals or raw materials for use in making veterinary medicines and biologicals;

b) definition of the responsibilities of operators;

c) good manufacturing practices as appropriate;

d) reporting on adverse effects to the *Competent Authority*; and

e) mechanisms for traceability and recall.

6) Retailing, use and traceability of veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the following elements:

a) control over the distribution of veterinary medicines and biologicals and arrangements for traceability, recall and conditions of use;

b) establishment of rules for the prescription and provision of veterinary medicines and biologicals to end users;

c) restriction to authorised professionals and, as appropriate, authorized veterinary paraprofessionals of commerce in veterinary medicines and biologicals that are subject to prescription;

d) the supervision by an authorised professional of organisations approved for holding and use of veterinary medicines and biologicals;

e) the regulation of advertising claims and other marketing and promotional activities; and

f) reporting on adverse effects to the *Competent Authority*.

Article 3.4.12.

Human food production chain

Veterinary legislation should provide a basis for actions to safeguard the human food production chain through controls at all critical steps, consistent with national food safety standards. The role of the *Veterinary Services* in food safety is described in Chapter 6.1.

1) General provisions

Veterinary legislation should provide a basis for actions to address the following elements:

a) controls over all stages of the production, processing and distribution of food of animal origin;

b) recording all significant animal and public health events that occur during primary production;

c) giving operators of food production premises the primary responsibility for compliance with food safety requirements, including traceability established by the *Competent Authority*;

d) inspection for compliance with food standards, where this is relevant to health or safety;

e) inspection of premises;

f) prohibition of the marketing of products not fit for human consumption; and

g) provisions for recall from the marketplace of all products likely to be hazardous for human or animal health.

2) Products of animal origin intended for human consumption

Veterinary legislation should provide a basis for actions to address the following elements:

a) arrangements for inspection and audit;

b) the conduct of inspection and audit ~~on the basis of veterinary expertise~~;

c) health standards; and

d) the application of health identification marks that are visible to the intermediary or final user.

The *Competent Authority* should have the necessary powers and means to rapidly withdraw any products deemed to be hazardous from the food chain or to prescribe uses or treatments that ensure the safety of such products for human or animal health.

3) Operators responsible for premises and establishments pertaining to the food chain

Veterinary legislation should provide a basis for actions to address the following elements as appropriate:

a) registration of premises and establishments by the *Competent Authority*;

b) the use of risk-based management procedures; and

c) prior authorisation of operations that are likely to constitute a significant *risk* to human or animal health.

Article 3.4.13.

Import and export procedures and veterinary certification

Veterinary legislation should provide a basis for actions to address the elements relating to import and export procedures and veterinary certification referred to in Section 5 of the *Terrestrial Code.*

— Text deleted.

Annex IX

CHAPTER 4.6.

COLLECTION AND PROCESSING OF BOVINE, SMALL RUMINANT AND PORCINE SEMEN

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Article 4.6.1.

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 4.5.

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

Article 4.6.2.

Conditions applicable to testing of bulls and teaser animals

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

1. Prior to entering pre-entry isolation facility

   The *animals* should comply with the following requirements prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the *diseases* in question.

   a) Bovine brucellosis – Point 3 or 4 of Article 11.3.5.

   b) Bovine tuberculosis – Point 3 or 4 of Article 11.6.5.

   c) Bovine viral diarrhoea (BVD)

      The *animals* should be subjected to:

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

      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 11.11.3.; 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 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* of origin of the *animals*.

2. Testing in the pre-entry isolation facility 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 pre-entry isolation facility for at least 28 days. The *animals* should be tested as described below a minimum of 21 days after entering the pre-entry isolation facility, except for *Campylobacter fetus* subsp. *venerealis* and *Tritrichomonas foetus*, for which testing may commence after seven days in pre-entry isolation. All the results should be negative except in the case of BVD 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

i) The *animals* should be subjected to a virus isolation test or a test for virus antigen, with negative results Only when all the *animals* in pre-entry isolation have had negative results may the *animals* enter the semen collection facilities.

ii) All *animals* should be subjected to a serological test to determine the presence or absence of BVD antibodies.

iii) Only if no seroconversion occurs in the *animals* which tested seronegative before entry into the pre-entry isolation facility, may any *animal* (seronegative or seropositive) be allowed entry into the semen collection facilities.

iv) If seroconversion occurs, all the *animals* that remain seronegative should be kept in pre-entry isolation until there is no more seroconversion in the group for a period of three weeks. Serologically positive *animals* may be allowed entry into the semen collection facilities.

c) *Campylobacter fetus* subsp. *venerealis*

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

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

d) *Tritrichomonas foetus*

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

ii) *Animals* aged six months or older that could have had contact with females prior to pre-entry isolation 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 pre-entry isolation facility and the other *animals* of the same group should remain in pre-entry isolation and be retested, with negative results, not less than 21 days after removal of the positive *animal*.

f) Bluetongue

The *animals* should comply with the provisions referred to in Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* where the pre-entry isolation facility is located.

3. 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 or *zone* where the semen collection facilities are located is not free:

a) Bovine brucellosis

b) Bovine tuberculosis

c) BVD

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 tested.

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 six 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 Article 8.3.10. or Article 8.3.11.

f) *Tritrichomonas 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 six 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 11.11.3.

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

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

5. 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 11.11.7.

Article 4.6.3.

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.

Annex IX (contd)

1. Prior to entering pre-entry isolation facility

The *animals* should comply with the following requirements prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the *diseases* in question.

a) Caprine and ovine brucellosis – Article 14.1.6.

b) Ovine epididymitis – Article 14.7.3.

c) Contagious agalactia – Points 1 and 2 of Article 14.3.1.

d) Peste des petits ruminants – Points 1, 2, and 4 or 5 of Article 14.8.7.

e) Contagious caprine pleuropneumonia – Article 14.4.7., depending on the CCPP status of the country or *zone* of origin of the *animals*.

f) Paratuberculosis – Free from clinical signs for the past two years.

g) Scrapie – Comply with Article 14.9.8. if the *animals* do not originate from a scrapie free country or *zone* as defined in Article 14.9.3.

h) Maedi-visna – Article 14.6.2.

i) Caprine arthritis/encephalitis – Article 14.2.2. in the case of goats.

j) Bluetongue

The *animals* should comply with Articles 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* of origin of the *animals*.

k) Tuberculosis – In the case of goats, a single or comparative tuberculin test, with negative results.

2. Testing in the pre-entry isolation facility 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 pre-entry isolation facility for at least 28 days. The *animals* should be tested as described below a minimum of 21 days after entering the pre-entry isolation facility, with negative results.

a) Caprine and ovine brucellosis – Point 1c) of Article 14.1.8.

b) Ovine epididymitis – Point 1d) of Article 14.7.4.

c) Maedi-visna and caprine arthritis/encephalitis – Test on *animals*

d) Bluetongue

The *animals* should comply with the provisions referred to in Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* where the pre-entry isolation facility is located.

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 or *zone* where the semen collection facilities are located 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 – The *animals* should comply with the provisions referred to in Article 8.3.10. or Article 8.3.11.

Article 4.6.4.

Conditions applicable to testing of boars

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

1. Prior to entering pre-entry isolation facility

   The *animals* should be clinically healthy, physiologically normal and comply with the following requirements within 30 days prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the *diseases* in question.

   a) Porcine brucellosis – Article 15.3.3.

   b) Foot and mouth disease – Articles 8.5.12., 8.5.13. or 8.5.14.

   c) Aujeszky's disease – Article 8.2.9. or Article 8.2.10.

   d) Transmissible gastroenteritis – Article 15.5.2.

   e) Swine vesicular disease – Article 15.4.5. or Article 15.4.7.

   f) African swine fever – Article 15.1.5. or Article 15.1.6.

   g) Classical swine fever – Article 15.2.5. or Article 15.2.6.

   h) Porcine reproductive and respiratory syndrome – Test complying with the standards in the *Terrestrial Manual*.

2. Testing in the pre-entry isolation facility 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 pre-entry isolation facility for at least 28 days. The *animals* should be subjected to diagnostic tests as described below a minimum of 21 days after entering the pre-entry isolation facility, with negative results.

   a) Porcine brucellosis – Article 15.3.5.

   b) Foot and mouth disease – Articles 8.5.15., 8.5.16., 8.5.17. or 8.5.18.

   c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.

   d) Transmissible gastroenteritis – Article 15.5.4.

   e) Swine vesicular disease – Article 15.4.9. or Article 15.4.10.

   f) African swine fever – Article 15.1.8. or Article 15.1.9.

   g) Classical swine fever – Article 15.2.8. or Article 15.2.9.

   h) Porcine reproductive and respiratory syndrome – 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 country or *zone* where the semen collection facilities are located is not free:

Annex IX (contd)

a) Porcine brucellosis – Article 15.3.5.

b) Foot and mouth disease – Articles 8.5.15., 8.5.16., 8.5.17. or 8.5.18.

c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.

d) Transmissible gastroenteritis – Article 15.5.4.

e) Swine vesicular disease – Article 15.4.9. or Article 15.4.10.

f) African swine fever – Article 15.1.8. or Article 15.1.9.

g) Classical swine fever – Article 15.2.8. or Article 15.2.9.

h) Porcine reproductive and respiratory syndrome – The test complying with the standards in the *Terrestrial Manual*.

Article 4.6.5.

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 4.6.6.

Conditions applicable to the collection of semen

1) The floor of the mounting area should be clean and provide safe footing. 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 animals should be sanitised 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.

Article 4.6.7.

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 sterilised 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 should have been distilled or demineralised, sterilised (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 should 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 should also be sterilised 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 (75 µg), divekacin (25 µg).

      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 and identification of frozen semen

   Semen for export should be stored in straws separately from other genetic material not meeting the requirements of this chapter with fresh liquid nitrogen in sterilised or 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).

   Prior to export, semen straws ~~or pellets~~ should clearly and permanently 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.

Annex IX (contd)

4. Sperm sorting

Equipment used for sex-sorting sperm should be clean and disinfected between *animals* according to the recommendations of the licencer of the system. Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from *animals* of same or better health status.

Semen straws containing sex-sorted sperm should be permanently identified as such.

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CHAPTER 4.7.

COLLECTION AND PROCESSING OF *IN VIVO* DERIVED EMBRYOS FROM LIVESTOCK AND EQUIDS

EU position

The EU supports the adoption of this modified 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 approved by the *Competent Authority*.

2) The team should be supervised by a team *veterinarian*.

3) 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.

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 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 embryo collection team should keep a record of its activities, which should be maintained for inspection by the *Veterinary Authority* for a period of at least two years after the embryos have been exported.

7) The embryo 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.

Article 4.7.3.

Conditions applicable to processing laboratories

A 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 and being examined and prepared for freezing and storage.

Annex IX (contd)

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 processing laboratory should be under the direct supervision of the team *veterinarian* and be 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 processing 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 frequently, and always before and after each occasion on which embryos for export are processed.

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* or *flock* from which the donor *animals* have been sourced.

   b) The donor *animals* should not be situated in a *herd* or *flock* subject to veterinary restrictions for OIE *listed disease* or pathogens for relevant species (see Chapter 1.2. of the *Terrestrial Code*), other than those that are in International Embryo Transfer Society (IETS) Category 1 for the species of embryos being collected (see Article 4.7.14.).

   c) At the time of collection, the donor *animals* should be clinically inspected by the team *veterinarian*, or by a *veterinarian* responsible to the team *veterinarian* and certified to be free of clinical signs of *diseases*.

2. Semen donors

   a) Semen used to inseminate donor *animals* artificially should have been produced and processed in accordance with the provisions of Chapter 4.6.

   b) When the donor of the semen used to inseminate donor females for embryo production is 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 test an aliquot of semen from the same collection date.

   c) Where natural service or fresh semen is used, donor sires should meet the health conditions set out in Chapter 4.6. 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 categorisation (Article 4.7.14.), comprises the risk potential for embryo contamination and depends on:

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

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

   c) the pathogenic characteristics of the specified disease agents that are of concern to the *Veterinary Authority* of the *importing country*.

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 should be washed at least ten times with at least 100–fold dilutions between each wash, and a fresh pipette should be used for transferring the embryos through each wash.

   b) Only embryos from the same donor should be washed together, and no more than ten embryos should be washed at any one time.

   c) Sometimes, for example when inactivation or removal of certain viruses, such as 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, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free of adherent material.

   e) All shipments of embryos should be accompanied by a statement signed by the team *veterinarian* certifying that these embryo processing procedures have been completed.

   ~~*[NOTE: All shipments of embryos should 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 categorisation~~1~~ (Article 4.7.14.) and which are of concern to the *Veterinary Authority* of the *importing country*, encompasses the risk reductions resulting from:

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

   b) testing of embryo-collection (flushing) fluids and non-viable embryos, or other samples such as blood, in a laboratory 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 and storage of embryos 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 collection, processing, washing and storage media as recommended in the IETS Manual[2].

Annex IX (contd)

2. Equipment

a) All equipment used to collect, handle, wash, freeze and store embryos should ideally be new or at least sterilised prior to use as recommended in the IETS Manual~~2~~.

b) Used equipment should not be transferred between countries for re-use by the embryo collection team.

Article 4.7.7.

Optional tests and treatments

1) The testing of samples can be requested by an *importing country* to confirm the absence of pathogenic organisms that may be transmitted via *in vivo* derived 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. Samples may include:

a) Non-viable embryos and oocytes

Where the viable, zona pellucida intact embryos from a donor are intended for export, all non-fertilised oocytes and degenerated or zona pellucida compromised embryos collected from that donor should be washed according to the IETS Manual~~2~~ and pooled for testing if requested by the *importing country*. Non-viable embryos and oocytes from the donor should be processed and stored together.

b) Embryo collection (flushing) 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 and oocytes then any debris that is retained on the filter should be rinsed off into the retained fluid.

c) Washing fluids

The last four washes of the embryos and oocytes should be pooled according to the IETS Manual.

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~~. Enzyme treatment is necessary only when pathogens for which the IETS recommends this additional treatment (such as with trypsin) may be present. It should be noted that such treatment is not 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 and transport of embryos

1) The embryos for export 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.

2) Only embryos from the same individual donor should be stored together in the same ampoule, vial or straw.

3) The embryos should if possible, depending on the species, be frozen, stored with fresh liquid nitrogen in cleaned and sterilised tanks or containers under strict hygienic conditions at the approved storage place.

4) Ampoules, vials or straws should 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 should not be exported until the appropriate veterinary certificates are completed.

Article 4.7.9.

Procedure for micromanipulation

When micromanipulation of the embryos is to be carried out, this should be done after completion of the treatments described in point 2 of Article 4.7.5. and conducted in accordance with Chapter 4.9.

Article 4.7.10.

Specific conditions applicable to porcine embryos

The *herd* of origin should be free of clinical signs of swine vesicular disease and brucellosis. The development of effective cryopreservation methods for the storage of zona pellucida-intact porcine embryos is still at a very early stage.

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 unsuitable for those from horses routinely involved in events or competitions at the international level. For instance, in appropriate circumstances horses travelling with an *international veterinary certificate* may be exempt 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 these species that only zona pellucida-intact embryos can be used in *international trade*. The development of cryopreservation methods for storage of camelid embryos is still at an early stage, and also that pathogen interaction studies with camelid embryos have not yet been carried out.

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.

Annex IX (contd)

Article 4.7.14.

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

Based on the conclusions of the IETS~~1~~, the following *diseases* and pathogenic agents are categorised 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~~2~~.

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

   – Aujeszky's disease (pigs): 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
   – Scrapie (sheep).

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~~2~~, 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.

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~~2~~, 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 (not a *listed disease*)
   – Bovine spongiform encephalopathy (goats) (not a *listed disease* of goats)
   – Bovine viral diarrhoea virus (cattle)
   – *Campylobacter fetus* (sheep) (not a *listed disease* of sheep)
   – Foot and mouth disease (pigs, sheep and goats)
   – *Haemophilus somnus* (cattle) (not a *listed disease*)
   – Maedi-visna (sheep)
   – *Mycobacterium paratuberculosis* (cattle)
   – *Neospora caninum* (cattle) (not a *listed disease*)
   – Ovine pulmonary adenomatosis (not a *listed disease*)
   – Porcine reproductive and respiratory disease syndrome (PRRS)
   – Rinderpest (cattle)
   – Atypical scrapie (not a *listed disease*)
   – 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~~2~~ between collection and transfer.

b) The following *diseases* or pathogenic agents are in Category 4:

– African swine fever
– Akabane (cattle) (not a *listed disease*)
– Bovine anaplasmosis
– Bluetongue (goats)
– Border disease (sheep) (not a *listed disease*)
– Bovine herpesvirus-4 (not a *listed disease*)
– *Chlamydia psittaci* (cattle, sheep)
– Contagious equine metritis
– Enterovirus (cattle, pigs) (not a *listed disease*)
– Equine rhinopneumonitis
– Equine viral arteritis
– *Escherichia coli* O9:K99 (cattle) (not a *listed disease*)
– *Leptospira borgpetersenii serovar hardjobovis (*cattle*)* (not a *listed disease*)
– *Leptospira* sp. (pigs) (not a *listed disease*)
– Lumpy skin disease
– *Mycobacterium bovis* (cattle)
– *Mycoplasma* spp. (pigs)
– Ovine epididymitis (*Brucella ovis*)
– Parainfluenza-3 virus (cattle) (not a *listed disease*)
– Parvovirus (pigs) (not a *listed disease*)
– Porcine circovirus (type 2) (pigs) (not a *listed disease*)
– Scrapie (goats)
– *Tritrichomonas foetus* (cattle)
– *Ureaplasma and Mycoplasma* spp. (cattle, goats) (not a *listed disease*)
– Vesicular stomatitis (cattle, pigs).

— Text deleted.

Annex X

CHAPTER 6.4.

BIOSECURITY PROCEDURES IN POULTRY PRODUCTION

EU position

The EU supports the adoption of this modified chapter.

Article 6.4.1.

Introduction

Infectious agents of *poultry* are a threat to *poultry* health and, at times, human health and have significant social and economic implications. In *poultry* production, especially under intensive conditions, prevention is the most viable and economically feasible approach to the control of infectious agents.

Biosecurity procedures should be implemented with the objective of preventing the introduction and dissemination of infectious agents in the *poultry* production chain. Biosecurity will be enhanced with the adoption and implementation of the principles of Good Agricultural Practices and the Hazard Analysis Critical Control Point (HACCP) system.

Article 6.4.2.

Purpose and scope

This chapter deals with biosecurity procedures in intensive *poultry* production. It should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976) and Guidelines for the control of *Campylobacter* and *Salmonella* in chicken meat (CAC/GL 78-2011).

This chapter identifies several biosecurity measures. The choice of measures to be implemented will vary according to national conditions, including *poultry infection* status, the risk of introduction and dissemination of infectious agents and the cost effectiveness of control measures.

Recommendations on specific infectious agents may be found in relevant *disease* chapters in the *Terrestrial Code*.

Article 6.4.3.

Definitions

Breeders: means *poultry* destined for the production of fertile eggs for incubation for the purpose of producing *day-old birds*.

Live bird markets: means markets where live birds from various sources and species are sold for *slaughter*, further rearing or production.

Article 6.4.4.

Recommendations on the location and construction of poultry establishments

1. All establishments (poultry farms and hatcheries)

   a) A suitably isolated geographical location is recommended. Factors to consider include the location of other *poultry* and livestock *establishments*, wild bird concentrations and the distance from roads used to transport *poultry*.

   b) *Poultry establishments* should be located and constructed to provide adequate drainage for the site. Run-off or untreated site wastewater should not discharge into waterfowl habitats.

c) *Poultry* houses and hatcheries should be designed and constructed (preferably of smooth impervious materials) so that cleaning and *disinfection* can be carried out effectively. Ideally, the area immediately surrounding the *poultry* houses and hatcheries should be paved with concrete or other impervious material to facilitate cleaning and *disinfection*.

d) The *establishment* should be surrounded by a security fence to prevent the entry of unwanted animals and people.

e) A sign indicating restricted entry should be posted at the entrance to the *establishment*.

2. Additional measures for poultry farms

a) *Establishments* should be designed to house a single species and a single production type. The design should also consider the 'all-in all-out' single age group principle. If this is not feasible, the *establishment* should be designed so that each *flock* can be managed as a separate *epidemiological unit*.

b) *Poultry* houses, and buildings used to store feed, eggs or other material, should be constructed and maintained to prevent the entry of wild birds, rodents and arthropods.

c) Where feasible, the floors of *poultry* houses should be constructed using concrete or other impervious materials and designed so that cleaning and *disinfection* can be carried out effectively.

d) Where feasible, feed should be delivered into the farm from outside the security fence.

3. Additional measures for hatcheries

a) The design of the hatchery should take account of work flow and air circulation needs, with 'one way flow' movement of eggs and *day-old birds* and one way air flow in the same direction.

b) The hatchery buildings should include physical separation of areas used for the following:

i) personnel changing, showering and sanitary facilities;

ii) receipt, storage and transfer of eggs;

iii) incubation;

iv) hatching;

v) sorting, sexing and other handling of *day-old birds*;

vi) storage of egg boxes and boxes for *day-old birds*, egg flats, chick box liners, chemicals and other items;

vii) equipment washing;

viii) waste disposal;

ix) dining facilities for personnel;

x) office space.

Article 6.4.5.

Recommendations applicable to the operation of poultry establishments

1. All establishments (poultry farms and hatcheries)

a) All *establishments* should have a written *biosecurity plan*. Personnel in the *establishments* should have access to basic training in biosecurity relevant to *poultry* production and understand the implications to animal health, human health and food safety.

b) There should be good communication between personnel involved in the *poultry* production chain to ensure that steps are taken to minimise the introduction and dissemination of infectious agents.

c) Traceability at all levels of the *poultry* production chain should be possible.

d) Records should be maintained on an individual *flock* basis and include data on bird health, production, medications, vaccination, mortality and *surveillance*. In hatcheries, records should include data on fertility, hatchability, vaccination and treatments. Records should be maintained on cleaning and *disinfection* of farm and hatchery buildings and equipment. Records should be readily available for inspection on site.

e) Monitoring of *poultry* health on the *establishment* should be under the supervision of a *veterinarian*.

f) To avoid the development of antimicrobial resistance, antimicrobials should be used according to relevant directions of the *Veterinary Services* and manufacturer's instructions and in accordance with Chapters 6.8., 6.9., and 6.10. ~~and 6.11.~~

g~~f~~) *Establishments* should be free from unwanted vegetation and debris that could attract or harbour pests.

h~~g~~) Procedures for the prevention of entry of wild birds into *poultry* houses and buildings, and the control of vermin such as rodents and arthropods should be implemented.

i~~h~~) Access to the *establishment* should be controlled to ensure only authorised persons and *vehicles* enter the site.

j~~i~~) All personnel and visitors entering an *establishment* should follow a biosecurity procedure. The preferred procedure is for visitors and personnel entering the *establishment* to shower and change into clean clothes and footwear provided by the *establishment*. Where this is not practical, clean outer garments (coveralls or overalls, head covering and footwear) should be provided. Entry of visitors and *vehicles* should be registered by the *establishment.*

k~~j~~) Personnel and visitors should not have had recent contact with other *poultry*, *poultry* waste, or *poultry* processing plant(s). This time period should be based on the level of risk of transmission of infectious agents. This will depend on the *poultry* production purpose, biosecurity procedures and *infection* status.

l~~k~~) Any *vehicle* entering an *establishment* should be cleaned and disinfected according to a *biosecurity plan*. Delivery *vehicles* should be cleaned, and disinfected before *loading* each consignment of eggs or *poultry*.

2. Additional measures for all poultry farms

a) Whenever possible, the 'all-in all-out' single age group principle should be used. If this is not feasible and several *flocks* are maintained on one *establishment*, each *flock* should be managed as a separate *epidemiological unit*.

b) All personnel and visitors entering a *poultry* house should wash their hands with soap and water or sanitize them using a disinfectant. Personnel and visitors should also change footwear, use a boot spray or use a properly maintained disinfectant footbath. The disinfectant solution in the footbath should be changed on a regular basis to ensure its efficacy, according to the manufacturer's instructions.

c) Any equipment should be cleaned and sanitized before being taken into a poultry house.

d) Animals, other than *poultry* of the appropriate (resident) species and age, should not be permitted access to *poultry* houses. No animals should have access to other buildings, such as those used to store feed, eggs or other material.

e) The drinking water supply to *poultry* houses should be potable according to the World Health Organization or to the relevant national standard, and microbiological quality should be monitored if there is any reason to suspect contamination. The water delivery system should be cleaned and disinfected between *flocks* when the *poultry* house is empty.

f) Birds used to stock a *poultry* house should preferably be obtained from breeder *flocks* and hatcheries that are free from vertically transmitted infectious agents.

Annex X (contd)

g) Heat treated feeds with or without the addition of other bacteriocidal or bacteriostatic treatments, such as addition of organic acids, are recommended. Where heat treatment is not possible, the use of bacteriostatic or bactericidal treatments is recommended.

Feed should be stored in a manner to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents. The movement of feed between *flocks* should be avoided.

h) The litter in the *poultry* house should be kept dry and in good condition.

i) Dead birds should be removed from *poultry* houses as quickly as possible but at least daily. These should be disposed of in a safe and effective manner.

j) Personnel involved in the catching of birds should be adequately trained in bird handling and basic biosecurity procedures.

k) To minimise stress *poultry* should be transported in well ventilated *containers* and should not be over crowded. Exposure to extreme temperatures should be avoided.

l) *Containers* should be cleaned and disinfected between each use, or disposed of in a safe manner.

m) When a *poultry* house is depopulated, it is recommended that all faeces and litter be removed from the house and disposed of in a safe manner to minimise the risk of dissemination of infectious agents.

If litter is not removed and replaced between *flocks* then the litter should be treated in a manner to minimise the risk of dissemination of infectious agents from one *flock* to the next.

After removal of faeces and litter, cleaning and *disinfection* of the *poultry* house and equipment should be done in accordance with Chapter 4.13.

n) For *poultry flocks* that are allowed to range outdoors, feeders, feed and other items which may attract wild birds should be kept indoors. *Poultry* should not be allowed access to sources of contamination, such as household waste, litter storage areas, other animals, stagnant water and water of unknown quality. The nesting area should be inside the *poultry* house.

~~o)~~ ~~To avoid the development of antimicrobial resistance, antimicrobials should be used according to relevant directions of the *Veterinary Services* and manufacturer's instructions and in accordance with Chapters 6.8., 6.9., 6.10., 6.11.~~

3. Additional measures for layers

Refer to Section 3 of the Codex Alimentarius Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976).

4. Additional measures for breeders

a) Nest box litter and liners should be kept clean.

b) *Hatching eggs* should be collected at frequent intervals, at least daily, and placed in new or clean and disinfected packaging materials.

c) Grossly dirty, cracked, broken, or leaking eggs should be collected separately and should not be used as *hatching eggs*.

d) *Hatching eggs* should be cleaned and sanitized as soon as possible after collection using an approved sanitising agent, in accordance with the manufacturer's instructions.

e) *Hatching eggs* or their packaging materials should be marked to assist traceability and veterinary investigations.

f) The *hatching eggs* should be stored in a dedicated room as soon as possible after cleaning and sanitisation. Storage conditions should minimise the potential for microbial contamination and growth and ensure maximum hatchability. The room should be well ventilated, kept clean, and regularly disinfected using disinfectants approved for this purpose.

5. Additional measures for hatcheries

a) Dead in shell embryos should be removed from hatcheries as soon as they are found and disposed of in a safe and effective manner.

b) All hatchery waste, garbage and discarded equipment should be contained or at least covered while on site and removed from the hatchery and its environs as soon as possible.

c) After use, hatchery equipment, tables and surfaces should be promptly and thoroughly cleaned and disinfected with an approved disinfectant.

d) Egg handlers and sexers and handlers of *day-old birds* should wash their hands with soap and water before commencing work and between working with batches of *hatching eggs* or *day-old birds* from different breeder *flocks*.

e) *Hatching eggs* and *day-old birds* from different breeder *flocks* should be identifiable during incubation, hatching, sorting and transportation.

f) *Day-old birds* should be delivered to the farm in new *containers* or in clean, disinfected *containers*.

Article 6.4.6.

Prevention of further dissemination of infectious agents of poultry

When a *flock* is suspected or known to be infected, a *veterinarian* should be consulted immediately and, in addition to the general biosecurity measures described previously, management procedures should be adjusted to effectively isolate it from other *flocks* on the *establishment* and other epidemiologically related *establishments*. The following measures are recommended:

1) Personnel should manage *flocks* to minimise the risk of dissemination of infectious agents to other *flocks* and *establishments*, and to humans. Relevant measures include handling of an infected *flock* separately, last in sequence and the use of dedicated personnel, clothing and equipment.

2) When *infection* has been confirmed, epidemiological investigations should be carried out to determine the origin and route of transmission of the infectious agent.

3) *Poultry* carcasses, litter, faeces and other potentially contaminated farm waste should be disposed of in a safe manner to minimise the risk of dissemination of infectious agents. The disposal method used will depend on the infectious agent involved.

4) Depending on the epidemiology of the *disease*, the results of a *risk assessment*, and public and animal health policies, destruction or *slaughter* of a *flock* before the end of the normal production period may be used. When infected *flocks* are destroyed or slaughtered, they should be processed in a manner to minimise exposure of humans and other *flocks* to the infectious agent, and in accordance with recommendations of the *Veterinary Service* and relevant chapters in the *Terrestrial Code*. Based on *risk assessment*, non-infected, high risk *flocks* may be destroyed or slaughtered before the end of their normal production period.

   Before restocking, the *poultry* house including equipment should be cleaned, disinfected and tested to verify that the cleaning has been effective. Special attention should be paid to feed equipment and water systems.

   Microbiological monitoring of the efficacy of *disinfection* procedures is recommended when pathogenic agents have been detected in the previous *flock*.

5) Depending on the epidemiology of the *disease*, *risk assessment*, vaccine availability and public and animal health policies, vaccination is an option to minimise the dissemination of the infectious agent.

   When used, vaccines should be administered in accordance with the directions of the *Veterinary Services* and the manufacturer's instructions. Recommendations in the *Terrestrial Manual* should be followed as appropriate.

Annex X (contd)

Article 6.4.7.

Recommendations to prevent the dissemination of infectious agents to and from live bird markets

1) Personnel should be educated on the significance of infectious agents and the need to apply biosecurity practices to prevent dissemination of these agents. Education should be targeted to personnel at all levels of operations in these markets, such as drivers, owners, handlers, processors.

   Programmes should be implemented to raise consumer awareness about the risks associated with activities of live bird markets.

2) Personnel should wash their hands with soap and water before and after handling birds.

3) Birds from diseased *flocks* should not be transported to live bird markets.

4) All *containers* and *vehicles* should be cleaned and disinfected every time they leave the market.

5) Live birds that leave the market and go to a farm should be kept separately from other birds for a period of time to minimise the potential dissemination of infectious agents of *poultry*.

6) Periodically the market should be emptied, cleaned and disinfected. This is of particular importance when an infectious agent of *poultry* deemed significant by the *Veterinary Services* has been identified in the market or the region.

7) Where feasible, *surveillance* should be carried out in these markets to detect infectious agents of *poultry*. The *surveillance* programme should be determined by the *Veterinary Services*, and in accordance with recommendations in relevant chapters of the *Terrestrial Code*.

8) Efforts should be made to ensure the possibility of tracing all birds entering and leaving the markets.

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— Text deleted.

Annex XI

CHAPTER 6.9.

RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE

EU position

The EU is of the opinion that the OIE Terrestrial Code chapters on Antimicrobial resistance should be further reviewed considerably and would therefore appreciate a deep reflection and further work in this area in the future.

While this proposed modified chapter has somewhat improved and is a step in the right direction, the EU would wish to go further.

The EU understands that most of its important comments submitted further to the September 2012 report of the Code Commission have not been considered by the OIE. These comments are therefore reiterated in the text below, along with some general comments, for consideration by the OIE *ad hoc* group on Antimicrobial Resistance at its next meeting.

Given the outcomes of the recent first global OIE conference on the Responsible and Prudent Use of Antimicrobial Agents for Animals, the EU encourages the OIE to continue work to further improve Chapter 6.9. in the near future. To this effect, the EU would like to offer technical support to the OIE for future work on the *Terrestrial Code* chapters related to AMR by participation of EU experts in the relevant *ad hoc* groups.

Considering the above, the EU can in general support the adoption of this modified chapter at the 81st OIE General Session.

General EU comments

The title of the chapter "Responsible and prudent use of antimicrobial agents in veterinary medicine" seems not to well reflect the current content of Chapter 6.9. Indeed, the chapter mainly focuses on some aspects of the marketing authorisation of antimicrobial agents and the description of the stakeholder's responsibilities. The EU agrees that these two elements are basic principles that have to be taken into account. However, in order to assure that Member Countries will be able to develop and implement national strategies, additional elements and aspects related to the prudent use of antimicrobials need to be included and enhanced in Chapter 6.9. (e.g. prevention and reduction of the need to use antimicrobials in different species, best practices, enforcement, husbandry systems, considerations regarding Critically Important Antimicrobials [CIAs] and the link with public health). Therefore, the EU would encourage the OIE to consider adding these aspects to the chapter when further revising it in the near future.

Furthermore, the EU also considers that there is a need to review and clarify the criteria to classify antimicrobial agents as critically important for veterinary medicine. Such classification should be based on both animal health and public health aspects ("*One health*"), and close collaboration with the WHO in this field would be desirable.

Finally, the EU would like to announce that it intends to reiterate its substantial comments on Chapter 6.10. "Risk assessment for antimicrobial resistance arising from the use of antimicrobial agents in animals" (specific EU comments on that chapter will be provided to the OIE by the deadline of 16 August 2013).

Article 6.9.1.

Purpose

This document ~~These recommendations~~ provides guidance for the responsible and prudent use of *antimicrobial agents* in veterinary medicine, with the aim of protecting both animal and human health as well as the environment. It defines the respective responsibilities of the *Competent Authority* and stakeholders ~~involved in the authorisation, production, control, distribution and use of veterinary medicinal products (VMP) containing antimicrobial agent(s)~~ such as ~~the national regulatory authority,~~ the veterinary pharmaceutical industry, *veterinarians*, animal feed manufacturers, distributors and food animal producers who are involved in the authorisation, production, control, importation, exportation, distribution and use of veterinary medicinal products (VMP) containing *antimicrobial agent(s)*. ~~The *Competent Authorities* responsible for the registration and control of all groups involved in the authorisation production, distribution and use of veterinary antimicrobials have specific obligations~~.

Responsible and ~~P~~prudent use is ~~principally~~ determined ~~by~~ taking into account ~~the outcome of~~ the specifications detailed in the marketing authorisation ~~procedure~~ and ~~by~~ their implementation ~~of specifications~~ when *antimicrobial~~s~~ agents* are administered to *animals* and ~~are~~ is part of good veterinary and good agricultural practice.

EU comment

As veterinary professional judgement is an essential aspect of responsible and prudent use of antimicrobials, the EU suggests adding a reference to it as follows:

"Responsible and prudent use is determined taking into account the specifications detailed in the marketing authorisation and their implementation under veterinary professional judgment and is part of good veterinary and good agricultural practice.".

Activities associated with the ~~R~~responsible and prudent use of *antimicrobial agents* ~~activities~~ should ~~need to~~ involve all relevant stakeholders.

Coordination of these activities at the national or regional level is recommended and may support the implementation of targeted actions by the stakeholders involved and enable clear and transparent communications.

Article 6.9.2.

Objectives of responsible and prudent use

Responsible and ~~P~~prudent use includes ~~a set of~~ implementing practical measures and recommendations intended to ~~prevent and/or reduce~~ improve animal health and *animal welfare* while preventing or reducing the selection, emergence and spread of antimicrobial-resistant bacteria in *animals* and humans. Such measures include ~~to~~:

1) ensuring the rational use ~~maintain the efficacy~~ of *antimicrobial agents* in *animals* ~~and to ensure the rational use of antimicrobials in *animals*~~ with the purpose of optimising both their efficacy and safety ~~in *animals*~~;

EU comment

The EU suggests adding the following additional point 1bis:

"1bis) be restrictive in both the human and veterinary use of critically important antimicrobials and newly developed antimicrobials, eventually with the aim in the future to reserve critically important antimicrobials as much as possible for human use;".

Indeed, restrictive use in both human and veterinary field is of overall importance to prevent development of resistance, and it might be necessary in the future to reserve use of certain antimicrobials to human use.

2) complying with the ethical obligation and economic need to keep *animals* in good health;

3) preventing~~,~~ or reducing, as far as possible, the transfer of resistant micro-organisms ~~and/~~or resistance determinants ~~(with their any resistance determinants)~~ within animal populations, their environment and ~~from *animals* to~~ between *animals* and humans;

~~4. maintain the efficacy of *antimicrobial agents* used in food producing *animals*;~~

~~5. prevent or reduce the transfer of resistant micro-organisms or resistance determinants from *animals* to humans;~~

~~6~~4) contributing to the maintenance of ~~maintaining~~ the efficacy and usefulness of *antimicrobial agents* used in animal and human medicine ~~and prolong the usefulness of the antimicrobials~~;

EU comment

The EU suggests adding the following at the end of point 4 above:

"taking particularly into account international recommendations on critically important antimicrobials.".

~~7. prevent the contamination of animal derived food with antimicrobial residues that exceed the established maximum residue limit (MRL);~~

~~8~~5) protecting consumer health by ensuring the safety of food of animal origin with respect to residues of *antimicrobial agents* ~~drugs, and the ability to transfer antimicrobial drug resistant micro-organisms to humans~~.

Article 6.9.3.

Responsibilities of the Competent Authority ~~regulatory authorities~~

1. Marketing authorisation

All Member Countries should combat the unauthorised manufacture, compounding, importation, advertisement, trade, distribution, storage and use of unlicensed, adulterated and counterfeit products, including bulk active ingredients, through appropriate regulatory controls and other measures.

~~The national r~~The ~~Regulatory~~ *Competent Authority* ~~authorities~~ ~~are~~ is responsible for granting marketing authorisation which~~. This~~ should be done in accordance with the provisions of the *Terrestrial Code*. It has ~~They have~~ a significant role in specifying the terms of this authorisation and in providing the appropriate information to ~~the~~ *veterinarians* and all ~~the~~ other relevant stakeholders.

The *Competent Authority* should establish and implement efficient statutory registration procedures that evaluate the quality, safety and efficacy of VMP containing *antimicrobial agent(s)*. According to Article 3.1.2., the *Competent Authority* should be free from any commercial, financial, hierarchical, political or other pressures which might affect its judgement or decisions.

Member Countries lacking the necessary resources to implement an efficient registration procedure for VMP containing *antimicrobial agent(s)*, and which are importing them, should undertake the following measures:

a) evaluate the efficacy of administrative controls on the import of these VMP;

b) evaluate the validity of the registration procedures of the exporting and manufacturing country as appropriate;

c) develop the necessary technical co-operation with experienced relevant authorities to check the quality of imported VMP as well as the validity of the recommended conditions of use.

The *Competent Authorities* of *importing countries* should request the pharmaceutical industry to provide quality certificates prepared by the *Competent Authority* of the exporting and manufacturing country as appropriate.

Marketing authorisation is granted on the basis of the data submitted by the pharmaceutical industry or applicant and only if the criteria of safety, quality and efficacy are met.

Member Countries are encouraged to apply the existing guidelines established by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

An evaluation of the potential risks and benefits to both animals and humans resulting from the use of *antimicrobial agents*, with particular focus on use in food-producing animals, should be carried out. The evaluation should focus on each individual *antimicrobial agent* and the findings should not be generalised to the antimicrobial class to which the particular active ingredient belongs. Guidance on usage should be provided for all target species, route of administration, dosage regimens, withdrawal period and different durations of treatment that are proposed.

The *Competent Authority* should expedite the process for new *antimicrobial agent(s)* in order to address a specific need for the treatment of *animal disease*.

All Member Countries should actively combat the unauthorised manufacture, compounding, importation, advertisement, trade, distribution and use of unlicensed and counterfeit products, including bulk active ingredients, through appropriate regulatory controls and other measures.

2. Submission of data for the granting of the marketing authorisation

The pharmaceutical industry has to submit the data requested for the granting of the marketing authorisation. The Marketing authorisation is granted on the basis of the data submitted by the pharmaceutical industry or applicant and only if the criteria of safety, quality and efficacy are met. An evaluation assessment of the potential risks and benefits to both animals and humans resulting from the use of antimicrobial agents, with particular focus on use in food-producing animals, should be carried out. The evaluation should focus on each individual antimicrobial agents product and the findings should not be generalised to the class of antimicrobials class to which the particular active ingredient principle belongs. Guidance on usage should be provided for all target species, route of administration, doseage regimens, ranges or withdrawal period and different durations of treatment that are proposed.

3. Market authorisation approval

The *Competent Authority* Regulatory authorities should ensure attempt to expedite expedite that the market approval process of a new VMPs containing *antimicrobial agent(s)* occurs without undue delay in order to address a specific need for the treatment of *animal* disease.

4. Registration procedures

The *Competent Authority* should establish and implement efficient statutory registration procedures that evaluate the quality, safety and efficacy of the VMPs containing antimicrobial agent(s). According to Article 3.1.2. of Chapter 3.1. of the *Terrestrial Code*, such the *Competent Authority* should be free from any commercial, financial, hierarchical, political or other pressures which might affect their its judgement or decisions.

Member Countries are encouraged to apply the existing guidelines established by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

Member Countries lacking the necessary resources to implement an efficient registration procedure for veterinary medicinal products (VMPs), and whose supply principally depends on imports from foreign countries and which are importing VMP, should undertake the following measures:

a) check the efficacy of administrative controls on the import of these VMPs;

b) check the validity of the registration procedures of the exporting and manufacturing country as appropriate;

c) develop the necessary technical co-operation with experienced authorities to check the quality of imported VMPs as well as the validity of the recommended conditions of use.

The *Competent Authorities* Regulatory authorities of *importing countries* should request the pharmaceutical industry to provide quality certificates prepared by the *Competent Authority* of the exporting and manufacturing country as appropriate. All Member cCountries should make every effort to actively combat the manufacture, advertisement, trade, distribution and use of unlicensed and counterfeit bulk active pharmaceutical ingredients and products including bulk active ingredients.

52. Quality control of antimicrobial agent(s) and VMP containing the antimicrobial agent(s)

Quality controls should be performed:

a) in compliance with the provisions of good manufacturing practices;

b) to ensure that analysis specifications of *antimicrobial agent(s)* used as active ingredients comply with the provisions of approved registration documentations (such as monographs) approved by the relevant *Competent Authority*;

c) to ensure that the quality and concentration (stability) of *antimicrobial agent(s)* in the marketed dosage form(s) are maintained until the expiry date, established under the recommended storage conditions;

d) to ensure the stability of *antimicrobial agent(s)* when mixed with feed or drinking water;

e) to ensure that all *antimicrobial agent(s)* and the VMP containing the them antimicrobial agent(s) are manufactured to the appropriate quality and purity in order to guarantee their safety and efficacy.

63. Assessment of therapeutic efficacy

a) Preclinical trials

i) Preclinical trials should:

- establish the spectrum ~~range~~ of activity of *antimicrobial agent(s)* against relevant ~~on both~~ pathogens and non-pathogens (commensals);
- assess the capacity ~~ability~~ of the *antimicrobial agent(s)* to select for resistance *in vitro* and *in vivo*, taking into consideration intrinsically resistant and pre-existing resistant strains;
- establish an appropriate dosage regimen (dose, dosing interval and duration of the treatment) and route of administration necessary to ensure the therapeutic efficacy of the *antimicrobial agent(s)* and limit the selection of antimicrobial resistance. ~~(~~Pharmacokinetic and pharmacodynamic data and models can assist in this appraisal~~.)~~.

ii) The activity of *antimicrobial agent(s)* towards the targeted micro-organism should be established by pharmacodynamics. The following criteria should be taken into account:

EU comment

In the above point, it is suggested to amend the first sentence as follows:

"The dosage regimens allowing maintenance of effective antimicrobial levels should be based on pharmacokinetics."

Indeed, the dosage cannot be established by kinetics alone.

- spectrum of activity and mode of action;
- minimum inhibitory and bactericidal concentrations against recent isolates;
- time- or concentration-dependent activity or co-dependency;
- activity at the site of *infection*.

iii) The dosage regimens allowing maintenance of effective antimicrobial levels should be established by pharmacokinetics. The following criteria should be taken into account:

- bio-availability according to the route of administration;
- distribution ~~concentration~~ of the *antimicrobial agent(s)* in the treated *animal* ~~at the site of *infection*~~ and concentration at the site of *infection* ~~its distribution in the treated *animal*~~;
- metabolism ~~that may lead to the inactivation of antimicrobials~~;
- excretion routes.

Use of combinations of *antimicrobial agents* should be scientifically supported.

b) Clinical trials

Clinical trials in the target animal species should be performed to confirm the validity of the claimed therapeutic indications and dosage regimens established during the preclinical phase. The following criteria should be taken into account:

i) diversity of the clinical cases encountered when performing multi-centre trials;

ii) compliance of protocols with good clinical practice, ~~such as Veterinary International Cooperation on Harmonisation (VICH) guidelines (VICH GL 9)~~;

iii) eligibility of studied clinical cases, based on appropriate criteria of clinical and bacteriological diagnoses;

iv) parameters for qualitatively and quantitatively assessing the efficacy of the treatment.

74. Assessment of the potential of antimicrobials agent(s) to select for resistance

Other studies may be requested in support of the assessment of the potential of *antimicrobials* *agents* to select for resistance (Guidelines providing information for developing such studies are available, e.g. VICH GL 27). The party applying for market authorisation should, where possible, supply data derived in target animal species under the intended conditions of use.

For this the following may be considered:

a) the concentration of either active *antimicrobial agent(s)* or metabolite(s) compound in the gut of the *animal* (where the majority of potential food-borne pathogens reside) at the defined dosage level;

b) pPathway for the human exposure to antimicrobial resistant micro-organisms the route and level of human exposure to food borne or other resistant organisms;

c) the degree of cross-resistance within and between the class of antimicrobials classes and between classes of antimicrobials;

d) the intrinsic and pre-existing, baseline level of resistance in the pathogens of human health concern (baseline determination) in both *animals* and humans.

EU comment

In the view of the EU, a further point should be added above relating to the consequence assessment, as follows:

"e) the severity and frequency of the disease caused in humans".

85. Establishment of acceptable daily intake (ADI), maximum residue level limit (MRL) and withdrawal periods for antimicrobial agents compounds in food producing animals

a) When setting the acceptable daily intake (ADI) and MRL for an *antimicrobial agents* substance, the safety evaluation should also include the potential biological effects on the intestinal flora of humans (Guidelines are available, e.g. VICH GL 33).

b) The establishment of an ADI for each *antimicrobial agent*, and an MRL for each animal-derived food, should be undertaken before a VMP containing it is granted marketing authorisation.

c) For all VMP containing *antimicrobial agent(s)*, withdrawal periods should be established for each animal species in order to ensure produce food in compliance with the MRLs, taking into account:

i) the MRLs established for the *antimicrobial agent* in the target animal and target edible tissues under consideration;

ii) the composition of the product and the pharmaceutical form;

iii) the target animal species;

iiiiv) the dosage regimen and the duration of treatment;

iv) the route of administration.

d) The applicant should describe provide methods for regulatory testing of residues in food based on the established marker residues.

96. Protection of the environment

An assessment of the impact of the proposed antimicrobial use on the environment should be conducted (Guidelines are available, e.g. VICH GL-6 and GL-38). Efforts should be made to ensure that the environmental impact of antimicrobial use is restricted to a minimum.

EU comment

The EU does not support the deletion of the second sentence in the point above. Indeed, assessing the impact of the use of antimicrobials on the environment would not make much sense without ensuing efforts to minimise such impact.

Instead of "restricted to a minimum", the sentence could end by "restricted as far as possible".

~~10~~7. Establishment of a summary of product characteristics for each VMP ~~veterinary medicinal products~~ containing antimicrobial agent(s) ~~product~~

The summary of product characteristics contains the information necessary for the appropriate use of VMP~~s~~ containing ~~veterinary~~ *antimicrobial agent(s)* ~~product (VAP)~~ and constitutes the official reference for their labelling and package insert. This summary should contain the following items:

a) active ingredient and class;

b) pharmacological properties;

c) any potential adverse effects;

d) target animal species and, as appropriate, age or production category;

e) therapeutic indications;

f) target micro-organisms;

g) dosage regimen and ~~administration~~ route of administration;

h) withdrawal periods;

i) incompatibilities and interactions;

j) storage conditions and shelf-life;

k) operator safety;

l) particular precautions before use;

m) particular precautions for the proper disposal of un-used or expired products;

n) information on conditions of use relevant to the potential for selection of resistance;

o) contraindication.

~~11~~8. Post-marketing antimicrobial surveillance

The information collected through existing pharmacovigilance programmes, including lack of efficacy, and any other relevant scientific data, should form part of the comprehensive strategy to minimise antimicrobial resistance. In addition to this, the following should be considered:

a) General epidemiological surveillance

The surveillance of animal micro-organisms resistant to *antimicrobial agent(s)* is essential. The relevant authorities should implement a programme according to Chapter 1.4. ~~*Terrestrial Code*~~.

b) Specific surveillance

Specific surveillance to assess the impact of the use of a specific *antimicrobial agent* may be implemented after the granting of ~~the~~ marketing authorisation. The surveillance programme should evaluate not only resistance ~~development~~ in target animal pathogens, but also in food-borne pathogens, and~~/or~~ commensals if possible. This ~~Such a surveillance~~ will also contribute to general epidemiological surveillance of antimicrobial resistance.

EU comment

The EU suggests replacing the word "if possible" by "as relevant".

~~12~~9. Supply and administration of the VMP ~~veterinary medicinal products~~ containing antimicrobial agent(s) ~~used in veterinary medicine~~

The relevant authorities should ensure that all the VMP containing *antimicrobial agent(s)* used in *animals* are:

a) prescribed by a *veterinarian* or ~~other authorised person~~ other suitably trained person authorised to prescribe VMP containing *antimicrobial agent(s)* in accordance with the national legislation and under the supervision of a *veterinarian*;

b) supplied only through licensed~~/~~ or authorised distribution systems;

c) administered to *animals* by a *veterinarian* or under the supervision of a *veterinarian* or by other authorised persons.

The relevant authorities should develop effective procedures for the safe collection and disposal or destruction of unused or expired V~~A~~MPs containing *antimicrobial agent(s)*. ~~VMP~~ Their labels should have appropriate instructions for disposal and destruction.

~~13~~10. Control of advertising

All advertising of *antimicrobial~~s~~ agents* should be compatible with the principles of responsible and prudent use and should be controlled by ~~a~~ code~~s~~ of advertising standards~~, and.~~ T~~t~~he relevant authorities must ensure that the advertising of ~~antimicrobial~~ these products:

EU comment

In the point above, the EU suggests adding the words "<u>, including on the internet,</u>" after the words "All advertising of *antimicrobial agents*", as this is of growing concern in some countries.

a) complies with the marketing authorisation granted, in particular regarding the content of the summary of product characteristics;

b) is restricted to a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agent(s)* in ~~authorised professionals, according to~~ accordance with the national legislation and under the supervision of a *veterinarian* ~~in each country~~.

~~14~~11. Training on the usage of antimicrobial agents ~~users~~

The training on the usage ~~of users~~ of *antimicrobial~~s~~ agents* should ~~involve~~ include all the relevant organisations, such as *Competent Authority* ~~regulatory authorities~~, pharmaceutical industry, veterinary schools, research institutes, veterinary professional organisations and other approved users such as food-animal owners and manufacturers of medicated animal feed ~~animal feed manufacturers~~. This training should focus on preserving the effectiveness of *antimicrobial agents* and include:

a) information on *disease* prevention~~, and~~ management and mitigation strategies;

b) the ability of *antimicrobial~~s~~ agent(s)* to select for resistant~~ce~~ micro-organisms in *animals* and the relative importance of that resistance to public and animal health ~~in food producing *animals*~~;

c) the need to observe responsible use recommendations for the use of *antimicrobial agent(s)* in animal husbandry in agreement with the provisions of the marketing authorisations~~.~~;

d) appropriate storage conditions, proper disposal of unused or expired VMP;

e) record keeping.

~~15~~12. Research

The relevant authorities should encourage public- and industry-funded research, for example on methods to identify and mitigate the public health risks associated with specific *antimicrobial agent* uses, or on the ecology of antimicrobial resistance.

Article 6.9.4.

Responsibilities of the veterinary pharmaceutical industry with regards to VMP ~~veterinary medicinal products~~ containing antimicrobial agent(s)

1. Marketing authorisation ~~of VAPs~~

The veterinary pharmaceutical industry has responsibilities to:

a) supply all the information requested by the national *Competent Authority* ~~regulatory authorities~~;

b) guarantee the quality of this information in compliance with the provisions of good manufacturing, laboratory and clinical practices;

c) implement a pharmacovigilance programme and on request, specific surveillance for bacterial susceptibility and resistance data.

2. Marketing and export ~~of VAPs~~

For the marketing and export of VMP~~s~~ containing *antimicrobial agent(s)* ~~VAPs~~:

a) only licensed and officially approved VMP~~s~~ containing *antimicrobial agent(s)* ~~VAPs~~ should be sold and supplied, and then only through licensed/authorised distribution systems;

b) the pharmaceutical industry should provide quality certificates prepared by the *Competent Authority* of the exporting and~~/or~~ manufacturing countries to the *importing country*;

c) the national regulatory authority should be provided with the information necessary to evaluate the amount of *antimicrobial agents* marketed.

3. Advertising

The veterinary pharmaceutical industry should respect principles of responsible and prudent use and should comply with established codes of advertising standards, including to:

a) distribute ~~disseminate~~ information in compliance with the provisions of the granted authorisation;

b) discourage ~~ensure that~~ the advertising of VMP~~s~~ containing *antimicrobial agent(s)* ~~antimicrobials~~ directly to the food animal producer ~~is discouraged~~.

4. Training

The veterinary pharmaceutical industry should participate in training programmes as defined in point 14 of Article 6.9.3.

5. Research

The veterinary pharmaceutical industry should contribute to research as defined in point 15 of Article 6.9.3.

Article 6.9.5.

Responsibilities of wholesale and retail distributors

1. Distributors of ~~Retailers distributing~~ V~~A~~MP~~s~~ containing *antimicrobial agent(s)* should only do so on the prescription of a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agent(s)* in accordance with the national legislation and under the supervision of a *veterinarian*.~~,~~ ~~and~~ A~~a~~ll products should be appropriately labelled.
2. The recommendations on the responsible and prudent use of VMP~~s~~ containing *antimicrobial~~s~~ agent(s)* should be reinforced by retail distributors who should keep detailed records of:
   a) date of supply;
   b) name of prescriber;
   c) name of user;
   d) name of product;
   e) batch number;
   f) expiration date;
   g) quantity supplied;~~.~~

h) copy of prescription.

3. Distributors should also be involved in training programmes on the responsible and prudent use of VMPs containing *antimicrobials agent(s)* antimicrobials, as defined in point 14 of Article 6.9.3.

Article 6.9.6.

Responsibilities of veterinarians

The concern of the *veterinarian*'s responsibility is to promote public health, and animal health and *welfare*. The *veterinarian*'s responsibilities including identification preventing, prevention identifying and treatmenting of animal *diseases*. The promotion of sound animal husbandry methods, hygiene procedures, biosecurity and vaccination strategies (good farming practice) can help to minimise the need for antimicrobial use in food-producing *animals*.

Veterinarians should only prescribe *antimicrobial agent(s)* for *animals* under their care.

1. Use of antimicrobial agent(s)

The responsibilities of *veterinarians* are to carry out a proper clinical examination of the *animal(s)* and then:

a) only administer or prescribe *antimicrobial agent(s)* only when necessary and taking into consideration the OIE list of *antimicrobial agents* of veterinary importance;

EU comment

The EU reiterates its suggestion of making a reference also to the WHO list of critically important antimicrobials in the point above. This reference could be inserted as follows:

"[…] and taking into consideration the WHO list of critically important antimicrobials for human medicine and the OIE list of antimicrobial agents of veterinary importance;".

Indeed, in order to comply with the objective as stated in Article 6.9.2 ("contribute to maintaining the efficacy and usefulness of antimicrobial agents used in animal and human medicine and prolong the usefulness of the antimicrobials"), the responsible veterinarian should, when choosing an antimicrobial, also consider the WHO list of critically important antimicrobials. Without this addition, this chapter would not address antimicrobials of special importance for public health, as currently the OIE list does not take public health aspects into account. Indeed, these are described in the WHO list. For example, antimicrobials such as 3rd generation cephalosporins and fluoroquinolones should only be chosen by veterinarians in situations where no other antimicrobial can be expected to be effective, preferably based on results of diagnostic tests including antimicrobial susceptibility testing. Furthermore, the OIE list classifies a majority of the antimicrobial classes available for use in animals as critically important and there is no prioritisation within the CIA category. It is therefore not clear how the information from the OIE list alone should be used by the veterinarian.

b) make an appropriate choice of the *antimicrobial agent(s)* based on treatment clinical experience and diagnostic laboratory information (pathogen isolation, identification and antibiogram) where possible of the efficacy of treatment;

c) provide a detailed treatment protocol, including precautions and withdrawal times, especially when prescribing extra-label or off-label use.

2. Choosing an antimicrobial agent(s)

a) The expected efficacy of the treatment is based on:

i) the clinical experience of the *veterinarians,* their diagnostic insight and therapeutic judgement;

ii) diagnostic laboratory information (pathogen isolation, identification and antibiogram);

iii) known pharmacodynamics including the activity towards the pathogens involved;

iv~~ii~~) the appropriate dosage regimen and route of administration;

~~iv~~) ~~known~~ pharmacokinetics and~~/~~ tissue distribution to ensure that the selected therapeutic agent is ~~active~~ effective at the site of infection;

vi) the epidemiological history of the rearing unit, particularly in relation to the antimicrobial resistance profiles of the pathogens involved.

Should a first-line antimicrobial treatment fail or should the *disease* recur, a second line treatment should ideally be based on the results of diagnostic tests. In the absence of such results, an appropriate *antimicrobial agent* belonging to a different class or sub-class should be used.

~~To minimise the likelihood of antimicrobial resistance developing in target or other organisms, it is recommended that antimicrobials agents be targeted to pathogens likely to be the cause of *infection*.~~

In emergencies ~~On certain occasions~~, a *veterinarian* may treat ~~a group of~~ *animals* ~~that may have been exposed to pathogens may need to be treated~~ without recourse to an accurate diagnosis and antimicrobial susceptibility testing, to prevent the development of clinical *disease* and for reasons of *animal welfare*.

b) Use of combinations of *antimicrobial~~s~~ agents* should be scientifically supported. Combinations of *antimicrobial~~s~~ agents* may be used for their synergistic effect to increase therapeutic efficacy or to broaden the spectrum of activity.

3. Appropriate use of the VMP~~s~~ containing antimicrobial agent(s) chosen

A prescription for VMP~~s~~ containing *antimicrobial agent(s)* ~~*antimicrobial agents*~~ should indicate precisely the ~~treatment~~ dosage regimen, ~~the dose, the treatment intervals, the duration of the treatment~~, the withdrawal period where applicable and the amount of VMP~~s~~ containing *antimicrobial agent(s)* ~~drug~~ to be provided ~~delivered~~, depending on the dosage and the number of *animals* to be treated.

The extra-label or off-label use of ~~a veterinary~~ VMP~~s~~ containing *antimicrobial agent(s)* ~~drug~~ may be permitted in appropriate circumstances and should be in agreement with the national legislation in force including the withdrawal periods to be used, as applicable. It is the *veterinarian*'s responsibility to define the conditions of responsible use in such a case including the dosage regimen, ~~and therapeutic regimen,~~ the route of administration and the withdrawal period~~, and the duration of the treatment~~.

The use of compounded VMP containing *antimicrobial agent(s)* and extra-label or off-label use of registered VMP containing *antimicrobial agent(s)* should be limited to circumstances where an appropriate registered product is not available.

4. Recording of data

Records on VMP~~s~~ containing ~~veterinary~~ *antimicrobial agent(s)* ~~drugs~~ should be kept in conformity with the national legislation. Information records should include the following:

a) quantities of VMP~~s~~ ~~medication~~ used per animal species;

b) a list of all VMP~~s~~ ~~medicines~~ supplied to each food-producing animal holding;

c) treatment schedules including animal identification and withdrawal period ~~a list of medicine withdrawal period~~;

d) ~~a record of~~ antimicrobial susceptibility~~ies~~ data;

e) comments concerning the response of *animals* to treatment ~~medication~~;

f) the investigation of adverse reactions to antimicrobial treatment, including lack of response due to antimicrobial resistance. Suspected adverse reactions should be reported to the appropriate regulatory authorities.

EU comment

In the point above, the EU suggests adding the word "possible" before "antimicrobial resistance", as other factors may be responsible for the lack of response to treatment (such as wrong diagnosis, wrong treatment, etc). Indeed, practicing veterinarians will usually not

know the exact cause for adverse reactions or the lack of response to treatment they observe in the field.

Veterinarians should also periodically review farm records on the use of VMAPs containing *antimicrobial agent(s)* to ensure compliance with their directions/ or prescriptions and use these records to evaluate the efficacy of treatments regimens.

5. Labelling

All medicines VMPs supplied by a *veterinarian* should be labelled according to the national legislation.

6. Training/ and continued professional development

Veterinary professional organisations should participate in the training programmes as defined in point 14 of Article 6.9.3. It is recommended that veterinary professional organisations develop for their members species-specific clinical practice recommendations on the responsible and prudent use of VMAPs containing *antimicrobial agent(s)* (e.g. Guidelines for the judicious use of antimicrobials in various animal species developed by the American Veterinary Medical Association).

Article 6.9.7.

Responsibilities of food-animal producers

1. Food-animal producers, with the assistance and guidance of a *veterinarian*, are responsible for implementing animal health and *welfare* programmes on their farms (good farming practice) in order to promote animal health and food safety.

2. Food-animal producers should:

   a) draw up a health plan with the attending *veterinarian* that outlines preventive measures (e.g. feedlot health plans, mastitis control plans, endo- and ectoparasite control, and vaccination programmes, and biosecurity measures, etc.);

   b) use VMPs containing *antimicrobial agent(s)* *antimicrobial agents* only on the veterinary prescription of a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agent(s)* in accordance with the national legislation and under the supervision of a *veterinarian*, and according to the provisions of the prescription;

   c) use VMPs containing *antimicrobial agent(s)* *antimicrobial agents* in accordance with product label instructions, including storage conditions, the species, for the uses and at the dosages on the approved/registered labels and in accordance with product label instructions, or the instructions the advice of the attending a *veterinarian* familiar with the *animals* and the production site;

   d) isolate sick *animals*, when appropriate, to avoid the transfer of pathogens; dispose of dead or dying *animals* promptly under conditions approved by the relevant authorities;

   e) comply with the storage conditions of antimicrobials in the rearing unit, according to the provisions of the leaflet and package insert;

   ef) address on-farm biosecurity measures hygienic conditions and take basic hygiene precautions as appropriate regarding contacts between people (*veterinarians*, breeders, owners, children) and the *animals* treated;

   fg) comply with and record the recommended withdrawal periods to ensure that residue levels in animal-derived food do not present a risk for the consumer;

   gh) use VMP containing *antimicrobial agent(s)* within the expiry date and dispose of unused and expired surplus VMPs containing *antimicrobial agent(s)* antimicrobials under safe conditions safe for the environment; medicines they should only be used within the expiry date, for the condition for which they were prescribed and, if possible, in consultation with the prescribing *veterinarian*;

   hi) maintain all the laboratory records of bacteriological and susceptibility tests; these data should be made available to the *veterinarian* responsible for treating the *animals*;

   ij) keep adequate records of all VMPs containing *antimicrobial agent(s)* medicines used, including the following:

      i) name of the product/ and active substance, and batch number and expiry date;

      ii) name of prescriber and/or the supplier;

      iii) date of administration;

iv) identification of the *animal* or group of *animals* to which the *antimicrobial agent* was administered;

v) clinical conditions treated;

vi) dosage;

vii) withdrawal periods ~~(~~including ~~date of~~ the end-date of the withdrawal periods~~)~~;

viii) result of laboratory tests;

ix) effectiveness of therapy;

j~~k~~) inform the responsible *veterinarian* of recurrent *disease* problems.

3. Training

Food-animal producers should participate in the training programmes as defined in Point 14 of Article 6.9.3. It is recommended that food-animal producer organisations work in cooperation with the veterinary professional organisations to implement existing guidelines for the responsible and prudent use of VMP~~s~~ containing *antimicrobial agent(s)*.

Article 6.9.8.

Responsibilities of animal feed manufacturers

1. The supply of medicated feed containing *antimicrobial agents* to farmers keeping food-producing animals by animal feed manufacturers should be allowed ~~Animal feed manufacturers preparing medicated feeds should do so~~ only on the prescription of a *veterinarian*. Alternatively, such medicated feed may be prescribed by ~~or~~ other suitably trained person~~s~~ authorised to prescribe VMP containing *antimicrobial agent(s)* in accordance with the national legislation and under the supervision of a *veterinarian*. Animal feed manufacturers preparing medicated feed should do so following rules put in place by the *Competent Authority* in accordance with the national legislation. All medicated feeds and medicated premixes ~~products~~ should be appropriately labelled.

2. The regulations and recommendations on the responsible and prudent use of VMP containing *antimicrobial agent(s)* should be reinforced by animal feed manufacturers who should keep detailed records ~~as noted in Article 6.9.5~~.

3. Use only approved sources of medications

Animal feed manufacturers preparing medicated feed should ensure that only approved sources of medications are added to feed at a level, purpose and species as permitted by the drug premix label or a veterinary prescription.

EU comment

In order to avoid adverse effects such as incompatibilities, instability, inhomogeneous mixing results and carry over, the EU is of the opinion that only medicated premixes specifically authorised by the competent authority for the manufacture of medicated feeds should be used to produce medicated feeds containing antimicrobial agents.

Therefore, the EU suggests the following wording for point 3 above:

"3. Use only medicated premixes authorised by the *Competent Authority*:

Animal feed manufacturers preparing medicated feeds should ensure that only medicated premixes authorised by the *Competent Authority* for that purpose are added to feeds at a level, purpose and species as permitted by the medicated premix label or a veterinary prescription".

4. Ensure appropriate labelling with product identification, direction for use and withdrawal time

Animal feed manufacturers preparing medicated feed should ensure that medicated animal feed are labelled with the appropriate information (e.g. level of medication, approved claim, intended species, directions for use, warning, cautions) so as to ensure effective and safe use by the producer.

5. Implement appropriate production practices to prevent contamination of other feeds

Animal feed manufacturers preparing medicated feed should implement appropriate production practices to avoid unnecessary carry over and unsafe cross contamination of unmedicated feed.

EU comment

As suggested above, "animal feed manufacturers" should be replaced by "manufacturers of medicated animal feeds" in the title and in point 2 of the article above.

Furthermore, as explained in the comment on point 1 of this Article, the following should be added at the end of point 5 above:

", such as HACCP".

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— Text deleted

Annex XII

CHAPTER 6.11.

ZOONOSES TRANSMISSIBLE FROM NON-HUMAN PRIMATES

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Article 6.11.1.

Introduction

There are about 376 different species of non-human primates belonging to 3 suborders which are split into 15 families. The tree shrew family (previously considered as belonging to the primates) has not been included in these recommendations.

All non-human primate species are included in Appendix I or Appendix II of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and may be transported internationally only if accompanied by the permits or certificates required under CITES.

Most imported non-human primates are destined for research, educational or breeding purposes and their sourcing should be in accordance with Article 7.8.7. Before non-human primates are used for any purpose, all alternatives to their use should be explored.

Public health and safety, *animal welfare* and pathogen introduction to wild populations are the primary issues of concern in the importation and keeping of non-human primates. This is especially true where close contact between humans and animals, their body fluids, faeces and tissues is likely to occur. Minimising the *risk* requires well-trained personnel and the following of stringent personal hygiene standards.

The likelihood of carrying zoonotic pathogens is related to the taxonomic position and the region of origin of the species concerned. It can be considered to increase from prosimians to marmosets and tamarins, then to other New World monkeys, to Old World monkeys and apes. The likelihood of carrying zoonotic agents is also greater in wild-caught non-human primates than in captive-bred animals which have been maintained in a well-defined environment under veterinary supervision. For non-human primates taken from the wild, usually only very limited health related information can be given by the supplier and by the *Veterinary Authority* of the *exporting country*.

Most pathogens referred to in this chapter are not included in the OIE List, and there is, consequently, no requirement to report them on a regular basis within the OIE animal disease reporting system. However, the requirement to report exceptional epidemiological events remains in effect.

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

Article 6.11.2.

General recommendations

Veterinary Authorities of *exporting countries* should issue *international veterinary certificates* only upon presentation of valid CITES documentation.

Veterinary Authorities should make sure that the animals are individually identified by approved methods that assure traceability and to avoid transmission of *disease* (see Chapter 4.15.).

For reasons of public health, *animal welfare* and pathogen introduction to wild populations, *Veterinary Authorities* of *importing countries* should not authorise the import of non-human primates for the purpose of being kept as pets.

In the case of a non-human primate being imported directly from a country within the natural range of the animals species concerned, and where only limited diagnostic testing is available, *Veterinary Authorities* of *importing countries* should place more emphasis on quarantine procedures and less on veterinary certification. As a matter of principle, limited health guarantees given by the supplier or the *Veterinary Authority* of the country of origin should not constitute

an obstacle to imports, but very strict post import quarantine requirements should be imposed. Particularly, the quarantine should meet the standards set in Chapter 5.9., and should be of sufficient length to minimise the *risk* of transmission of *diseases* where tests are not readily available or of limited value.

Annex XII (contd)

Veterinary Authorities of *importing countries* may reduce the quarantine requirements for non-human primates imported from premises with permanent veterinary supervision provided that the animals were born or have been kept for at least 2 years on these premises, are individually identified and accompanied by proper certification issued by qualified officials, and the official certification is supplemented by a complete documentation of the clinical history of each animal and its group of origin.

In cases where it is necessary to import non-human primates which are known or suspected to be carriers of a zoonotic disease, the import should not be restricted by any of these recommendations, provided that the *Veterinary Authority* of the *importing country* requires the placing of the animals in an establishment located on its territory which has been approved to receive them and which meets the standards set in Chapter 5.9.

Article 6.11.3.

General certification and transportation requirements

Veterinary Authorities of *importing countries* should require:

for all non-human primates

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

    a) have been individually identified (the means of identification should be stated in the certificate); and

    b) have been examined on the day of shipment and found to be healthy, free from clinical signs of contagious *disease,* and fit for transport;

2. the attachment to the *international veterinary certificate* of all relevant records, including all vaccinations, tests and treatments performed during the lifetime of each primate before shipment;

3. the necessary CITES permit from the relevant wildlife authority;

4. the transport of the animals by air in accordance with the Live Animals Regulations of the International Air Transport Association or by rail or road under equivalent standards for surface transport.

Article 6.11.4.

Quarantine requirements for non-human primates from an uncontrolled environment

Veterinary Authorities of *importing countries* should require for shipments which originate from the wild or other sources where they were not subjected to permanent veterinary supervision:

1. the presentation of the documentation referred to in Article 6.11.3.;

2. the immediate placement of the animals in a *quarantine station* meeting the standards set in Chapter 5.9. for at least 12 weeks; and during this quarantine:

    a) all animals should be monitored daily for signs of illness and, if necessary, be subjected to a clinical examination;

    b) all animals dying for any reason should be subjected to complete post-mortem examination at a laboratory approved for this purpose;

    c) any cause of illness or death should be determined before the group to which the animals belong is released from quarantine;

    d) animals should be subjected to the following diagnostic tests and treatments in accordance with Chapter 4.15.:

Disease/agent	Animal groups	Schedule	Methods
Endo- and ectoparasites	All species	At least two tests, one of which should be at the start, the other towards the end of the quarantine.	Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.
Tuberculosis (*Mycobacterium tuberculosis* complex)	Marmosets and tamarins	Two tests at an interval of 2 to 4 weeks.	Skin test or serology. In-vitro gamma interferon assay or polymerase chain reaction (PCR) assay. The skin test using mammalian tuberculin (old tuberculin) is the most reliable of all. Skin tests in marmosets, tamarins or small prosimians should be performed in the abdominal skin rather than in the eyelid. In some species (e.g. orang utan), skin tests for tuberculosis are notorious for false positive results. Comparative tests using both mammalian and avian PPD, together with cultures, radiography, ELISA, in-vitro gamma interferon assay and PCR of gastric or bronchial lavage, faeces or tissues may eliminate confusion.
	Prosimians, New World monkeys, Old World monkeys, gibbons and great apes	At least three tests at intervals of 2 to 4 weeks.	

Disease/agent	Animal groups	Schedule	Methods
Other bacterial pathogens (*Salmonella*, *Shigella*, *Yersinia* and others as appropriate)	All species	Daily test for 3 days after arrival, and at least one or two more tests at intervals of 2 to 4 weeks.	Faecal culture. The fresh faeces or rectal swabs should ~~have to~~ be cultured immediately or ~~to~~ be placed immediately in the appropriate transportation medium.
Hepatitis B	Gibbons and great apes	First test during first week; second test after 3 to 4 weeks.	Serological tests for anti-hepatitis B core antigen and for hepatitis B surface antigen, and additional parameters as appropriate.

Veterinary Authorities of *importing countries* should recognise the public health importance of *zoonoses* listed in the table above as well as measles (a human disease, sometimes affecting non-human primates), hepatitis A, monkey pox, Marburg disease or Ebola/Reston virus, retroviruses, etc., even though this article does not recommend specific testing or treatment protocols for these agents during the quarantine period. *Veterinary Authorities* should recognise that, if animals are infected, the importation and spread of many such agents will be best controlled by the detection of clinical signs of *disease* during a 12-week quarantine period The precautions described in Article 6.11.7. must be strictly applied when handling such non-human primates in order to protect human health and safety.

Annex XII (contd)

Certain endemic viruses, such as herpesviruses or retroviruses, may be present in both wild and captive populations of primates. These viruses are often asymptomatic in primate species. If animals are being imported to be introduced to other populations of the same species, it may be advisable to determine if the animals selected for importation have similar viral profiles to the established population.

Article 6.11.5.

Certification and quarantine requirements for marmosets and tamarins from premises under veterinary supervision

Veterinary Authorities of *importing countries* should require:

for marmosets and tamarins from premises under veterinary supervision

1. the presentation of an *international veterinary certificate* attesting that the shipment meets the requirements specified in Article 6.11.3., and that the animals:

   a) were either born in the premises of origin or have been kept there for at least 2 years;

   b) come from premises which are under permanent veterinary supervision, and where a suitable health monitoring programme is followed, including microbiological and parasitological tests as well as necropsies;

   c) have been kept in buildings and enclosures in which no *case* of tuberculosis has occurred during the last 2 years prior to shipment;

2. a description of the health monitoring programme implemented by the establishment of origin;

3. the placement of the animals in a *quarantine station* meeting the standards set in Chapter 5.9. for at least 30 days; and during this period:

   a) all animals should be monitored daily for signs of illness and, if necessary, be subjected to a clinical examination;

   b) all animals dying for any reason should be subjected to complete post-mortem examination at a laboratory approved for this purpose;

   c) animals should be subjected to the following diagnostic tests and treatments in accordance with Chapter 4.15.:

Disease/agent	Animal groups	Schedule	Methods
Bacterial pathogens (*Salmonella*, *Shigella*, *Yersinia* and others as appropriate)	All species	Daily test for 3 days after arrival	Faecal culture. (See further comments in the Table of Article 6.11.4.)
Endo- and ectoparasites	All species	At least two tests, one of which should be at the start, the other towards the end of the quarantine	Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.

Veterinary Authorities of *importing countries* should not normally require any tests for viral *infections* or for tuberculosis. However, stringent precautions to ensure human health and safety should be followed as recommended in Article 6.11.7.

Article 6.11.6.

Certification and quarantine requirements for other non-human primates from premises under veterinary supervision

Veterinary Authorities of *importing countries* should require:

for prosimians, New World monkeys, Old World monkeys, gibbons and great apes from premises under veterinary supervision

1. the presentation of an *international veterinary certificate* attesting that the shipment meets the requirements specified in Article 6.11.3., and that the *animals:*

   a) were either born in the premises of origin or have been kept there for at least 2 years;

   b) come from premises which are under permanent veterinary supervision, and where a suitable health monitoring programme is followed, including microbiological and parasitological tests as well as necropsies;

   c) have been kept in buildings and enclosures in which no *case* of tuberculosis has occurred during the last 2 years prior to shipment;

   d) come from premises in which no *case* of tuberculosis or other major *zoonosis* including rabies has occurred during the last 2 years prior to shipment in the building where the *animals* were kept;

   e) were subjected to a tuberculosis test on two occasions with negative results, at an interval of at least 2 weeks between each test during the 30 days prior to shipment;

   f) were subjected to a diagnostic test for pathogenic enteric bacteria including *Salmonella, Shigella* and *Yersinia;*

   g) were subjected to diagnostic tests for, and appropriate treatment against, endo- and ectoparasites;

   h) were subjected to a diagnostic test for hepatitis B virus and their current status documented (gibbons and great apes only);

2. the placement of the *animals* in a *quarantine station* for at least 30 days, and during this period:

   a) all *animals* should be monitored daily for signs of illness and, if necessary, subjected to a clinical examination;

   b) all *animals* dying for any reason should be subjected to complete post-mortem examination at a laboratory approved for this purpose;

   c) any cause of illness or death should be determined before the group to which the *animals* belong is released from quarantine;

   d) *animals* should be subjected to the following diagnostic tests and treatments in accordance with Chapter 4.15.:

Disease/agent	**Animal groups**	**Schedule**	**Methods**
Tuberculosis (*Mycobacterium tuberculosis* complex)	All species	One test	Skin test or serology. In-vitro gamma interferon assay or polymerase chain reaction (PCR) assay. (See further comments in the Table of Article 6.11.4.)
Other bacterial pathogens (*Salmonella*, *Shigella*, *Yersinia* and others as appropriate)	All species	Daily test for 3 days after arrival, and another test at least one week later	Faecal culture. (See further comments in the Table of Article 6.11.4.)
Endo- and ectoparasites	All species	At least two tests, one of which should be at the start, the other towards the end of the quarantine	Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.

Veterinary Authorities of *importing countries* may not normally require any tests for viral *diseases.* However, stringent precautions to ensure human health and safety should be followed as recommended in Article 6.11.7.

Annex XII (contd)

Article 6.11.7.

Precautionary measures to be followed by staff exposed to non-human primates or to their body fluids, faeces and tissues

The presence in most non-human primates of some zoonotic agents is almost unavoidable, even after release from quarantine. The *Competent Authority* should, therefore, encourage the management of institutions whose staff are exposed to non-human primates or their body fluids, faeces or tissues (including when performing necropsies) to comply with the following recommendations:

1. to provide staff with training in the proper handling of primates, their body fluids, faeces and tissues, with respect to *zoonoses* containment and personal safety;

2. to inform their staff that certain species should be considered as having lifelong *infections* with some zoonotic agents, e.g. Asian macaques with Herpes B virus;

3. to ensure that the staff follows personal hygiene practices, including the use of protective clothing, and the prohibition of eating, drinking and smoking in potentially infective areas;

4. to implement a screening programme for personnel health, including monitoring for tuberculosis, pathogenic enteric bacteria and endoparasites and other agents that are deemed necessary;

5. to implement an immunisation programme as appropriate, including e.g. tetanus, measles, poliomyelitis, rabies, hepatitis A and B, and other *diseases* such as yellow fever endemic in the area of origin of the African and American non-human primates;

6. to develop guidelines for the prevention and treatment of *zoonoses* that may be transmitted by bites and scratches, e.g. rabies and herpes viruses;

7. to issue to their staff a card which states that they work with non-human primates or with their body fluids, faeces or tissues, and which may be presented to the medical profession in case of illness;

8. to dispose of carcasses, body fluids, faeces and tissues in a manner which is not detrimental to public health.

— Text deleted.

Annex XIII

DRAFT CHAPTER 7.X.

ANIMAL WELFARE AND BROILER CHICKEN PRODUCTION SYSTEMS

EU position

The EU thanks the OIE and in general supports the adoption of this new chapter. The EU does however have some comments as indicated in the text below and would ask the OIE to take these into consideration at a future revision.

Article 7.X.1.

Definitions

For the purpose of this chapter:

Broiler
means a birds of the species *Gallus gallus* kept ~~primarily~~ for commercial meat production. Poultry kept in village or backyard *flock*s are not included.

Harvesting
means the catching and loading of birds on farm for transportation to the *slaughterhouse/abattoir.*

~~***Slatted floor***~~
~~means a housing system where the broilers are kept on raised floors, on which droppings do not accumulate, but they fall through.~~

~~***Backyard flocks***~~
~~means village or backyard production with minimal biosecurity and birds/products consumed locally.~~

Article 7.X.2.

Scope

These recommendations cover the production period from arrival of ~~the~~ *day-old birds* ~~chicks~~ on the farm to harvesting the broilers in commercial production systems. Such systems involve confinement of the birds, the application of biosecurity measures, and trade in the products of those birds, regardless of scale of production~~, in the products of those birds~~. These recommendations cover ~~systems include~~ broilers kept in cages, on slatted floors, litter or dirt and indoors or outdoors. ~~Village or backyard production, with minimal biosecurity and birds or products consumed locally, backyard flocks is not included in this scope even if the broilers or products are traded locally.~~

Broiler production systems include:

1. Completely housed system

   Broilers are completely confined in a poultry house, with or without environmental control ~~and often at a higher *stocking density* than in other production systems~~.

2. Partially housed system

   Broilers are kept ~~confined~~ in a poultry house ~~but provided~~ with access to a restricted outdoor area.

3. Completely outdoors system

   ~~At no time during the production period are~~ Broilers are not confined inside a poultry house at any time during the production period but are confined in a designated outdoor area. ~~Broilers are often kept at a lower *stocking density* in these systems than others.~~

This chapter should be read in conjunction with Chapters 7.2., 7.3. and 7.4. on the welfare of the broiler during *transport*

to the *slaughterhouse/abattoir*.

~~Article 7.X.3.~~

~~**Commercial broiler production systems**~~

~~Commercial Broiler production systems include:~~

1. ~~Intensive systems~~

   ~~Broilers are completely confined in a poultry house, with or without environmental control and usually at a higher *stocking density* than in other production systems. Broilers may be kept in cages, with (e.g. wire or plastic floor or deep litter floor) or on litter, or slatted floors or a combination~~

2. ~~Semi intensive systems~~

   ~~Broilers are confined in a poultry house but provided with access to a restricted outdoor area.~~

3. ~~Extensive systems~~

   ~~Broilers are not confined throughout the production period in a poultry house. and are usually kept at a lower *stocking density*than in intensive or semi intensive systems.~~

Article 7.X.43.

Criteria or measurables for the welfare of broilers

~~Measurables can be based on the outcomes for the broiler (outcome based criteria) or the design of the system (resource or design based criteria). Outcome based measurables may give a better indication of welfare than resource based measures because they reflect the complex interaction of several variables (e.g. experience and attitude of handlers and disease situation) that may be overlooked when relying on criteria that focus on the design of the system.~~

The following outcome-based measurable, specifically animal-based measurable, can be useful indicators of *animal welfare*. The use of these indicators and the appropriate thresholds should be adapted to the different situations where broilers are managed, also taking into account the strain of bird concerned. Consideration should also be given to the resources provided and the design of the system.

Some ~~measurables~~ criteria can be measured in the farm setting, such as ~~(e.g.~~ gait, mortality and morbidity rates~~)~~, while others are best measured at the *slaughterhouse/abattoir*. For example, at slaughter *flocks* can be assessed for presence of bruising, broken limbs and injuries. The age of these lesions can help to determine the source ~~(e.g. catching)~~ ~~(Nicol & Scott, 1990)~~. Back scratching, ~~hock and feet~~ foot ~~burns~~ contact dermatitis and breast blisters are also easily observed at the *slaughterhouse/abattoir*. Other conditions such as ascites, leg deformities, dehydration and *disease* conditions can also be assessed at ~~this point~~ *slaughter*. It is recommended that values for welfare measurables be determined with reference to appropriate national, sectoral or perhaps regional norms for commercial broiler production.

EU comment

The EU asks the OIE to consider amending the second and fourth sentences of the above paragraph as follows:

"For example, at slaughter *flocks* can be assessed for presence of bruising, broken limbs and other injuries."

"Back scratching, and contact dermatitis ~~and breast blisters~~ are also easily observed at the *slaughterhouse/abattoir*."

Justification

A more precise text which is in line with wording used elsewhere in the chapter. Broken limbs are also an injury and breast blisters are part of the contact dermatitis complex, cf. point 3 of this article.

The following outcome-based criteria and measurables are useful indicators of broiler welfare:

1. Mortality, ~~(dead, culled)~~ culling and morbidity

   Daily, weekly and cumulative mortality, ~~(dead or culled)~~ culling and morbidity rates should be within expected ranges. Any unforeseen increase in ~~the daily mortality or morbidity~~ these rates could reflect an animal welfare problem.

2. Gait

Broilers are susceptible to developing a variety of infectious and non-infectious musculoskeletal disorders ~~(see review in Mench, 2004)~~. ~~If severe~~ These disorders may lead to ~~overt~~ lameness~~,~~ and ~~if less severe~~ to gait abnormalities. Broilers that are lame or have ~~more serious~~ gait abnormalities may have difficulty reaching the food and water, may be trampled by other broilers, and may experience pain. Musculoskeletal problems have many causes, including ~~related to~~ genetics, nutrition, sanitation, lighting, litter quality, and other environmental and management factors ~~(see Mench, 2004; Dawkins et al., 2004)~~. Broilers in commercial *flocks* should be assessed for gait abnormalities~~, and corrective actions identified to reduce the incidence of problems in subsequent flocks~~. There are several gait scoring systems available ~~(Kestin et al., 1992; Garner et al., 2002; Webster et al., 2008; Weeks et al., 2002; Berg and Sanotra, 2003)~~. ~~Regardless of the scoring or assessment system used, broilers that are unable to access feed or water should be humanely euthanized as soon as possible after they have been observed.~~

3. Contact dermatitis

Contact dermatitis affects skin surfaces ~~which~~ that have prolonged contact with wet litter or other wet flooring surfaces~~, including the foot pad, rear surface of the hock and, when severe, the breast area~~. The condition~~s~~ ~~are~~ is manifested as blackened skin progressing to erosions and fibrosis on the lower surface of the foot pad, at the back of the hocks, and sometimes in the breast area. If severe, the foot and hock lesions may contribute to lameness and lead to secondary *infections*. Validated s~~S~~coring systems for contact dermatitis have been developed for use in *slaughterhouse/abattoir* ~~(see Welfare Quality®, 2009)~~.

4. Feather condition

Evaluation of the feather condition of broilers provides useful information about aspects of welfare. Plumage dirtiness ~~and naked area are~~ is correlated with contact dermatitis ~~both hock burns~~ and lameness for individual birds ~~(Arnould and Colin, 2009)~~ or may be associated with the environment and production system. Plumage dirtiness can be assessed as part of on-farm inspections, ~~when the broilers are caught for *transport* to the *slaughterhouse/abattoir* and~~ at the time of harvesting or prior to plucking. A scoring system has been developed for this purpose ~~(RSPCA, 2008)~~.

5. Incidence of diseases, metabolic disorders and parasitic infestations

Ill-health, regardless of the cause, is a welfare concern, and may be exacerbated by poor environmental or husbandry management.

~~Ascites, sudden death syndrome and respiratory diseases (including infectious bronchitis, avian pneumovirus *infection* and mycoplasmosis) are of great economic and welfare significance in broilers (SCAHAW, 2000).~~

EU comment

The EU does not agree with the deletion of the sentence above and asks the OIE to consider reinserting a slightly shortened version of it, as follows.

"Ascites, sudden death syndrome and respiratory diseases (including infectious bronchitis, avian pneumovirus *infection* and mycoplasmosis) are useful indicators of welfare in broilers."

Alternatively the following sentence may be included:

"Ill-health, regardless of cause, is a welfare concern, and may be exacerbated by poor environmental conditions or husbandry management. Possible indicators include: ascites, sudden death syndrome and respiratory diseases (including infectious bronchitis, avian pneumovirus infection and mycoplasmosis)."

Justification

Ascites is a good indicator of poor welfare when it is found. Ascites may have a low prevalence in some countries however experience has shown that an increase in prevalence of this condition can bring awareness to poor on-farm conditions. Ascites is linked with poor ventilation, rapid growth rates and high levels of ammonia. Ascites is one of the indicators included in the Welfare Quality protocols for broilers (http://www.welfarequalitynetwork.net/network/45848/7/0/40).

6. ~~Normal~~ Behaviour

~~Broiler behaviour can be a sensitive indicator of welfare problems.~~

a) Fear behaviour

Fearful broilers show avoidance of humans, and this behaviour is seen in *flocks* where *animal handlers* walk through the poultry house quickly when performing their tasks rather than moving more slowly while interacting with the broilers ~~(Cransberg et al., 2000)~~. Fearfulness (e.g. of sudden loud noises) can also lead to the broilers piling on top of, and even suffocating, one another. Fearful broilers may be less productive ~~(Hemsworth et al., 1994)~~. Validated methods have been developed for evaluating fearfulness.

b) Spatial distribution

Changes in the spatial distribution (e.g. huddling) of the birds may indicate thermal discomfort ~~(e.g. broilers will huddle when they are cold)~~ or the existence of areas of wet litter or uneven provision of light, food or water ~~(if broilers are unevenly distributed)~~.

c) Panting and wing spreading

Excessive panting and wing spreading ~~may~~ indicates heat stress or high levels of ammonia ~~or high levels of ammonia~~.

d) Dust bathing

Dust bathing is an intricate body maintenance behaviour performed by many birds, including broilers ~~(Olsson and Keeling, 2005)~~. During ~~a~~ dust bathing ~~bout~~, broilers work loose material, such as litter, through their feathers. Dust bathing helps to keep the feathers in good condition, which in turns helps to maintain body temperature and protect against skin injury. Reduced dust bathing behaviour in the *flock* may indicate problems with litter or range quality, such as litter or ground being ~~that is~~ wet or not friable.

e) Feeding, drinking and foraging

Reduced feeding or drinking behaviour can indicate management problems, including inadequate feeder or drinker space or placement, dietary imbalance, poor water quality, or feed contamination. Feeding and drinking behaviour are often depressed when broilers are ill, and ~~feeding is~~ intake may be also reduced during periods of heat stress and increased during cold stress. Foraging is the act of searching for food, typically by walking and pecking or scratching the litter substrate; reduced foraging activity could suggest problems with litter quality or presence of conditions that decrease bird movement ~~(e.g. gait problems)~~.

f)~~7.~~ ~~Abnormal behaviour~~ Feather pecking and cannibalism

~~Feather pecking is or pulling of the feathers~~ Feather pecking can result in significant feather loss~~.~~ and may lead to cannibalism. Cannibalism is the tearing of the flesh of another bird, and can result in severe injury. ~~, or and even the~~ death ~~of the pecked broiler~~. These ~~are~~ abnormal behaviours ~~(Mench and Keeling, 2001; Rodenberg and Koene, 2004; Newberry, 2004)~~ have ~~with~~ multi-factorial causes. ~~that are not usually seen in commercial broiler stocks, although they can occur under some circumstances. Feather pecking may sometimes lead to cannibalism or may occur independently; once started, these problems can spread rapidly through the *flock*.~~

7~~8~~. Water and feed consumption

Monitoring daily water consumption ~~can be~~ is a useful tool to indicate *disease* and other welfare conditions, taking into consideration ambient temperature, relative humidity, feed consumption and other related factors. Problems with the water supply can result in wet litter, diarrhoea, dermatitis or dehydration.

Changes in feed consumption can ~~also~~ indicate unsuitability of feed, the presence of *disease* or ~~and~~ other welfare problems ~~conditions of the *flock* as well as suitability of the feed~~.

8~~9~~. Performance

a) Growth rate – an index that indicates the average daily gain (gr) of weight per average broiler of a *flock*.

b) Feed conversion – an index that ~~indicates the quantity of feed (kg) that is necessary for a gain of bodyweight of one kilogram of the average broiler of a *flock*~~ measures the quantity of feed consumed by a *flock* relative to the total live weight harvested, expressed as the weight of feed required to produce one kg of broiler bodyweight. Higher values than expected may indicate welfare problems.

EU comment

The EU does not agree with the statement in the last sentence and asks the OIE to consider deleting it.

~~"Higher values than expected may indicate welfare problems.~~"

Justification

The EU would like to query the evidence base for this sentence. For example for a group of say X strain broilers we may introduce bales and perches to increase their activity levels. If we increase their activity levels by enriching their environment their feed conversion rate will increase this is not necessarily a welfare problem because their welfare has improved.

c) Liveability – an index that indicates the percentage of broilers present at the end of the production period; more commonly this indicator is measured as its opposite,~~:~~ mortality ~~(see point 1 of Article X.X.4.)~~.

9~~10~~. Injury rate

~~Broilers are susceptible to a number of injuries, and~~ The rate of these injuries can indicate welfare problems in the *flock* during production or ~~capture~~ harvesting. Injuries include those due to other broilers (scratches, feather loss or wounding due to feather pecking and cannibalism) and those due to environmental conditions, such as ~~(e.g.~~ skin lesions,~~)~~ and those due to human intervention, such as ~~e.g.~~ catching. The most ~~frequent~~ prevalent injuries seen during catching are bruises, broken limbs, dislocated hips, and damaged wings. ~~Fractures are located mainly on femur, radius, ulna, furcula and ischium. Dislocation of the femur at the hip joint is the most prevalentcommon traumatic injury.~~

10~~1~~. Eye conditions

Conjunctivitis can indicate the presence of irritants such as dust and ammonia. High ammonia levels ~~will~~ can also cause corneal burns and eventual blindness ~~(Morrow 2008:541)~~. Abnormal eye development can be associated with low light intensity.

11~~2~~. Vocalisation

Vocalisation can indicate emotional states, both positive and negative ~~and distress in chickens (Jeon et al., 2005)~~. Interpretation of *flock* vocalisations is possible by experienced *animal handlers*.

Article 7.X.~~5~~4.

Recommendations

1. Biosecurity and animal health

a) Biosecurity and disease prevention

Biosecurity means a set of measures designed to maintain a *flock* at a particular health status and to prevent the entry (or exit) of specific infectious agents.

~~Biosecurity programmes should be implemented, commensurate with the risk of disease and in accordance with relevant recommendations found in Terrestrial Code chapters on OIE listed diseases.~~

Biosecurity programmes should be designed and implemented, commensurate with the best possible ~~desired~~ *flock* health status and current *disease* risk (endemic and exotic or transboundary) that is specific to each epidemiological group of broilers and in accordance with relevant recommendations found in the *Terrestrial Code* ~~chapters on OIE listed diseases~~.

These programmes should address the control of the major routes for *disease* and pathogen transmission:

~~a~~i) direct transmission from other *poultry*, domesticated and wild animals and humans,

~~b~~ii) fomites, such as equipment, facilities and *vehicles*,

~~c~~iii) *vectors* (e.g., arthropods and rodents),

~~d~~iv) aerosols,

~~e~~v) water supply,

~~f~~vi) feed.

Outcome-based measurables: incidence of *diseases*, metabolic disorders and parasitic *infestations*, mortality, ~~and~~ performance.

b) Animal health management, ~~/~~ preventive medicine and~~/~~ veterinary treatment

Animal health management means a system designed to optimise the health and welfare of the broilers. It includes prevention, treatment and control of *diseases* and adverse conditions.

Those responsible for the care of broilers should be aware of the signs of ill-health or distress, such as a change in feed and water intake, reduced growth, changes in behaviour, abnormal appearance of feathers, faeces, or other physical features.

If persons in charge are not able to identify the causes of *disease*, ~~of~~ ill-health or distress, or to correct these, or if they suspect the presence of a ~~listed~~ reportable *disease*, they should seek advice from ~~those having training and experience, such as~~ ~~poultry~~ *veterinarians* or other qualified advisers. Veterinary treatments should be prescribed by a ~~qualified~~ *veterinarian*.

There should be an effective programme for the prevention and treatment of *diseases* consistent with the programmes established by the *Veterinary Services* as appropriate.

Vaccinations and ~~other~~ ~~administered~~ treatments should be administered, on the basis of veterinary or other expert advice, ~~undertaken with consideration of the welfare of the broilers~~ by ~~qualified~~ personnel skilled in the procedures and with consideration for the welfare of the broilers.

Sick or injured broilers should be ~~culled~~ humanely killed as soon as possible. Similarly, killing broilers for diagnostic purposes should be done in a humane manner according to Chapter 7.6. ~~of the *Terrestrial Code*~~.

Outcome-based measurables: incidence of *diseases*, metabolic disorders and parasitic *infestations,* mortality, ~~and~~ performance, gait.

2. Environment and management

a) Thermal environment

Thermal conditions for broilers should be appropriate for their stage of development, and extremes of heat, humidity and cold should be avoided. For the growing stage, a heat index ~~the Thermal Heat Index (THI)~~ can assist in identifying the comfort zones for the broilers at varying temperature and relative humidity levels.

When environmental conditions move outside these zones, ~~various~~ strategies ~~can~~ should be used ~~in different production systems~~ to mitigate the adverse effects on the broilers. ~~: e.g.~~ These may include higher air speeds, ~~and~~ evaporative cooling and reducing stocking density ~~can alleviate the effects of high heat and humidity in intensive systems~~.

~~Ventilation should aim at controlling relative humidity to prevent the development of wet litter. Assessing litter condition on a regular basis is recommended.~~

EU comment

The EU does not agree with the deletion of the above sentence and asks the OIE to consider reinserting it. Alternatively a slightly amended sentence as follows may be inserted:

"The operation of minimum ventilation rates during cold weather may result in increased litter moisture content. Increasing ventilation and heat provision during this time should be considered."

Justification

The EU has a suggested replacement for the use of combined ventilation and heating systems to aid removal of moisture (not caused by relative humidity but caused by large volumes of water content in the poultry excreta that has not been evaporated) The Swedish system found that litter condition could be improved by increasing ventilation at the same time as increasing heat sources at time of greatest risk for wet litter.

Management ~~system~~ of the thermal environment should be checked ~~at least twice a day~~ frequently enough so that failure of the system would be noticed before it caused a welfare problem.

Outcome-based measurables: ~~normal and abnormal~~ behaviour, mortality, contact dermatitis, water and feed consumption, performance, feather condition.

b) Lighting

There should be an adequate period of continuous darkness during each 24 hour period to allow the broilers to rest. There should also be an adequate period of continuous light. ~~Reference should be made to relevant national, regional or international recommendations.~~

The light intensity during the light period should be sufficient and homogeneously distributed to allow the broilers to find feed and water ~~in the first few days~~ after they are placed in the poultry house, to stimulate activity, and allow adequate inspection.

There should be a period for gradual adjustment ~~Broilers should be gradually adjusted~~ to lighting changes.

Outcome-based measurables: gait, metabolic disorders, performance, ~~normal and abnormal~~ behaviour, eye condition, ~~eye condition~~ ~~and~~ injury rate.

c) Air quality

Adequate ventilation is required at all times to provide fresh air, to remove waste gases such as carbon dioxide and ammonia, dust and excess moisture content from the environment.

Ammonia concentration should not routinely exceed 25 ppm at broiler level ~~(Kristensen and Wathes, 2000; Jones et al., 2005)~~.

Dust levels should be kept to a minimum. ~~Methods for doing so that can include maintaining appropriate ventilation and satisfactory litter moisture levels.~~ Where the health and welfare of broilers depend on an artificial ventilation system, provision should be made for an appropriate back-up power and alarm system.

Outcome-based measurables: incidence of respiratory *diseases*, metabolic disorders, ~~and parasitic infestations (respiratory diseases), behaviour (panting, huddling),~~ eye conditions, performance, contact dermatitis ~~and spatial distribution of the birds~~.

d) Noise

Broilers are adaptable to different levels and types of noise. However, ~~E~~exposure of broilers to sudden or loud noises should be minimised where possible to prevent stress and fear reactions, such as ~~(e.g. piling)~~. Ventilation fans, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in such a way that they cause the least possible amount of noise.

Location of farms should, where possible, take into account existing local sources of noise.

Outcome-based measurables: daily mortality rate, morbidity, performance, injury rate, ~~and~~ fear behaviour.

e) Nutrition

Broilers should always be fed a diet appropriate to their age and genetics, which contains adequate nutrients to meet their requirements for good health and welfare.

Feed and water should be acceptable to the broilers ~~palatable~~ and free from contaminants at a concentration ~~potentially~~ hazardous to broiler health.

The water system should be cleaned regularly to prevent growth of hazardous microorganisms.

Broilers should be provided with adequate access to feed on a daily basis. Water should be available continuously.

Special provision~~s~~ should be made to enable young chicks ~~to~~ access to appropriate feed and water.

Broilers that are physically unable to access feed or water should be humanely killed as soon as possible.

Outcome-based measurables: feed and water consumption, performance, ~~normal and abnormal~~ behaviour, gait, incidence of *diseases,* metabolic disorders and parasitic *infestations,* mortality, ~~and~~ injury rate.

f) Flooring, bedding, resting surfaces and ~~(~~litter quality~~)~~

The floor of a poultry house should preferably be easy to clean and disinfect.

The provision of loose and dry bedding material is desirable in order to encourage dust bathing and foraging.

Litter should be managed to minimise any detrimental effects on welfare and health. Poor litter quality can lead to ~~foot pad~~ contact dermatitis~~, hock burns~~ and breast blisters. Litter should be replaced or adequately treated when required to ~~control~~ prevent ~~a~~ *disease* ~~*outbreak*~~ in the next *flock*.

EU comment

The EU asks the OIE to consider deleting breast blisters from the second sentence of the above paragraph:

"Poor litter quality can lead to contact dermatitis~~, and breast blisters~~."

Justification

Breast blisters are part of the contact dermatitis complex and thus superfluous.

Litter quality is partly related to the type of substrate used and partly to different management practices. The type of substrate should be chosen carefully. Litter should be maintained so that it is dry and friable and not dusty, caked or wet. Poor litter quality can result from a range of factors including water spillage, inappropriate feed composition, enteric infections, poor ventilation and overcrowding.

If broilers are kept on slatted floors, ~~often used~~ where a very humid climate precludes the use of other flooring substrates, the floors should be designed, constructed and maintained to adequately support the broilers, prevent injuries and ~~to~~ ensure that manure can fall through or be adequately removed.

To prevent injury and keep them warm, *day-old birds* should be placed on an appropriate type of flooring suitable for their size ~~to prevent injury~~.

If *day-old birds* are housed on litter ~~based systems~~, before they ~~day old~~ ~~birds~~ enter the poultry house, ~~the floor should have~~ a layer of ~~bedding of~~ uncontaminated substrate, such as ~~(e.g.~~ wood shavings, straw, rice husk, shredded paper, treated used litter~~)~~ should be added to a ~~of~~ sufficient depth to allow ~~elicit~~ normal behaviour and to separate ~~protect~~ them from the floor.

Outcome-based measurables: contact dermatitis, feather condition, ~~metabolic disorders;~~ gait, behaviour (dust bathing and foraging), eye conditions, incidence of *diseases*, metabolic disorders and parasitic *infestations*, ~~(respiratory disease)~~ ~~and~~ performance.

g) Prevention of feather pecking and cannibalism ~~Social environment~~

Feather pecking and cannibalism are rarely seen in broilers because of their young age. However, management methods, such as ~~(e.g.~~ reducing light intensity, providing foraging materials, nutritional modifications, reducing stocking density, selecting the appropriate genetic stock~~)~~ should be implemented ~~to reduce feather pecking and cannibalism in growing systems~~ where ~~these behaviours~~ feather pecking and cannibalism are a potential problem.

If these management strategies fail, therapeutic beak trimming ~~should be considered as~~ is the last ~~option~~ resort ~~and after a thorough investigation~~.

Outcome-based measurables: injury rate, ~~normal and abnormal~~ behaviour, feather condition, ~~and~~ mortality.

h) Stocking density

Broilers should be housed ~~in~~ at a~~n appropriate~~ stocking density that allows them~~.~~ to access feed and water and to move and adjust their posture normally. The following factors should be taken into account: management capabilities, ambient conditions, housing system, production~~s~~ system~~s~~, litter quality, ventilation, biosecurity strategy, genetic stock~~s~~, and market age and weight.

~~To determine the appropriate stocking density so that the floor space provided will ensure good welfare (comfort, ability to express normal postural adjustment and to access feed and water), the amount of floor space that needs to be provided per bird in order for the broilers to access feed and water and adjust their posture normally, the following factors should be taken into account: management capabilities, ambient conditions, housing systems, productions systems, litter quality, ventilation, biosecurity strategy, genetic stocks, and market age and weight of broilers.~~

Outcome-based measurables: injury rate, contact dermatitis, mortality, ~~normal and abnormal~~ behaviour, gait, incidence of *diseases*, metabolic disorders and parasitic *infestations*, performance, ~~and~~ feather condition.

i) Outdoor areas

Broilers can be given access to outdoor areas as soon as they have sufficient feather cover and are old enough to range safely. There should be sufficient exit areas to allow them ~~broilers~~ to ~~enter and~~ leave and re-enter the poultry house freely.

Management of outdoor areas is important in ~~extensive and semi-intensive~~ partially housed and completely outdoors production systems. Land and ~~(~~pasture~~)~~ management measures should be taken to reduce the risk of broilers being infected by pathogens or infested by parasites. This might include limiting the stocking density ~~and /~~ or using several pieces of land consecutively in ~~(~~rotation~~)~~.

Outdoor areas should be placed on well drained ground and managed ~~appropriately~~ to minimise swampy conditions and mud~~. Outdoor areas should preferably be placed on well drained ground.~~

Outdoor areas should ~~be managed appropriately to ensure that~~ provide shelter for broilers and be ~~they are~~ free from ~~of~~ poisonous plants and ~~other~~ contaminants.

~~Particularly in extensive systems where birds~~ broilers ~~do not have access to an indoor area,~~ Protection from adverse climatic conditions ~~(e.g. heat, cold, rain)~~ should be provided in completely outdoors systems.

Outcome-based measurables: ~~normal and abnormal~~ behaviour, incidence of parasitic *infestations*, performance, contact dermatitis, feather condition, injury rate, mortality, ~~rate~~ and morbidity.

j) Protection from predators

Broilers should be protected from predators.

Outcome-based measurables: fear behaviour, mortality, ~~and~~ injury rate.

k) ~~Genetic selection~~ Choice of broiler strain

Welfare and health considerations, in addition to productivity, should be taken into account when choosing a strain for a particular location or production system. For example, broilers selected with faster growth rates may have greater risks of metabolic disorders and contact dermatitis which should be mitigated by relevant management procedures.

Outcome-based measurables: gait, metabolic disorders, contact dermatitis, mortality, ~~normal and abnormal~~ behaviour, ~~and~~ performance.

l) Painful interventions

Painful interventions, such as ~~(e.g.~~ beak trimming, toe trimming, dubbing~~)~~ should not be routinely practised on broilers.

If therapeutic beak trimming is required, it should be carried out by trained and skilled personnel at as early an age as possible and care should be taken to remove the minimum amount of beak necessary using a method which minimises pain and controls bleeding ~~(Glatz and Miao, 2005; Hester and Shea-Moore, 2003)~~.

Surgical caponisation should not be performed without adequate pain and *infection* control methods and should only be performed by *veterinarians* or trained and skilled personnel under veterinary supervision.

Outcome-based measurables: ~~use of any of the above procedures~~ mortality, culling and morbidity, behaviour.

m) Handling and inspection

Broilers should be inspected at least daily ~~twice a day~~. Inspection should have three main objectives: ~~1)~~ to identify sick or injured broilers to treat or cull them;~~,~~ ~~2)~~ to detect and correct any welfare or health problem in the *flock* ~~(e.g. related to the supply of feed and water, thermal conditions, ventilation, litter quality);~~ and ~~3)~~ to pick up dead broilers.

Inspection should be done in such a way that broilers are not unnecessarily disturbed, for example *animal handlers* should move quietly and slowly through the *flock*.

When broilers are handled, they should not be injured or unnecessarily frightened or stressed.

Broilers which have an incurable illness ~~sickness~~, significant deformity or injury should be removed from the *flock* and ~~humanely~~ killed humanely as soon as possible as described in Chapter 7.6.

Cervical dislocation is an accepted~~able~~ method for killing small numbers of broilers if carried out competently as described in ~~(see~~ Article 7.6.17. ~~of the *Terrestrial Code*~~). ~~For a complete description of killing methods see Article 7.6.175. of the *Terrestrial Code*.~~

Outcome-based measurables: ~~normal and abnormal~~ behaviour, performance, injury rate, mortality, vocalisation, ~~and~~ morbidity.

n) Personnel training

All people responsible for the broilers should have received appropriate training or be able to demonstrate ~~so~~ that they are competent to carry out their responsibilities and should have sufficient knowledge of broiler behaviour, handling techniques, emergency killing ~~euthanasia~~ procedures, biosecurity, general signs of *disease*, and indicators of poor *animal welfare* ~~such as stress and pain,~~ and procedures for their alleviation.

Outcome-based measurables: all measurables could apply.

o) Emergency plans

Broiler producers should have emergency plans to minimise and mitigate the consequences of natural disasters, *disease outbreaks* and the failure of mechanical equipment. Planning may include the provision of fail-safe alarm devices to detect malfunctions, backup generators, access to maintenance providers, alternative heating or cooling arrangements, ability to store water on farm, access to water cartage services, adequate on farm storage of feed and alternative feed supply and a plan for managing ~~emergency~~ ventilation emergencies.

~~An~~ The emergency plans ~~for animal health~~ should be ~~developed~~ consistent with national programmes established or recommended by *Veterinary Services* ~~as appropriate~~.

p) Location, construction and equipment of farms

The location of ~~poultry~~ broiler farms should be chosen to be safe from the effects of fires and floods and other natural disasters to the extent practical. In addition farms should be sited to avoid or minimise biosecurity risks, exposure of ~~birds~~ broilers to chemical and physical contaminants, noise and adverse climatic conditions.

~~Poultry~~ Broiler houses, outdoor areas and equipment to which broilers have access should be designed and maintained to avoid injury or pain to the ~~birds~~ broilers.

~~Poultry~~ Broiler houses should be constructed and electrical and fuel installations should be fitted to minimise the risk of fire and other hazards.

Broiler producers should have a maintenance programme in place for all equipment ~~that, in case of~~ the failure of which can jeopardise broiler welfare.

q) On farm harvesting

Broilers should not be subject to an excessive period of feed withdrawal prior to the expected *slaughter* time.

Water should be available up to the time of harvesting ~~catching~~.

Broilers that are not fit for *loading* or *transport* because they are sick or injured should be killed humanely ~~(e.g. severely injured or severely ill) should be culled or separated prior to harvesting the *flock*~~.

Catching should be carried out by skilled *animal handlers* and every attempt should be made to minimise stress and fear reactions, and injury. If a broiler is injured during catching, it should be ~~culled~~ killed humanely.

Broilers should not be picked up by their neck or wings.

Broilers should be carefully placed in the *transport container*.

Mechanical catchers, where used, should be designed, operated and maintained to minimise injury, stress and fear to the broilers. A contingency plan is advisable in case of mechanical failure.

Catching should preferably be carried out under dim or blue light to calm the broilers.

Catching should be scheduled to minimise the time to *slaughter* as well as climatic stress during catching, *transport* and holding.

Stocking density in *transport containers* should suit climatic conditions and maintain comfort.

Containers should be designed and maintained to avoid injury, and they should be cleaned and, if necessary, disinfected regularly ~~clean and disinfected and designed and maintained to avoid injury to the broilers birds~~.

Outcome-based measurables: injury rate, ~~and~~ mortality rate ~~(~~at harvesting ~~catching~~ and ~~dead~~ on arrival at the *slaughterhouse/abattoir*~~)~~.

~~2.18. Humane killing~~

~~Injured and sick birds should be killed humanely.~~

~~Cervical dislocation is considered a humane method for killing small numbers of broilers birds (see Article 7.6.17. of the *Terrestrial Code*).~~

~~For a description of other methods for the humane killing of broilers see Article 7.6.5. of the *Terrestrial Code*.~~

~~**Scientific references (which will be deleted after adoption of this chapter)**~~

~~Arnould, C. and L. Colin. 2009. Relationship between various measures used to assess the welfare of broiler chickens on farm. 8th European Symposium on Poultry Welfare, Cervia, Italy. World's Poultry Science Journal (abstract book).~~

~~Berg, C. and G.S. Sanotra. 2003. Can a modified latency-to-lie test be used to validate gait-scoring results in commercial broiler flocks? Animal Welfare, 12, 55–659.~~

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Annex XIV

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Article 7.1.1.

Definition

Animal welfare means how an *animal* is coping with the conditions in which it lives. An *animal* is in a good state of *welfare* if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear, and distress.

Good *animal welfare* requires *disease* prevention and appropriate veterinary treatment, shelter, management and nutrition, humane handling and humane *slaughter* or *killing*. *Animal welfare* refers to the state of the *animal*; the treatment that an *animal* receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

Article 7.1.2.

Guiding principles for animal welfare

1) That there is a critical relationship between animal health and *animal welfare*.

2) That the internationally recognised 'five freedoms' (freedom from hunger, thirst and malnutrition; freedom from fear and distress; freedom from physical and thermal discomfort; freedom from pain, injury and *disease*; and freedom to express normal patterns of behaviour) provide valuable guidance in *animal welfare*.

3) That the internationally recognised 'three Rs' (reduction in numbers of *animals*, refinement of experimental methods and replacement of *animals* with non-animal techniques) provide valuable guidance for the use of *animals* in science.

4) That the scientific assessment of *animal welfare* involves diverse elements which need to be considered together, and that selecting and weighing these elements often involves value-based assumptions which should be made as explicit as possible.

5) That the use of *animals* in agriculture, education and research, and for companionship, recreation and entertainment, makes a major contribution to the wellbeing of people.

6) That the use of *animals* carries with it an ethical responsibility to ensure the *welfare* of such *animals* to the greatest extent practicable.

7) That improvements in farm *animal welfare* can often improve productivity and food safety, and hence lead to economic benefits.

8) That equivalent outcomes based on performance criteria, rather than identical systems based on

Article 7.1.3.

Scientific basis for recommendations

1) *Welfare* is a broad term which includes the many elements that contribute to an *animal*'s quality of life, including those referred to in the 'five freedoms' listed above.

2) The scientific assessment of *animal welfare* has progressed rapidly in recent years and forms the basis of these recommendations.

3) Some measures of *animal welfare* involve assessing the degree of impaired functioning associated with injury, *disease*, and malnutrition. Other measures provide information on *animals*' needs and affective states such as hunger, pain and fear, often by measuring the strength of *animals*' preferences, motivations and aversions. Others assess the physiological, behavioural and immunological changes or effects that *animals* show in response to various challenges.

4) Such measures can lead to criteria and indicators that help to evaluate how different methods of managing *animals* influence their welfare.

Article 7.1.4.

General principles for the welfare of animals in livestock production systems

1) Genetic selection should always take into account the health and *welfare* of *animals*.

2) *Animals* chosen for introduction into new environments should be suited to the local climate and able to adapt ~~successfully~~ to local *diseases*, parasites and nutrition.

3~~2~~) The physical environment, including the substrate (walking surface, resting surface, etc.), should be suited to the species and breed so as to minimise risk of injury and transmission of *diseases* or parasites to *animals*.

4~~3~~) The physical environment should allow comfortable resting, safe and comfortable movement including normal postural changes, and the opportunity to perform types of natural behaviour that *animals* are motivated to perform.

5~~4~~) Social grouping of *animals* should be managed to allow positive social behaviour and minimise injury, distress and chronic fear.

6~~5~~) For housed *animals*, air quality, temperature and humidity ~~in confined spaces~~ should support good animal health and not be aversive ~~to *animals*~~. Where extreme conditions occur, *animals* should not be prevented from using their natural methods of thermo-regulation.

7~~6~~) *Animals* should have access to sufficient feed and water, suited to the *animals*' age and needs, to maintain normal health and productivity and to prevent prolonged hunger, thirst, malnutrition or dehydration.

8~~7~~) *Diseases* and parasites should be prevented and controlled as much as possible through good management practices. *Animals* with serious health problems should be isolated and treated promptly or killed humanely if treatment is not feasible or recovery is unlikely.

9~~8~~) Where painful procedures cannot be avoided, the resulting pain should be managed to the extent that available methods allow.

10~~9~~) The handling of *animals* should foster a positive relationship between humans and animals and should not cause injury, panic, lasting fear or avoidable stress.

11~~10~~) Owners and handlers should have sufficient skill and knowledge to ensure that *animals* are treated in accordance with these principles.

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Annex XV

CHAPTER 7.9.

ANIMAL WELFARE AND BEEF CATTLE PRODUCTION SYSTEMS

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Article 7.9.1.

Definitions

Beef cattle production systems are defined as all commercial cattle production systems where the purpose of the operation includes some or all of the breeding, rearing and finishing of cattle intended for beef consumption.

Article 7.9.2.

Scope

This chapter addresses the welfare aspects of beef cattle production systems, from birth through to finishing. This scope does not include veal production.

Article 7.9.3.

Commercial beef cattle production systems

Commercial beef cattle production systems include:

1. Intensive

   These are systems where cattle are in confinement and are fully dependent on humans to provide for basic animal needs such as food, shelter and water on a daily basis.

2. Extensive

   These are systems where cattle have the freedom to roam outdoors, and where the cattle have some autonomy over diet selection (through grazing), water consumption and access to shelter.

3. Semi Intensive

   These are systems where cattle are exposed to any combination of both intensive and extensive husbandry methods, either simultaneously, or varied according to changes in climatic conditions or physiological state of the cattle.

Article 7.9.4.

Criteria or measurables for the welfare of beef cattle

The following outcome-based measurables, specifically animal-based measurables, can be useful indicators of *animal welfare*. The use of these indicators and the appropriate thresholds should be adapted to the different situations where beef cattle are managed. Consideration should also be given to the design of the system.

1. Behaviour

   Certain behaviours could indicate an *animal welfare* problem. These include decreased feed intake, increased respiratory rate or panting (assessed by panting score), and the demonstration of stereotypic, aggressive, depressive or other abnormal behaviours.

Annex XV (contd)

2. Morbidity rates

Morbidity rates, including *disease*, lameness, post-procedural complication and injury rates, above recognised thresholds may be direct or indirect indicators of the *animal welfare* status of the whole *herd*. Understanding the aetiology of the *disease* or syndrome is important for detecting potential *animal welfare* problems. Scoring systems, such as lameness scoring, can provide additional information.

Post-mortem examination is useful to establish causes of *death* in cattle. Both clinical and post-mortem pathology could be utilised as an indicator of *disease*, injuries and other problems that may compromise *animal welfare*.

3. Mortality rates

Mortality rates, like morbidity rates, may be direct or indirect indicators of the *animal welfare* status. Depending on the production system, estimates of mortality rates can be obtained by analysing causes of *death* and the rate and temporo-spatial pattern of mortality. Mortality rates should ~~can~~ be recorded regularly, i.e. ~~reported~~ daily, monthly, annually or with reference to key husbandry activities within the production cycle.

4. Changes in weight and body condition

In growing animals, weight gain may be an indicator of animal health and *animal welfare*. Poor body condition ~~score~~ and significant weight loss may be an indicator of compromised welfare.

5. Reproductive efficiency

Reproductive efficiency can be an indicator of animal health and *animal welfare* status. Poor reproductive performance can indicate *animal welfare* problems. Examples may include:

– anoestrus or extended post-partum interval,
– low conception rates,
– high abortion rates,
– high rates of dystocia.

6. Physical appearance

Physical appearance may be an indicator of animal health and *animal welfare*, as well as the conditions of management. Attributes of physical appearance that may indicate compromised welfare include:

– presence of ectoparasites,
– abnormal coat colour or texture or excessive soiling with faeces, mud or dirt,
– dehydration,
– emaciation.

7. Handling responses

Improper handling can result in fear and distress in cattle. Indicators could include:

– chute or race exit speed,
– chute or race behaviour score,
– percentage of animals slipping or falling,
– percentage of animals moved with an electric goad,
– percentage of animals striking fences or gates,
– percentage of animals injured during handling, such as broken horns, broken legs, and lacerations,
– percentage of animals vocalizing during restraint.

8. Complications due to routine procedure management

Surgical and non-surgical procedures are commonly performed in beef cattle for improving animal performance, facilitating management, and improving human safety and *animal welfare*. However, if these procedures are not performed properly, *animal welfare* can be compromised. Indicators of such problems could include:

– post procedure *infection* and swelling,

– myiasis,

– mortality.

Article 7.9.5.

Recommendations

Each recommendation includes a list of relevant outcome-based measurables derived from Article 7.9.4. This does not exclude other measures being used where appropriate.

1. Biosecurity and animal health

a) Biosecurity and disease prevention

Biosecurity means a set of measures designed to maintain a *herd* at a particular health status and to prevent the entry or spread of infectious agents.

Biosecurity plans should be designed and implemented, commensurate with the desired *herd* health status and current *disease* risk and, for OIE *listed diseases*, in accordance with relevant recommendations found in the *Terrestrial Code.*

These biosecurity plans should address the control of the major sources and pathways for spread of pathogens:

i) cattle,
ii) other *animals*,
iii) people,
iv) equipment,
v) vehicles,
vi) air,
vii) water supply,
viii) feed.

Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, changes in weight and body condition ~~score~~.

b) Animal health management

Animal health management means a system designed to optimise the physical and behavioural health and welfare of the cattle *herd*. It includes the prevention, treatment and control of *diseases* and conditions affecting the *herd*, including the recording of illnesses, injuries, mortalities and medical treatments where appropriate.

There should be an effective programme for the prevention and treatment of *diseases* and conditions consistent with the programmes established by a qualified *veterinarian* as appropriate.

Those responsible for the care of cattle should be aware of the signs of ill-health or distress, such as reduced feed and water intake, changes in weight and body condition, changes in behaviour or abnormal physical appearance.

Annex XV (contd)

Cattle at higher risk of *disease* or distress will require more frequent inspection by *animal handlers*. If *animal handlers* are not able to correct the causes of ill-health or distress or if they suspect the presence of a listed reportable *disease* they should seek advice from those having training and experience, such as *veterinarians* or other qualified advisers.

Vaccinations and other treatments administered to cattle should be undertaken by people skilled in the procedures and on the basis of veterinary or other expert advice.

Animal handlers should have experience in recognising and dealing with non-ambulatory cattle. They should also have experience in managing chronically ill or injured cattle.

Non-ambulatory cattle should have access to water at all times and be provided with feed at least once daily. They should not be transported or moved unless absolutely necessary ~~except~~ for treatment or diagnosis. Such movements should be done carefully using methods avoiding dragging or excessive lifting.

When treatment is attempted, cattle that are unable to stand up unaided and refuse to eat or drink should be killed humanely according to Chapter 7.5. as soon as recovery is deemed unlikely.

Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, behaviour, physical appearance, ~~and~~ changes in weight and body condition ~~score~~.

2. Environment

a) Thermal environment

Although cattle can adapt to a wide range of thermal environments particularly if appropriate breeds are used for the anticipated conditions, sudden fluctuations in weather can cause heat or cold stress.

i) Heat stress

The risk of heat stress for cattle is influenced by environmental factors including air temperature, relative humidity and wind speed, and animal factors including breed, age, body condition, metabolic rate and coat colour and density.

Animal handlers should be aware of the risk that heat stress poses to cattle. If conditions are expected to induce heat stress ~~reach this threshold~~, routine daily activities that require moving cattle should cease. If the risk of heat stress reaches very high levels the *animal handlers* should institute an emergency action plan that could include reduction of stocking density, provision of shade, free access to drinking water, and cooling by the use of sprinkled water that penetrates the hair coat.

Outcome-based measurables: behaviour, including panting score and respiratory rate, morbidity rate, mortality rate,

ii) Cold stress

Protection from extreme weather conditions should be provided when these conditions are likely to create a serious risk to the welfare of cattle, particularly in neonates and young cattle and others that are physiologically compromised. This could be provided by natural or man made shelter structures.

Animal handlers should also ensure that cattle have access to adequate feed and water during cold stress. During extreme cold weather conditions, *animal handlers* should institute an emergency action plan to provide cattle with shelter, appropriate feed and water.

Outcome-based measurables: mortality rates, physical appearance, behaviour including abnormal postures, shivering and huddling.

b) Lighting

Confined cattle that do not have access to natural light should be provided with supplementary lighting which follow natural periodicity sufficient for their health and welfare, to facilitate natural behaviour patterns and to allow adequate inspection of the cattle.

Outcome-based measurables: behaviour, morbidity, physical appearance.

c) Air quality

Good air quality is an important factor for the health and welfare of cattle. It is affected by air constituents such as gases, dust and micro-organisms, and is strongly influenced by management, particularly in intensive systems. The air composition is influenced by the stocking density, the size of the cattle, flooring, bedding, waste management, building design and ventilation system.

Proper ventilation is important for effective heat dissipation in cattle and preventing the build up of NH_3 and effluent gases in the confinement unit. Poor air quality and ventilation are risk factors for respiratory discomfort and *diseases*. The ammonia level in enclosed housing should not exceed 25 ppm.

Outcome-based measurables: morbidity rate, behaviour, mortality rate, changes in weight and body condition ~~score~~.

d) Noise

Cattle are adaptable to different levels and types of noise. However, exposure of cattle to sudden or loud noises should be minimised where possible to prevent stress and fear reactions (e.g. stampede). Ventilation fans, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in such a way that they cause the least possible amount of noise.

Outcome-based measurables: behaviour.

e) Nutrition

The nutrient requirements of beef cattle have been well defined. Energy, protein, mineral and vitamin contents of the diet are major factors determining the growth, feed efficiency, reproductive efficiency, and body composition.

Cattle should be provided with access to an appropriate quantity and quality of balanced nutrition that meets their physiological needs. Where cattle are maintained in extensive conditions, short term exposure to climatic extremes may prevent access to nutrition that meets their daily physiological needs. In such circumstances the *animal handler* should ensure that the period of reduced nutrition is not prolonged and that mitigation strategies are implemented if welfare is at risk of being compromised.

Animal handlers should have adequate knowledge of appropriate body condition ~~scores~~ for their cattle and should not allow body condition to fall outside an acceptable range. If supplementary feed is not available, steps should be taken to avoid starvation, including *slaughter*, sale or relocation of the cattle, or humane *killing*.

Feedstuffs and feed ingredients should be of satisfactory quality to meet nutritional needs. Where appropriate, feed and feed ingredients should be tested for the presence of substances that would adversely impact on animal health.

Cattle in intensive production systems typically consume diets that contain a high proportion of grain(s) (corn, milo, barley, grain by-products) and a smaller proportion of roughages (hay, straw, silage, hulls, etc.). Diets with insufficient roughage can contribute to abnormal oral behaviour in finishing cattle, such as tongue rolling. As the proportion of grain increases in the diet, the relative risk of digestive upset in cattle increases. *Animal handlers* should understand the impact of cattle size and age, weather patterns, diet composition and sudden dietary changes in respect to digestive upsets and their negative consequences (acidosis, bloat, liver abscess, laminitis). Where appropriate beef producers should consult a cattle nutritionist for advice on ration formulation and feeding programmes.

Beef producers should become familiar with potential micronutrient deficiencies or excesses for intensive and extensive production systems in their respective geographical areas and use appropriately formulated supplements where necessary.

All cattle need an adequate supply and access to palatable water that meets their physiological requirements and is free from contaminants hazardous to cattle health.

Outcome-based measurables: mortality rates, morbidity rates, behaviour, changes in weight and body condition ~~score~~, reproductive efficiency.

Annex XV (contd)

f) Flooring, bedding, resting surfaces and outdoor areas

In all production systems cattle need a well-drained and comfortable place to rest. All cattle in a group should have sufficient space to lie down and rest at the same time.

Pen floor management in intensive production systems can have a significant impact on cattle welfare. Where there are areas that are not suitable for resting such as excessive water and faecal accumulation, these areas should not be of a depth that would compromise welfare and should not comprise the whole of usable area available to the cattle.

Slopes of pens should be maintained to allow water to drain away from feed troughs and not pool excessively in the pens.

Pens should be cleaned as conditions warrant and, at a minimum, after each production cycle.

If cattle are kept ~~housed~~ on a slatted floor ~~shed~~, the slat and gap widths should be appropriate to the hoof size of the cattle to prevent injuries. Wherever possible, cattle on slatted floors should have access to a bedded area.

In straw or other bedding systems, the bedding should be maintained to provide cattle with a dry and comfortable place in which to lie.

Surfaces of concrete alleys should be grooved or appropriately textured to provide adequate footing for cattle.

Outcome-based measurables: morbidity rates (e.g. lameness, pressure sores), behaviour, changes in weight and body condition ~~score~~, and physical appearance.

g) Social environment

Management of cattle should take into account the social environment as it relates to *animal welfare*, particularly in intensive systems. Problem areas include: agonistic and mounting activity, mixing of heifers and steers, feeding cattle of different size and age in the same pens, high stocking density, insufficient space at the feeder, insufficient water access and mixing of bulls.

Management of cattle in all systems should take into account the social interactions of cattle within groups. The *animal handler* should understand the dominance hierarchies that develop within different groups and focus on high risk animals, such as very young, very old, small or large size for cohort group, for evidence of bullying and excessive mounting behaviour. The *animal handler* should understand the risks of increased agonistic interactions between animals, particularly after mixing groups. Cattle that are suffering from excessive agonistic activity or mounting behaviour should be removed from the group.

Horned and non-horned cattle should not be mixed because of the risk of injury.

Adequate fencing should be provided to minimise any *animal welfare* problems that may be caused by mixing of inappropriate groups of cattle.

Outcome-based measurables: behaviour, physical appearance, changes in weight and body condition ~~score~~, morbidity and mortality rate.

h) Stocking density

High stocking densities may increase the occurrence of injuries ~~injury rate~~ ~~injuries~~ and have an adverse effect on growth rate, feed efficiency and behaviour, such as locomotion, resting, feeding and drinking.

Stocking density should be managed such that crowding does not adversely affect normal behaviour of cattle. This includes the ability to lie down freely without the risk of injuries, move freely around the pen and access feed and water. Stocking density should also be managed such that weight gain and duration of time spent lying is not adversely affected by crowding. If abnormal behaviour is seen, measures should be taken such as reducing stocking density.

In extensive systems, stocking density should be matched to the available feed supply.

Outcome-based measurables: behaviour, morbidity rate, mortality rate, changes in weight and body condition ~~score~~, physical appearance.

i) Protection from predators

Cattle should be protected as much as possible from predators.

Outcome-based measurables: mortality rate, morbidity rate (injury rate), behaviour, physical appearance.

3. Management

a) Genetic selection

Welfare and health considerations, in addition to productivity, should be taken into account when choosing a breed or subspecies for a particular location or production system. Examples of these include nutritional maintenance requirement, ectoparasite resistance and heat tolerance.

Individual animals within a breed can be genetically selected to propagate offspring that exhibit traits beneficial to animal health and welfare. These include maternal instincts, ease of calving, birth weight, milking ability, body conformation and temperament.

Outcome-based measurables: morbidity rate, mortality rate, behaviour, physical appearance, reproductive efficiency.

b) Reproductive management

Dystocia can be a welfare risk to beef cattle. Heifers should not be bred before they are physically mature enough to ensure the health and welfare of both dam and calf at birth. The sire has a highly heritable effect on final calf size and as such can have a significant impact on ease of calving. Sire selection should therefore account for the maturity and size of the female. Heifers and cows should not be implanted, inseminated or mated in such a way that the progeny results in increased risk to dam and calf welfare.

Pregnant cows and heifers should be managed during pregnancy so as not to become too fat or too thin. Excessive fatness increases the risk of dystocia, and both excessive condition gain and loss increase the risk of metabolic disorders during late pregnancy or after parturition.

Where possible, cows and heifers should be monitored when they are close to calving. Animals observed to be having difficulty in calving should be assisted by a competent handler as soon as possible after they are detected.

Outcome-based measurables: morbidity rate (rate of dystocia), mortality rate (cow and calf), reproductive efficiency.

c) Colostrum

Receiving adequate immunity from colostrum generally depends on the volume and quality of colostrum ingested, and how soon after birth the calf receives it.

Where possible, *animal handlers* should ensure that calves receive sufficient colostrum within 24 hours of birth.

Outcome-based measurables: mortality rate, morbidity rate, changes in weight.

Annex XV (contd)

d) Weaning

For the purposes of this chapter, weaning means the transfer of the calf from a milk-based diet to a fibrous diet. In beef cattle production systems, weaning can be a stressful time in the calf's life.

Calves should be weaned only when their ruminant digestive system has developed sufficiently to enable them to maintain growth and welfare.

There are different weaning strategies utilised in the beef cattle production systems. These include abrupt separation, fenceline separation and the use of devices placed in the nose of the calf to discourage suckling.

Special care should be taken if abrupt weaning is immediately followed by additional stressors such as transportation, as calves are at risk of increased morbidity under these circumstances.

If necessary, beef cattle producers should seek expert advice on the most appropriate time and method of weaning for their type of cattle and production system.

Outcome-based measurables: morbidity rate, mortality rate, behaviour, physical appearance, changes in weight and body condition ~~score~~.

e) Painful husbandry procedures

Husbandry practices that have the potential to cause pain are routinely practiced on cattle for reasons of production efficiency, animal health and welfare and human safety. These procedures should be performed in such a way as to minimise any pain and stress to the animal. ~~Performing~~ These procedures should be performed at as early an age as possible or using anaesthesia or analgesia under the recommendation or supervision of a *veterinarian* ~~should be considered~~.

Future options for enhancing *animal welfare* in relation to these procedures include: ~~1)~~ ceasing the procedure and addressing the current need for the operation through management strategies; ~~2)~~ breeding cattle that do not require the procedure; or ~~3)~~ replacing the current procedure with a non-surgical alternative that has been shown to enhance *animal welfare.*

Example of such interventions include: castration, dehorning, ovariectomy (spaying), tail docking, identification.

i) Castration

Castration of beef cattle is performed in many production systems to reduce inter-animal aggression, improve human safety, avoid the risk of unwanted pregnancies in the *herd*, and enhance production efficiency.

Where it is necessary to castrate beef cattle, producers should seek guidance from *veterinarians* as to the optimum method and timing for their type of cattle and production system.

Methods of castration used in beef cattle include surgical removal of the testes, ischaemic methods, and crushing and disruption of the spermatic cord.

Where practical, cattle should be castrated before the age of three months, or at the first available handling opportunity beyond this age using the method available that causes least pain or suffering to the animal.

Producers should seek guidance from *veterinarians* on the availability and advisability of analgesia or anaesthesia for castration of beef cattle, particularly in older animals.

Operators performing castration of beef cattle should be trained and competent in the procedure used, and be able to recognise the signs of complications.

ii) Dehorning (including disbudding)

Beef cattle ~~that are naturally horned~~ are commonly dehorned in order to reduce animal injuries and hide damage, improve human safety, reduce damage to facilities and facilitate transport and handling. Where practical and appropriate for the production system, the selection of polled cattle is preferable to dehorning.

Where it is necessary to dehorn beef cattle, producers should seek guidance from veterinary advisers as to the optimum method and timing for their type of cattle and production system.

Where practical, cattle should be dehorned while horn development is still at the horn bud stage, or at the first available handling opportunity beyond this age. This is because the procedure involves less tissue trauma when horn development is still at the horn bud stage, and there is no attachment of horn to the skull of the animal.

Methods of dehorning (disbudding) at the horn bud stage include removal of the horn buds with a knife, thermal cautery of the horn buds, or the application of chemical paste to cauterise the horn buds. Methods of dehorning when horn development has commenced involve the removal of the horn by cutting or sawing through the base of the horn close to the skull.

Producers should seek guidance from *veterinarians* on the availability and advisability of analgesia or anaesthesia for dehorning of beef cattle, particularly in older animals, where horn development is more advanced.

Operators performing dehorning of beef cattle should be trained and competent in the procedure used, and be able to recognise the signs of complications.

iii) Ovariectomy (spaying)

Ovariectomy of heifers is sometimes required to prevent unwanted pregnancies under extensive rangeland conditions. Surgical spaying should be performed by *veterinarians* or by highly trained operators. Producers should seek guidance from *veterinarians* on the availability and advisability of analgesia or anaesthesia for spaying of beef cattle. The use of analgesia or anaesthesia should be encouraged.

iv) Tail docking

Tail docking has been performed in beef cattle to prevent tail tip necrosis in confinement operations. Research shows that increasing space per animal and proper bedding are effective in preventing tail tip necrosis. Therefore it is not recommended for producers to dock the tails of beef cattle.

v) Identification

Ear-tagging, ear-notching, tattooing, freeze branding and radio frequency identification devices (RFID) are preferred methods of permanently identifying beef cattle from an *animal welfare* standpoint. In some situations however hot iron branding may be required or be the only practical method of permanent identifying beef cattle. If cattle are branded, it should be accomplished quickly, expertly and with the proper equipment. Identification systems should be established also according to Chapter 4.1.

Outcome-based measurables: postprocedural complication rate, morbidity rate, behaviour, physical appearance, changes in weight and body condition ~~score~~.

f) Handling and inspection

Beef cattle should be inspected at intervals appropriate to the production systems and the risks to the health and *welfare* of the cattle. In intensive farming systems, cattle should be inspected at least once a day.

Some animals may benefit from more frequent inspection for example: neonatal calves, cows in late gestation, newly weaned calves, and cattle experiencing environmental stress and those that have undergone painful husbandry or veterinary surgical procedures.

Animal handlers need to be competent in recognising the clinical signs of health, *disease* and *welfare* of beef cattle. There should be a sufficient number of *animal handlers* to adequately ensure the health and welfare of the cattle.

Beef cattle identified as sick or injured should be given appropriate treatment at the first available opportunity by competent and trained *animal handlers*. If *animal handlers* are unable to provide appropriate treatment, the services of a *veterinarian* should be sought.

If the animal's condition suggests the prognosis is poor with little chance of recovery, the animal should be humanely killed as soon as possible. For a description of methods for the humane *killing* of beef cattle see Article 7.6.5.

Recommendations on the handling of cattle are also found in Chapter 7.5.

Where beef cattle are herded into a handling facility from extensive conditions, they should be moved quietly and calmly at the pace of the slowest animal. Weather conditions should be taken into account and cattle should not be herded in excessively hot or cold conditions. Cattle should not be driven to the point of distress. In situations where the gathering and handling of the cattle is likely to be stressful, consideration should be given to the avoidance of multiple handling events by combining necessary management procedures within the one handling event. Where handling itself is not stressful, management procedures should be staged over time to avoid additive stress of multiple procedures.

Properly trained dogs can be effective aids for cattle herding. Cattle are adaptable to different visual environments. However, exposure of cattle to sudden or persistent movement or visual contrasts should be minimised where possible to prevent stress and fear reactions.

Electroimmobilisation should not be used.

Outcome-based measurables: handling response, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight and body condition ~~score~~.

g) Personnel training

All people responsible for beef cattle should be competent according to their responsibilities and should understand cattle husbandry, behaviour, biosecurity, general signs of *disease*, and indicators of poor *animal welfare* such as stress, pain and discomfort, and their alleviation.

Competence may be gained through formal training or practical experience.

Outcome-based measurables: handling response, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight and body condition ~~score~~.

h) Emergency plans

Where the failure of power, water and feed supply systems could compromise *animal welfare*, beef producers should have contingency plans to cover the failure of these systems. These plans may include the provision of fail-safe alarms to detect malfunctions, back-up generators, access to maintenance providers, ability to store water on farm, access to water cartage services, adequate on-farm storage of feed and alternative feed supply.

Plans should be in place to minimise and mitigate the effects of natural disasters or extreme climatic conditions, such as heat stress, drought, blizzard, fire and flooding. Humane *killing* procedures for sick or injured cattle should be part of the emergency action plan. In times of drought, animal management decisions should be made as early as possible and these should include a consideration of reducing cattle numbers. Emergency plans should also cover the management of the farm in the face of an emergency *disease outbreak*, consistent with national programmes and recommendations of *Veterinary Services* as appropriate.

i) Location, construction and equipment

Farms for beef cattle should be situated in an appropriate geographical location for the health, *welfare* and productivity of the cattle.

All facilities for beef cattle should be constructed, maintained and operated to minimise the risk to the *welfare* of the cattle.

Equipment for handling and restraining beef cattle should only be used in a way that minimises the risk of injury, pain or distress.

Cattle in intensive or extensive production systems should be offered adequate space for comfort and socialisation.

Cattle that are kept tethered should, as a minimum, be able to lie down, and if tethered outdoors, turn around and walk.

In intensive production systems the feeder should be sufficiently large so that cattle have adequate access to feed and they should be clean and free of spoiled, mouldy, sour, packed or unpalatable feed. Also cattle should have access to water at all times.

Floors in housing facilities should be properly drained, and barns and races and chutes should provide traction to prevent injuries to cattle.

Races, chutes and pens should be free from sharp edges and protrusions to prevent injury to cattle.

Alleys and gates should be designed and operated to avoid impeding cattle movement. Slippery surfaces should be avoided. Grooved concrete, metal grating (not sharp), rubber mats or deep sand can be used to minimise slipping and falling. Quiet handling is essential to minimise slipping. When gates and catches are operated, excessive noise should be minimised, because it may cause distress to the cattle.

Hydraulic, pneumatic and manual restraining equipment should be adjusted, as appropriate, to the size of cattle to be handled. Hydraulic and pneumatic operated restraining equipment should have pressure limiting devices to prevent injuries. Regular cleaning and maintenance of working parts is imperative to ensure the system functions properly and is safe for the cattle.

Mechanical and electrical devices used in housing facilities should be safe for cattle.

Dipping baths are sometimes used in beef cattle production for ectoparasite control. Where these are used, they should be designed and operated to minimise the risk of crowding to prevent injury and drowning.

The loading of the cattle at the farms should be conducting accordingly to Chapters 7.2., 7.3. and 7.4.

Outcome-based measurables: handling response, morbidity rate, mortality rate, behaviour, changes in weight and body condition ~~score~~, physical appearance, lameness.

j) Humane killing

For sick and injured cattle a prompt diagnosis should be made to determine whether the animal should be humanely killed or receive additional care.

The decision to humanely kill an animal and the procedure itself should be undertaken by a competent person.

Reasons for humane *killing* may include:

i) severe emaciation, weak cattle that are non-ambulatory or at risk of becoming downers;

ii) non-ambulatory cattle that will not stand up, refuse to eat or drink, have not responded to therapy;

iii) rapid deterioration of a medical condition for which therapies have been unsuccessful;

iv) severe, debilitating pain;

v) compound (open) fracture;

vi) spinal injury;

vii) central nervous system *disease*; and

viii) multiple joint *infections* with chronic weight loss.

For a description of methods for the humane *killing* of beef cattle see Article 7.6.5.

— Text deleted.

Annex XVI

CHAPTER 7.8.

USE OF ANIMALS IN RESEARCH AND EDUCATION

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Preamble: The purpose of this chapter is to provide advice and assistance for OIE Members to follow when formulating regulatory requirements, or other form of oversight, for the use of live *animals* in research and education. Wherever the term "research" is used, it includes basic and applied research, testing and the production of biological materials; "education" includes teaching and training. A system of animal use oversight should be implemented in each country. The system will, in practice, vary from country to country and according to cultural, economic, religious and social factors. However, the OIE recommends that Members address all the essential elements identified in this chapter in formulating a regulatory framework that is appropriate to their local conditions. This framework may be delivered through a combination of national, regional and institutional jurisdictions and both public sector and private sector responsibilities should be clearly defined.

The OIE recognises the vital role played by the use of live *animals* in research and education. The OIE Guiding Principles for Animal Welfare state that such use makes a major contribution to the wellbeing of people and *animals* and emphasise the importance of the Three Rs (see Article 7.8.3.). Most scientists and members of the public agree that the *animals* should only be used when necessary; ethically justified (thereby avoiding unnecessary duplication of animal-based research); and when no other alternative methods, not using live *animals*, are available; that the minimum number of *animals* should be used to achieve the scientific or educational goals; and that such use of *animals* should cause as little pain or distress as possible. In addition, animal suffering is often recognised separately from pain and distress and should be considered alongside any lasting harm which is expected to be caused to *animals*.

The OIE emphasises the need for humane treatment of *animals* and that good quality science depends upon good *animal welfare*. It is the responsibility of all involved in the use of *animals* to ensure that they give due regard to these recommendations. In keeping with the overall approach to *animal welfare* detailed in the Guiding Principles, the OIE stresses the importance of standards based on outcomes for the *animal*.

The OIE recognises the significant role of *veterinarians* in animal-based research. Given their unique training and skills, they are essential members of a team including scientists and animal care technicians. This team approach is based on the concept that everyone involved in the use of *animals* has an ethical responsibility for the *animals*' *welfare*. The approach also ensures that animal use leads to high quality scientific and educational outcomes and optimum *welfare* for the *animals* used.

The OIE recognises that the use of live *animals* in research and education is a legitimate activity and, as a consequence, domestic and international transport of *animals* is essential to maintaining progress in advancing human and animal health. Such transport should be conducted in a legal manner, ensuring the safety of the *animal* and applying humane principles.

The OIE recommends that records on animal use should be maintained at an institutional level, as appropriate to the institution and project proposals and species used. Key events and interventions should be recorded to aid decision making and promote good science and *welfare*. A summary of these records may be gathered on a national basis and be published to provide a degree of public transparency, without compromising personnel or animal safety, or releasing proprietary information.

Article 7.8.1.

Definitions

Biocontainment: means the system and procedures designed to prevent the accidental release of biological material including allergens.

Bioexclusion: means the prevention of the unintentional transfer of adventitious organisms with subsequent *infection* of *animals*, resulting in adverse effects on their health or suitability for research.

Biosecurity: means a continuous process of *risk assessment* and *risk management* designed to minimise or eliminate microbiological *infection* with adventitious organisms that can cause clinical *disease* in the infected *animals* or humans, or make *animals* unsuitable for biomedical research.

Cloned animal: means a genetic copy of another living or dead *animal* produced by somatic cell nuclear transfer or other reproductive technology.

Distress: means the state of an *animal*, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

Endangered species: means a population of organisms which is at risk of becoming extinct because it is either few in numbers, or threatened by changing environmental or predation parameters.

Environmental enrichment: means increasing the complexity (e.g. with toys, cage furniture, foraging opportunities, social housing, etc.) in a captive *animal*'s environment to foster the expression of non-injurious species-typical behaviours and reduce the expression of maladaptive behaviours, as well as provide cognitive stimulation.

Ethical review: means consideration of the validity and justification for using *animals* including: an assessment and weighing of the potential harms for *animals* and likely benefits of the use and how these balance (see harm-benefit analysis below); and consideration of experimental design; implementation of the Three Rs; animal husbandry and care and other related issues such as personnel training. Ethical judgements are influenced by prevailing societal attitudes.

Harm-benefit analysis: means the process of weighing the likely adverse effects (harms) to the *animals* against the benefits likely to accrue as a result of the proposed project.

Humane endpoint: means the point in time at which an experimental *animal*'s pain or distress is avoided, terminated, minimised or reduced, by taking actions such as giving treatment to relieve pain or distress, terminating a painful procedure, removing the *animal* from the study, or humanely killing the *animal*.

Laboratory animal: means an *animal* that is intended for use in research. In most cases, such *animals* are purpose-bred to have a defined physiological, metabolic, genetic or pathogen free status.

Operant conditioning: means the association that an *animal* makes between a particular response (such as pressing a bar) and a particular reinforcement that may be positive (for example, a food reward) or negative (e.g. a mild electric shock). As a result of this association, the occurrence of a specific behaviour of the *animal* can be modified (e.g. increased or decreased in frequency or intensity).

Pain: means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

Project proposal (sometimes called protocol): means a written description of a study or experiment, programme of work, or other activities that includes the goals of the work, characterises the use of the *animals*, and includes ethical considerations.

Suffering: means an unpleasant, undesired state of being that is the outcome of the impact on an *animal* of a variety of noxious stimuli or the absence of important positive stimuli. It is

Article 7.8.2.

Scope

This chapter applies to *animals* as defined in the *Terrestrial Code* (excluding bees) bred, supplied or used in research (including testing) and higher education. *Animals* to be used for production of biologicals or humanely killed for harvesting their cells, tissues and organs for scientific purposes are also covered. Members should consider both the species and the developmental stage of the *animal* in implementing these standards.

Article 7.8.3.

The Three Rs

The internationally accepted tenet, the 'Three Rs', comprises the following alternatives:

1) replacement refers to the use of methods utilising cells, tissues or organs of *animals* (relative replacement), as well as those that do not require the use of *animals* to achieve the scientific aims (absolute replacement);

2) reduction refers to the use of methods that enable researchers to obtain comparable levels of information from fewer *animals* or to obtain more information from the same number of *animals*;

3) refinement refers to the use of methods that prevent, alleviate or minimise pain, suffering, distress or lasting harm and enhance *welfare* for the *animals* used. Refinement includes the appropriate selection of relevant species with a lesser degree of structural and functional complexity in their nervous systems and a lesser apparent capacity for experiences that derive from this complexity. Opportunities for refinement should be considered and implemented throughout the lifetime of the *animal* and include, for example, housing and transportation as well as procedures and euthanasia.

Article 7.8.4.

The oversight framework

The role of a *Competent Authority* is to implement a system (governmental or other) for verification of compliance by institutions. This usually involves a system of authorisation (such as licensing or registering of institutions, scientists, or projects) and compliance which may be assessed at the institutional, regional or national level.

The oversight framework encompasses both ethical review of animal use and considerations related to animal care and *welfare*. This may be accomplished by a single body or distributed across different groups. Different systems of oversight may involve *animal welfare* officers, regional, national or local committees or bodies. An institution may utilise a local committee (often referred to as Animal Care and Use Committee, Animal Ethics Committee, Animal Welfare Body or Animal Care Committee) to deliver some or all of this oversight framework. It is important that the local committee reports to senior management within the institution to ensure it has appropriate authority, resources and support. Such a committee should undertake periodic review of its own policies, procedures and performance.

Ethical review of animal use may be undertaken by regional, national or local ethical review bodies or committees. Consideration should be given to ensuring the impartiality and independence of those serving on the committees.

In providing this oversight and ensuring the implementation of the Three Rs, the following expertise should be included as a minimum:

a) one scientist with experience in animal research, whose role is to ensure that protocols are designed and implemented in accordance with sound science;

b) one *veterinarian*, with the necessary expertise to work with research *animals*, whose specific role is to provide advice on the care, use and *welfare* of such *animals*;

c) one public member, where appropriate, to represent general community interests who is independent of the science and care of the *animals* and is not involved in the use of *animals* in research.

Additional expertise may be sought from the animal care staff, as these professional and technical staff are centrally involved in ensuring the *welfare* of *animals* used. Other participants, especially in relation to ethical review, may include statisticians, information scientists and ethicists and biosafety specialists, as appropriate to the studies conducted. It may be appropriate, in teaching institutions, to involve student representation.

Annex XVI (contd)

Oversight responsibilities include three key elements:

1. Project proposal review

The purpose of the project proposal is to enable assessment of the quality of, and justification for, the study, work or activity.

Project proposals, or significant amendments to these, should be reviewed and approved prior to commencement of the work. The proposal should identify the person with primarily responsibility for the project and should include a description of the following elements, where relevant:

a) the scientific or educational aims, including consideration of the relevance of the experiment to human or animal health or *welfare*, the environment, or the advancement of biological knowledge;

b) an informative, non-technical (lay) summary may enhance understanding of the project and facilitate the ethical review of the proposal by allowing full and equitable participation of members of the oversight body or committees who may be dealing with matters outside their specific field. Subject to safeguarding confidential information, such summaries may be made publicly available;

c) the experimental design, including justification for choice of species, source and number of *animals*, including any proposed reuse;

d) the experimental procedures;

e) methods of handling and restraint and consideration of refinements such as animal training and operant conditioning;

f) the methods to avoid or minimise pain, discomfort, distress, suffering or lasting impairment of physical or physiological function, including the use of anaesthesia or analgesia and other means to limit discomfort such as warmth, soft bedding and assisted feeding;

g) application of humane endpoints and the final disposition of *animals*, including methods of euthanasia;

h) consideration of the general health, husbandry and care of the species proposed to be used, including environmental enrichment and any special housing requirements;

i) ethical considerations such as the application of the Three Rs and a harm/benefit analysis; the benefits should be maximised and the harms, in terms of pain and distress, should be minimised;

j) an indication of any special health and safety risks; and

k) resources/infrastructure necessary to support the proposed work (e.g. facilities, equipment, staff trained and found competent to perform the procedures described in the proposed project).

The oversight body has a critical responsibility in determining the acceptability of project proposals, taking account of the *animal welfare* implications, the advancement of knowledge and scientific merit, as well as the societal benefits, in a risk-based assessment of each project using live *animals*.

Following approval of a project proposal, consideration should be given to implementing an independent (of those managing the projects) oversight method to ensure that animal activities conform with those described in the approved project proposal. This process is often referred to as post approval monitoring. Such monitoring may be achieved through animal observations made during the conduct of routine husbandry and experimental procedures; observations made by the veterinary staff during their rounds; or by inspections by the oversight body, which may be the local committee, *animal welfare* officer, compliance/quality assurance officer or government inspector.

l) the duration of approval of a project should normally be defined and progress achieved should be reviewed in considering renewal of a project approval.

2. Facility inspection

There should be regular inspections of the facilities, at least annually. These inspections should include the following elements:

a) the *animals* and their records, including cage labels and other methods of animal identification;

b) husbandry practices;

c) maintenance, cleanliness and security of the facility;

d) type and condition of caging and other equipment;

e) environmental conditions of the *animals* at the cage and room level;

f) procedure areas such as surgery; necropsy and animal research laboratories;

g) support areas such as washing equipment; animal feed, bedding and drug storage locations;

h) occupational health and safety concerns.

Principles of *risk management* should be followed when determining the frequency and nature of inspections.

3. Ethical evaluation

The ethical evaluation reflects the policies and practices of the institution in complying with regulations and relevant guidance. It should include consideration of the functioning of the local committee; training and competency of staff; veterinary care; husbandry and operational conditions, including emergency plans; sourcing and final disposition of *animals*; and occupational health and safety. The programme should be reviewed regularly. A requirement for the components of such a programme should be included in relevant regulations to empower the *Competent Authority* to take appropriate action to ensure compliance.

Article 7.8.5.

Assurance of training and competency

An essential component of the animal care and use programme is the assurance that the personnel working with the *animals* are appropriately trained and competent to work with the species used and the procedures to be performed, including ethical considerations. A system (institutional, regional or national) to assure competency should be in place, which includes supervision during the training period until competence has been demonstrated. Continuing professional and paraprofessional educational opportunities should be made available to relevant staff. Senior management, given their overarching responsibility for the animal care and use programme, should be knowledgeable about issues related to the competence of staff.

1. Scientific staff

Researchers using *animals* have a direct ethical and legal responsibility for all matters relating to the *welfare* of the *animals* in their care. Due to the specialised nature of animal research, focused training should be undertaken to supplement educational and experiential backgrounds of scientists (including visiting scientists) before initiating a study. Focused training may include such topics as the national or local regulatory framework and institutional policies. The laboratory *animalveterinarian* is often a resource for this and other training. Scientific staff should have demonstrated competency in procedures related to their research (e.g. surgery, anaesthesia, sampling and administration, etc.).

2. Veterinarians

It is important that *veterinarians* working in an animal research environment have veterinary medical knowledge and experience in the species used. Furthermore, they should be educated and experienced in the normal behaviour, behavioural needs, stress responses and adaptability of the species, as well as research methodologies. Relevant approvals issued by the *veterinary statutory body* and appropriate national or regional schemes (where these exist) should be adopted as the reference for veterinary training.

3. Animal care staff

Animal care staff should receive training that is consistent with the scope of their work responsibilities and have demonstrated competency in the performance of these tasks.

4. Students

Students should learn scientific and ethical principles using non-animal methods (videos, computer models, etc.) when such methods can effectively reduce or replace the use of live *animals* and still meet learning objectives. Wherever it is necessary for students to participate in classroom or research activities involving live *animals*, they should receive appropriate supervision in the use of *animals* until such time that they have demonstrated competency in the related procedure(s).

5. Members of the local oversight committee or others involved with oversight

Continuing education about the use of *animals* in research and education, including associated ethics, regulatory requirements and their institutional responsibility, should be provided.

Occupational health and safety training for research animal related risks should be provided as part of the assurance of training and competency for personnel. This might include consideration of human infectious *diseases* which may infect research *animals* and thus compromise research results, as well as possible *zoonoses*. Personnel should understand that there are two categories of hazards, those that are intrinsic to working in an animal facility and those associated with the research. Specific training may be required for particular species, for specific procedures, and for the use of appropriate protective measures for personnel who may be exposed to animal allergens. Research materials, such as chemicals of unknown toxicity, biological agents and radiation sources, may present special hazards.

Article 7.8.6.

Provision of veterinary care

Adequate veterinary care includes responsibility for promoting an *animal*'s health and *welfare* before, during and after research procedures and providing advice and guidance based on best practice. Veterinary care includes attention to the physical and behavioural status of the *animal*. The *veterinarian* should have authority and responsibility for making judgements concerning *animal welfare*. Veterinary advice and care should be available at all times. In exceptional circumstances, where species unfamiliar to the veterinarian are involved, a suitably qualified non-veterinary expert may provide advice.

1. Clinical responsibilities

Preventive medicine programmes that include vaccinations, ectoparasite and endoparasite treatments and other disease control measures should be initiated according to currently acceptable veterinary medical practices appropriate to the particular animal species and source. Disease surveillance is a major responsibility of the *veterinarian* and should include routine monitoring of colony *animals* for the presence of parasitic, bacterial and viral agents that may cause overt or sub clinical *diseases*. The *veterinarian* should have the authority to use appropriate treatment or control measures, including euthanasia if indicated, and access to appropriate resources, following diagnosis of an animal *disease* or injury. Where possible, the *veterinarian* should discuss the situation with the scientist to determine a course of action consistent with experimental goals. Controlled drugs prescribed by the veterinary staff should be managed in accordance with applicable regulations.

2. Post-mortem examinations

In the case of unexpected *diseases* or *deaths*, the *veterinarian* should provide advice based on post-mortem examination results. As part of health monitoring, a planned programme of post-mortem examinations may be considered.

3. Veterinary medical records

Veterinary medical records, including post-mortem records, are considered to be a key element of a programme of adequate veterinary care for *animals* used in research and education. Application of performance standards within the veterinary medical record programme allows the *veterinarian* to effectively employ professional judgment, ensuring that the *animal*receives the highest level of care available.

4. Advice on zoonotic risks and notifiable diseases

The use of some species of *animals* poses a significant risk of the transmission of zoonotic *disease* (e.g. some nonhuman primates). The *veterinarian* should be consulted to identify sources of *animals* that minimise these risks and to advice on measures that may be taken in the animal facility to minimise the risk of transmission (e.g. personal protective equipment, appropriate *désinfection* procedures, air pressure differentials in animal holding rooms, etc.). *Animals* brought into the institution may carry *diseases* that require notification to government officials. It is important that the *veterinarian* be aware of, and comply with, these requirements.

5. Advice on surgery and postoperative care

A programme of adequate veterinary care includes input into the review and approval process of preoperative, surgical and postoperative procedures by an appropriately qualified *veterinarian*. A *veterinarian*'s inherent responsibility includes providing advice concerning preoperative procedures, aseptic surgical techniques, the competence of staff to perform surgery and the provision of postoperative care. Veterinary oversight should include the detection and resolution of emerging patterns of surgical and post procedural complications.

6. Advice on analgesia, anaesthesia and euthanasia

Adequate veterinary care includes providing advice on the proper use of anaesthetics, analgesics, and methods of euthanasia.

7. Advice on humane endpoints

Humane endpoints should be established prior to commencement of a study in consultation with the *veterinarian* who also plays an important role in ensuring that approved humane endpoints are followed during the course of the study. It is essential that the *veterinarian* has the authority to ensure euthanasia or other measures are carried out as required to relieve pain and distress unless the project proposal approval specifically does not permit such intervention on the basis of the scientific purpose and the ethical evaluation.

Ideal humane endpoints are those that can be used to end a study before the onset of pain or distress, without jeopardising the study's objectives. In consultation with the *veterinarian*, humane endpoints should be described in the project proposal and, thus, established prior to commencement of the study. They should form part of the ethical review. Endpoint criteria should be easy to assess over the course of the study. Except in rare cases, *death* (other than euthanasia) as a planned endpoint is considered ethically unacceptable.

Article 7.8.7.

Source of animals

Animals to be used for research should be of high quality to ensure the validity of the data.

1. Animal procurement

Animals should be acquired legally. It is preferable that *animals* are purchased from recognised sources producing or securing high quality *animals*. The use of wild caught nonhuman primates is strongly-discouraged.

Purpose bred *animals* should be used whenever these are available and *animals* that are not bred for the intended use should be avoided unless there is compelling scientific justification or are the only available and suitable source. In the case of farm *animals*, non traditional breeds and species, and *animals* captured in the wild, non purpose bred *animals* are often used to achieve specific study goals.

2. Documentation

Relevant documentation related to the source of the *animals*, such as health and other veterinary certification, breeding records, genetic status and animal identification, should accompany the *animals*.

3. Animal health status

The health status of *animals* can have a significant impact on scientific outcomes. There also may be occupational health and safety concerns related to animal health status. *Animals* should have appropriate health profiles for their intended use. The health status of *animals* should be known before initiating research.

Annex XVI (contd)

4. Genetically defined animals

A known genetic profile of the *animals* used in a study can reduce variability in the experimental data resulting from genetic drift and increase the reproducibility of the results. Genetically defined *animals* are used to answer specific research questions and are the product of sophisticated and controlled breeding schemes which should be validated by periodic genetic monitoring. Detailed and accurate documentation of the colony breeding records should be maintained.

5. Genetically altered (also genetically modified or genetically engineered) or cloned animals

A genetically altered *animal*~~s~~ is one that has had undergone genetic modification of its nuclear or mitochondrial genomes through a deliberate human intervention, or the progeny of such an *animal*(s), where they have inherited the modification. If genetically altered or cloned *animals* are used, such use should be conducted in accordance with relevant regulatory guidance. With such *animals*, as well as harmful mutant lines arising from spontaneous mutations and induced mutagenesis, consideration should be given to addressing and monitoring special husbandry and *welfare* needs associated with abnormal phenotypes. Records should be kept of biocontainment requirements, genetic and phenotypic information, and individual identification, and be communicated by the animal provider to the recipient. Archiving and sharing of genetically altered lines is recommended to facilitate the sourcing of these customised *animals*.

6. Animals captured in the wild

If wild *animals* are to be used, the capture technique should be humane and give due regard to human and animal health, *welfare* and safety. Field studies have the potential to cause disturbance to the habitat thus adversely affecting both target and non-target species. The potential for such disturbance should be assessed and minimised. The effects of a series of stressors, such as trapping, handling, transportation, sedation, anaesthesia, marking and sampling, can be cumulative, and may produce severe, possibly fatal, consequences. An assessment of the potential sources of stress and management plans to eliminate or minimise distress should form part of the project proposal.

7. Endangered species

Endangered species should only be used in exceptional circumstances where there is strong scientific justification that the desired outcomes cannot be achieved using any other species.

8. Transport, importation and exportation

Animals should be transported under conditions that are appropriate to their physiological and behavioural needs and pathogen free status, with care to ensure appropriate physical containment of the *animals* as well as exclusion of contaminants. The amount of time *animals* spend on a journey should be kept to a minimum. It is important to ensure that there is a well constructed journey plan, with key staff identified who have responsibility for the *animals* and that relevant documentation accompanies *animals* during transport to avoid unnecessary delays during the journey from the sender to the receiving institution.

9. Risks to biosecurity

In order to minimise the risk of contamination of *animals* with unwanted infectious microorganisms or parasites that may compromise the health of *animals* or make them unsuitable for use in research, the microbiological status of the *animals* should be determined and regularly assessed. Appropriate biocontainment and bioexclusion measures should be practised to maintain their health status and, if appropriate, measures taken to prevent their exposure to certain human or environmental commensals.

Article 7.8.8.

Physical facility and environmental conditions

A well-planned, well-designed, well-constructed, and properly maintained facility should include animal holding rooms as well as areas for support services such as for procedures, surgery and necropsy, cage washing and appropriate storage. An animal facility should be designed and constructed in accordance with all applicable building standards. The design and size of an animal facility depend on the scope of institutional research activities, the *animals* to be housed, the physical relationship to the rest of the institution, and the geographic location. For indoor housing, non-porous, non-toxic and durable materials should be used which can be easily cleaned and sanitised. *Animals* should normally be housed in facilities designed for that purpose. Security measures (e.g. locks, fences, cameras, etc.) should be in place to protect the *animals* and prevent their escape. For many species (e.g. rodents), environmental conditions should be controllable to minimise physiological changes which may be potentially confounding scientific variables and of *welfare* concern.

Important environmental parameters to consider include ventilation, temperature and humidity, lighting and noise:

1. Ventilation

The volume and physical characteristics of the air supplied to a room and its diffusion pattern influence the ventilation of an *animal*'s primary enclosure and are thus important determinants of its microenvironment. Factors to consider when determining the air exchange rate include range of possible heat loads; the species, size, and number of *animals* involved; the type of bedding or frequency of cage changing; the room dimensions; and the efficiency of air distribution from the secondary to the primary enclosure. Control of air pressure differentials is an important tool for biocontainment and bioexclusion.

2. Temperature and humidity

Environmental temperature is a physical factor which has a profound effect on the *welfare* of *animals*. Typically, animal room temperature should be monitored and controlled. The range of daily fluctuations should be appropriately limited to avoid repeated demands on the *animals*' metabolic and behavioural processes to compensate for large changes in the thermal environment as well as to promote reproducible and valid scientific data. Relative humidity may also be controlled where appropriate for the species.

3. Lighting

Light can affect the physiology, morphology and behaviour of various *animals*. In general, lighting should be diffused throughout an animal holding area and provide appropriate illumination for the *welfare* of the *animals* while facilitating good husbandry practices, adequate inspection of *animals* and safe working conditions for personnel. It may also be necessary to control the light/dark cycle.

4. Noise

Separation of human and animal areas minimises disturbance to animal occupants of the facility. Noisy *animals*, such as dogs, pigs, goats and nonhuman primates, should be housed in a manner which ensures they do not adversely affect the *welfare* of quieter *animals*, such as rodents, rabbits and cats. Consideration should be given to insulating holding rooms and procedure rooms to mitigate the effects of noise sources. Many species are sensitive to high frequency sounds and thus the location of potential sources of ultrasound should be considered.

Article 7.8.9.

Husbandry

Good husbandry practices enhance the health and *welfare* of the *animals* used and contributes to the scientific validity of animal research. Animal care and accommodation should, as a minimum, demonstrably conform to relevant published animal care, accommodation and husbandry guidelines and regulations.

The housing environment and husbandry practices should take into consideration the normal behaviour of the species, including their social behaviour and age of the *animal*, and should minimise stress to the *animal*. During the conduct of husbandry procedures, personnel should be keenly aware of their potential impact on the *animals*' *welfare*.

1. Transportation

See Article 7.8.10.

2. Acclimatisation

Newly received *animals* should be given a period for physiological and behavioural stabilisation before their use. The length of time for stabilisation will depend on the type and duration of transportation, the age and species involved, place of origin, and the intended use of the *animals*. Facilities should be available to isolate *animals* showing signs of ill health.

Annex XVI (contd)

3. Cages and pens

Cages and pens should be made out of material that can be readily cleaned and decontaminated. Their design should be such that the *animals* are unlikely to injure themselves. Space allocations should be reviewed and modified as necessary to address individual housing situations and animal needs (for example, for prenatal and postnatal care, obese *animals*, and group or individual housing). Both the quantity and quality of space provided is important. Whenever it is appropriate, social *animals* should be housed in pairs or groups, rather than individually, provided that such housing is not contraindicated by the protocol in question and does not pose an undue risk to the *animals*.

4. Enrichment

Animals should be housed with a goal of maximising species appropriate behaviours and avoiding or minimising stress induced behaviours. One way to achieve this is to enrich the structural and social environment of the *animals* and to provide opportunities for physical and cognitive activity. Such provision should not compromise the health and safety of the *animals* or people, nor interfere with the scientific goals.

5. Feeding

Provision should be made for each *animal* to have access to feed to satisfy its physiological needs. Precautions should be taken in packing, transporting, storing and preparing feed to avoid chemical, physical and microbiological contamination, deterioration or destruction. Utensils used for feeding should be regularly cleaned and, if necessary, sterilised.

6. Water

Uncontaminated potable drinking water should normally be available at all times. Watering devices, such as drinking tubes and automatic watering systems, should be checked daily to ensure their proper maintenance, cleanliness, and operation.

7. Bedding

Animals should have appropriate bedding provided, with additional nesting material if appropriate to the species. Animal bedding is a controllable environmental factor that can influence experimental data and *animal welfare*. Bedding should be dry, absorbent, non-dusty, non-toxic and free from infectious agents, vermin or chemical contamination. Soiled bedding should be removed and replaced with fresh material as often as is necessary to keep the *animals* clean and dry.

8. Hygiene

The successful operation of a facility depends very much on good hygiene. Special care should be taken to avoid spreading infection between *animals* through fomites, including through personnel traffic between animal rooms. Adequate routines and facilities for the cleaning, washing, decontamination and, when necessary, sterilisation of cages, cage accessories and other equipment should be established. A very high standard of cleanliness and organisation should also be maintained throughout the facility.

9. Identification

Animal identification is an important component of record keeping. *Animals* may be identified individually or by group. Where it is desirable to individually identify *animals*, this should be done by a reliable and the least painful method.

10. Handling

Staff dealing with *animals* should have a caring and respectful attitude towards the *animals* and be competent in handling and restraint. Familiarising *animals* to handling during routine husbandry and procedures reduces stress both to *animals* and personnel. For some species, for example dogs and non-human primates, a training programme to encourage cooperation during procedures can be beneficial to the *animals*, the animal care staff and the scientific programme. For certain species, social contact with humans should be a priority. However, in some cases handling should be avoided. This may be particularly the case with wild *animals*. Consideration should be given to setting up habituation and training programmes suitable for the *animals*, the procedures and length of projects.

Article 7.8.10.

Transportation

Transportation is a typically stressful experience for *animals*. Therefore, every precaution should be taken to avoid unnecessary stress caused by inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. General recommendations are made in Chapters 7.3. and 7.4. There may be a justifiable reason to transport *animals* whose welfare is compromised as a consequence of scientific procedures which the *animals* are under-going or for which they are intended. In such cases, every precaution should be taken to avoid further stress. In addition, *animals* should be transported under conditions and in *containers* that are appropriate to their physiological and behavioural needs and pathogen free status, with care to ensure appropriate physical containment and safety of the *animals*. ~~In the event of a delay,~~ A contingency plan which addresses any possible delays should be in place, and the name of an emergency contact person should be prominently displayed on the *container*.

1) The source of *animals* and therefore the mode and conditions of *transport* should be considered in the project proposal review described in point 1 c) of Article 7.8.4.

   a) The consigner and consignee should coordinate the means, route and duration of *transport* with emphasis on the potential impact on the health and *welfare* of the *animal(s)*.

   b) The potential for delays in transportation should be anticipated and avoided.

2) The documentation required for international *transport* should be based on the OIE Model Veterinary Certificate for International Trade in Laboratory Animals (Chapter 5.13.):

   a) There should be assurance that complete, relevant and legible documentation accompanies *animals* during *transport* to avoid unnecessary delays during the *journey* from the sender to the receiving institution.

   b) Electronic certificates should be implemented, wherever possible.

3) There should be a well defined *journey* plan, commencing from the point when *animals* are placed in their *containers* until they are removed from the *containers* at their final destination:

   a) The *journey* plan should be designed so that the time in transit is the shortest possible and most comfortable for the *animal*. Where *journeys* of some distance are involved, this is often best achieved through air transport, preferably by direct routes.

   b) Key staff should be identified who have responsibility for the *animals* and have the authority for making decisions in unforseen circumstances. Such staff should be contactable at all times.

   c) The *journey* plan should be under the general oversight of a *veterinarian* or other competent person, knowledgeable and experienced in the biology and needs of the particular species. The following should specifically be addressed:

      i) Some *animals,* such as genetically altered *animals* may have special requirements.

      ii) Issues of biosecurity and bioexclusion, e.g. through *container* design and handling.

4) In accordance with Chapters 7.3. and 7.4. and IATA regulations, an appropriate environment, such as *container* design and construction, temperature, food, and water should be provided to the *animal* throughout the planned *journey*. Adequate supplies of food, water and bedding should be provided to accommodate a delay of at least 24 hours.

Annex XVI (contd)

5) Personnel handling *animals* throughout the planned *journey* should be trained in the basic needs of *animals* and in good handling practices for the species to facilitate the *loading* and *unloading* of *animals*.

6) Delivery

   a) Consignments of *animals* should be accepted into the facility without avoidable delay and, after inspection, should be removed from their *containers* under conditions compatible with their pathogen free status.

   b) They should then be transferred to clean cages or pens and be supplied with feed and water as appropriate.

   c) Social *animals* transported in established pairs or groups should be maintained in these on arrival.

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— Text deleted.

Annex XVII

CHAPTER 8.4.

INFECTION WITH *ECHINOCOCCUS GRANULOSUS*

EU position

The EU thanks the OIE and in general supports the adoption of this modified chapter. Two previous comments on point 2b) of Article 8.4.3, which the EU thinks would further improve the text, are reiterated in the text below for consideration by the Code Commission at its next meeting.

Article 8.4.1.

General provisions

Echinococcus granulosus is a widely distributed cestode (tapeworm) ~~found worldwide~~. The adult worms occur in the small intestine~~s~~ of canids (definitive host), and larval stages (hydatid ~~cysts~~) in tissues of liver, lung and other ~~various~~ organs of other mammals (intermediate host) ~~mammalian hosts~~, including humans. *Infection* with the larval stage of the parasite in the intermediate host, referred to as 'cystic echinococcosis' or 'hydatidosis', is associated with significant economic losses in livestock production and causes a major disease burden in humans.

For the purpose of the *Terrestrial Code*, infection with *E. granulosus* is defined as a zoonotic parasitic *infection* of canids, ungulates, and macropod marsupials with *E. granulosus* (ovine, bovine, cervid, camelid and porcine strains).

For the purpose of this chapter, offal is defined as internal organs of ungulates and macropod marsupials.

Transmission of *E. granulosus* to canids ~~(definitive hosts)~~ occurs through ingestion of hydatid-infected offal ~~from a range of domestic and wild species of herbivores and omnivores (intermediate hosts)~~.

Infection in intermediate hosts, as well as in humans, occurs by ingestion of *E. granulosus* ~~parasite~~ eggs from contaminated environments. In humans, *infection* may also occur following contact with infected canids or by consumption of food or water contaminated with *E. granulosus* eggs from canine~~d~~ faeces.

~~Preventing transmission can be achieved by targeting both the definitive and intermediate hosts.~~ *Infection* in humans can be prevented by good food hygiene and personal hygiene, community health education and preventing *infection* of canids. ~~Good communication and c~~ Collaboration between the *Competent Authority* and the public health authority is an essential component in ~~achieving success in the prevention~~ preventing and controlling ~~of~~ *E. granulosus* transmission.

This chapter provides recommendations for prevention of, control of, and *surveillance* for infection with *E. granulosus* in dogs and livestock.

When authorising the import or transit of the *commodities* covered in this chapter, with the exception of those listed in Article 8.4.2., *Veterinary Authorities* should apply the recommendations in this chapter.

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

[NOTE: The following terms 'owned dog', 'responsible dog ownership' and 'stray dog' used throughout this chapter are defined in Chapter 7.7. Once this chapter is adopted, this note will be deleted and these definitions will be moved to the glossary of the Terrestrial Code.*]*

Article 8.4.2.

Safe commodities

When authorising import or transit of the following *commodities* of livestock, *Veterinary Authorities* should not require any *E. granulosus* related conditions regardless of the status of the animal population of the *exporting country* or *zone*:

– skeletal muscle *meat* and skeletal muscle meat products;

– processed fat;

– casings;

– *milk* and *milk products*;

– hides and skins ~~of livestock~~;

– embryos, oocytes and semen.

Article 8.4.3.

Programmes for the prevention and control of infection with *Echinococcus granulosus*

In order to ~~achieve success in the~~ prevent~~ion~~ and control ~~of~~ infection with *E. granulosus,* the *Veterinary Authority* or other *Competent Authority* should carry out community awareness programmes ~~on~~ about ~~to inform people of~~ the risk factors associated with transmission of *E. granulosus* ~~and the importance of hydatidosis in animals and humans~~, the role of dogs (including stray dogs)~~,~~ and the importance of responsible dog ownership~~.~~. The *Veterinary Authority* or other *Competent Authority* should also ~~and~~ implement the following ~~the need to implement preventive~~ prevention and control measures~~.~~; ~~and the importance of responsible dog ownership~~.

1. Prevention of infection in dogs (owned and stray)

   ~~The following measures should be undertaken:~~

   a) Dogs should not be fed offal ~~from any animal species~~ unless it has been treated in accordance with Article 8.4.6.

   b) Dogs should be prevented from scavenging on ~~not have access to~~ dead ~~animals of~~ ungulates and macropod marsupials, ~~any animal species, including *wildlife* species; all dead animals~~ ~~which~~ Dead animals should be disposed of in accordance with provisions in ~~Chapter~~ Article 4.12.6.

   c) The *Veterinary Authority* or other *Competent Authority* should ensure that *slaughterhouses/abattoirs* have implemented measures that prevent access of dogs to the premises, and to animal carcasses and waste containing offal.

   d) When livestock cannot be slaughtered in a *slaughterhouse/abattoir,* and are ~~home~~ slaughtered on-farm, dogs should be prevented from having access to raw offal, and not be fed offal unless it has been treated in accordance with Article 8.4.6.

2. Control of infection in dogs (owned and stray)

   a) For control of stray dog populations, the *Veterinary Authority* or other *Competent Authority* should ~~ensure compliance with~~ implement relevant aspects of Chapter 7.7.

   b) Dogs known to be infected or suspected of having access to raw offal, or in contact with livestock should be dewormed at least every 4-6 weeks with praziquantel (5 mg/kg) or another cestocidal product with comparable efficacy~~.~~. W~~w~~here possible, faeces excreted up to 72 hours post treatment should be disposed of by incineration or burial.

EU comments

As dogs infected or suspected to be infected due to a single access to raw offal or livestock need be dewormed only once, whereas only dogs having continuous or regular access to these possible sources of infection should be treated regularly, the EU suggests amending the above point accordingly, as follows:

"b) Dogs known to be infected or suspected of having had access to raw offal, or to have been in contact with livestock should be dewormed once, whereas dogs having continuous or regular access to these possible sources of infection should be dewormed at least every […]".

Furthermore, the EU does not agree with the suggested treatment interval of 4 to 6 weeks, which should be reduced to an interval of 4 to 5 weeks, corresponding to the incubation period of the parasite. Indeed, in the 2001"WHO/OIE Manual on Echinococcosis in Humans and Animals: a Public Health Problem of Global Concern" (http://whqlibdoc.who.int/publications/2001/929044522X.pdf), in Fig. 1.1 on page 5 relating to "Days 37-45", it is shown that the adult parasite can be gravid with embryonated eggs as early as 37 days , which corresponds to 5,3 weeks. Therefore, an interval of maximum 5 weeks seems more appropriate.

c) In areas of persistent transmission, the *Veterinary Authority* and other *Competent Authority* should collaborate to identify the possible origins of the *infection*, and review and amend the control programme, as appropriate~~, the control programme~~.

3. Control of infection in livestock

a) The *Veterinary Authority* should ensure that all slaughtered livestock are subjected to post-mortem meat inspection in accordance with Chapter 6.2., including inspection of offal for hydatids ~~cysts~~.

b) When hydatids ~~cysts~~ are detected during post-mortem meat inspection:

i) offal containing hydatids ~~cysts~~ should be disposed of in accordance with Article 4.12.6. ~~destroyed by incineration or burial, or rendered~~, or treated in accordance with Article 8.4.6.;

ii) an investigation should be carried out by the *Veterinary Authority* ~~*Services*~~ and other *Competent Authority* to identify the possible origin of the *infection*, and review and amend, as appropriate, the control programme.

Article 8.4.4.

Surveillance and monitoring for infection with *Echinococcus granulosus*

An *animal identification* and *traceability* system should be implemented in accordance with the provisions of Chapters 4.1. and 4.2.

1. Monitoring in dogs

a) ~~Monitoring~~ Monitoring for infection with *E. granulosus* in dogs should be undertaken at regular intervals as it is an essential activity ~~component~~ for assessing ~~the current situation regarding~~ the risk of transmission ~~within different~~ to dog populations and for evaluating the success of control programmes. This can be achieved through testing of faeces from dogs, and canine~~d~~ faecal samples from the environment.

b) ~~Appropriate~~ M~~m~~onitoring strategies should be ~~designed~~ appropriate ~~according~~ to local conditions, in particular, where large populations of stray dogs and wild canids exist. Under these circumstances ~~surveillance~~ testing of environmental samples (faeces, soil) may provide a useful indicator of infection pressure.

~~c) Where control programmes are conducted, regular monitoring for infection status should be undertaken. This can be achieved through testing of faeces from dogs, and canid faecal samples from the environment.~~

2. Surveillance in slaughterhouses/abattoirs

a) The *Veterinary Services* should carry out systematic surveillance for hydatids ~~cysts~~ in livestock in *slaughterhouses/abattoirs*.

b) Data collected should be used for the design or ~~adaptation~~ amendment of control programmes.

Veterinary Authorities should use ~~any~~ information from public health authorities on cases of human hydatidosis~~, provided by the public health authorities~~, in initial design and any subsequent modification of *surveillance* and monitoring programmes.

Article 8.4.5.

Recommendations for the importation of dogs and wild canids from an infected country

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the *animal* has been treated between 24 ~~48~~ and 72 hours prior to ~~shipment~~ embarkation with praziquantel (5 mg/kg), or another cestocidal product with comparable efficacy against intestinal forms of *E. granulosus*;

Annex XVII (contd)

2) adequate precautions have been taken to avoid reinfection of the *animal* between treatment and embarkation.

Article 8.4.6.

Procedures for the inactivation of *Echinococcus granulosus* ~~cysts~~ hydatids in offal

For the inactivation of *E. granulosus* ~~cysts~~ hydatids present in offal, one of the following procedures should be used:

1) heat treatment to a core temperature of at least 80°C for 10 minutes or an equivalent time~~/~~ and temperature;

2) freezing to minus 20°C or below for at least 2 days.

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— Text deleted.

Annex XVII (contd)

CHAPTER X.X.

INFECTION WITH *ECHINOCOCCUS MULTILOCULARIS*

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Article X.X.1.

General provisions

Echinococcus multilocularis is a cestode (tapeworm) which is widespread in some parts of the Northern Hemisphere, and it is maintained mainly in wild animal populations. The adult worms occur in the small intestine~~s~~ of canids (definitive hosts), particularly foxes~~,~~. ~~and~~ L~~l~~arval stages (metacestode) in tissues of ~~various~~ liver and other organs of other mammal~~s~~.~~ian~~ ~~hosts~~ (~~c~~ommonly rodents~~)~~, (intermediate hosts). ~~including~~ H~~h~~umans are infected occasionally~~. Infection~~ with the larval stage ~~of the parasite in the intermediate host~~, which causes severe disease~~,~~ ~~in humans~~ (~~r~~eferred to as '~~a~~lveolar echinococcosis'~~)., but~~ Infection does not cause discernible health impacts in livestock.

~~For the purpose of the *Terrestrial Code*, infection with *E. multilocularis* is defined as a zoonotic parasitic infection of domestic and wild canids, felids, rodents and pigs.~~

~~Transmission of *E. multilocularis* to canids (definitive hosts) occurs through ingestion of metacestode infected viscera from a range of wild small mammalian species (intermediate hosts).~~ Foxes and some other wild canids are the most important definitive hosts in maintaining the cycle at the wildlife-human interface through contaminating both rural and urban environments. Dogs may also act as important and efficient definitive host~~s~~ in both rural and urban environments, providing an important potential source for human infections. Even though the potential role of felids in transmission of infection to humans cannot be excluded, their epidemiological role is considered negligible. Pigs may become infected but the parasite remains infertile; therefore, they have no role in transmission of the parasite.

For the purpose of the *Terrestrial Code*, infection with *E. multilocularis* is defined as a zoonotic parasitic *infection* of domestic and wild canids, and rodents.

Transmission of *E. multilocularis* to canids occurs through ingestion of metacestode-infected organs from a range of wild small mammals.

Infection in intermediate hosts, as well as in humans, occurs by ingestion of ~~parasite~~ *E. multilocularis* eggs from contaminated environments. In humans, infection may also occur following contact with infected definitive hosts or by consumption of food or water contaminated with ~~*E. multilocularis* eggs from~~ ~~canine~~ faeces of canids.

Prevention of infection in humans is difficult, particularly in areas with a high infection pressure maintained by rural and urban foxes. ~~The risk of infections may be reduced by~~ ~~g~~Good food hygiene and personal hygiene, community health education and preventing *infection* of dogs reduces the risk of human infection ~~and cats~~. Good communication and collaboration between the *Competent Authority* and public health authorities is an important component in monitoring the extent of infection with *E. multilocularis* in human and animal populations.

This chapter provides recommendations for prevention, control and monitoring of infection with *E. multilocularis* in dogs ~~and cats~~, and monitoring in wild canids.

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

[NOTE: The following terms 'owned dog', 'responsible dog ownership' and 'stray dog' used throughout this chapter are defined in Chapter 7.7. Once this chapter is adopted, this note will be deleted and these definitions will be moved to the glossary of the Terrestrial Code.*]*

Annex XVII (contd)

Article X.X.1bis.

Safe commodities

When authorising import or transit of any *commodities* of livestock, *Veterinary Authorities* should not require any *E. multilocularis* related conditions regardless of the status of the animal population of the *exporting country* or *zone:*

Article X.X.2.

Prevention and control of infection with *Echinococcus multilocularis* in owned and stray dogs ~~(owned and stray) and cats~~

In order to achieve success in the prevention and control of infection with *E. multilocularis,* the *Competent Authority* should carry out community awareness programmes to inform people of the risk factors associated with transmission of *E. multilocularis*. Such programmes should include information on ~~and~~ the importance of ~~alveolar~~ echinococcosis in animals and humans, the role of foxes, ~~and~~ other wild canids, and dogs ~~(including stray dogs), and cats~~, the need to implement preventive and control measures, and the importance of responsible dog ownership ~~and cat ownership~~.

Whenever the epidemiological situation indicates that ~~makes~~ a control programme is necessary, the following measures should be undertaken:

1) Owned dogs ~~and cats~~ should not be allowed to roam freely unless treated according to point 3.

2) For control of stray dog populations, the *Competent Authority* should ensure compliance with relevant aspects of Chapter 7.7.

3) Dogs ~~and cats~~ known to be infected should immediately be treated with praziquantel (5 mg/kg) or another cestocidal product with a comparable efficacy; dogs suspected of having access to rodents or other small mammals should be treated ~~at least~~ every 21–26 days. Where possible, faeces excreted up to 72 hours post treatment should be disposed of by incineration or burial.

Article X.X.3.

Monitoring for infection with *Echinococcus multilocularis*

1. Monitoring in foxes and other wild canids

   a) Monitoring for infection with *E. multilocularis* in foxes and other wild canids should be undertaken as it is an essential component for assessing the ~~current situation regarding~~ prevalence of *infection*.

   b) ~~Appropriate~~ M~~m~~onitoring strategies should be ~~designed~~ appropriate ~~according~~ to local conditions, in particular, where large populations of definitive hosts exist. Under these circumstances testing of environmental sampl~~in~~ges (faeces) may provide a useful indicator of infection pressure.

2. Surveillance in slaughterhouses/abattoirs

   ~~a)~~ As an indicator of the presence of the parasite in the environment t~~T~~he *Veterinary Services* should consider carrying out targeted *surveillance* for larval lesions of *E. multilocularis* in livers of pigs raised in outdoor conditions~~, as an indicator of the presence of the parasite in the environment~~.

   ~~b) Data collected will provide useful additional information regarding prevalence of infection.~~

Veterinary Authorities should use ~~any~~ ~~i~~nformation from public health authorities on cases of human infection~~, provided by public health authorities~~, in the initial design and any subsequent modification of *surveillance* and monitoring programmes ~~for estimation of parasite transmission~~.

Annex XVII (contd)

Article X.X.4.

Recommendations for the importation of dogs~~,~~ and wild canids ~~and cats~~ from an infected country

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the *animal* has been treated between 24 ~~48~~ and 72 hours prior to embarkation ~~shipment~~ with praziquantel (5 mg/kg), or another cestocidal product with a comparable efficacy against intestinal forms of *E. multilocularis*;

2) adequate precautions have been taken to avoid reinfection of the *animal* between treatment and embarkation.

— Text deleted.

Annex XVIII

CHAPTER 8.13.

INFECTION WITH *TRICHINELLA* SPP.

EU position

The EU thanks the OIE and in general supports the adoption of this modified chapter. Some comments are inserted in the text below.

Article 8.13.1.

General provisions

Trichinellosis is a widely distributed *zoonosis* caused by eating raw or undercooked *meat* from *Trichinella*-infected food *animals* or *wildlife*. Given that clinical signs of trichinellosis are not generally recognised in *animals*, the importance of trichinellosis lies exclusively in the risk posed to humans and costs of control in slaughter populations.

The adult parasite and the larval forms live in the small intestine and muscles (respectively) of many mammalian, avian and reptile host species. Within the genus *Trichinella*, twelve genotypes have been identified, ~~nine~~ eight of which have been designated as species. There is geographical variation amongst the genotypes.

EU comment

The EU does not agree with the proposed change in the paragraph above. Indeed, a ninth species of *Trichinella* has been described recently (Reference: Krivokapich *et al*. 2012. *Trichinella patagoniensis* n. sp. (Nematoda), a new encapsulated species infecting carnivorous mammals in South America. International Journal for Parasitology 42, 903–910, http://www.sciencedirect.com/science/article/pii/S0020751912001932).

Prevention of *infection* in susceptible species of domestic *animals* intended for human consumption relies on the prevention of exposure of those *animals* to the *meat* and *meat products* of *Trichinella*-infected animals. This includes consumption of food waste of domestic animal origin, rodents and *wildlife*.

Meat and *meat products* derived from *wildlife* should ~~always~~ be considered a potential source of *infection* for humans. Therefore untested *meat* and *meat products* of *wildlife* may pose a public health risk.

For the purposes of the *Terrestrial Code*, *Trichinella infection* is defined as an *infection* of suids or equids by parasites of the genus *Trichinella*.

This chapter provides recommendations for on-farm prevention of *Trichinella infection* in domestic pigs (*Sus scrofa domesticus*), and safe trade of *meat* and *meat products* derived from suids and equids. This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005).

Methods for the detection of *Trichinella infection* in pigs and other animal species include direct demonstration of *Trichinella* larvae in muscle samples. Demonstration of the presence of *Trichinella*-specific circulating antibodies using a validated serological test may be useful for epidemiological purposes.

When authorising the import or transit of the commodities covered in this chapter, with the exception of those listed in Article 8.13.2., *Veterinary Authorities* should apply the recommendations in this chapter.

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

Article 8.13.2.

Safe commodities

When authorising the import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Trichinella* related conditions, regardless of the status of the animal population of the *exporting country* or *zone*:

1) hides, skins, hair and bristles;

2) semen, embryos and oocytes.

Article 8.13.3.

Measures to prevent infection in domestic pig herds kept under controlled management conditions

1) Prevention of *infection* is dependent on minimising exposure to potential sources of *Trichinella*:

   a) facilities and the surrounding environment should be managed to prevent exposure of pigs to rodents and *wildlife*;

   b) raw food waste of animal origin should not be present at the farm level;

EU comment

The EU suggests clarifying in point b) above that i) raw food waste should not be fed to domestic pigs kept under controlled management conditions, and ii) to explain why such material should not be present at the farm level. Indeed, saying only that such material should not be present may give rise to confusion. The following wording is therefore suggested:

"b) raw food waste of animal origin should not be fed to domestic pigs and should not be present at the farm level in order to avoid any cross contamination of feed;"

   c) feed should comply with the requirements in Chapter 6.3. and should be stored in a manner to prevent access by rodents and *wildlife*;

   d) a rodent control programme should be in place;

   e) dead *animals* should be immediately removed and disposed of in accordance with provisions of Chapter 4.12.;

   f) introduced pigs should originate from *herds* officially recognised as being under controlled management conditions as described in point 2, or from *herds* of a *compartment* with a negligible risk of *Trichinella infection*, as described in Article 8.13.5.

2) The *Veterinary Authority* may officially recognise pig *herds* as being under controlled management conditions if:

   a) all management practices described in point 1 are complied with and recorded;

   b) ~~at least two~~ visits by approved auditors, ~~a minimum of 6 months apart,~~ have been made periodically. ~~in the 12 months preceding recognition~~ to verify compliance with good management practices described in point 1; the frequency of inspections should be risk-based, taking into account historical information, *slaughterhouse* monitoring results, knowledge of established farm management practices and the presence of susceptible *wildlife*;

   c) a subsequent programme of audits is conducted, taking into account the factors described in point b.

Article 8.13.4.

Prerequisite criteria for the establishment of ~~a~~ compartments with a negligible risk of *Trichinella* infection in domestic pigs kept under controlled management conditions

~~A~~ *C~~c~~ompartments* with a negligible risk of *Trichinella infection* in domestic pigs kept under controlled management conditions can only be established in countries, in which ~~if~~ the following criteria, as applicable, are met ~~in the country, as applicable~~:

1) *Trichinella infection* ~~in all species of susceptible *animals*~~ is notifiable in the whole *territory* and communication procedures on the occurrence of *Trichinella infection* are ~~is~~ established between the *Veterinary Authority* and the ~~P~~public ~~H~~health ~~A~~authority;

2) the *Veterinary Authority* has ~~current~~ knowledge of, and authority over, all domestic pigs;

3) the *Veterinary Authority* has ~~current~~ knowledge of the distribution of susceptible species of *wildlife*;

4) an *animal identification* and *traceability* system for domestic pigs is implemented in accordance with the provisions of Chapters 4.1. and 4.2.;

~~5) appropriate provisions are in place for tracing of *meat* from *wild animals* harvested for human consumption~~;

5)~~6)~~ the *Veterinary Services* have the capability ~~*surveillance* appropriate~~ to ~~the~~ assess~~ed~~ the epidemiological situation, ~~and capable of~~ detect~~ing~~ the presence of *Trichinella infection* (including genotype, if relevant) in domestic pigs and identify exposure pathways~~, is in place~~.

Article 8.13.5.

Compartment with a negligible risk of *Trichinella* infection in domestic pigs kept under controlled management conditions

The *Veterinary Authority* may recognise a *compartment* in accordance with Chapter 4.4. ~~may be officially recognised~~ as having negligible risk of *Trichinella infection* in domestic pigs kept under controlled management conditions if the following conditions are met:

1) all *herds* of the *compartment* comply with the requirements in Article 8.13.3.;

2) ~~the criteria described in~~ Article 8.13.4. has~~ve~~ been complied with for at least 24 months;

3) the absence of *Trichinella infection* in the *compartment* has been demonstrated by a *surveillance* programme, ~~. The choice of design, including duration, prevalence and confidence levels should be based on~~ which takes into account ~~the prevailing, or~~ current and historical information, and *slaughterhouse* monitoring results~~, epidemiological situation~~, as appropriate, in accordance with Chapter 1.4. ~~and using tests described in the *Terrestrial Manual*~~;

4) once a *compartment* is established, a subsequent programme of audits of all *herds* within the *compartment* is in place to ensure compliance with Article 8.13.3.;

5) if ~~the~~ an audit identifie~~sd~~ a lack of compliance with ~~one or more of~~ the criteria described in Article 8.13.3. and the *Veterinary Authority* determine~~sd~~ this to be a significant breach of biosecurity, the *herd(s)* concerned should be removed from the *compartment* until compliance is re-established.

EU comment

The EU would like to ask the OIE to clarify the application of the concept of compartmentalisation in this chapter, e.g. as regards the consequences of significant breaches in biosecurity in certain herds for the status of the compartment, as it seems to differ from the general principles described in Chapter 4.4. which stipulate that any establishments within a compartment with epidemiological links to each other should be regarded as an epidemiological unit and handled accordingly.

Article 8.13.6.

Recommendations for the importation of meat or meat products of domestic pigs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* or *meat products*:

1) has been produced in accordance with the Codex Code of Hygienic Practice for Meat (CAC/RCP 58-2005);

AND

2) either:

   a) comes from domestic pigs originating from a *compartment* with a negligible risk for *Trichinella infection* in accordance with Article 8.13.5.;

   OR

b) comes from domestic pigs that tested negative by ~~the digestion~~ an approved method for the detection of *Trichinella* larvae~~, as described in the *Terrestrial Manual*~~;

OR

c) was processed to ensure the inactivation of *Trichinella* larvae in accordance with Codex recommendations [under study].

Article 8.13.7.

Recommendations for the importation of meat or meat products of wild or feral pigs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* or *meat products*:

1) has been produced in accordance with the Codex Code of Hygienic Practice for Meat (CAC/RCP 58-2005);

AND

2) either:

a) comes from *wild* or *feral* pigs that tested negative by an approved ~~the digestion~~ method for the detection of *Trichinella* larvae~~, as described in the *Terrestrial Manual*~~;

OR

b) was processed to ensure the inactivation of *Trichinella* larvae in accordance with Codex recommendations [under study].

EU comment

The EU understands the current draft *Codex* standard on *Trichinella* does not include a recommendation on processing of meat to inactivate *Trichinella* larvae. Indeed, only testing [corresponding to point a) above] is recommended in the draft *Codex* standard. The reason for this is that there appears to be a lack of scientific evidence to support the efficacy of such processing. The EU therefore suggests deleting point b) above.

Article 8.13.8.

Recommendations for the importation of meat or meat products of domestic equids

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* or *meat products*:

1) has been produced in accordance with the Codex Code of Hygienic Practice for Meat (CAC/RCP 58-2005);

AND

2) comes from domestic equids that tested negative by an approved ~~the digestion~~ method for the detection of *Trichinella* larvae ~~as described in the *Terrestrial Manual*~~.

Article 8.13.9.

Recommendations for the importation of meat or meat products of wild and feral equids

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* or *meat products*:

1) has been inspected in accordance with the provisions in Chapter 6.2;

AND

2) comes from *wild* or *feral* equids that tested negative by an approved ~~the digestion~~ method for the detection of *Trichinella* larvae ~~as described in the *Terrestrial Manual*~~.

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— Text deleted.

Annex XIX

CHAPTER 8.10.

INFECTION WITH RABIES VIRUS

EU position

The EU acknowledges the wish of the OIE to encourage countries whose dog population is currently infected with rabies to implement a structured control strategy with a view to achieve eventual eradication of canine rabies and would therefore support the newly proposed article 8.10.1bis. However, the EU can support the adoption of this modified chapter only if its important comment, inserted in the text below, is taken into account.

Article 8.10.1.

General provisions

For the purposes of the *Terrestrial Code*:

1) Rabies is a *disease* caused by one member of the *Lyssavirus* genus: the *Rabies virus* (formerly referred to as classical rabies virus; genotype-1). All mammals are susceptible to *infection*.

2) A case is any *animal* infected with the *Rabies virus* species.

3) The *incubation period* for rabies is variable, and considered to be six months. The *infective period* for dogs, cats and ferrets is considered to start ten days before the onset of the first apparent clinical signs.

Globally, the most common source of exposure of humans to rabies virus is the dog. Other mammals, particularly members of the Orders Carnivora and Chiroptera, also present a risk.

The aim of this chapter is to mitigate the risk of rabies to human and animal health and to prevent the international spread of the *disease*.

For the purpose of the *Terrestrial Code*, a country that does not fulfil the requirements in Article 8.10.2. is considered to be infected with *Rabies virus*.

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

~~Members should implement and maintain a programme for the management of stray dog populations consistent with Chapter 7.7.~~

EU comment

The EU cannot accept the deletion of the clause above, which should be reverted; see comment on Article 8.10.2. below for rationale.

Article 8.10.1bis.

Control of canine rabies in dogs

In order to minimise public health risks due to canine rabies, and eventually eradicate rabies in dogs, *Veterinary Authorities* should implement the following:

1) rabies should be notifiable in the whole country and any change in the epidemiological situation or relevant events should be reported in accordance with Chapter 1.1.;

2) an effective system of *disease surveillance* in accordance with Chapter 1.4. should be in operation, with a minimum requirement being an on-going early detection programme to ensure investigation and reporting of suspected *cases* of rabies in *animals*;

3) specific regulatory measures for the prevention and control of rabies should be implemented consistent with the recommendations in the *Terrestrial Code*, including *vaccination*, identification and effective procedures for the importation of dogs, cats and ferrets;

4) a programme for the management of stray dog populations consistent with Chapter 7.7. should be implemented and maintained.

Article 8.10.2.

Rabies free country

A country may be considered free from rabies when:

1) the *disease* is notifiable and any change in the epidemiological situation or relevant events are reported in accordance with Chapter 1.1.;

2) an ongoing system of *disease surveillance* in accordance with Chapter 1.4. has been in operation for the ~~p~~last two years, with a minimum requirement being an on-going early detection programme to ensure investigation and reporting of rabies suspect *animals*;

3) regulatory measures for the prevention of rabies are implemented consistent with the recommendations in the *Terrestrial Code*, including for the importation of *animals*;

4) a programme for the management of stray dog populations consistent with Chapter 7.7. has been implemented and maintained for the past two years;

EU comment

The EU cannot accept the new point 4) above. Indeed, it is not quite the same as the clause proposed for deletion in Article 8.10.1. Indeed, every Member Country would be obliged to have implemented and maintained for the past 2 years a programme for the management of stray dog populations as a prerequisite for declaring rabies freedom. However, countries that do not have a stray dog population should not need to implement and maintain such a programme, and may already be free of rabies yet would not comply with the newly proposed point 4) above. Therefore, the EU can support the adoption of this modified chapter only if the point 4) above is deleted and the text proposed for deletion in Article 8.10.1. is reverted.

~~4~~5) no *case* of indigenously acquired rabies virus *infection* has been confirmed during the past two years;

~~5~~6) no imported *case* in the Orders Carnivora or Chiroptera has been confirmed outside a *quarantine station* for the past six months;

~~6~~7) an imported human *case* of rabies does not affect the rabies free status.

Article 8.10.3.

Recommendations for importation from rabies free countries

For domestic mammals, and captive wild mammals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) showed no clinical sign of rabies the day prior to or on the day of shipment;

2) and either:

   a) were kept since birth or at least six months prior to shipment in a free country; or

   b) were imported in conformity with the regulations stipulated in Articles 8.10.5., 8.10.6., 8.10.7. or 8.10.8.

Article 8.10.4.

Recommendations for importation from rabies free countries

For wild mammals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) showed no clinical sign of rabies the day prior to or on the day of shipment;

2) and either:

   a) have been captured at a distance that precludes any contact with *animals* in an infected country. The distance should be defined according to the biology of the species exported, including home range and long distance movements; or

   b) have been kept in captivity for the six months prior to shipment in a rabies free country.

Article 8.10.5.

Recommendations for importation of dogs, cats and ferrets from countries considered infected with rabies

Veterinary Authorities should require the presentation of an *international veterinary certificate* complying with the model of Chapter 5.11, attesting that the *animals*:

1) showed no clinical sign of rabies the day prior to or on the day of shipment;

2) were permanently identified and their identification number stated in the *certificate*;

AND EITHER:

3) were vaccinated or revaccinated, in accordance with the recommendations of the manufacturer. The vaccine should have been produced and used in accordance with the *Terrestrial Manual*; and

4) were subjected not less than 3 months and not more than 12 months prior to shipment to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5IU/ml;

OR

5) were kept in a *quarantine station* for six months prior to export.

Article 8.10.6.

Recommendations for importation of domestic ruminants, equids, camelids and suids from countries considered infected with rabies

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) showed no clinical sign of rabies the day prior to or on the day of shipment;

2) were permanently identified and the identification number stated in the *certificate*;

3) EITHER

   a) were kept for the 6 months prior to shipment in an *establishment* where there has been no *case* of rabies for at least 12 months prior to shipment;

   OR

   b) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer. The vaccine was produced and used in accordance with the *Terrestrial Manual*.

Article 8.10.7.

Recommendations for importation from countries considered infected with rabies

For rodents and lagomorphs born and reared in a biosecure facility

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 in a biosecure facility where there has been no *case* of rabies for at least 12 months prior to shipment.

Article 8.10.8.

Recommendations for importation of wildlife from countries considered infected with rabies

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) showed no clinical sign of rabies the day prior to or on the day of shipment;

2) were kept for the six months prior to shipment in an *establishment* where separation from susceptible *animals* was maintained and where there has been no *case* of rabies for at least 12 months prior to shipment.

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— Text deleted.

Annex XX

CHAPTER 8.12.

INFECTION WITH RINDERPEST VIRUS

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Article 8.12.1.

Preamble

The global eradication of rinderpest has been achieved and was announced in mid-2011 based on the following:

1) Evidence demonstrates that there is no significant risk that rinderpest virus (RPV) remains in susceptible domesticated or *wild* host populations anywhere in the world.

2) All OIE Member and non-member countries have completed the pathway defined by the OIE for recognition of national rinderpest freedom and have been officially recognised by the OIE as free from the *infection*.

3) All *vaccination* against rinderpest has ceased throughout the world.

However, ~~rinderpest virus~~ ~~and~~ ~~as~~ RPV-containing material including live vaccines continue to be held in a number of institutions around the world and this poses a ~~small~~ risk of virus re-introduction into susceptible *animals*.

As sequestration and destruction of virus stocks proceed, the risks of reintroduction of *infection* into *animals* is expected to progressively diminish. The possibility of deliberate or accidental release of virus demands continuing vigilance, especially in the case of those countries known to host an institution holding RPV-containing material ~~be retaining the virus~~. This chapter takes into account the new global status and provides recommendations to prevent re-emergence of the *disease* and to ensure adequate *surveillance* and protection of livestock.

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

Article 8.12.2.

Definitions and general provisions

For the purpose of the *Terrestrial Code*:

RPV-containing material means field and laboratory strains of RPV; vaccine strains of RPV including valid and expired vaccine stocks; tissues, sera and other clinical material from *animals* known or suspected to be infected; diagnostic material containing or encoding live virus, recombinant morbilliviruses (segmented or non-segmented) containing unique RPV nucleic acid or amino acid sequences, and full length genomic material including virus RNA and cDNA copies of virus RNA. Sub-genomic fragments of morbillivirus nucleic acid that are not capable of being incorporated in a replicating morbillivirus or morbillivirus-like virus are not considered as RPV-containing material.

Ban on *vaccination* against rinderpest means a ban on administering any vaccine containing RPV or RPV components to any *animal*.

~~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* is defined as an *animal* infected with ~~rinderpest virus (~~RPV~~)~~ whether or not showing clinical signs.

For the purpose of this chapter, ~~the term~~ 'susceptible *animals*' ~~applies to~~ means domestic, ~~*feral*~~ feral and ~~*wild*~~ wild artiodactyls.

~~'Ban on *vaccination* against RP' means a ban on administering any vaccine containing RPV or RPV components to any *animal*.~~

Annex XX (contd)

Article 8.12.3.

Ongoing surveillance post global freedom

All countries in the world, whether or not Member Countries of the OIE, have completed all the procedures necessary to be recognised as free from ~~RP~~ rinderpest *infection* and annual re-confirmation of ~~RP~~ rinderpest absence is no longer required. However, countries are still required to carry out general *surveillance* in accordance with Chapter 1.4. to detect ~~RP~~ rinderpest should it recur and to comply with OIE reporting obligations concerning the occurrence of unusual epidemiological events in accordance with Chapter 1.1. Countries should also maintain national contingency plans for responding to events suggestive of ~~RP~~ rinderpest.

Article 8.12.4.

Recommendations for international trade in livestock and their products

When authorising import or transit of livestock and their products, *Veterinary Authorities* should not require any ~~RP~~ rinderpest related conditions.

Article 8.12.5.

Response to recurrence of ~~RP~~ rinderpest

~~In the post-eradication era, any direct or indirect detection of RPV in an *animal* or animal product confirmed in an OIE-FAO Reference Laboratory using a prescribed test, shall constitute a global emergency requiring immediate, concerted action for its investigation and elimination.~~

1. Definition of a suspected case of rinderpest ~~RP~~

   Rinderpest ~~RP~~ should be suspected if one or more *animals* of a susceptible species is found to be exhibiting clinical signs consistent with 'stomatitis-enteritis syndrome'.

   Stomatitis-enteritis syndrome ~~which~~ is defined as fever with ocular and nasal discharges in combination with ~~any one or more of the following~~:

   a) clinical signs of erosions in the oral cavity~~;~~ with diarrhoea~~;~~, dysentery~~;~~, dehydration or *death*;

   or

   b) necropsy findings of haemorrhages on serosal surfaces~~;~~, haemorrhages and erosions on alimentary mucosal surfaces~~;~~ and lymphadenopathy.

   Stomatitis-enteritis syndrome could indicate ~~rinderpest RP as well as~~ a number of ~~other~~ *diseases* ~~which should elicit a suspicion of rinderpest RP and~~ from which rinderpest ~~RP needs to~~ should be differentiated by appropriate laboratory investigation~~, including bovine virus diarrhoea/mucosal disease, malignant catarrhal fever, infectious bovine rhinotracheitis, foot and mouth disease and bovine papular stomatitis~~.

   The detection of RPV specific antibodies in an *animal* of a susceptible species with or without clinical signs is considered a suspected *case* of rinderpest ~~RP~~.

2. Procedures to be followed in the event of the suspicion of rinderpest ~~RP~~

   ~~In the post-eradication era,~~ Any direct or indirect detection of RPV in an *animal* or animal product shall ~~must~~ be notified~~reported~~ immediately. ~~to OIE and FAO. Confirmation in an appointed OIE FAO Reference Laboratory . using a prescribed test, shall constitute a global emergency requiring immediate, concerted action for its investigation and elimination.~~

   Upon detection of a suspected *case*, the national contingency plan should be implemented immediately. If the ~~contingency procedure cannot rule out the suspicion~~ presence of rinderpest ~~RP~~ cannot be ruled out, ~~samples should be submitted to an international reference laboratory. These~~ samples should be collected ~~in duplicate~~ in accordance with Chapter 2.1.15. of the *Terrestrial Manual* ~~with one set being~~ and dispatched to one of the appointed OIE-FAO Reference Laboratories for rinderpest ~~RP~~ for confirmation and, if applicable, ~~to enable~~ for molecular characterisation of the virus to facilitate identification of its source. A full epidemiological investigation should ~~simultaneously~~ be conducted simultaneously to provide supporting information and to assist in identifying the possible source and spread of the virus.

3. Definition of a case of rinderpest ~~RP~~

Rinderpest ~~RP~~ should be considered as confirmed when, based on a report from an appointed OIE-FAO reference laboratory for rinderpest:

a) RPV has been isolated from an *animal* or a product derived from that *animal* and identified; or

b) viral antigen or viral RNA specific to RPV has been identified in samples from one or more *animals*; or

c) antibodies to RPV have been identified in one or more *animals* with either epidemiological links to a confirmed or suspected *outbreak* of rinderpest ~~RP~~, or showing clinical signs consistent with recent *infection* with RPV.

4. Procedures to be followed after confirmation of rinderpest ~~RP~~

A case of rinderpest confirmed in an appointed OIE-FAO Reference Laboratory using a prescribed test shall constitute a global emergency requiring immediate, concerted action for its investigation and elimination.

Immediately following the confirmation of the presence of RPV ~~virus~~, viral RNA or antibody, the appointed OIE-FAO Reference Laboratory should inform the country concerned, the OIE and the FAO, allowing the initiation of the international contingency plan.

In the event of the confirmation of rinderpest ~~RP~~, the entire country ~~shall be~~ is considered to be infected. ~~until~~ When epidemiological investigation has indicated the extent of the infected area, ~~allowing definition of~~ *infected* and *protection zones* can be defined for the purposes of disease control. In the event of limited *outbreaks*, a single *containment zone*, which includes all *cases*, may be established for the purpose of minimising the impact on the country. The *containment zone* should be established in accordance with Chapter 4.3. and may cross international boundaries.

Emergency *vaccination* is acceptable only with live-attenuated tissue culture rinderpest ~~RP~~ vaccine, produced in accordance with the *Terrestrial Manual*. Vaccinated *animals* should always be clearly identified at a herd or individual level.

5. Global rinderpest ~~RP~~ freedom is suspended and the sanitary measures for trade with the infected country or countries shall revert to those in Articles 8.12.5. to 8.12.19. ~~Chapter 8.12.~~ of the *Terrestrial Animal Health Code* 2010 Edition.

Article 8.12.6.

Recovery of free status

Should there be a confirmed occurrence of rinderpest ~~RP~~, as defined above, a country or *zone* shall be considered as RPV infected until shown to be free through targeted *surveillance* involving clinical, serological and virological testing procedure ~~*surveillance*~~. ~~The country or *zone* shall be considered free only after the OIE has accepted the evidence submitted to it.~~

The time needed to recover rinderpest ~~RP~~ free status of the ~~entire~~ country or *zone*, or of the *containment zone*~~,~~ if one is established, depends on the methods employed to achieve the elimination of *infection*.

One of the following waiting periods applies:

1) three months after the last *case* where a *stamping-out policy* and serological *surveillance* are applied in accordance with Article 8.12.8.; or

2) three months after the *slaughter* of all vaccinated *animals* where a *stamping-out policy*, emergency *vaccination* and serological *surveillance* are applied in accordance with Article 8.12.8.

The recovery of rinderpest ~~RP~~ free status requires an international expert mission to verify the successful application of containment and eradication measures, as well as a review of documented evidence by the OIE.

The country or *zone* shall be considered free only after the OIE has accepted the evidence submitted to it.

Annex XX (contd)

Article 8.12.7.

Recovery of global freedom

Global rinderpest ~~RP~~ freedom shall be reinstated provided that within six months of the confirmation of an *outbreak*, the following conditions have been met:

1) the *outbreak* was recognised in a timely manner and handled in accordance with the international contingency plan;

2) reliable epidemiological information clearly demonstrated that there was minimal spread of virus;

3) robust control measures consisting of stamping out *herds* containing infected *animals*, and any vaccinated *animals*, combined with sanitary procedures including movement controls were rapidly implemented and were successful in eliminating the RPV. ~~were rapidly implemented and were successful in eliminating the virus . The control measures consisted of stamping out of infected herds and any vaccinated *animals*, combined with sanitary procedures including quarantine and other movement controls~~;

4) the origin of the virus was established, and it did not relate to an undetected reservoir of *infection*;

5) a risk assessment indicates that there is negligible risk of recurrence;

6) if *vaccination* was applied, all vaccinated *animals* were slaughtered or destroyed.

7) the affected country or *zone* has regained free status in accordance with Article 8.12.6.

If the conditions above are not met, the global rinderpest ~~RP~~ freedom is lost and Chapter 8.12 of the *Terrestrial Animal Health Code* 2010 Edition is reinstated. Recovery of global rinderpest ~~RP~~ freedom would then require reestablishment of an internationally coordinated rinderpest ~~RP~~ eradication programme and assessments of rinderpest ~~RP~~ free country status.

Article 8.12.8.

Surveillance for recovery of ~~RP~~ rinderpest free status

A ~~country~~ Member Country applying for reinstatement of rinderpest ~~RP~~ free status in accordance with 8.12.6. should provide evidence demonstrating effective *surveillance* in accordance with Chapter 1.4.

1) The target for *surveillance* should be all ~~significant~~ populations of rinderpest ~~RP~~ susceptible species within the country. In certain areas some *wildlife* populations, such as African buffaloes, act as sentinels for rinderpest ~~RP~~ *infection*.

2) Given that rinderpest ~~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 suspected *cases*. A procedure should be established for the rapid collection and transport of samples from suspect *cases* to an appointed OIE-FAO Reference Laboratory ~~recognised *laboratory*~~ for diagnosis ~~as described in the *Terrestrial Manual*~~.

3) An awareness programme should be established for all animal health professionals including *veterinarians*, both official and private, and livestock owners to ensure that rinderpest ~~RP~~'s clinical and epidemiological characteristics and risks of its recurrence are understood. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of rinderpest ~~RP~~.

4) Differing clinical presentations can result from variations in levels of innate host resistance *(Bos indicus* breeds being more resistant than *B. taurus),* and variations in the virulence of the attacking strain. In the case of sub-acute (mild) *cases,* clinical signs are irregularly displayed and difficult to detect. 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. ~~In the case of sub-acute (mild) *cases,* clinical signs are irregularly displayed and difficult to detect.~~

Annex XX (contd)

Article 8.12.9.

Annual update on RPV-containing material

Annual reports on RPV containing material should be submitted to the OIE by the end of November each year by the *Veterinary Authority* of ~~the~~ a Member Country hosting an institution or institutions holding RPV-containing material. A separate report, drawn up in accordance with the model below, should be produced ~~by~~ for each institution. A final report should be submitted to the OIE for each institution when all materials have been destroyed and no new activities are foreseen for the future.

~~For the purpose of this article, "RPV-containing material" means field and laboratory strains of RPV; vaccine strains of RPV including valid and expired vaccine stocks; tissues, sera and other clinical material from infected or suspect *animals*; and diagnostic material containing or encoding live virus. Recombinant morbilliviruses (segmented or non-segmented) containing unique rinderpest virus nucleic acid or amino acid sequences are considered to be rinderpest virus. Full length genomic material including virus RNA and cDNA copies of virus RNA is considered to be RPV-containing material. Sub-genomic fragments of morbillivirus nucleic acid that are not capable of being incorporated in a replicating morbillivirus or morbillivirus-like virus are not considered as RPV-containing material.~~

— Text deleted.

Annex XX (contd)

Model annual report on rinderpest virus (RPV)-containing material as of 1 November [year]

Name of institution:

Biosecurity level of the facility holding RPV-containing material

Postal address:

Title and name of contact person:

Email/phone/fax:

1. RPV-containing material currently held as of 1 November [year]

Type	~~Vaccine stocks~~ Live viruses, including field isolates but excluding vaccine strains	Vaccine stocks including seed strains ~~virus~~	Other ~~virus isolates~~ potentially infectious materials	~~Other (serum, tissue etc)~~
Check [x] if yes	[ ]	[ ]	[ ]	[ ]
Strain/Genetic characterisation				
Quantity/doses (if applicable)				
Ownership (if other institution)				

Annex XX (contd)

2. RPV-containing material destroyed during the past 12 months

Type	~~Vaccine stocks~~ Live viruses, including field isolates but excluding vaccine strains	Vaccine stocks including seed strains ~~virus~~	Other ~~virus isolates~~ potentially infectious materials	~~Other (serum, tissue etc)~~
Check [x] if yes	[ ]	[ ]	[ ]	[ ]
Strain/Genetic characterisation				
Quantity/doses (if applicable)				

3. RPV-containing material transferred to another institution during the past 12 months

Type	~~Vaccine stocks~~ Live viruses, including field isolates but excluding vaccine strains	Vaccine stocks including seed strains ~~virus~~	Other ~~virus isolates~~ potentially infectious materials	~~Other (serum, tissue etc)~~
Check [x] if yes	[ ]	[ ]	[ ]	[ ]
Transferred to				
Strain/Genetic characterisation				
Quantity/doses (if applicable)				

4. RPV-containing material received from another institution during the past 12 months

Type	~~Vaccine stocks~~ Live viruses, including field isolates but excluding vaccine strains	Vaccine stocks including seed strains ~~virus~~	Other ~~virus isolates~~ potentially infectious materials	~~Other (serum, tissue etc)~~
Check [x] if yes	[ ]	[ ]	[ ]	[ ]
Received from				
Strain/Genetic characterisation				
Quantity/doses (if applicable)				

5. Research or any other use conducted on RPV-containing material during the past 12 months

[Please specify]

Annex XXI

CHAPTER 4.14.

OFFICIAL HEALTH CONTROL OF BEE DISEASES

EU position

The EU supports the adoption of this modified chapter.

Article 4.14.1.

Purpose

This chapter is intended to set out guidelines for *official health control* of bee *diseases*. These are needed for the control of endemic bee *diseases* at the country level and to detect incursions of exotic *diseases*, thereby ensuring safe *international trade* of bees, bee products and used apicultural equipment. The guidelines are designed to be general in nature and more specific recommendations or requirements are made in chapters on bee *diseases*.

Article 4.14.2.

Overview

In each country or region, official health control of bee *diseases* should include:

1) official *registration* of the *apiaries* by the *Veterinary Authority* or other ~~by the~~ *Competent Authority* in the whole country or region;

2) an organisation for permanent health *surveillance*;

3) approval of breeding *apiaries* for export trade;

4) measures for cleaning, *disinfection* and *disinfestation* of apicultural equipment;

5) rules precisely stating the requirements for issuing an *international veterinary certificate*.

Article 4.14.3.

Official registration of the apiaries by the Veterinary Authority or other ~~by the~~ Competent Authority in the whole country or region

The *registration* of *apiaries* is the first step in developing a regional management plan for bee *disease surveillance a*nd control. With knowledge of bee density and location it is possible to design valid sampling schemes, to predict the spread of *disease* and to design inspection programmes to target areas of high risk.

The official *registration* of *apiary* sites should be annual and may provide information such as the presumptive locations of the *apiary* sites in the next 12 months, the average number of colonies in each *apiary* site, and the name and address of the principal owner of the bees in the *apiary*.

The main *apiary* locations (places where the *bee hives* are located the longest time in the year) should be registered first, followed as far as possible by the seasonal *apiary* locations.

Article 4.14.4.

Organisation for permanent official sanitary surveillance of apiaries

Veterinary Authorities or other *Competent Authorities* of countries are requested to regulate the organisation for permanent official sanitary *surveillance* of *apiaries*.

Permanent official sanitary *surveillance* of *apiaries* should be under the authority of the *Veterinary Authority* or other *Competent Authority* and should be performed either by representatives of this *Authority* or by representatives of an

approved organisation, with the possible assistance of bee-keepers specially trained to qualify as 'health inspectors and advisers'.

The official *surveillance* service thus established should be entrusted with the following tasks:

1) visit *apiaries*:

   a) annual visits to an appropriate sample of *apiaries*, based on the estimated risk in the whole country or region, during the most appropriate periods for the detection of *diseases*;

   b) additional visits to *apiaries* may be carried out for specific purposes including trade or transfer to other regions, or any other purpose whereby *diseases* could be spread;

2) collect samples required for the diagnosis of *diseases* and despatch them to a laboratory; the results of laboratory examinations should be communicated within the shortest delay to the *Veterinary Authority* or other *Competent Authority*;

3) apply hygiene measures, comprising, in particular, treatment of colonies of bees, as well as *disinfection* of the equipment and possibly the destruction of affected or suspect colonies and of the contaminated equipment so as to ensure rapid eradication of any *outbreak* of a *disease*.

Article 4.14.5.

Conditions for approval of breeding apiaries for export trade

Veterinary Authorities or other *Competent Authorities* of *exporting countries* are requested to regulate the conditions for approval of breeding *apiaries* for export trade.

The *apiaries* should:

1) have received, for at least the past two years, visits by a health inspector and adviser, carried out at least once a year using a *risk*-based approach during the most appropriate periods for detection of *listed diseases* of bees. During these visits, there should be a systematic examination of at least 10% of the hives containing bees and of the used apicultural equipment (especially stored combs), and the collection of samples to be sent to a laboratory and, depending on the situation of the *importing* and *exporting countries*, no positive results were reported to the *Veterinary Authorities* or other *Competent Authorities* for the relevant *listed disease* of bees;

2) be regularly sampled, depending on the epidemiological situation of the *importing* and *exporting countries*, and found free from the relevant *listed diseases* of bees. To achieve this, a statistically valid number of bee colonies should be examined by any method complying with the relevant chapters of the *Terrestrial Manual*.

Bee-keepers should:

3) immediately notify the *Veterinary Authority* or other *Competent Authority* of any suspicion of a *listed disease* of bees in the breeding *apiary* and in other epidemiologically linked *apiaries*;

4) not introduce into the *apiary* any bee (including pre-imago stages) or used apicultural equipment or product originating from another *apiary* unless that *apiary* is recognised by the *Veterinary Authority* or other *Competent Authority* to be of equivalent or higher health status or the used apicultural equipment or product has been treated in agreement with a procedure described in the relevant chapters of the *Terrestrial Code*;

5) apply special breeding and despatch techniques to ensure protection against any outside contamination, especially for the breeding and sending of queen-bees and accompanying bees and to enable retesting in the *importing country*;

6) collect at least every 30 days, during the breeding and despatch period, appropriate samples to be sent to a laboratory and all the positive results officially reported to the *Veterinary Authority* or other *Competent Authority*.

Article 4.14.6.

Conditions for sanitation and disinfection or disinfestation of apicultural equipment

Veterinary Authority or other *Competent Authority* of countries are requested to regulate the use of products and means for sanitation and *disinfection* or *disinfestation* of apicultural equipment in their own country, taking into account the following recommendations.

1) Any apicultural equipment kept in an *establishment* which has been recognised as being affected with a contagious *disease* of bees should be subjected to sanitary measures ensuring the elimination of pathogens.

2) In all cases, these measures comprise the initial cleaning of the equipment, followed by sanitation or *disinfection* or *disinfestation* depending on the *disease* concerned.

3) Any infested or contaminated equipment which cannot be subjected to the above-mentioned measures should be destroyed, preferably by burning.

4) The products and means used for sanitation and *disinfection* or *disinfestation* should be accepted as being effective by the *Veterinary Authority* or other *Competent Authority*. They should be used in such a manner as to exclude any risk of contaminating the equipment which could eventually affect the health of bees or adulterate the products of the hive.

Article 4.14.7.

Preparation of the international veterinary certificate for export

This certificate covers hives containing bees, brood-combs, royal cells, used apicultural equipment and bee products.

This document should be prepared in accordance with the model contained in Chapter 5.10. and taking into account the chapters on bee *diseases*.

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Annex XXII

CHAPTER 9.1.

INFESTATION OF HONEY BEES WITH *ACARAPIS WOODI* ~~ACARAPISOSIS OF HONEY BEES~~

EU position

The EU supports the adoption of this modified chapter.

Article 9.1.1.

General provisions

For the purposes of the *Terrestrial Code* ~~this chapter~~, acarapisosis, also known as acarine disease or tracheal mite *infestation*, is an *infestation* ~~*disease*~~ of ~~the~~ adult honey bees (~~*Apis* species~~ of the genus *Apis*), primarily *Apis mellifera L.*~~, and possibly of other *Apis* species (such as *Apis cerana*). It is caused by~~ with the ~~Tarsonemid~~ mite *Acarapis woodi* ~~(*A. 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~~ which spreads by direct contact from adult honey bee to adult honey 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 ~~and general information on the *disease*~~ are ~~provided described~~ described in the *Terrestrial Manual*.

~~When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.1.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the acarapisosis status of the honey bee population of the *exporting country* or *zone*.~~

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.1.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the acarapisosis status of the honey bee population of the *exporting country* or *zone*.

Article 9.1.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any acarapisosis ~~*A. woodi*~~ related conditions, regardless of the acarapisosis ~~*A. woodi*~~ status of the honey bee population of the *exporting country* or *zone*:

1) pre-imago (eggs, larvae and pupae) of honey bees;

~~1~~2) honey bee semen;

3) ~~and~~ honey bee venom;

~~2~~34) used apicultural equipment ~~associated with beekeeping~~;

~~345~~) ~~extracted~~ honey;

6) bee-collected pollen;

7) propolis;

8) beeswax; and

9) royal jelly ~~processed, honey bee collected pollen, propolis and royal jelly~~.

Annex XXII (contd)

~~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 acarapisosis status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.1.3.

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 reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the whole country.

Article 9.1.4.

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 9.1.3. 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 acarapisosis after conducting a *risk assessment* as referred to in Article 9.1.3. and when:

   a) the *Veterinary Authority* or other *Competent Authority* with responsibility for 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* or other *Competent Authority*, with no positive ~~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 no positive ~~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)~~ either there is no wild or self-sustaining feral population of ~~*Apis*~~ species of the genus *Apis* ~~*A. mellifera* or other possible host species~~ in the country or *zone*/~~*compartment* (under study)~~, or there is an ongoing *surveillance* programme of the wild or self-sustaining feral population of species of the genus *Apis* which demonstrates no evidence of the presence of the *disease* in the country or *zone*;

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 9.1.5.

Recommendations for the importation of live queen ~~honey bees~~, worker ~~bees~~ and drones ~~honey bees~~ with or without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the honey bees come from ~~an~~ *apiari~~es~~y* situated in a country or *zone*/~~*compartment* (under study)~~ free from acarapisosis or the *apiary* meets the conditions prescribed in Chapter 4.14.~~3.~~ (article 4.14.5.). With regards to the provisions detailed in point 2 of Article 4.14.5., this will be achieved by a statistically valid number of honey bees per colony being examined by any method complying with the relevant chapter of the *Terrestrial Manual* and found free of all life stages of *A. woodi*.

~~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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Annex XXII (contd)

CHAPTER 9.2.

INFECTION ~~AMERICAN FOULBROOD~~ OF HONEY BEES WITH *PAENIBACILLUS LARVAE* (AMERICAN FOULBROOD)

EU position

The EU thanks the OIE and in general supports the adoption of this modified chapter. A comment is inserted in the text below.

Article 9.2.1.

General provisions

For the purposes of the *Terrestrial Code* ~~this Chapter~~, American foulbrood is a *disease* of the larval and pupal stages of ~~the~~ honey bees (species of the genus *Apis*) ~~*mellifera* and other *Apis* spp.~~ caused by *Paenibacillus larvae*, which is widely distributed ~~and occurs in most countries where such bees are kept~~. *Paenibacillus 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 with American foulbrood infected pre-imago honey bees ~~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. ~~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*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.2.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the American foulbrood status of the honey bee population of the *exporting country* or *zone*.

Article 9.2.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any American foulbrood related conditions, regardless of the American foulbrood status of the honey bee population of the *exporting country* or *zone*:

1) honey bee semen;

2) honey bee venom;

3) honey bee eggs.

~~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 American foulbrood status of the honey bee population of the *exporting country* or *zone*.~~

EU comment

The EU takes note of the peer reviewed import risk analysis that supports the inclusion of eggs in the list of safe commodities. As eggs are to be considered as safe commodities, the EU suggests reviewing the Terrestrial Manuel chapter 2.2.2. "American foulbrood of honey bees"

in this sense, especially the second paragraph of section A "Introduction" that starts with "*The infection can be transmitted to larvae by nurse bees or by spores remaining at the base of a brood cell*".

Article 9.2.3.

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 reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.2.4.

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 9.2.3. 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 9.2.3. and when:

   a) the *Veterinary Authority* or other *Competent Authority* with responsibility for 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* or other *Competent Authority*, with no positive ~~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* or other *Competent Authority*, with no positive ~~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)~~ either there is no wild or self-sustaining feral population of species of the genus *Apis* ~~*A. mellifera* or other possible host species~~ in the country or *zone~~/compartment~~* ~~(under study)~~ , or there is an ongoing *surveillance* programme of the wild or self-sustaining feral population of species of the genus *Apis* which demonstrates no evidence of the presence of the *disease* in the country or *zone*;

   f) all equipment associated with previously infected *apiaries* has been sterilised or destroyed;

   g) the importation of the *commodities* listed in this Chapter into the country or *zone~~/compartment~~* ~~(under study)~~ is

carried out in conformity with the recommendations of this Chapter.

Article 9.2.5.

Recommendations for the importation of live queen ~~honey bees~~, worker ~~bees~~ and drones ~~honey bees~~ honey bees with or without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the honey bees come from ~~an~~ *apiaries~~y~~* situated in a country or *zone/~~compartment~~* ~~(under study)~~ ~~officially~~ free from American foulbrood ~~or the *apiary* meets the conditions prescribed in Article 4.14.3~~.; or

2) the shipment comprises only honey bees without associated brood combs and:

   a) the honey bees come from ~~an~~ *apiaries~~y~~* meeting the conditions prescribed in Article 4.14.5.; and

   b) the *apiary* where the honey bees come from is situated in the centre of an area with a radius of 3 kilometres where there has been no *outbreak* of American foulbrood during the past 30 days.

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 *commodities* ~~products~~:

1) come from ~~an~~ *apiaries~~y~~* situated in ~~were sourced from a free~~ country or *zone/~~compartment~~* ~~(under study)~~ free from American foulbrood; 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 *P. larvae* by bacterial culture or PCR in accordance with the *Terrestrial Manual*.

Article 9.2.7.

Recommendations for the importation of used apicultural 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 ~~an~~ *apiaries~~y~~* situated in a country or *zone* free from American foulbrood; or

2) was sterilised under the supervision of the *Veterinary Authority* in conformity with one of the following procedures:

   a) by irradiation with 10 kGy (suitable for all the used equipment); or

   b) 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

   c) by immersion for at least 10 minutes in molten paraffin wax heated to 160°C (suitable only for wooden equipment); or ~~processing to ensure the destruction of both bacillary and spore forms of *P. larvae*, in conformity with one of the procedures referred to in Chapter X.X. recommended by the OIE (under study)~~.

   d) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*.

Article 9.2.8.

Recommendations for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly for use in apiculture

Veterinary Authorities of *importing countries* ~~officially free from American foulbrood~~ should require the presentation of an *international veterinary certificate* attesting that the *commodities* ~~products~~:

1) come from ~~an~~ *apiar~~y~~ies* situated ~~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* by irradiation with 10 kGy or any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*; ~~in conformity with one of the procedures referred to in Chapter X.X. recommended by the OIE (under study).~~; or

3) have been found free from spore forms of *P. larvae* by a test method described in the relevant chapter of the *Terrestrial Manual*.

Article 9.2.9.

Recommendations for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly for human consumption

Veterinary Authorities of *importing countries* free from American foulbrood should require the presentation of an *international veterinary certificate* attesting that the products:

1) come from ~~an~~ *apiar~~y~~ies* situated in a country or *zone* free from American foulbrood; or

2) have been processed to ensure the destruction of both bacillary and spore forms of *P. larvae* by irradiation with 10 kGy or any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*; or

3) have been found free from spore forms of *P. larvae* by a test method described in the relevant chapter of the *Terrestrial Manual*.

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Annex XXII (contd)

CHAPTER 9.3.

INFECTION ~~EUROPEAN FOULBROOD~~ OF HONEY BEES WITH *MELISSOCOCCUS PLUTONIUS* (EUROPEAN FOULBROOD)

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Article 9.3.1.

General provisions

For the purposes of the *Terrestrial Code* ~~this Chapter~~, European foulbrood is a *disease* of the larval and pupal stages of ~~the~~ honey bees (species of the genus *Apis*) ~~*Apis mellifera* and other *Apis* spp.~~, caused by *Melissococcus plutonius*, a non-sporulating bacterium, which is widely distributed ~~and occurs in most countries where such bees are kept~~. ~~The causative agent is the non-sporulating bacterium *Melissococcus plutonius*.~~ 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*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the European foulbrood status of the honey bee population of the *exporting country* or *zone*.

Article 9.3.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any European foulbrood related conditions, regardless of the European foulbrood status of the honey bee population of the *exporting country* or *zone*:

1) honey bee semen;

2) honey bee venom~~.~~;

~~3) honey bee eggs.~~

~~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 European foulbrood status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.3.3.

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 reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all *apiaries* in the whole country.

Article 9.3.4.

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 9.3.3. 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 9.3.3. and when:

a) the *Veterinary Authority* or other *Competent Authority* with responsibility for 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* or other *Competent Authority*, with no positive ~~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* or other *Competent Authority*, with no positive ~~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)~~ either there is no wild or self-sustaining feral population of ~~*A. mellifera* or other possible host species~~ species of the genus *Apis* in the country or *zone/~~compartment~~* ~~(under study)~~, or there is an ongoing *surveillance* programme of the wild or self-sustaining feral population of species of the genus *Apis* which demonstrates no evidence of the presence of the *disease* in the country or *zone*;

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 9.3.5.

Recommendations for the importation of live queen ~~honey bees~~, worker ~~bees~~ and drones~~
honey bees with or without associated brood combs**

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

Annex XXII (contd)

1) the honey bees come from ~~an~~ *apiaries~~y~~* situated in a country or *zone~~/compartment~~* ~~(under study)~~ free from European foulbrood; ~~or the *apiary* meets the conditions prescribed in Article 4.14.3~~

2) the shipment comprises only honey bees without associated brood combs and:

   a) the honey bees come from ~~an~~ *apiaries~~y~~* meeting the conditions prescribed in Article 4.14.5.; and

   b) the *apiary* where the honey bees come from is situated in the centre of an area with a radius of 3 kilometres where there has been no *outbreak* of European foulbrood during the past 30 days.

Article 9.3.6.

Recommendations for the importation of ~~eggs~~ eggs, ~~–~~larvae and pupae of honey bees

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *commodities* ~~products~~:

1) come from ~~an~~ *apiaries~~y~~* situated in ~~were sourced from~~ a ~~free~~ country or *zone~~/compartment~~* ~~(under study)~~ free from European foulbrood; 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 *M. plutonius* by bacterial culture or PCR in accordance with the *Terrestrial Manual*.

Article 9.3.7.

Recommendations for the importation of used apicultural 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 ~~an~~ *apiaries~~y~~* situated in a country or *zone* free from European foulbrood; or

2) was sterilised under the supervision of the *Veterinary Authority* in conformity with one of the following procedures:

   a) by ~~either~~ immersion in 0.5% sodium hypochlorite for at least 20 minutes (suitable only for non-porous materials such as plastic and metal); or

   b) by ~~gamma~~ irradiation with ~~using a cobalt 60 source at a dose rate of~~ ~~10~~15 kGy; or

   c) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*. ~~processing to ensure the destruction of *M. plutonius*, in conformity with one of the procedures referred to in Chapter~~ recommended by the OIE ~~(under study)~~.

Article 9.3.8.

Recommendations for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly for use in apiculture

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *commodities* ~~products~~:

1) come from ~~an~~ *apiar~~y~~ies* situated ~~were collected~~ in a country or *zone~~/compartment~~* ~~(under study)~~ free from European foulbrood; or

2) have been processed to ensure the destruction of *M. plutonius* by irradiation with ~~10~~15 kGy or any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*; or~~, in conformity with one of the procedures referred to in Chapter X.X. recommended by the OIE (under study).~~

3) have been found free of *M. plutonius* by a test method described in the relevant chapter of the *Terrestrial Manual*.

Article 9.3.9.

Recommendations for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly for human consumption

Veterinary Authorities of *importing countries* free from European foulbrood should require the presentation of an *international veterinary certificate* attesting that the *commodities*:

1) come from ~~an~~ *apiaries~~y~~* situated in a country or *zone* free from European foulbrood; or

2) have been processed to ensure the destruction of *M. plutonius* by irradiation with ~~10~~15 kGy or any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*; or

3) have been found free of *M. plutonius* by a test method described in the relevant chapter of the *Terrestrial Manual*.

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Annex XXII (contd)

CHAPTER 9.4.

INFESTATION WITH *AETHINA TUMIDA* (SMALL HIVE BEETLE) ~~SMALL HIVE BEETLE INFESTATION~~

~~(*Aethina tumida*)~~

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Article 9.4.1.

General provisions

For the purposes of the *Terrestrial Code* ~~this chapter~~, infestation with *Aethina tumida* (also known as small hive beetle [SHB]) is an *infestation* of bee colonies ~~of~~(species of the genera *Apis* ~~species,~~ and *Bombus* ~~species~~ and also stingless bees) ~~social bee colonies~~ by the beetle *Aethina tumida*, which is a free-living predator ~~parasite~~ and scavenger affecting bee populations. ~~of the honey bee *Apis mellifera* L. It can also parasitise~~ invade ~~bumble bee *Bombus terrestris* and stingless bee *Trigona carbonaria* 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.~~

For the purpose of this chapter, *Aethina tumida* refers to all life stages of the beetle (eggs, larvae, pupae and adult).

The adult beetle is attracted to bee colonies to reproduce, although it can potentially 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 female beetles can live for at least 6 months and, in favourable reproductive conditions, the female is capable of producing up to a thousand eggs over a lifespan of four to six months ~~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* and reproduction ~~in the debris~~ may go unnoticed~~, but the growth of the beetle population is rapid, leading to high bee mortality in the hive~~. When the bees cannot prevent beetle mass reproduction on the combs, this leads to abandonment ~~and/~~or collapse of the colony. 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 invading new ~~colonising~~ hives. ~~Dispersal of beetles includes following or accompanying swarms of bees~~. Spread of *infestation* does not require contact between adult bees. ~~However, t~~The movement of adult bees, honeycomb and other apiculture products and used apicultural 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*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.4.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *A. tumida* status of the honey bee and bumble bee population of the *exporting country* or *zone*.

Article 9.4.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *A. tumida*

related conditions, regardless of the *A. tumida* status ~~of the honey bee and bumble bee population~~ of the *exporting country* or *zone*:

1) honey bee semen ~~and honey bee venom~~;

2) honey bee venom ~~packaged extracted honey~~ for human consumption, ~~refined or rendered beeswax, propolis and frozen or dried royal jelly~~.

~~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 *A. tumida* status of the honey bee and bumble bee population of the *exporting country* or *zone*.~~

Article 9.4.3.

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 *risk assessment* has been conducted, identifying all potential factors for *A. tumida* occurrence and their historic perspective;

2)~~1)~~ the presence of *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;

3)~~2)~~ on-going awareness and training programmes should be in place to encourage reporting of all *cases* suggestive of *A. tumida* infestation;

~~3~~4) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.4.4.

Country or zone free from *A. tumida*

1. Historically free status

A country or *zone* may be considered free from *A. tumida* ~~the pest~~ after conducting a *risk assessment* as referred to in Article 9.4.3. 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 9.4.3. and when:

a) the *Veterinary Authority* or other *Competent Authority* with responsibility for 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) the presence of *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 report~~ed *case*~~ of the presence of *A. tumida* ~~infestation~~, an annual survey supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive ~~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 *Veterinary Authority* or other *Competent Authority*, with no positive ~~negative~~ results, is carried out on a representative sample of *apiaries* to indicate that there have been no presence of *A. tumida* ~~new *cases*~~; such surveys may be targeted towards areas with a higher likelihood of *infestation*;

Annex XXII (contd)

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 following ~~referred to in Chapter X.X. recommended by the OIE (under study)~~ procedures:

i) heating to 50°C core temperature and holding at that temperature for 24 hours; or

ii) freezing at core temperature of -12°C or less for at least 24 hours; or

iii) irradiation with 400 Gy; or

iv) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*;

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 9.4.5.

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)

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the bees come from ~~an~~ *apiaries~~y~~* situated in a country or *zone* ~~officially~~ free from *A. tumida* ~~infestation~~;

OR

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* including an attestation from the *Veterinary Authority* of the exporting third country stating that:~~

~~1~~2) the bees come from hives or colonies which were inspected immediately prior to dispatch and show no ~~signs or suspicion~~ evidence of the presence of *A. tumida* ~~or its eggs, larvae or pupae~~ based on a visual inspection and the use of one of the methods described in the relevant chapter of the *Terrestrial Manual*; and

~~2~~3) 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~~4) 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~~5) the packaging material, *containers*, accompanying products and food are new; and ~~The consignment of bees is covered with fine mesh through which a live beetle cannot enter~~

6) all precautions have been taken to prevent *infestation* or contamination with *A. tumida*, in particular, measures that prevent *infestation* of queen cages such as no long term storage of queens prior to shipment and covering the consignment of bees with fine mesh through which a live beetle cannot enter.

Article 9.4.6.

Recommendations for the importation of live worker ~~bees,~~ and drone bees ~~or bee colonies~~ with or without associated brood combs ~~or for live bumble bees~~

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that ~~:1.~~ the bees come from ~~an~~ *apiaries~~y~~* situated in 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

Article 9.4.7.

Recommendations for the importation of eggs, larvae and pupae of honey bees or bumble bees

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1) the products *commodities* were sourced come from an *apiariesy* situated in a country or *zone* free from *A. tumida* infestation;

OR

2) the products *commodities* have been bred and kept under a controlled environment within a recognised establishment which is supervised and controlled by the *Veterinary Authority* or other *Competent Authority*; and

3) the establishment was inspected immediately prior to dispatch and all eggs, larvae and pupae show no evidence 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 *infestation* or contamination with *A. tumida* or its eggs, larvae or pupae.

Article 9.4.8.

Recommendations for the importation of used apicultural equipment associated with beekeeping

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the equipment:

EITHER

a) comes from an *apiariesy* situated in 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

db) has been thoroughly cleaned, and treated to ensure the destruction of *A. tumida* spp., in conformity with one of the following procedures referred to in Chapter X.X. recommended by the OIE (under study):

i) heating to 50°C core temperature and holding at that temperature for 24 hours; or

ii) freezing at core temperature of -12°C or less for at least 24 hours; or

iii) irradiation with 400 Gy; orand

iv) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*;

AND

2) all precautions have been taken to prevent infestation/ contamination with *A. tumida*.

Annex XXII (contd)

Article 9.4.8bis.

Recommendations for the importation of honey

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the honey:

EITHER

a) comes from ~~an~~ *apiariesy* situated in a country or *zone* free from *A. tumida*;

OR

b) ~~is~~ has been strained through a filter of pore size no greater than 0.42 mm;

OR

c) has been treated to ensure the destruction of *A. tumida*, in conformity with one of the following procedures:

i) heating to 50°C core temperature and holding at that temperature for 24 hours; or

ii) freezing at core temperature of -12°C or less for at least 24 hours; or

iii) irradiation with 400 Gy; or

iv) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*;

AND

2) all precautions have been taken to prevent contamination with *A. tumida*.

Article 9.4.9.

Recommendations for the importation of ~~honey~~-bee-collected pollen~~, and beeswax (in the form of honeycomb)~~

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the bee-collected pollen ~~products~~:

EITHER

a) comes from ~~an~~ *apiariesy* situated in a country or *zone* free from *A. tumida* ~~infestation~~; ~~and~~

~~b) contains no live honey bees or bee brood;~~

OR

~~c~~b) contains no live ~~honey~~ bees or bee brood; and

~~d~~c) has been ~~thoroughly cleaned, and~~ treated to ensure the destruction of *A. tumida* ~~spp.~~, in conformity with one of the following procedures ~~referred to in Chapter X.X. recommended by the OIE (under study)~~:

~~i)~~ ~~heating to 50°C core temperature and holding at that temperature for 24 hours, or~~

~~ii)~~ freezing at core temperature of -12°C or less for at least 24 hours; or

~~iii)~~ irradiation with 400 Gy; or

iii) desiccation by freeze drying or equivalent; or

iv) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*;

AND

2) all precautions have been taken to prevent ~~infestation/~~ contamination with *A. tumida*.

Article 9.4.10.

Recommendations for the importation of beeswax and propolis

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the *commodities*:

EITHER

a) come from ~~an~~ *apiari~~es~~y* situated in a country or *zone* free from *A. tumida*;

OR

b) contain no live bees or bee brood; and

c) are processed propolis or processed beeswax;

OR

d) contain no live bees or bee brood; and

e) have been treated to ensure the destruction of *A. tumida*, in conformity with one of the following procedures:

i) freezing at core temperature of -12°C or less for at least 24 hours; or

ii) irradiation with 400 Gy; or

iii) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*;

AND

2) all precautions have been taken to prevent contamination with *A. tumida*.

Article 9.4.11.

Recommendations for the importation of royal jelly

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

Annex XXII (contd)

1) the royal jelly:

EITHER

a) comes from ~~an~~ *apiaries~~y~~* situated in a country or *zone* free from *A. tumida*;

OR

b) is encapsulated for human consumption;

OR

c) has been treated to ensure the destruction of *A. tumida*, in conformity with one of the following procedures:

i) heating to 50°C core temperature and holding at that temperature for 24 hours; or

ii) freezing at core temperature of -12°C or less for at least 24 hours; or

iii) desiccation by freeze drying or equivalent; or

iv) irradiation with 400 Gy; or

v) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*;

AND

2) all precautions have been taken to prevent contamination with *A. tumida*.

~~Article 9.4.10.~~

~~**Recommendations for the importation of comb honey**~~

~~*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;~~

~~OR~~

~~3) were frozen subjected to a treatment at a temperature of -12°C or lower at least 24 hours~~

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Annex XXII (contd)

CHAPTER 9.5.

~~*TROPILAELAPS*~~ INFESTATION OF HONEY BEES WITH *TROPILAELAPS* SPP.

EU position

The EU supports the adoption of this modified chapter.

Article 9.5.1.

General provisions

For the purposes of the *Terrestrial Code* ~~this chapter~~, *Tropilaelaps* infestation of ~~the~~ honey bees (species of the genus *Apis* ~~species~~) ~~*Apis mellifera* L.~~ is caused by different species of *Tropilaelaps* mites (including the mites *Tropilaelaps clareae*, *T. koenigerum*, *T. thaii* and *T. mercedesae*). The mite is an ectoparasite of ~~bee~~ brood of honey bees ~~of *Apis* species *Apis mellifera* L., *Apis laboriosa* and *Apis dorsata*~~, and cannot survive for periods of more than ~~7~~ 21 days away from bee brood.

Early signs of ~~*infection*~~ *infestation* normally go unnoticed, but the growth in the mite population is rapid leading to high hive mortality. The ~~*infection*~~ *infestation* spreads by direct contact from adult honey bee to adult honey bee, and by the movement of infested honey 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*.

~~When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.5.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *Tropilaelaps* status of the honey bee population of the *exporting country* or *zone*.~~

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.5.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *Tropilaelaps* spp. status of the honey bee population of the *exporting country* or *zone*.

Article 9.5.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Tropilaelaps* spp. related conditions, regardless of the *Tropilaelaps* spp. status ~~of the honey bee population~~ of the *exporting country* or *zone*:

1) honey bee semen;

2) honey bee venom;

3) honey bee eggs;

4) royal jelly.

~~1) honey bee semen, honey bee eggs and honey bee venom;~~

~~2) extracted honey, pollen, propolis, and~~ royal jelly. ~~for human consumption; and~~

~~3) processed beeswax (not in the form of honeycomb)~~.

~~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 *Tropilaelaps* status of the honey bee population of the *exporting country* or *zone*.~~

Annex XXII (contd)

Article 9.5.3.

Determination of the *Tropilaelaps* spp. status of a country or zone~~/compartment~~

The *Tropilaelaps* spp. 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* spp. occurrence and their historic perspective;

2) the presence of *Tropilaelaps* spp. ~~infestation~~ should be notifiable in the whole country or *zone~~/compartment~~* ~~(under study)~~ and all clinical signs suggestive of *Tropilaelaps* spp. 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* spp. infestation;

4) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.5.4.

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 *Tropilaelaps* spp. ~~the *disease*~~ after conducting a *risk assessment* as referred to in Article 9.5.3. 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* spp. ~~infestation~~ after conducting a *risk assessment* as referred to in Article 9.5.3. and when:

a) the *Veterinary Authority* or other *Competent Authority* with responsibility for 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) the presence of *Tropilaelaps* spp. ~~infestation~~ is notifiable in the whole country or *zone~~/compartment~~* ~~(under study)~~, and any clinical *cases* suggestive of *Tropilaelaps* spp. infestation are subjected to field and *laboratory* investigations;

c) for the 3 years following the last report~~ed~~ ~~*case*~~ of the presence of *Tropilaelaps* spp. ~~infestation~~, an annual survey supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive ~~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* spp. ~~infestation~~ if at least 1% of the *apiaries* were ~~infected~~ infested at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of *infestation*;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive ~~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 *infestation* ~~*disease*~~;

e) ~~(under study)~~ either there is no wild or self-sustaining feral population of ~~*Apis*~~ species of the genus *Apis* ~~*A. mellifera*, *A. dorsata* or *A. laboriosa*, or other possible host species~~ in the country or *zone~~/compartment~~* ~~(under study)~~, or there is an ongoing *surveillance* programme of the wild or self-sustaining feral population of species of the genus *Apis* which demonstrates no evidence of the presence of the mite in the country or *zone*;

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 9.5.5.

Recommendations for the importation of live queen honey bees, worker honey bees, and drones honey bees, and with associated larvae of honey bees, pupae of honey bees, and brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the *commodities* bees come from an *apiariesy* situated in a country or *zone/compartment* (under study) officially free from *Tropilaelaps* spp.; infestation the *apiary* meets the conditions prescribed in Article 4.14.3.

OR

2) In the case ofin which the country or *zone* is not free from *Tropilaelaps* infestation, *Veterinary Authorities* of *importing countries* should only allow the importation of the shipment comprises only queen honey bees with attendant worker honey bees without associated brood combs and the honey bees should require that the honey bees meet the following conditions:

1a) come from an artificial broodless swarm with the caged queen; and

2b) caged queen and swarm have been treated with an effective veterinary medicinal product and kept isolated for 21 days from brood prior to the shipment; and

3c) were inspected by a representative of the *Veterinary Services* prior to the shipment and showed no evidence of the presence of the mites.

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 seven days.

Article 9.5.76.

Recommendations for the importation of used apicultural 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 an *apiariesy* situated in a country or *zone/compartment* (under study) free from *Tropilaelaps* spp. infestation; or

2) contains no live honey bees or bee brood and has been held in a bee-proof environment away from contact with live honey bees for at least 7 21 days prior to shipment; or

3) has been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the following procedures: referred to in Chapter X.X. recommended by the OIE (under study).

a) heating to 50°C core temperature and holding at that temperature for 20 minutes; or

b) freezing at core temperature of -12°C or less for at least 24 48 hours once the core reached -20°C; or

c) fumigation with methyl bromide at a rate of 48 g per cubic metre at atmospheric pressure and at a temperature of 10-15°C for a period of 2 hours; or

d) irradiation with 350 Gy; or

e) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*.

Article 9.5.~~8~~7.

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 honey ~~products~~:

1) comes from ~~an~~ *apiaries~~y~~* situated in a country or *zone/~~compartment~~* ~~(under study)~~ free from *Tropilaelaps* spp. ~~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 21 days prior to shipment; or~~

2) has been ~~is~~ strained ~~honey~~ through a filter of pore size no greater than 0.42 mm; or

3) has~~ve~~ been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the following procedures ~~referred to in Chapter X.X. recommended by the OIE (under study).~~:

a) heating to 50°C core temperature and holding at that temperature for 20 minutes; or

b) freezing at core temperature of -12°C or less for at least 24 ~~48~~ hours ~~once the core reached -20°C~~; or

~~c) fumigation with methyl bromide at a rate of 48 g per cubic metre at atmospheric pressure and at a temperature of 10-15°C for a period of 2 hours, or~~

~~d~~c) irradiation with 350 Gy; or~~.~~

d) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*.

Article 9.5.8.

Recommendations for the importation of bee-collected pollen

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bee-collected pollen:

1) comes from ~~an~~ *apiaries~~y~~* situated in a country or *zone* free from *Tropilaelaps* spp.; or

2) has been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the following procedures:

a) freezing at core temperature of -12°C or less for at least 24 hours; or

b) irradiation with 350 Gy; or

c) desiccation by freeze drying or equivalent; or

d) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*.

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Article 9.5.9.

Recommendations for the importation of beeswax and propolis

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *commodities*:

1) come from ~~an~~ *apiaries~~y~~* situated in a country or *zone* free from *Tropilaelaps* spp.; or

2) are processed beeswax or processed propolis; or

3) have been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the following procedures:

   a) freezing at core temperature of -12°C or less for at least 24 hours; or

   b) fumigation with methyl bromide at a rate of 48 g per cubic metre at atmospheric pressure and at a temperature of 10-15°C for a period of 2 hours; or

   c) irradiation with 350 Gy; or

   d) desiccation by freeze drying or equivalent; or

   e) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*.

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— Text deleted

CHAPTER 9.6.

INFESTATION ~~VARROOSIS~~ OF HONEY BEES WITH *VARROA* SPP. (VARROOSIS)

EU position

The EU thanks the OIE and in general supports the adoption of this modified chapter. A comment is inserted in the text below.

Article 9.6.1.

General provisions

For the purposes of the *Terrestrial Code* ~~this chapter~~, varroosis is a *disease* of ~~the~~ honey bees~~,~~ (~~*Apis*~~ species of the genus *Apis*) ~~*Apis mellifera* L. It is~~ caused by ~~the Korea and Japan haplotypes of the~~ mites in the genus *Varroa* ~~*destructor*~~, primarily *Varroa destructor*~~, in combination with viruses (particularly Deformed Wing Virus)~~. ~~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 honey bees ~~*Apis* spp. *mellifera* L. During its life cycle, sexual reproduction occurs inside the honey bee brood cells. Early signs of *infection* normally go unnoticed, and only when *infection* is heavy does it become apparent. The *infection*~~ and spreads by direct contact from adult honey bee to adult honey bee, and by the movement of infested honey bees, ~~and~~ bee brood, bee products and used apicultural equipment ~~associated with beekeeping. The mite can also act as a vector for viruses of the honey bee. The mite acts as a vector and an activator for viruses of the honey bee. Symptoms of varroosis are the results of the combined action of *Varroa* spp. mites and viruses. Honey bee colonies are natural asymptomatic carriers of viruses. Varroosis is not transferred by viruses alone and needs mites to be spread from one colony to the other.~~

The number of mites ~~parasites~~ steadily increases with increasing brood production ~~activity~~ and the growth of the honey bee population, especially late in the season when clinical signs of *infestation* can first be recognised. The lifespan of an individual mite depends on temperature and humidity but, in practice, it can be said to last from some days to a few months.

Honey bee colonies are often carriers of viruses. The mite acts as a *vector* for viruses (particularly deformed wing virus) facilitating their penetration and the *infection* of the honey bees. Most of the symptoms of varroosis are therefore the results of the combined action of *Varroa* spp. mites and viruses. The viral load within the colony increases with the mite *infestation*. Insufficient or late treatments lead to the killing of mites but the virus load remains high for several weeks with deleterious effects on the honey bee population. The control of the varroosis is mainly performed by the control of *Varroa* spp. and the diagnosis of varroosis is also performed by measuring the parasitic load.

EU comment

The EU thanks the OIE for having reverted to the current case definition and takes note of the new text in the paragraph above. The EU is of the opinion that this information, though per se acceptable, is not necessary in the Terrestrial Code as it is neither related to the case definition, nor to the specific trade recommendations. Such information would perhaps be better placed in the Terrestrial Manual, where it is usually found in part A "Introduction" of the disease specific chapters. Indeed, in Chapter 2.2.7. "Varroosis of honey bees" of the Manual (last adopted in May 2008), reference is made in section A to increased susceptibility of *Varroa* infested honey bees to deformed wing and acute paralysis virus. This section of the Manual should be updated and expanded to include the information contained in the paragraph above.

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

~~When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.6.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the varroosis status of the honey bee population of the *exporting country* or *zone*.~~

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.6.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the varroosis status of the honey bee population of the *exporting country* or *zone*.

Article 9.6.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Varroa* spp. related conditions, regardless of the *Varroa* spp. status of the honey bee population of the *exporting country* or *zone*:

1) honey bee semen;

2) honey bee venom;

3) honey bee eggs;

4) royal jelly

Annex XXII (contd)

~~1) honey bee semen, honey bee eggs and honey bee venom;~~

~~2) extracted honey, pollen, propolis, and royal jelly for human consumption and processed beeswax (not in the form of honeycomb).~~

~~3) extracted honey, and processed beeswax.~~

~~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 varroosis status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.6.3.

Determination of *Varroa* spp. ~~varroosis~~ status of a country or zone~~/compartment~~

The *Varroa* spp. ~~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 *Varroa* spp. ~~varroosis~~ occurrence and their historic perspective;

2) the presence of *Varroa* spp. ~~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 reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.6.4.

Country or zone~~/compartment (under study)~~ free from *Varroa* spp.~~varroosis~~

1. Historically free status

   A country or *zone~~/compartment~~ (under study)* may be considered free from *Varroa* spp. ~~the *disease*~~ after conducting a *risk assessment* as referred to in Article 9.6.3. 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 *Varroa* spp. ~~varroosis~~ after conducting a *risk assessment* as referred to in Article 9.6.3. and when:

a) the *Veterinary Authority* or other *Competent Authority* with responsibility for 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) the presence of *Varroa* spp. ~~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 report~~ed case~~ of the presence of *Varroa* spp. ~~varroosis~~, an annual survey supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive ~~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 *Varroa* spp. ~~varroosis~~ if at least 1% of the *apiaries* were infested ~~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* ~~*disease*~~;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive ~~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 *infestation* ~~*disease*~~;

e) ~~(under study)~~ either there is no wild or self-sustaining feral population of ~~*Apis*~~ species ~~*A. mellifera*, the Korea and Japan haplotypes of *Apis cerana* or other possible host species~~ of the genus *Apis* in the country or *zone*~~/compartment~~ (under study), or there is an ongoing *surveillance* programme of the wild or self-sustaining feral population of species of the genus *Apis* which demonstrates no evidence of the presence of the mite in the country or *zone*;

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.bis~~

~~**Apiary free from varroosis**~~

~~1. The *apiary* is located in a country or *zone* complying with the requirements in points 2. a) b) and f) of Article 9.6.4.;~~

~~2. the *apiary* should be situated in an area with a radius of 50 kilometres in which no *case* of varroosis has been reported for at least the past 2 years; and~~

~~3. the *apiary* meets the conditions prescribed in Article 4.14.3.~~

Article 9.6.5.

Recommendations for the importation of live queen honey bees, worker honey bees, ~~and drones~~ honey bees, ~~with or without associated brood combs~~ larvae of honey bees, pupae of honey bees and brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the *commodities* ~~bees~~ come from ~~an~~ *apiaries*~~y~~ situated in a country or *zone*~~/compartment~~ (under study) officially free from *Varroa* spp. ~~varroosis; the *apiary* meets the conditions prescribed in Article 9.6.4. bis~~; or

2) ~~In the case of the country or zone is not free from varroosis, *Veterinary Authorities* of *importing countries* should only allow the importation of~~ the shipment comprises only queen honey bees with attendant worker honey bees without associated brood combs and the honey bees ~~should require that the bees meet the following conditions~~:

~~1.~~a) come from an artificial broodless swarm with the caged queen; ~~and~~

~~2.~~b) caged queen and swarm have been treated with an effective veterinary medicinal product; ~~and~~

~~3.~~c) were inspected by a representative of the *Veterinary Services* prior to the shipment and showed no evidence of the presence of the mites;

d) the queen honey bees were inspected by the *Veterinary Services* of the *importing country* based on a visual inspection described in the relevant chapter of the *Terrestrial Manual* and the attendant worker honey bees were killed.

~~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*.~~

Annex XXII (contd)

Article 9.6.~~7~~6.

Recommendations for the importation of used apicultural 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 ~~an~~ *apiaries*~~y~~ situated in a country or *zone*/~~*compartment* (under study)~~ free from *Varroa* spp. ~~varroosis~~; or

2) contains no live honey bees or bee brood and has been held in a bee-proof environment ~~away from contact with live honey bees~~ for at least ~~7~~ 21 days prior to shipment; or

3) has been treated to ensure the destruction of *Varroa* spp. ~~species *destructor*~~, in conformity with one of the following procedures:

a) heating to 50°C core temperature and holding at that temperature for 20 minutes; or

b) freezing at core temperature of -12°C or less for at least 2448 hours ~~once the core reached -20°C~~; or

c) fumigation with methyl bromide at a rate of 48 g per cubic metre at atmospheric pressure and at a temperature of 10-15°C for a period of 2 hours; or

d) irradiation with 350 Gy; or

e) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*.

~~referred to in Chapter X.X. recommended by the OIE (under study).~~

Article 9.6.~~8~~7.

Recommendations for the importation of ~~honey bee collected pollen~~ and propolis ~~for apiculture use~~, unprocessed beeswax ~~(in the form of honeycomb)~~, and ~~comb~~ honey ~~and propolis~~

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the honey ~~products~~:

1) comes from ~~an~~ *apiaries*~~y~~ situated in a country or *zone*/~~*compartment* (under study)~~ free from *Varroa* spp. ~~varroosis~~; or

2) ~~is~~ has been strained ~~honey~~ through a filter of pore size no greater than 0.42 mm; 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 21 days prior to shipment; or~~

3) has~~ve~~ been treated to ensure the destruction of *Varroa* spp.~~species~~ ~~*destructor*~~, in conformity with one of the following procedures ~~referred to in Chapter X.X. recommended by the OIE (under study)~~:

a) heating to 50°C core temperature and holding at that temperature for 20 minutes; or

b) freezing at core temperature of -12°C or less for at least 2448 hours ~~once the core reached -20°C~~; or

~~c) fumigation with methyl bromide at a rate of 48 g per cubic metre at atmospheric pressure and at a temperature of 10-15°C for a period of 2 hours, or~~

~~d~~c) irradiation with 350 Gy; or

d) by any procedure of equivalent efficacy ~~and~~ recognised by the *Veterinary Authorities* of the *importing* and *exporting countries*.

Article 9.6.8.

Recommendations for the importation of bee-collected pollen

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bee-collected pollen:

1) comes from ~~an~~ *apiaries~~y~~* situated in a country or *zone* free from *Varroa* spp.; or

2) has been treated to ensure the destruction of *Varroa* spp., in conformity with one of the following procedures:

a) freezing at core temperature of -12°C or less for at least 24 hours; or

b) irradiation with 350 Gy; or

c) desiccation by freeze drying or equivalent; or

d) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*.

Article 9.6.9.

Recommendations for the importation of beeswax and propolis

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *commodities*:

1) come from ~~an~~ *apiaries~~y~~* situated in a country or *zone* free from *Varroa* spp.; or

2) are processed beeswax or processed propolis; or

3) have been treated to ensure the destruction of *Varroa* spp., in conformity with one of the following procedures:

a) freezing at core temperature of -12°C or less for at least 24 hours; or

b) fumigation with methyl bromide at a rate of 48 g per cubic metre at atmospheric pressure and at a temperature of 10-15°C for a period of 2 hours; or

c) irradiation with 350 Gy; or

d) desiccation by freeze drying or equivalent; or

e) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*.

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— Text deleted.

Annex XXIII

CHAPTER 10.4.

INFECTION WITH AVIAN INFLUENZA VIRUSES ~~OF NOTIFIABLE AVIAN INFLUENZA~~

EU position

The EU thanks the OIE and supports the adoption of this modified chapter. Reference is made to the EU comment on point 6 of Article 1.2.3., inserted in the text of Annex VI.

Article 10.4.1.

General provisions

~~1)~~ ~~Infection with Hh~~highly pathogenic avian influenza ~~viruses~~ in birds and low pathogenicity notifiable avian influenza ~~viruses~~ in *poultry*, ~~as defined below, should be notified in accordance with the *Terrestrial Code*.~~

~~2)~~1) For the purposes of the *Terrestrial Code*, ~~notifiable~~ avian influenza ~~(NAI)~~ is defined as an *infection* of *poultry* caused by any influenza A virus of the H5 or H7 subtypes or by any influenza A ~~AI~~ virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75 percent mortality) as described below. ~~NAI~~ These viruses ~~can be~~ are divided into high pathogenicity ~~highly pathogenic~~ ~~notifiable~~ avian influenza ~~(HPNAI)~~ viruses and low pathogenicity ~~notifiable~~ avian influenza ~~(LPNAI)~~ viruses:

a) ~~HPNAI~~ High pathogenicity avian influenza viruses have an IVPI in six-week-old chickens greater than 1.2 or, as an alternative, cause at least 75 percent mortality in four-to eight-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 percent 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~~ high pathogenicity avian influenza isolates, the isolate being tested should be considered as ~~HPNAI~~ high pathogenicity avian influenza virus;

b) ~~LPNAI~~ low pathogenicity avian influenza viruses are all influenza A viruses of H5 and H7 subtype that are not ~~HPNAI~~ high pathogenicity avian influenza viruses.

2) The following defines the occurrence of *infection* with an avian influenza virus:

The virus has been isolated and identified as such or specific viral ribonucleic acid (RNA) has been detected in *poultry* or a product derived from *poultry*.

3) *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*.

~~4)~~ ~~The following defines the occurrence of *infection* with NAI an avian influenza virus:~~

~~The virus has been isolated and identified as such or specific viral RNA has been detected in *poultry* or a product derived from *poultry*.~~

~~4)5~~4) For the purposes of the *Terrestrial Code*, the *incubation period* for ~~NAI~~ avian influenza shall be 21 days.

~~5)6~~5) This chapter deals not only with the occurrence of clinical signs caused by ~~NAI~~ avian influenza ~~virus~~, but also with the presence of *infection* with ~~NAI~~ avian influenza virus~~es~~ in the absence of clinical signs.

Annex XXIII (contd)

6)~~7~~6) Antibodies to H5 or H7 subtype ~~of NAI virus~~, which have been detected in *poultry* and are not a consequence of vaccination, ~~have to~~ should be immediately investigated. In the case of isolated serological positive results, ~~NAI~~ *infection* with ~~NAI~~ avian influenza viruses may be ruled out on the basis of a thorough epidemiological and laboratory investigation that does not demonstrate further evidence of ~~NAI~~ such *infection*.

~~7) 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*.~~

7)~~8)~~ For the purposes of the *Terrestrial Code*, '~~NAI~~ avian influenza free establishment' means an *establishment* in which the *poultry* have shown no evidence of ~~NAI~~ *infection* with ~~NAI~~ avian influenza viruses, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.

8)~~9)~~ 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*.

9)~~10)~~ *Infection* with influenza A viruses of high pathogenicity in birds other than poultry, including wild birds, should be notified according to Article 1.1.3. However, a Member should not impose ~~immediate~~ bans on the trade in *poultry commodities* in response to such ~~a~~ notification, or other information on the presence of any influenza A virus ~~according to Article 1.1.3. of the *Terrestrial Code*, of *infection* with highly pathogenic HPAI or and low pathogenic LPAI avian influenza viruses~~ in birds other than *poultry*, including wild birds.

Article 10.4.2.

Determination of the ~~NAI~~ avian influenza status of a country, zone or compartment

The ~~NAI~~ avian influenza status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1) ~~NAI~~ avian influenza is notifiable in the whole country, an on-going ~~NAI~~ avian influenza awareness programme is in place, and all notified suspect occurrences of ~~NAI~~ avian influenza 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 an ~~NAI~~ avian influenza *surveillance* programme in accordance with Articles 10.4.27. to 10.4.33.;

3) consideration of all epidemiological factors for ~~NAI~~ avian influenza occurrence and their historical perspective.

Article 10.4.3.

~~NAI~~ Avian influenza free country, zone or compartment

A country, *zone* or *compartment* may be considered free from ~~NAI~~ avian influenza when it has been shown that ~~neither HPNAI nor LPNAI~~ *infection* in *poultry* with ~~HPAI or LPNAI~~ avian influenza viruses has not 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 *poultry* in a previously free country, *zone* or *compartment*, ~~NAI~~ avian influenza free status can be regained:

1) In the case of ~~HPNAI~~ *infections* with ~~HPAI~~ high pathogenicity avian influenza viruses, three 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* with ~~LPNAI~~ low pathogenicity avian influenza viruses, *poultry* may be kept for *slaughter* for human consumption subject to conditions specified in Article 10.4.19. or a *stamping-out policy* may be applied; in either case, three 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 free from infection with ~~HPAI~~ high pathogenicity avian influenza viruses in poultry

A country, *zone* or *compartment* may be considered free from ~~HPNAI~~ *infection* with ~~HPAI~~ high pathogenicity avian influenza viruses in *poultry* when:

1) it has been shown that ~~HPNAI~~ *infection* in *poultry* with ~~HPAI~~ high pathogenicity avian influenza viruses has not been present in the country, *zone* or *compartment* for the past 12 months, although its ~~LPNAI~~ status with respect to ~~LPNAI~~ low pathogenicity avian influenza viruses 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~~ avian influenza but any ~~NAI~~ virus detected has not been identified as ~~HPNAI~~ high pathogenicity avian influenza 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 *poultry* in a previously free country, *zone* or *compartment*, the ~~HPNAI~~ 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 10.4.27. to 10.4.33. has been carried out during that three-month period.

Article 10.4.5.

Recommendations for importation from an ~~NAI~~ avian influenza 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~~ avian influenza on the day of shipment;

2) the *poultry* were kept in an ~~NAI~~ avian influenza 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*~~;~~.

~~4) if~~ If the *poultry* have been vaccinated against ~~NAI~~ avian influenza, ~~it has been done in accordance with the provisions of the *Terrestrial Manual* and~~ the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.6.

Recommendations for the importation of live birds other than poultry

Regardless of the ~~NAI~~ avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) on the day of shipment, the birds showed no clinical sign of *infection* with a virus which would be considered ~~NAI~~ avian influenza in *poultry*;

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~~ avian influenza in *poultry* during the isolation period;

3) a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.4.29., 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~~ avian influenza in *poultry*;

Annex XXIII (contd)

4) the birds are transported in new or appropriately sanitized *containers*~~;~~.

~~5) if~~ If the birds have been vaccinated against ~~NAI~~ avian influenza, ~~it has been done in accordance with the provisions of the *Terrestrial Manual* and~~ the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.7.

Recommendations for importation from an ~~NAI~~ avian influenza 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 an ~~NAI~~ avian influenza free country, *zone* or *compartment* since they were hatched;

2) the *poultry* were derived from parent *flocks* which had been kept in a ~~NAI~~ avian influenza 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*~~;~~.

~~4) if~~ If the *poultry* or the parent *flocks* have been vaccinated against ~~NAI~~ avian influenza, ~~it has been done in accordance with the provisions of the *Terrestrial Manual* and~~ the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.8.

Recommendations for importation from a ~~HPNAI free~~ country, zone or compartment free from infection with ~~HPAI~~ high pathogenicity avian influenza viruses in poultry

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* free from *infection* with ~~HPAI~~ high pathogenicity avian influenza viruses in *poultry* since they were hatched;

2) the *poultry* were derived from parent *flocks* which had been kept in an ~~NAI~~ avian influenza free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;

3) the *poultry* are transported in new or appropriately sanitized *containers*~~;~~.

~~4) if~~ If the *poultry* or the parent *flocks* have been vaccinated against ~~NAI~~ avian influenza, ~~it has been done in accordance with the provisions of the *Terrestrial Manual* and~~ the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.9.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the ~~NAI~~ avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) on the day of shipment, the birds showed no clinical sign of *infection* with a virus which would be considered ~~NAI~~ avian influenza in *poultry*;

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~~ a virus which would be considered avian influenza in *poultry*;

4) the birds are transported in new or appropriately sanitized *containers*~~;~~.

~~5) if~~ If the birds or parent *flocks* have been vaccinated against ~~NAI~~ avian influenza, ~~it has been done in accordance with the provisions of the *Terrestrial Manual* and~~ the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.10.

Recommendations for importation from an ~~NAI~~ avian influenza 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 an ~~NAI~~ avian influenza free country, *zone* or *compartment*;

2) the eggs were derived from parent *flocks* which had been kept in an ~~NAI~~ avian influenza 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 packaging materials~~;~~.

~~4) if~~ If the parent *flocks* have been vaccinated against ~~NAI~~ avian influenza, ~~it has been done in accordance with the provisions of the *Terrestrial Manual* and~~ the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.11.

Recommendations for importation from a ~~HPNAI free~~ country, zone or compartment free from infection with ~~HPAI~~ high pathogenicity avian influenza viruses in poultry

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* free from *infection* with ~~HPAI~~ high pathogenicity avian influenza viruses in *poultry*;

2) the eggs were derived from parent *flocks* which had been kept in an ~~NAI~~ avian influenza free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;

3) the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);

4) the eggs are transported in new or appropriately sanitized packaging materials~~;~~.

~~5) if~~ If the parent *flocks* have been vaccinated against ~~NAI~~ avian influenza, ~~it has been done in accordance with the provisions of the *Terrestrial Manual* and~~ the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.12.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the ~~NAI~~ avian influenza status of the country of 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 seven days prior to and at the time of the collection of the eggs to demonstrate freedom from *infection* with a virus which would be considered avian influenza in *poultry* ~~NAIV viruses~~;

Annex XXIII (contd)

2) the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);

3) the eggs are transported in new or appropriately sanitized packaging materials~~;~~.

~~4) if~~ If the parent *flocks* have been vaccinated against ~~NAI~~ avian influenza, ~~it has been done in accordance with the provisions of the *Terrestrial Manual* and~~ the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.13.

Recommendations for importation from an ~~NAI~~ avian influenza free country, zone or compartment

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 ~~NAI~~ avian influenza free country, *zone* or *compartment*;

2) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.14.

Recommendations for importation from a ~~HPNAI free~~ country, zone or compartment free from infection with ~~HPAI~~ high pathogenicity avian influenza viruses in poultry

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 a ~~HPNAI free~~ country, *zone* or *compartment* free from *infection* with ~~HPAI~~ high pathogenicity avian influenza viruses in *poultry*;

2) the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);

3) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.15.

Recommendations for importation of egg products of poultry

Regardless of the ~~NAI~~ avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) the *commodity* is derived from eggs which meet the requirements of Articles 10.4.13. or 10.4.14.; or

2) the *commodity* has been processed to ensure the destruction of ~~NAI~~ avian influenza virus in accordance with Article 10.4.25.;

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of ~~NAI~~ avian influenza virus.

Article 10.4.16.

Recommendations for importation from an ~~NAI~~ avian influenza 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~~ avian influenza on the day of semen collection;

2) were kept in an ~~NAI~~ avian influenza free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.17.

Recommendations for the importation from a ~~HPNAI free~~ country, zone or compartment free from infection with ~~HPAI~~ high pathogenicity avian influenza viruses in poultry

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 *infection* with ~~HPNAI~~ high pathogenicity avian influenza virus on the day of semen collection;

2) were kept in a ~~HPNAI free~~ country, *zone* or *compartment* free from *infection* with ~~HPAI~~ high pathogenicity avian influenza viruses in *poultry* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.18.

Recommendations for the importation of semen of birds other than poultry

Regardless of the ~~NAI~~ avian influenza status of the country 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~~ avian influenza in *poultry* during the isolation period;

3) were tested within 14 days prior to semen collection and shown to be free ~~of~~ from ~~NAI~~ *infection* with a virus which would be considered avian influenza in *poultry*.

Article 10.4.19.

Recommendations for importation from ~~either~~ a ~~NAI or HPNAI free~~ country, zone or compartment free from ~~NAI~~ avian influenza or free from infection with ~~HPAI~~ high pathogenicity avian influenza viruses in poultry

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 country, *zone* or *compartment* free from ~~HPNAI~~ *infection* with high pathogenicity avian influenza viruses in *poultry* since they were hatched or for at least the past 21 days;

2) which have been slaughtered in an approved *abattoir* in a country, *zone* or *compartment* free from ~~HPNAI~~ *infection* with high pathogenicity avian influenza viruses in *poultry* and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any signs suggestive of ~~NAI~~ avian influenza.

Article 10.4.20.

Recommendations for the importation of meat products of poultry

Regardless of the ~~NAI~~ avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

Annex XXIII (contd)

1) the *commodity* is derived from *fresh meat* which meet the requirements of Article 10.4.19.; or

2) the *commodity* has been processed to ensure the destruction of ~~NAI~~ avian influenza virus in accordance with Article 10.4.26.;

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of ~~NAI~~ avian influenza virus.

Article 10.4.21.

Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use

Regardless of the ~~NAI~~ avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) these *commodities* were processed in an ~~NAI~~ avian influenza free country, *zone* or *compartment* from *poultry* which were kept in an ~~NAI~~ avian influenza 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 ~~NAI~~ avian influenza virus (under study);

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of ~~NAI~~ avian influenza virus.

Article 10.4.22.

Recommendations for the importation of feathers and down of poultry

Regardless of the ~~NAI~~ avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) these *commodities* originated from *poultry* as described in Article 10.4.19. and were processed in an ~~NAI~~ avian influenza free country, *zone* or *compartment*; or

2) these *commodities* have been processed to ensure the destruction of ~~NAI~~ avian influenza virus (under study);

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of ~~NAI~~ avian influenza virus.

Article 10.4.23.

Recommendations for the importation of feathers and down of birds other than poultry

Regardless of the ~~NAI~~ avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) these *commodities* have been processed to ensure the destruction of ~~NAI~~ any virus which would be considered avian influenza in *poultry* ~~virus~~ (under study); and

2) the necessary precautions were taken to avoid contact of the *commodity* with any source of ~~NAI~~ viruses which would be considered avian influenza in *poultry* ~~virus~~.

Article 10.4.24.

Recommendations for the importation of feather meal and poultry meal

Regardless of the ~~NAI~~ avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) these *commodities* were processed in a ~~NAI~~ avian influenza free country, *zone* or *compartment* from *poultry* which were kept in a ~~NAI~~ avian influenza 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) with moist heat 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; or

   c) with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74ºC;

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of ~~NAI~~ avian influenza viruses.

Article 10.4.25.

Procedures for the inactivation of the ~~AI virus~~ avian influenza viruses in eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of ~~AI virus~~ avian influenza viruses present in eggs and egg products:

	Core 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	20 hours
Dried egg white	54.4	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~~ avian influenza viruses in meat

The following times for industry standard temperatures are suitable for the inactivation of ~~AI virus~~ avian influenza viruses present in *meat*.

Annex XXIII (contd)

	Core temperature (°C)	Time
Poultry meat	60.0	507 seconds
	65.0	42 seconds
	70.0	3.5 seconds
	73.9	0.51 second

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 10.4.27.

Surveillance: introduction

Articles 10.4.27. to 10.4.33. define the principles and provide a guide on the *surveillance* for ~~NAI~~ avian influenza complementary to Chapter 1.4., applicable to Members seeking to determine their ~~NAI~~ avian influenza 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~~ avian influenza status is also provided.

The presence of ~~avian~~ influenza A viruses in wild birds creates a particular problem. In essence, no Member can declare itself free from avian influenza A ~~(AI)~~ in wild birds. However, the definition of ~~NAI~~ avian influenza 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~~ avian influenza differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from ~~NAI~~ avian influenza 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~~ avian influenza 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* with avian influenza viruses is assured at an acceptable level of confidence.

Surveillance for ~~NAI~~ avian influenza 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* with ~~NAIV~~ avian influenza viruses.

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 ~~NAIV~~ *infection* with ~~NAIV~~ avian influenza viruses should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect *cases* of ~~NAI~~ avian influenza to a *laboratory* for ~~NAI~~ avian influenza 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~~ avian influenza *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~~ avian influenza 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~~ avian influenza should be investigated immediately. As suspicion cannot always 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~~ avian influenza diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;

   b) implement, when relevant, regular and frequent clinical inspection, serological and virological testing of high-risk groups of *animals*, such as those adjacent to an ~~NAI~~ avian influenza 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 potential sources of ~~NAIV~~ influenza A viruses.

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~~ avian influenza viruses. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. ~~Applications~~ Documentation for freedom from ~~NAIV~~ *infection* with ~~NAIV~~ avian influenza viruses 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~~ avian influenza should be ongoing. The frequency of active *surveillance* should be at least every six months. *Surveillance* should be composed of random and targeted approaches using molecular, virological, serological and clinical methods.

   The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of ~~NAIV~~ *infection* with ~~NAIV~~ avian influenza viruses at an acceptable level of confidence. Random *surveillance* is conducted using serological tests ~~described in the *Terrestrial Manual*~~. Positive serological results should be followed up with molecular or 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~~ avian influenza status of high risk populations.

   A Member should justify the *surveillance* strategy chosen as adequate to detect the presence of ~~NAIV~~ *infection* with ~~NAIV~~ avian influenza viruses in accordance with Chapter 1.4. and the prevailing epidemiological situation, including *cases* of ~~HPAI~~ high pathogenicity influenza A 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* with ~~NAIV~~ avian influenza viruses 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 should 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 ~~/~~and *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* ~~/~~and *infection* are technically well defined. The design of *surveillance* programmes to prove the absence of ~~NAIV~~ *infection* with, ~~NAIV~~ ~~/~~or circulation of, ~~NAIV~~ avian influenza viruses 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~~ avian influenza 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* with ~~NAIV~~ avian influenza viruses. In some cases, the only indication of ~~LPNAIV virus~~ *infection* with a low pathogenicity avian influenza virus 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~~ avian influenza 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 have restrictions imposed upon it until ~~NAI~~ avian influenza *infection* is ruled out.

Identification of suspect *flocks* is vital to the identification of sources of ~~NAIV~~ avian influenza viruses and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that ~~NAIV~~ avian influenza virus 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~~ avian influenza viruses. Positive ~~NAIV~~ avian influenza viruses antibody test results can have four possible causes:

a) natural *infection* with ~~NAIV~~ avian influenza viruses;

b) vaccination against ~~NAI~~ avian influenza ;

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 four 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~~ avian influenza *surveillance*. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of ~~NAIV~~ avian influenza viruses 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 should 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* with ~~NAIV~~ avian influenza viruses 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~~ freedom from ~~NAI~~ avian influenza or freedom from infection with ~~HPAI~~ high pathogenicity avian influenza viruses in poultry

1. Additional surveillance procedures for Members declaring freedom of the country, *zone* or *compartment* from ~~NAI~~ avian influenza or ~~HPNAI~~ from *infection* with ~~HPAI~~ high pathogenicity avian influenza viruses in *poultry* ~~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~~ of the entire country, or a *zone* or a *compartment* from ~~NAI~~ avian influenza or from *infection* with ~~HPAI~~ high pathogenicity avian influenza viruses in *poultry* 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 *infection* with ~~NAIV~~ avian influenza viruses or ~~HPNAIV~~ high pathogenicity avian influenza viruses ~~*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 *infection* with ~~NAIV~~ avian influenza viruses ~~or~~ ~~HPNAIV~~ 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 ~~HPNAIV~~ high pathogenicity avian influenza 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 should also comply with the provisions stipulated for NAI vaccines in the *Terrestrial Manual*~~. Based on the epidemiology of ~~NAI~~ avian influenza in the country, *zone* or *compartment*, it may be that a decision is reached to vaccinate only certain species or other *poultry* subpopulations.

Annex XXIII (contd)

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 six 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.

Additional surveillance procedures for countries, zones or compartments declaring that they have regained freedom from ~~NAI~~ avian influenza or from infection with ~~HPAI~~ high pathogenicity avian influenza viruses in poultry ~~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~~ avian influenza or from *infection* with ~~HPNAI~~ high pathogenicity avian influenza viruses ~~*infection*~~ in *poultry* 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~~ avian influenza ~~or HPNAI in *poultry* (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 randomised representative sample of the populations at risk.

Article 10.4.32.

Additional surveillance procedures for ~~NAI~~ avian influenza free establishments ~~within HPNAI free compartments: additional surveillance procedures~~

The declaration of ~~NAI~~ avian influenza free *establishments* requires the demonstration of absence of ~~NAIV~~ *infection* with ~~NAIV~~ avian influenza viruses. 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~~ avian influenza 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~~ influenza A viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorisation of ~~AI~~ influenza A viruses.

Poultry can be vaccinated with a variety of ~~AI~~ avian influenza 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~~ Influenza A 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~~ virus vaccines containing a ~~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~~ avian influenza *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~~ influenza A 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~~ avian influenza virus 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~~ avian influenza virus 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~~ avian influenza *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~~ avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins.

Annex XXIII (contd)

2. ~~The follow up~~ Procedure in case of ~~positive~~ test results indicative of infection ~~for determination of infection due to~~ with ~~HPNAI or LPNAI~~ avian influenza viruses

The detection of antibodies indicative of an ~~NAI virus~~ *infection* with an ~~NAI~~ avian influenza virus in unvaccinated *poultry* ~~as indicated in point a)i) above~~ should ~~will~~ result in the initiation of epidemiological and virological investigations to determine if the *infections* are due to high or low pathogenicity ~~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~~ avian influenza 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~~ avian influenza virus ~~and the method is described in the *Terrestrial Manual*~~. All ~~AI~~ influenza A 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 high or low pathogenicity avian influenza viruses ~~HPNAI, LPNAI~~ or ~~LPAI (not notifiable)~~ other ~~AI~~ influenza A 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~~ high or low pathogenicity avian influenza viruses. The use of antigen detection systems, because of low sensitivity, should be limited to ~~are best suited for~~ screening clinical field *cases* for *infection* by ~~Type A~~ influenza A virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

a) characterisation 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;

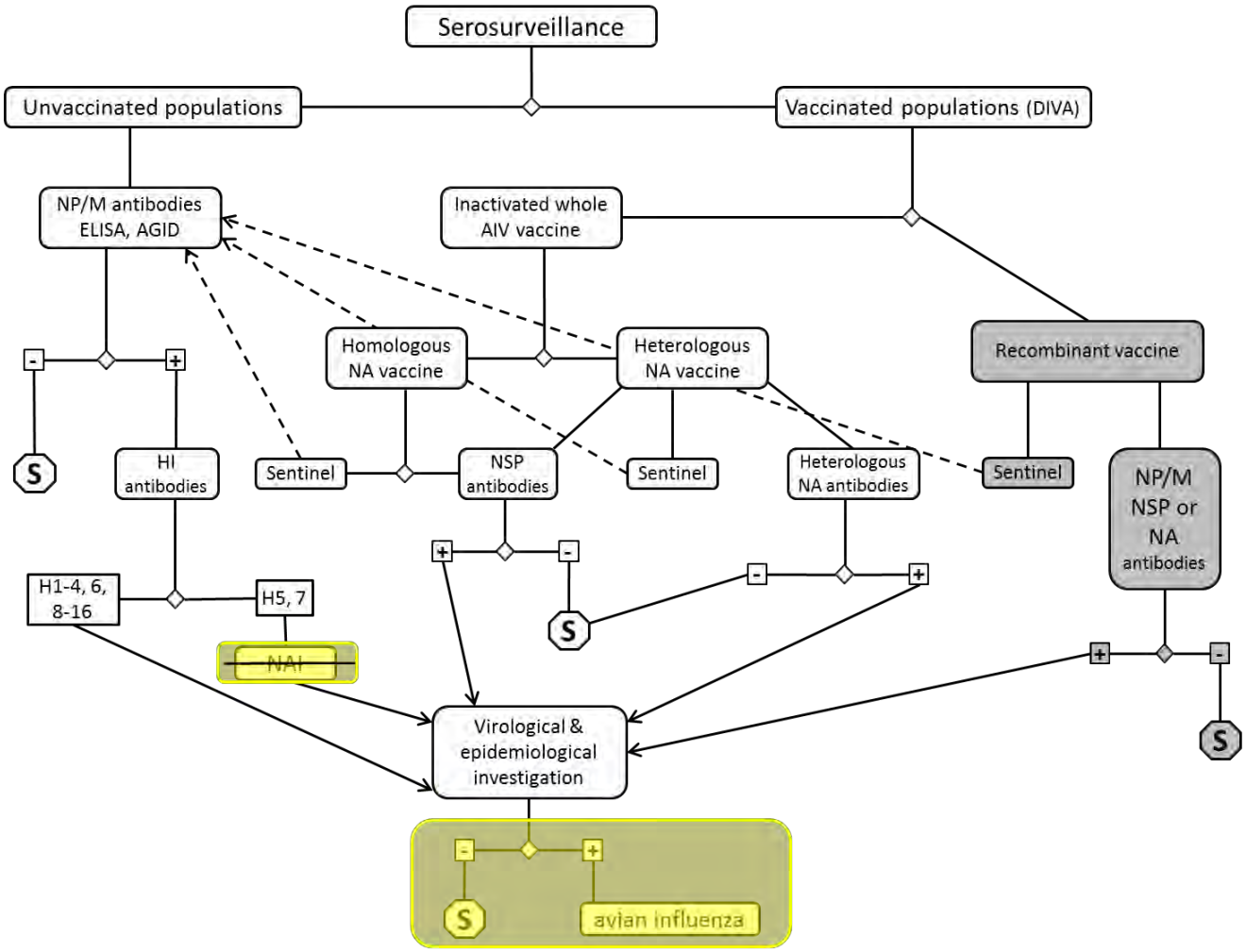
f) other parameters of regional significance in historic ~~NAIV~~ avian influenza virus transmission.

The entire investigative process should be documented as standard operating procedure within the epidemiological *surveillance* programme.

Figures 1 and 2 indicate the tests which are recommended for use in the investigation of *poultry flocks*.

Annex XXIII (contd)

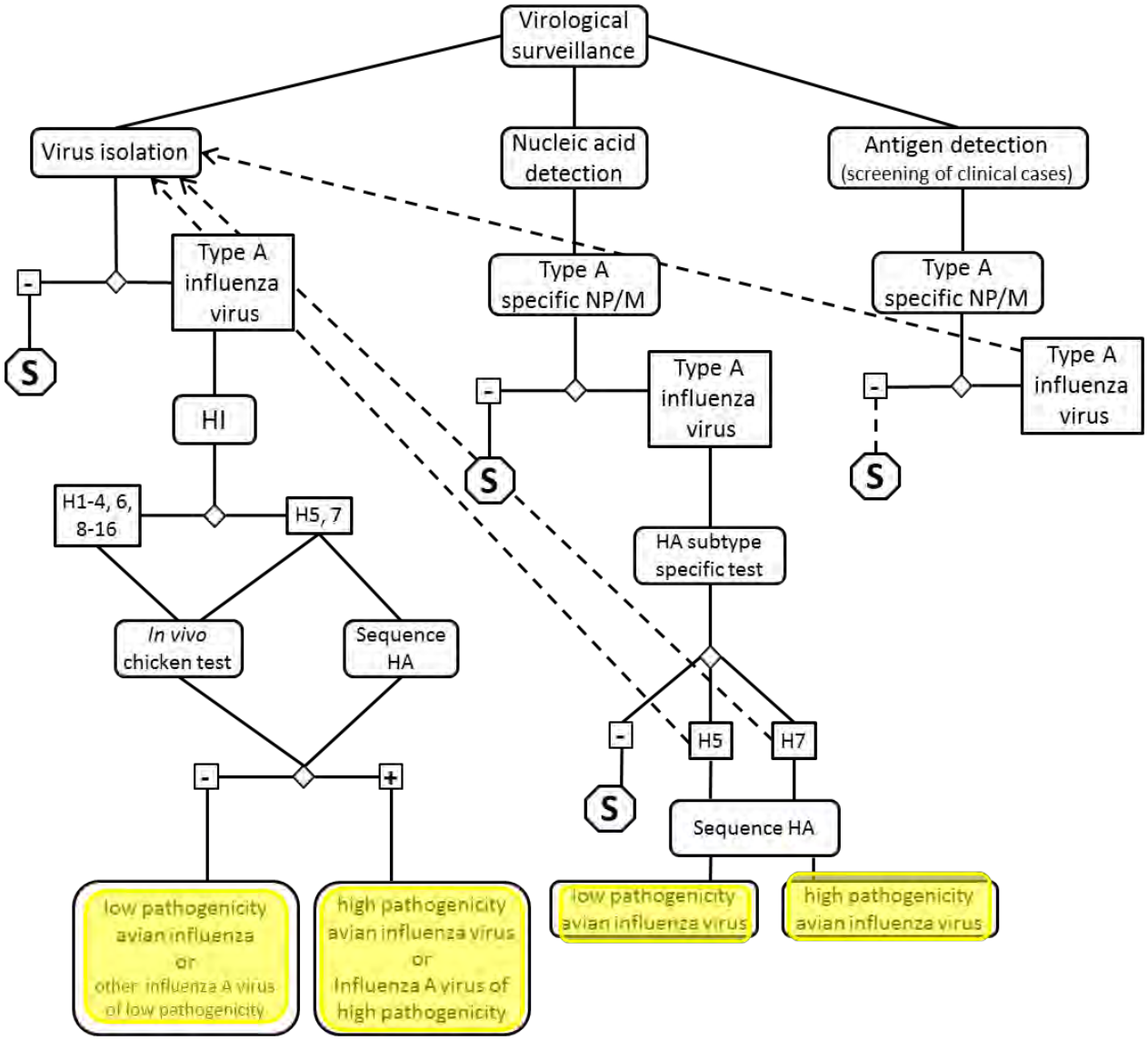
Fig. 1. ***Schematic representation of laboratory tests for determining evidence of ~~NAI~~ avian influenza infection through or following serological surveys***



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~~ avian influenza virus

Annex XXIII (contd)

Fig. 2. ***Schematic representation of laboratory tests for determining evidence of ~~NAI~~ avian influenza infection using virological methods***



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~~ avian influenza virus

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— Text deleted.

Annex XXIV

CHAPTER 10.9.

NEWCASTLE DISEASE

EU position

The EU in general supports the adoption of this modified chapter. For consistency with other recently revised chapters, the EU suggests changing the title of the chapter as follows:

"Infection with Newcastle Disease viruses".

That change should also be made in point 6 of Article 1.2.3., inserted in the text of Annex VI.

Article 10.9.1.

General provisions

1) For the purposes of the *Terrestrial Code*, 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) For the purposes of the *Terrestrial Code*, the *incubation period* for ND shall be 21 days.

4) This chapter deals with NDV *infection* of *poultry* as defined in Point 2 above, in the presence or absence of clinical signs.

5) 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.

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*.

7) A Member should not impose ~~immediate~~ bans on the trade in *poultry commodities* in response to information on the presence of any APMV-1 ~~a notification, according to Article 1.1.3. of the *Terrestrial Code*, of *infection* with NDV~~ in birds other than *poultry*, including wild birds.

Article 10.9.2.

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 10.9.22. to 10.9.26.;

3) consideration of all epidemiological factors for ND occurrence and their historical perspective.

Article 10.9.3.

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* in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.9.22. to 10.9.26.

If *infection* has occurred in *poultry* 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 10.9.22. to 10.9.26. has been carried out during that three-month period.

Article 10.9.4.

Recommendations for importation from an ND free country, zone or compartment as defined in Article 10.9.3.

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 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*;.

4) ~~if~~ If the *poultry* have been vaccinated against ND, ~~it has been done in accordance with the provisions of the *Terrestrial Manual* and~~ the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.9.5.

Recommendations for the importation of live birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) the birds showed no clinical sign suggestive of *infection* by NDV 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, selected in accordance with the provisions of Article 10.9.24., was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from *infection* with NDV;

4) the birds are transported in new or appropriately sanitized *containers*;.

5) ~~if~~ If the birds have been vaccinated against ND, ~~it has been done in accordance with the provisions of the *Terrestrial Manual* and~~ the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.9.6.

Recommendations for importation from an ND 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 hatched and kept in an ND free country, *zone* or *compartment* since they were hatched;

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*;

4) if If the *poultry* or parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.9.7.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) the birds showed no clinical sign suggestive of *infection* by NDV 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*;

5) if If the birds or parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.9.8.

Recommendations for importation from an ND 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 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 packaging materials;

4) if If the parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.9.9.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

Annex XXIV (contd)

1) the parent *flock* birds were subjected to a diagnostic test seven 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 6.4.);

3) the eggs are transported in new or appropriately sanitized packaging materials~~;~~.

~~4) if~~ If the parent *flocks* have been vaccinated against ND, ~~it has been done in accordance with the provisions of the *Terrestrial Manual* and~~ the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.9.10.

Recommendations for importation from an ND free country, zone or compartment

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 packaging materials.

Article 10.9.11.

Recommendations for importation of egg products of poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) the *commodity* is derived from eggs which meet the requirements of Article 10.9.10.; or

2) the *commodity* has been processed to ensure the destruction of NDV in accordance with Article 10.9.20.;

AND

3) the necessary precautions were taken to avoid contact of the egg products with any source of NDV.

Article 10.9.12.

Recommendations for importation from an ND 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 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 10.9.13.

Recommendations for the importation of semen of birds other than poultry

Regardless of the ND status of the country 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 10.9.14.

Recommendations for importation from an ND 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 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- and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any sign suggestive of ND.

Article 10.9.15.

Recommendations for importation of 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 meet the requirements of Article 10.9.14.; or

2) the *commodity* has been processed to ensure the destruction of NDV in accordance with Article 10.9.21.;

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.9.16.

Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use

Regardless of the ND status of the country 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);

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Annex XXIV (contd)

Article 10.9.17.

Recommendations for the importation of feathers and down of poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) these *commodities* originated from *poultry* as described in Article 10.9.14. and were processed in a ND free country, *zone* or *compartment*; or

2) these *commodities* have been processed to ensure the destruction of NDV (under study);

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.9.18.

Recommendations for the importation of feathers and down of birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) these *commodities* have been processed to ensure the destruction of NDV (under study); and

2) the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.9.19.

Recommendations for the importation of feather meal and poultry meal

Regardless of the ND status of the country 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) with moist heat 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; or

   c) with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74ºC for a minimum of 280 seconds;

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of ND virus.

Article 10.9.20.

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:

	Core temperature (°C)	**Time**
Whole egg	55	2,521 seconds
Whole egg	57	1,596 seconds
Whole egg	59	674 seconds
Liquid egg white	55	2,278 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 10.9.21.

Procedures for the inactivation of the ND virus in meat

The following times for industry standard temperatures are suitable for the inactivation of ND virus present in *meat*.

	Core temperature (°C)	**Time**
Poultry meat	65.0	39.8 seconds
	70.0	3.6 seconds
	74.0	0.5 second
	80.0	0.03 second

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 10.9.22.

Surveillance: introduction

Articles 10.9.22. to 10.9.26. define the principles and provide a guide on the *surveillance* for ND as defined in Article 10.9.1. 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 occurrence 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*.

Annex XXIV (contd)

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 10.9.23.

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 10.9.24.

Surveillance strategies

1. Introduction

   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 the *surveillance* for 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 should 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 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 10.9.2.) 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 characterisation if required.

Annex XXIV (contd)

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 four 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* should 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* should be in close contact with, but should be identified to be clearly differentiated from, the target population. Sentinel *poultry* should 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 10.9.25.

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 10.9.3.

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 should comply with the provisions of the *Terrestrial Manual*.~~

   In vaccinated populations there is a need to perform *surveillance* to ensure the absence of NDV circulation.The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The *surveillance* should be repeated at least every six 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 10.9.26.

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.

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Annex XXV

CHAPTER 1.6.

PROCEDURES FOR SELF DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE

EU position

The EU supports the adoption of this modified chapter.

Article 1.6.3.

Questionnaire on bovine spongiform encephalopathy

GENERAL INTRODUCTION

Acceptance of this submission is based on the compliance of the *Veterinary Service* of the applicant country~~,~~ or *zone* ~~or *compartment*~~ with the provisions of Chapter 3.1. of the *Terrestrial Code* and the compliance of BSE diagnostic laboratories with the provisions of Chapter 1.1.4. of the *Terrestrial Manual*. Documentary evidence should be provided to support this based on Chapter 3.2. of the *Terrestrial Code*.

Article 11.5.2. of the *Terrestrial Code* Chapter on BSE prescribes the criteria to determine the BSE risk status of the cattle population of a country~~,~~ or *zone* ~~or *compartment*~~. This document is the means whereby a claim for negligible risk (Article 11.5.3.) or controlled risk (Article 11.5.4.) can be made to the OIE.

The document comprises the following:

– Section 1 – Risk assessment (see Section 1 of Article 11.5.2.)

– Section 2 – Other requirements of Sections 2 to 4 of Article 11.5.2.

  – Ongoing awareness programme

  – Compulsory notification and investigation

  – Diagnostic capability

– Section 3 – Surveillance (Article 11.5.2. and Articles 11.5.20. to 11.5.22.)

– Section 4 – BSE history of the country~~,~~ or *zone* ~~or *compartment*~~ (Articles 11.5.3. and 11.5.4.).

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.

SECTION 1: RISK ASSESSMENT (see point 1 of Article 11.5.2.)

Introduction

The first step in determining the BSE risk status of the cattle population of a country~~,~~ or *zone* ~~or *compartment*~~ is to conduct a *risk assessment* (reviewed annually), based on Sections 2 and 3 and Chapter 4.3. of the *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective.

Annex XXV (contd)

Documentation guidelines

This section provides guidance on the data gathering and presentation of information required to support the risk entry ~~release~~ and exposure assessments in respect of:

Entry ~~Release~~ assessment:

1. The potential for the entry ~~release~~ of the BSE agent through importation of *meat-and-bone meal* or *greaves*.

2. The potential for the entry ~~release~~ of the BSE agent through the importation of potentially infected live cattle.

3. The potential for the entry ~~release~~ of the BSE agent through the importation of potentially infected products of bovine origin.

Exposure assessment:

4. The origin of bovine carcasses, by-products and *slaughterhouse* waste, the parameters of the rendering processes and the methods of cattle feed production.

5. 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 entry ~~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~~,~~ or *zone* ~~or *compartment*~~ status claim.

Entry ~~Release~~ assessment

1. The potential for the entry ~~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 eight 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 entry ~~release~~ of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose a higher likelihood of entry ~~release risk~~ than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown entry ~~release~~ risk.

This point is irrelevant if the exposure assessment outlined below in Article 11.5.27. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past eight 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:

a) 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

b) Documentation on annual volume, by country of origin, of *meat-and-bone meal*, *greaves* or feedstuffs containing them imported during the past eight years.

c) Documentation describing the species composition of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.

d) 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.

2. The potential for the entry ~~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 seven years?

Rationale: The likelihood of entry ~~release risk are~~ is dependent on:

- country~~,~~ or *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~~,~~ or *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~~,~~ or *zone* ~~or compartment~~ of origin because feeding practices result in greater exposure of one category;

- age at *slaughter*.

Evidence required:

a) Documentation including tables on the country~~,~~ or *zone* ~~or compartment~~ of origin of imports. This should identify the country~~,~~ or *zone* ~~or compartment~~ of origin of the cattle, the length of time they lived in that country~~,~~ or *zone* ~~or compartment~~ and of any other country in which they have resided during their lifetime.

b) Documentation including tables describing origin and volume of imports.

c) Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country, *zone* or *compartment* of origin.

3. The potential for the entry ~~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 seven years?

Rationale: The likelihood of entry ~~release risk are~~ is dependent on:

- the origin of the cattle products and whether these products contain tissues known to contain BSE infectivity (Article 11.5.13.);

- country~~,~~ or *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~~,~~ or *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~~,~~ or *zone* ~~or compartment~~ of origin because feeding practices result in greater exposure of one category;

- age at *slaughter*.

Annex XXV (contd)

Evidence required:

a) Documentation on the country~~,~~ or *zone* ~~or compartment~~ of origin of imports. This should identify the country~~,~~ or *zone* ~~or compartment~~ of origin of cattle from which the products were derived, the length of time they lived in that country~~,~~ or *zone* ~~or compartment~~ and of any other country in which they have resided during their lifetime.

b) Documentation describing origin and volume of imports.

c) Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country~~,~~ or *zone* ~~or compartment~~ of origin.

Exposure assessment

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 eight years?

Rationale: The overall risk of BSE in the cattle population of a country~~,~~ or *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~~,~~ or *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:

a) Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.

b) Documentation including tables describing the fate of imported cattle, including their age at *slaughter* or death.

c) Documentation describing the definition and disposal of specified risk material, if any.

d) Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.

e) 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.

f) Documentation describing the end use of imported cattle products and the disposal of waste.

g) Documentation describing monitoring and enforcement of the above.

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 eight years (Articles 11.5.3. and 11.5.4. 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 eight 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 eight years following the birth of the youngest *case*.

Evidence required:

a) Documentation describing the use of imported *meat-and-bone meal* and *greaves*, including the feeding of any animal species.

b) Documentation describing the use made of *meat-and-bone meal* and *greaves* produced from domestic cattle, including the feeding of any animal species.

c) 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.

d) 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 effective-ness 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						

e) 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 effective ness 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						

f) 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)	Type of plant (renderer or feed mill)	Plant ID	Nature of infraction	Method of resolution	Follow-up results
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				

g) 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)	Type of plant (renderer or feed mill)	Plant ID	Nature of infraction	Method of resolution	Follow-up results
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				

h) 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.

i) 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 (see points 2 to 4 of Article 11.5.2.)

1. Awareness programme (see point 2 of Article 11.5.2.)

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 programme is essential to ensure detection and reporting of BSE, especially in countries of low prevalence and competing differential diagnoses.

Evidence required:

a) Documentation indicating when the awareness programme was instituted and its continuous application and geographical coverage.

b) Documentation on the number and occupation of persons who have participated in the awareness programme (*veterinarians*, producers, workers at auctions, *slaughterhouses*, etc.).

c) Documentation of materials used in the awareness programme (the manual, supportive documents, or other teaching materials).

d) Documentation on the contingency plan.

2. Compulsory notification and investigation (see point 3 of Article 11.5.2.)

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:

a) Documentation on the date of official publication and implementation of compulsory notification. Including a brief description of incentives and penalties.

b) Documentation on the manual of procedures for investigation of suspect *animals* and follow-up of positive findings.

Annex XXV (contd)

3. Examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system (see point 4 of Article 11.5.2.)

Questions to be answered:

- Are the diagnostic procedures and methods those described in Chapter 2.4.6. of the *Terrestrial 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 *Terrestrial Manual*.

Evidence required:

a) Documentation as to the approved laboratories where samples of cattle tissues from the country~~,~~ or *zone* ~~or *compartment*~~ are examined for BSE. (If this is located outside the country, information should be provided on the cooperation agreement).

b) Documentation of the diagnostic procedures and methods used.

c) Documentation that the diagnostic procedures and methods have been applied through the entire *surveillance* period.

SECTION 3: BSE SURVEILLANCE AND MONITORING SYSTEMS (see point 4 of Article 11.5.2.)

Questions to be answered:

- Does the BSE *surveillance* programme comply with the guidelines in Articles 11.5.20. to 11.5.22. of the *Terrestrial Code*?
- What were the results of the investigations?

Rationale:

Point 4 of Article 11.5.2. and Articles 11.5.20. to 11.5.22. 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:

1. Documentation that the samples collected are representative of the distribution of cattle population in the country~~,~~ or *zone* ~~or *compartment*~~.

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. Documentation of the means and procedures whereby samples were assigned to the cattle subpopulations described in Article 11.5.21., including the specific provisions applied to ensure that *animals* described as clinical met the conditions of point 1 of Article 11.5.21.

4. Documentation of the number of *animals* meeting the conditions in point 1 of Article 11.5.21. as compared to the numbers of clinical samples submitted in previous years in accordance to the former provisions in the *Terrestrial Code*, and explanation of possible differences.

5. Documentation, based on the following table, of all clinically suspect *cases* notified complying with the definition in point 1 of Article 11.5.21.

Laboratory identification number	Age	Clinical signs	Point of detection (farm, market channels, slaughterhouse)

6. Documentation according to the following table, that the number of target points applicable to the country~~,~~ or *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 Articles 11.5.21. and 11.5.22.

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								

7. Indicate the number of adult cattle (over 24 months of age) in the country~~,~~ or *zone* ~~or *compartment*~~.

SECTION 4: BSE HISTORY OF THE COUNTRY~~,~~ OR ZONE ~~OR COMPARTMENT~~ (see Articles 11.5.3. and 11.5.4.)

Questions to be answered:

- Has BSE occurred in the country~~,~~ or *zone* ~~or *compartment*~~?
- How has it been dealt with?

Rationale:

The categorization of a country~~,~~ or *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~~,~~ or *zone* ~~or *compartment*~~. This section provides the opportunity to describe the BSE history in the country~~,~~ or *zone* ~~or *compartment*~~.

Evidence required:

1. Documentation of whether a *case* of BSE has ever been diagnosed in the country~~,~~ or *zone* ~~or *compartment*~~.

   In the case of positive BSE findings:

Annex XXV (contd)

2. Documentation on the origin of each BSE *case* in respect to the country~~,~~ or *zone* ~~or *compartment*~~. Indicate the birth date and place of birth.

3. Indicate the most recent year of birth in relation to all BSE *cases*.

4. Documentation that:

   - the *case(s)* and all the progeny of female *cases*, born within two 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~~,~~ or *zone* ~~or *compartment*~~, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

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— Text deleted.

CHAPTER 11.5.

BOVINE SPONGIFORM ENCEPHALOPATHY

EU position

The EU supports the adoption of this modified chapter.

Article 11.5.1.

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) tallow with maximum level of insoluble impurities of 0.15 percent in weight and derivatives made from this tallow;

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

   g) deboned skeletal muscle meat (excluding mechanically separated meat) 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, and which passed ante- and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.5.14.;

   h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

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

3) When authorising import of *commodities* according to the conditions prescribed in this chapter, the risk status of an *importing country* is not affected by the BSE risk status of the *exporting country*, *zone* or *compartment*.

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

Article 11.5.2.

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:

Annex XXV (contd)

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) Entry ~~Release~~ assessment

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

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

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

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

      iv) imported cattle, sheep and goats;

      v) imported animal feed and feed ingredients;

      vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 11.5.14. and may have been fed to cattle;

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

      The results of *surveillance* and other epidemiological investigations into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

   b) Exposure assessment

      If the entry ~~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 11.5.20. to 11.5.22.;

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 11.5.20. to 11.5.22.

When the *risk assessment* fails to demonstrate negligible risk, the Member should conduct Type A *surveillance* in accordance with Articles 11.5.20. to 11.5.22.

Article 11.5.3.

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 11.5.2., 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 11.5.20. to 11.5.22. 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 11.5.2. have been complied with for at least seven years; and

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

   OR

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

      i) the criteria in points 2 to 4 of Article 11.5.2. have been complied with for at least seven years; and

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

      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.

Annex XXV (contd)

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.

Article 11.5.4.

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 11.5.2., 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 11.5.20. to 11.5.22. 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 11.5.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, 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 11.5.2. have not been complied with for seven 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 eight years;

   OR

   b) there has been an indigenous *case* of BSE, the criteria in points 2 to 4 of Article 11.5.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

      and all BSE *cases*, as well as:

      i) 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

      ii) 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 11.5.5.

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 11.5.6.

Recommendations for the importation of bovine commodities from a country, zone or compartment posing a negligible BSE risk

For all commodities from cattle not listed in point 1 of Article 11.5.1.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 11.5.3.

Article 11.5.7.

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

For cattle selected for export

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 11.5.3.;

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.

Article 11.5.8.

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 11.5.4.;

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 11.5.4.;

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.

Annex XXV (contd)

Article 11.5.9.

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 two 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 11.5.10.

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 11.5.1.)

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 11.5.3.;

2) the cattle from which the *fresh meat* and *meat products* were derived passed ante- 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 11.5.11.

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 11.5.1.)

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 11.5.4.;

2) the cattle from which the *fresh meat* and *meat products* were derived passed ante- 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 11.5.14.,

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

Article 11.5.12.

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 11.5.1.)

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- 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 11.5.14.,

   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 11.5.13.

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 11.5.3., 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.

Annex XXV (contd)

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 11.5.4. and 11.5.5. should not be traded between countries.

Article 11.5.14.

Recommendations on commodities that should not be traded

1) From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 11.5.4. and 11.5.5., 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.

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 11.5.4., 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.

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 11.5.5., 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 11.5.15.

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- and post-mortem inspections; and that

   a) vertebral columns from cattle over 30 months of age at the time of *slaughter* and skulls 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).

Article 11.5.16.

Recommendations for the importation of tallow (other than as defined in Article 11.5.1.) 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- and post-mortem inspections, and has not been prepared using the tissues listed in points 1 and 2 of Article 11.5.14.

Article 11.5.17.

Recommendations for the importation of dicalcium phosphate (other than as defined in Article 11.5.1.) 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 11.5.15.

Article 11.5.18.

Recommendations for the importation of tallow derivatives (other than those made from tallow as defined in Article 11.5.1.) 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 11.5.16.; or

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

Article 11.5.19.

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.

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Article 11.5.20.

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 11.5.2. 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*.

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 11.5.20. to 11.5.22.

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 11.5.21.

Surveillance: description of cattle subpopulations

1. Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)

   Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in *herd* hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle *animals* on a daily basis. Since BSE causes no pathognomonic clinical signs, all 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 11.5.2.), 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 11.5.22.

Surveillance activities

In order to implement efficiently a *surveillance* strategy for BSE, a Member should 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*.

Annex XXV (contd)

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 seven 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 percent;

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 and population size;

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 percent.

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 percent.

Type B *surveillance* may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 11.5.3.) 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 11.5.4.), 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

Annex XXV (contd)

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
1,000,000	238,400	119,200
900,001–1,000,000	214,600	107,300
800,001–900,000	190,700	95,350
700,001–800,000	166,900	83,450
600,001–700,000	143,000	71,500
500,001–600,000	119,200	59,600
400,001–500,000	95,400	47,700
300,001–400,000	71,500	35,750
200,001–300,000	47,700	23,850
100,001–200,000	22,100	11,500
90,001–100,000	19,900	9,950
80,001–90,000	17,700	8,850
70,001–80,000	15,500	7,750
60,001–70,000	13,300	6,650
50,001–60,000	11,000	5,500
40,001–50,000	8,800	4,400
30,001–40,000	6,600	3,300
20,001–30,000	4,400	2,200
10,001–20,000	2,100	1,050
9,001–10,000	1,900	950
8,001–9,000	1,600	800
7,001–8,000	1,400	700
6,001–7,000	1,200	600
5,001–6,000	1,000	500
4,001–5,000	800	400
3,001–4,000	600	300
2,001–3,000	400	200
1,001–2,000	200	100

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.

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 seven consecutive years to achieve the target number of points determined in Table 1.

Table 2. Surveillance point values for samples collected from animals in the given subpopulation and age category.

Surveillance subpopulation			
Routine slaughter[1.]	**Fallen stock[2.]**	**Casualty slaughter[3.]**	**Clinical suspect[4.]**
Age ≥ 1 year and <2 years			
0.01	0.2	0.4	N/A
Age ≥ 2 year and <4 years (young adult)			
0.1	0.2	0.4	260
Age ≥ 4 year and <7 years (middle adult)			
0.2	0.9	1.6	750
Age ≥ 7 year and <9 years (older adult)			
0.1	0.4	0.7	220
Age ≥ 9 years (aged)			
0.0	0.1	0.2	45

Surveillance points remain valid for seven years (the 95th percentile of the incubation period).

Article 11.5.23.

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. Entry ~~Release~~ assessment

Entry ~~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.

Annex XXV (contd)

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; thorough epidemiological investigations of any indigenous *case* born after the date of the implementation of feed bans should be conducted.

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 11.5.24.

The potential for the entry ~~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 11.5.27. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past eight 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 eight 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 likelihood of entry ~~release risk~~ of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose a higher likelihood of entry ~~release risk~~ than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown likelihood of entry ~~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 eight 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 11.5.25.

The potential for the entry ~~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 study.

- *Animals* imported for breeding may pose a greater risk than *animals* imported for *slaughter* because of the hypothetical risk of maternal transmission and because they are kept to a greater age than *animals* imported for *slaughter*.

- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.

- Risk is proportional to volume of imports (Article 2.1.3.).

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

Rationale: The likelihood of entry ~~release risk are~~ is 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*.

Annex XXV (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 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 11.5.26.

The potential for the entry ~~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 2.1.3.).

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

Rationale: The likelihood of entry ~~release risk are~~ is dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 11.5.14.);
- 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*.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of *animals*, the length of time they lived in that country and of any other country in which they have resided during their lifetime.

- Documentation describing origins, species and volume of imports.

- Documentation describing the end use of imported animal products, and the disposal of waste.

- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.5.27.

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 eight years (see Articles 11.5.3. and 11.5.4.)?

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 eight years, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

Article 11.5.28.

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 11.5.19.

- BSE agent is present at much higher titres in central nervous system and reticulo-endothelial tissues (so-called ‘Specified Risk Materials’, or SRM).

Annex XXV (contd)

Question to be answered: How has animal waste been processed over the past eight 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 utilised 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 11.5.29.

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 should have demonstrated that appropriate measures have been taken to manage any risks identified.

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— Text deleted.

1. See point 4) of Article 11.5.21.
2. See point 3) of Article 11.5.21.
3. See point 2) of Article 11.5.21.
4. See point 1) of Article 11.5.21.

Annex XXVI

CHAPTER 11.8.

INFECTION WITH *MYCOPLASMA MYCOIDES* SUBSP. *MYCOIDES* SC (CONTAGIOUS BOVINE PLEUROPNEUMONIA)

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Article 11.8.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for contagious bovine pleuropneumonia (CBPP) shall be six 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 cattle (*Bos indicus*, *B. taurus* and *B. grunniens*) and water buffaloes (*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*.

When authorising import or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 11.8.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the CBPP status of the domestic cattle and water buffalo population of the *exporting country*, *zone* or *compartment*.

Article 11.8.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any CBPP related conditions, regardless of the CBPP status of the domestic cattle and water buffalo population of the *exporting country*, *zone* or *compartment*:

1) *milk* and *milk products*;

2) hides and skins;

3) *meat* and *meat products* (excluding lung).

Annex XXVI (contd)

Article 11.8.3.

CBPP free country~~,~~ or zone ~~or compartment~~

To qualify for inclusion in the existing list of CBPP free countries and *zones*, 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 or *zone* 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 11.8.4.

Recovery of free status

When a CBPP *outbreak* occurs in a CBPP free country~~,~~ or *zone* ~~*or compartment*~~, one of the following waiting periods is required to regain the status of CBPP free country~~,~~ or *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 11.8.3. applies.

Article 11.8.5.

CBPP infected country or zone

When the requirements for acceptance as a CBPP free country or *zone* are not fulfilled, a country or *zone* shall be considered as infected.

Article 11.8.5 bis.

CBPP free compartment

The bilateral recognition of a CBPP free *compartment* should follow the principles laid down in this chapter and in Chapters 4.3. and 4.4.

Article 11.8.6.

Recommendations for importation from CBPP free countries~~,~~ or zones, or from CBPP free 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 six months, and

3) are transported directly to the *slaughterhouse* in sealed *vehicles*.

Article 11.8.8.

Recommendations for importation from CBPP free countries~~,~~ or zones, or from CBPP free compartments

For bovine semen

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) showed no clinical sign of CBPP on the day of collection of the semen;

   b) were kept in a CBPP free country, *zone* or *compartment* since birth or for at least the past six months;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.8.9.

Recommendations for importation from CBPP infected countries ~~or zones~~

For bovine semen

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) showed no clinical sign of CBPP on the day of collection of the semen;

   b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;

   c) were isolated from other domestic bovidae from the day of the first complement fixation test until collection;

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d) were kept since birth, or for the past six months, in an *establishment* where no *case* of CBPP was reported during that period, and that the *establishment* was not situated in a CBPP *infected zone*;

e) AND EITHER:

i) have not been vaccinated against CBPP;

OR

ii) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than four months prior to collection; in this case, the condition laid down in point b) above is not required;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.8.10.

Recommendations for importation from CBPP free countries~~,~~ or zones, or from CBPP free compartments

For *in vivo* derived or *in vitro* produced embryos~~/~~or oocytes of bovidae

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

a) showed no clinical sign of CBPP on the day of collection of the embryos~~/~~or oocytes;

b) were kept in a CBPP free country, *zone* or *compartment* since birth or for at least the past six months;

2) the oocytes were fertilised with semen meeting the conditions of Article 11.8.8.;

3) the embryos~~/~~or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.8.11.

Recommendations for importation from CBPP infected countries ~~or zones~~

For *in vivo* derived or *in vitro* produced embryos~~/~~or oocytes of bovidae

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

a) showed no clinical sign of CBPP on the day of collection of the embryos~~/~~or oocytes;

b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;

c) were isolated from other domestic bovidae from the day of the first complement fixation test until collection;

d) were kept since birth, or for the past six months, in an *establishment* where no *case* of CBPP was reported during that period, and that the *establishment* was not situated in a CBPP *infected zone*;

e) AND EITHER:

i) have not been vaccinated against CBPP;

OR

ii) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than four months prior to collection; in this case, the condition laid down in point b) above is not required;

2) the oocytes were fertilised with semen meeting the conditions of Article 11.8.9.;

3) the embryos~~/~~or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.8.12.

Surveillance: introduction

Articles 11.8.12. to 11.8.~~17~~16. define the principles and provide a guide for the *surveillance* of CBPP in accordance with Chapter 1.4. applicable to Members seeking establishment of freedom from CBPP. Guidance is provided for Members seeking reestablishment of freedom from CBPP for the entire country or for a *zone* ~~or~~ ~~*compartment*~~, following an *outbreak* and for the maintenance of CBPP free status.

The impact and epidemiology of CBPP differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *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*.

Article 11.8.13.

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 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 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 *infected 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 11.8.14.

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 or *zone* ~~or *compartment*~~.

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 should 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.

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 should 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 11.8.15.

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 11.8.16.~~

~~**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.~~

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Article 11.8.~~17.~~16.

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 11.8.4.

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— Text deleted.

Annex XXVII

CHAPTER 12.1.

INFECTION WITH AFRICAN HORSE SICKNESS VIRUS

EU position

The EU in general supports the adoption of this modified chapter. However, an important comment is inserted in the text below for consideration by the Code Commission at its next meeting.

Article 12.1.1.

General provisions

For the purposes of the *Terrestrial Code*, African horse sickness (AHS) is defined as an *infection* of equids with African horse sickness virus (AHSV).

The following defines an *infection* with AHSV:

1) AHSV has been isolated and identified from an equid or a product derived from that equid; or

2) viral antigen or viral RNA specific to a serotype of AHSV has been identified in samples from an equid showing clinical signs consistent with AHS, or epidemiologically linked to a suspected or confirmed *case*; or

3) serological evidence of active *infection* with AHSV by detection of seroconversion with production of antibodies against structural or nonstructural proteins of AHSV that are not a consequence of *vaccination* have been identified in an equid that either shows clinical signs consistent with AHS, or is epidemiologically linked to a suspected or confirmed *case*.

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* adjacent to 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 Article 12.1.~~13~~11. to 12.1.~~15~~13.

~~The following defines a case of African horse sickness (AHS):~~

~~1) AHSV has been isolated and identified 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 suspected or confirmed *case*; 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 suspected or confirmed *case*.~~

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 equids and their semen, 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 two years and is not adjacent to an infected country or *zone*; or

   c) a *surveillance* programme has demonstrated no evidence of AHSV in the country or *zone* for at least twenty-four months; or

   d) the country or *zone* has not reported any *case* of AHS for at least 40 days and a *surveillance* programme has demonstrated no evidence of *Culicoides* for at least two years in the country or *zone*.

2) An AHS free country or *zone* adjacent to an infected country or *infected zone* should include a *zone* in which *surveillance* is conducted in accordance with Articles 12.1.~~13~~11. to 12.1.~~15~~13. *Animals* within this *zone* should be subjected to continuing *surveillance*. The boundaries of this *zone* should be clearly defined, and should take account of geographical and epidemiological factors that are relevant to AHS transmission.

3) An AHSV free country or *zone* will not lose its free status through the importation of vaccinated or seropositive equids and their semen, oocytes or embryos from infected countries or *infected zones*, provided these imports are carried out in accordance with this chapter.

4) To qualify for inclusion in the list of AHSV free countries or *zones*, a Member should:

   a) have a record of regular and prompt animal disease reporting;

   b) send a declaration to the OIE stating:

      i) the section under paragraph 1 on which the application is based;

      ii) no routine *vaccination* against AHS has been carried out during the past twelve months in the country or *zone*;

      iii) equids are imported in accordance with this chapter;

   c) supply documented evidence that:

      i) *surveillance* in accordance with Articles 12.1.~~13~~11. to 12.1.~~15~~13. is applied;

      ii) regulatory measures for the early detection, prevention and control of AHS have been implemented.

5) 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 4b)ii) and iii) and 4c) ii) above be re-submitted annually and changes in the epidemiological situation or other significant events be reported to the OIE according to the requirements in Chapter 1.1., and in particular, formally state that :

   a) there has been no *outbreak* of AHS during the past twelve months in the country or *zone*;

   b) no evidence of AHSV infection has been found during the past twelve months in the country or *zone*.

EU comment

There seems to be an inconsistency between points 2 and 5 of the Article above which should be examined by the OIE. Indeed, according to point 5, retention on the list requires that inter alia the information in points 4b)ii) and iii) and 4c) ii) above be re-submitted annually. No mention is made here of point 4c) i) (surveillance). On the other hand, point 2 stipulates that an AHS free country or zone, which would e.g. include countries recognised as historically free according to point 1 a) that are in a region of the world where AHS has never occurred and where such occurrence would be highly

unlikely due to e.g. climatic conditions, but which are adjacent to an infected country or zone, or a country or zone with unknown status, considered as infected in accordance with the current Article 12.1.4., should include a zone in which surveillance is conducted. This possible inconsistency was noted while reading the form for the annual reconfirmation of the African Horse Sickness free status of OIE Member Countries proposed by the *ad hoc* group on AHS in its report, which is attached to the report of the Scientific Commission, and more specifically questions 8 and 9 in the form which, if answered with yes, would lead to the obligation of submitting surveillance data – which would not be consistent with point 5 of Article 12.1.2. The EU is of the opinion that such surveillance in free countries for reasons of annual reconfirmation should only be necessary under certain conditions (e.g. reported or suspected outbreaks in adjacent country, or specific risk factors justifying surveillance), and not systematically. Indeed, the OIE Headquarters had already confirmed in writing to an individual Member Country in Central Europe that in case of unknown AHS status in a neighbouring country or zone, such surveillance would not be necessary in order to retain historical free status. Therefore, the EU strongly encourages the OIE to review this Article, taking into account the above, and to revise the proposed form for the annual reconfirmation of free status accordingly.

~~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* in which for part of a year, ongoing *surveillance* and monitoring consistently demonstrated neither evidence of AHSV transmission nor the evidence of the presence of adult *Culicoides*.~~

~~2. AHS is notifiable in the whole country.~~

~~3. For the application of Articles 12.1.8., 12.1.10. and 12.1.11., 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* 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 vectors*.~~

~~4.~~ ~~An AHSV seasonally free *zone* will not lose its free status through the importation of vaccinated or seropositive equids 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~~3.

AHSV infected country or zone

For the purpose of this chapter, an AHSV infected country or *zone* is one that does not fulfil the requirements to qualify as either AHSV free country or *zone* ~~or AHSV seasonally free *zone*~~.

Article 12.1.~~5~~4.

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

In the event of limited *outbreaks* within an AHS free country or *zone*, including within a *protection zone*, a single *containment zone*, which includes all *cases*~~, and should be large enough to contain any potentially infected~~

~~vectors,~~ can be established for the purpose of minimising the impact on the entire country or *zone*. For this to be achieved, the *Veterinary Authority* should provide documented evidence that:

1) the *outbreaks* are limited based on the following factors:

   a) immediately on suspicion, a rapid response including notification has been made;

   b) standstill of movements of equids has been imposed, and effective controls on the movement of equids and their products specified 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;~~ investigations on the likely source of the *outbreak* have been carried out;

   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 *infective periods* as defined in Article 12.1.1.;

2) the equids within the *containment zone* should be clearly identifiable as belonging to the *containment zone*;

3) increased passive and targeted *surveillance* in accordance with Articles 12.1.~~13~~11. to 12.1.~~15~~13. in the rest of the country or *zone* has not detected any evidence of *infection*;

4) animal health measures that effectively prevent the spread of AHS to the rest of the country or *zone*, taking into consideration the establishment of a *protection zone* within the *containment zone*, the seasonal vector conditions and existing physical, geographical and ecological barriers;

5) ongoing *surveillance* in accordance with Articles 12.1.~~13~~11. to 12.1.~~15~~13. is in place in the *containment zone*.

The free status of the areas outside the *containment zone* is suspended ~~pending the establishment of~~ while the *containment zone* is being established in accordance with points 1 to 5 above. The free status of the areas outside the *containment zone* ~~could~~ may be reinstated irrespective of the provisions of Article 12.1.~~6~~5., once the *containment zone* is recognised by the OIE.

In the event of the recurrence of AHSV in the *containment zone*, the approval of the *containment zone* is withdrawn.

The recovery of the AHS free status of the *containment zone* should follow the provisions of Article 12.1.~~6~~5.

Article 12.1.~~6~~5.

Recovery of free status

When an AHS *outbreak* occurs in an AHS free country or *zone*, to regain the free status, the provisions of Article 12.1.2. apply, irrespective of whether emergency *vaccination* has been applied.

Article 12.1.~~7~~6.

Recommendations for importation from AHSV free countries or zones

For equids

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(ies) or *zone(s)* since birth or for at least 40 days prior to shipment;

4) either:

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

b) were protected from attacks from *Culicoides* at all times when transiting through an *infected zone*.

~~Article 12.1.8.~~

~~**Recommendations for importation from AHSV seasonally free zones during the seasonally free period**~~

~~For equids~~

~~*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) and either~~

~~a) were kept in an AHSV seasonally free *zone* during the seasonally free period since birth or for at least 40 days prior to shipment; or~~

~~b) were held in isolation in a *vector*-protected *establishment* prior to shipment~~

~~i) for a period of at least 28 days and 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 *vector* protected *establishment*; or~~

~~ii) for a period of at least 40 days and 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 seven days after introduction into the *vector* protected *establishment*; or~~

~~iii) for a period of at least 14 days and an agent identification tests according to the *Terrestrial Manual* was carried out with a negative results on a blood samples collected not less than 14 days after introduction into the *vector* protected *establishment*;~~

~~4) were protected from attacks from *Culicoides* at all times when transiting through an *infected zone*.~~

Article 12.1.~~9~~7.

Recommendations for importation from AHSV infected countries or zones

For equids

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 in isolation in a *vector*-protected *establishment*

a) for a period of at least 28 days and 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 *vector*-protected *establishment*; or

b) for a period of at least 40 days and 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 seven days after introduction into the *vector*-protected *establishment*; or

c) for a period of at least 14 days and an agent identification test~~s~~ ~~according to the *Terrestrial Manual*~~ was carried out with a negative result~~s~~ on a blood sample~~s~~ collected not less than 14 days after introduction into the *vector*-protected *establishment*; or

d) for a period of at least 40 days and were vaccinated, at least 40 days before shipment, ~~in accordance with the *Terrestrial Manual*~~ against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 12.1.~~14~~12. and 12.1.~~15~~13, and were identified in the accompanying certification as having been vaccinated;

4) were protected from attacks by *Culicoides* at all times during transportation (including transportation to and at the *place of shipment*).

Article 12.1.~~10~~8.

Recommendations for the importation of equine 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 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-protected *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 seven days, during semen collection for this consignment.

Article 12.1.~~11~~9.

Recommendations for the importation of *in vivo* derived equine embryos or 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 or oocytes and for the following 40 days;

b) had not been 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 or oocytes, or

ii) kept in an AHSV free vector-protected *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 or 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 seven days during embryos or oocytes collection for this consignment;

2) the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7. or Chapter 4.9., as relevant;

3) semen used to fertilize the oocytes, complies at least with the requirements in Article 12.1.~~10~~8.

Article 12.1.~~12~~10.

Protecting animals from *Culicoides* attack

1. Vector-protected establishment or facility

The *establishment* or facility should be approved by the Veterinary Authority and the means of protection should at least comprise the following;

a) Appropriate physical barriers at entry and exit points, for example double-door entry-exit system;

b) openings of the building are *vector* screened with mesh of appropriate gauge impregnated regularly with an approved insecticide according to manufacturers' instruction;

c) *vector surveillance* and control within and around the building;

d) measures to limit breeding sites for *vectors* in vicinity of the *establishment* or facility;

e) Standard Operating Procedure, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of horses to the place of *loading*.

2. During transportation

When transporting equids 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*.

a) Transport by road:

Potential *risk management* strategies include a combination of:

i) treating animals with chemical repellents prior to and during transportation, in sanitized *vehicles* treated with appropriate residual contact insecticide;

ii) *loading*, transporting and *unloading* animals at times of low *vector* activity (i.e. bright sunshine and low temperature);

iii) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;

iv) darkening the interior of the *vehicle*, for example by covering the roof or sides of *vehicles* with shade cloth;

v) monitoring for *vectors* at common stopping and offloading points to gain information on seasonal variations;

vi) using historical, ongoing or AHS modelling information to identify low risk ports and transport routes.

b) Transport by air:

Prior to *loading* the equids, the crates, *containers* or jetstalls are sprayed with an insecticide approved in the country of dispatch.

Crates, *containers* or jet stalls in which equids are being transported and the cargo hold of the aircraft must be sprayed with an approved insecticide just after the doors to the aircraft are closed and prior to takeoff, or immediately prior to the closing of the aircraft doors after loading.

In addition, during any stopover in countries or *zones* not free of AHS, prior to, or immediately after the opening of any aircraft door and until all doors are closed, netting of appropriate gauge impregnated with an approved insecticide must be placed over all crates, *containers* or jetstalls.

Article 12.1.~~13~~11.

Surveillance: introduction

Articles 12.1.~~13~~11. to 12.1.~~15~~13. define the principles and provide guidance on *surveillance* for AHS, complementary to Chapter 1.4. and, for *vectors*, complementary to Chapter 1.5.

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 *captive wild, feral and wild* equine 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.

Article 12.1.~~14~~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 or *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.

Article 12.1.~~15~~13.

Surveillance strategies

The target population for *surveillance* aimed at identification of *disease* 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* or *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* or *infection* are technically well defined. *Surveillance* programmes to prove the absence of AHSV infection or 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 equine 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* 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 a hundred 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 *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 characterise 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 equine 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.

Vector surveillance is aimed at demonstrating the absence of vectors or defining 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, or to confirm continued absence of vectors.

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

Vector surveillance should be based on scientific sampling techniques. The choice of the number and types of traps to be used in *vector surveillance* and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

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

The use of a *vector surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low *vector infection* rates mean that such detections can be rare. Other *surveillance* strategies are preferred to detect virus circulation.

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— Text deleted

Annex XXVIII

CHAPTER 12.9.

INFECTION WITH EQUINE ARTERITIS VIRUS

EU position

The EU in general supports the adoption of this modified chapter. Comments are inserted in the text below.

Article 12.9.1.

General provisions

For the purposes of the *Terrestrial Code*, equine viral arteritis (EVA) is defined as an *infection* of domestic equids with equine arteritis virus (EAV).

This chapter deals not only with the occurrence of clinical signs caused by EAV, but also with the presence of *infection* with EAV in the absence of clinical signs. For the purposes of this chapter, isolation is defined as the separation of domestic equids from those of a different EVA health status, utilising appropriate biosecurity measures, with the objective of preventing the transmission of *infection*.

The *infective period* for EVA shall be 28 days for all categories of equids 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 12.9.2.

Recommendations for the importation of uncastrated male equids

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 during the 28 days prior to shipment and met one of the following requirements:

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 on a single blood sample collected during the 21 days prior to shipment with negative result; or

2) were subjected between six and nine months of age to a test for EVA~~, as prescribed in the *Terrestrial Manual*~~:

   EITHER:

   a) with a negative result,

   OR

   b) with a positive result, followed at least 14 days later by a second test showing a stable or decreasing titre;

   and were immediately vaccinated against EVA and regularly revaccinated according to the recommendations of the manufacturer; or

3) met the following requirements:

   a) were isolated; and

b) not earlier than seven days of commencing isolation were subjected to a test for EVA ~~as prescribed in the *Terrestrial Manual*~~ on a blood sample with negative results; and

c) were then immediately vaccinated; and

d) were kept separated from other equids for 21 days following *vaccination*; and

e) were revaccinated regularly according to the recommendations of the manufacturer; or

4) 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 six 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 six months prior to shipment; or

c) were subjected to a test for equine arteritis virus ~~as prescribed in the *Terrestrial Manual*~~ with negative results, carried out on semen collected within six months after the blood sample was tested, then immediately vaccinated, and revaccinated regularly in accordance with the recommendations of the manufacturer.

Article 12.9.3.

Recommendations for the importation of equids other than uncastrated males

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

EITHER

1) were kept in an *establishment* where no *animals* have shown any signs of EVA for the 28 days prior to shipment; and

a) were subjected to a test for EVA~~, as prescribed in the *Terrestrial Manual*,~~ carried out on blood samples collected either once within 21 days prior to shipment with negative result, or on two occasions at least 14 days apart within 28 days prior to shipment, which demonstrated stable or declining antibody titres; or

b) were regularly vaccinated according to the recommendations of the manufacturer;

OR

2) were isolated for the 28 days prior to shipment and during this period the *animals* showed no sign of EVA.

Article 12.9.4.

Recommendations for the importation of equine semen

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the donors were kept for the 28 days prior to semen collection in an *establishment* where no equid has shown any clinical sign of EVA during that period and showed no clinical sign of EVA on the day of semen collection; and

1) were subjected between six and nine months of age to a test for EVA~~, as prescribed in the *Terrestrial Manual*~~:

Either:

a) with a negative result,

OR

b) with a positive result, followed at least 14 days later by a second test showing a stable or decreasing titre;

and were immediately vaccinated for EVA and regularly revaccinated according to the recommendations of the manufacturer; or

2) were isolated and not earlier than seven days of commencing isolation 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 equids and regularly revaccinated according to the recommendations of the manufacturer; or

3) 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 equids not of an equivalent EVA status for 14 days prior to blood sampling until the end of semen collection; or

4) 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 six 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 six months prior to collection of the semen to be exported; or

c) were subjected to a test for equine arteritis virus ~~as prescribed in the *Terrestrial Manual*~~ with negative results, carried out on semen collected within six months after the blood sample was collected, then immediately vaccinated, and revaccinated regularly; or

5) for frozen semen, were 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 or on an aliquot of semen collected within 14 to 30 days after the first collection of the semen to be exported.

Article 12.9.5.

Recommendations for the importation of equine embryos

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the donor *animals* showed no clinical sign of EVA on the day of embryo collection; and

EITHER

1) were kept in an *establishment* where no *animals* have shown any signs of EVA for the 28 days prior to collection; and

a) were subjected to a test for EVA carried out on blood samples collected either once within 21 days prior to collection with negative result, or on two occasions at least 14 days apart within 28 days prior to collection, which demonstrated stable or declining antibody titres; or

b) were regularly vaccinated according to the recommendations of the manufacturer;

OR

2) were isolated for the 28 days prior to collection and during this period the *animals* showed no sign of EVA.

EU comments
The EU can in general support this new article. However, it is unclear whether these recommendations pertain only to *in vivo* derived embryos, or also to *in vitro* produced embryos. The EU would prefer the recommendations be applicable to both, even if it is true that *in vitro* production of embryos is not common practice in horses. Furthermore, it is noted that the requirements as to donor animals seem to target only the mare, while no requirements are foreseen for the stallion or the semen used to conceive the embryos. The EU would therefore suggest adding a requirement at the end of the article above, as follows:
"and that
EITHER
1) the stallion used to conceive the embryos meets the requirements of Article 12.9.2.;
OR
2) the fertilisation was achieved with semen meeting the requirements of Article 12.9.3."

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Annex XXIX

CHAPTER 14.5.

INFECTION WITH *CHLAMYDOPHILA ABORTUS* ~~INFECTION~~ (ENZOOTIC ABORTION OF EWES, OVINE CHLAMYDIOSIS)

EU position

The EU supports the adoption of this modified chapter.

Article 14.5.1.

General provisions

For the purposes of the *Terrestrial Code*, enzootic abortion of ewes (EAE), also known as ovine chlamydiosis or ovine enzootic abortion, is an *infection* of domestic sheep and goats by the bacterium *Chlamydophila abortus*.

Susceptible *animals* become infected through ingestion of infectious materials. In lambs and non-pregnant ewes, the *infection* remains latent until conception. Ewes exposed to *infection* late in pregnancy may not exhibit signs of *infection* until the subsequent pregnancy. Countries should take account of these risk factors.

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

Article 14.5.2.

Recommendations for the importation of sheep ~~and/~~or goats for breeding

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) have remained since birth, or for the previous two years, in *establishments* where no EAE has been diagnosed during the past two years;

2) showed no clinical sign of EAE on the day of shipment;

3) were subjected to a diagnostic test for EAE with negative results within the 30 days prior to shipment.

Article 14.5.3.

Sheep flocks ~~and/~~or goat herds free from EAE infection

To qualify as free from EAE *infection*, a sheep *flock* or goat *herd* shall satisfy the following requirements:

1) it is under official veterinary *surveillance*;

2) all sheep and goats showed no clinical evidence of EAE *infection* during the past two years;

3) a statistically valid number of sheep and goats over six months of age were subjected to a diagnostic test for EAE with negative results within the past six months;

4) all sheep or goats are permanently identified;

5) no sheep or goat has been added to the *flock* or *herd* since 30 days prior to the *flock* or *herd* test referred to in point 3 above unless:

a) either the additions were isolated from other members of the *flock* or *herd* in the *establishment* of origin for a minimum period of 30 days and then were subjected to a diagnostic test for EAE with negative results, before entry into the new *flock* or *herd*; or

b) they originated from an *establishment* of equal health status.

Annex XXIX (contd)

Article 14.5.4.

Recommendations for the importation of semen of sheep or goats

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that

~~1.~~ the donor *animals* showed no clinical signs on the day of semen collection; and:

1~~a)~~ have been kept in *establishments* or *artificial insemination centres* free from EAE according to Article 14.5.3. ~~during~~ for the ~~past~~ two years prior to collection, and have not been in contact with *animals* of a lower health status; or

2~~b)~~ have remained since birth, or for the ~~previous~~ two years prior to collection, in *establishments* where no EAE has been diagnosed ~~during the past two years~~ and were subjected to a diagnostic test for EAE with negative results two to three weeks after collection of the semen~~;~~.

~~2. an aliquot of the semen to be exported was shown to be free of *Chlamydophila abortus*.~~

Article 14.5.5.

Recommendations for the importation of embryos of sheep or goats

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the donor *animals* showed no clinical signs on the day of ~~embryo~~ collection and:

1) have been kept in *establishments* free from EAE according to Article 14.5.3. ~~during~~ for the ~~past~~ two years prior to collection and have not been in contact with *animals* of a lower health status; or

2) have remained since birth, or for the ~~previous~~ two years prior to collection, in *establishments* where no EAE has been diagnosed ~~during the past two years~~ and were subjected to a diagnostic test for EAE with negative results two to three weeks after collection ~~of the embryos~~.

The embryos should be collected, processed and stored in accordance with Chapter 4.7.

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— Text deleted.

Annex XXX

CHAPTER 14.8.

INFECTION WITH PESTE DES PETITS RUMINANTS VIRUS

EU position

The EU cannot support the adoption of this modified chapter, unless its important comments inserted in the text below are taken into account.

Furthermore, while in principle supporting the addition of this disease to the list of diseases for which the OIE officially recognises the disease status of Member Countries, the EU acknowledges and wishes to emphasise the significant increase in workload this represents for the OIE Headquarters and the Scientific Commission for the years to come. Therefore, the EU will be very interested in the implementation of the official status recognition procedure for the newly added diseases, which should be consolidated successfully before the addition of further diseases can be considered in the future.

Article 14.8.1.

General provisions

~~For the purposes of the *Terrestrial Code*, the *incubation period* for the peste des petits ruminants (PPR) shall be 21 days.~~

~~For the purpose of this chapter,~~ Peste des petits ruminants (PPR) susceptible *animals* are primarily domestic sheep and goats although ~~but also include~~ cattle, camels, buffaloes and some *wild* ruminant species can also be infected and may act as sentinels indicating the spill over of peste des petits ruminants virus (PPRV) from domestic small ruminants. Even if some wild small ruminants can be infective, only domestic sheep and goats play a significant epidemiological role.

For the purpose of the *Terrestrial Code*, PPR is defined as an *infection* of domestic sheep and goats with PPRV.

~~A case is an *animal* infected with peste des petits ruminants virus (PPRV).~~

This chapter deals not only with the occurrence of clinical signs caused by PPRV, but also with the presence of *infection* with PPRV in the absence of clinical signs.

The following defines the occurrence of PPRV *infection*:

a) PPRV, excluding vaccine strains, has been isolated and identified as such from a domestic sheep or goat ~~an *animal*~~ or a product derived from it ~~that *animal*~~; or

b) viral antigen or viral ribonucleic acid (RNA) specific to PPRV, excluding vaccine strains, has been identified in samples from a domestic sheep or goat ~~one or more *animals*~~ showing ~~one or more~~ clinical signs consistent with PPR, or epidemiologically linked to an *outbreak* of PPR, or giving cause for suspicion of association or contact with PPR; or

c) antibodies to PPRV antigens which are not the consequence of *vaccination*, have been identified in a domestic sheep or goat ~~one or more *animals*~~ with either epidemiological links to a confirmed or suspected *outbreak* of PPR ~~in susceptible *animals*~~, or showing clinical signs consistent with recent *infection* of PPRV.

A Member Country should not impose bans on the trade in domestic sheep and goat *commodities* in response to information on the presence of PPRV in other ruminants, provided that Article 14.8.3. is implemented.

EU comment

The EU does not agree with the provision above, which should be deleted. Indeed, as is stated in the first paragraph of Article 14.8.1., species other than domestic small ruminants can be infected with PPRV and may act as sentinels indicating spill over of PPRV from domestic small ruminants. In addition, according to said paragraph, only domestic sheep and goats play a significant epidemiological role. Furthermore, outbreaks of PPR in species other than domestic ruminants appear to be exceptional cases, which do not play a significant role in maintaining PPR infection. Therefore, presence of PPRV in other ruminants should be regarded as an indication of probable occurrence in domestic ruminants and should lead to epidemiological investigations and enhanced control measures.

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

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

Article 14.8.2.

Safe commodities

When authorising import or transit through their territory of the following *commodities*, *Veterinary Authorities* should not require any PPR related conditions regardless of PPR status of the *exporting country* or *zone*:

1) semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather, e.g. wet blue and crust leather), which have been submitted to the usual chemical and mechanical processes in use in the tanning industry;

2) *meat* and *meat products* from *animals* that have passed ante- and post-mortem inspections.

EU comment

The EU cannot accept the inclusion of meat and meat products of domestic sheep and goats that have passed ante- and post-mortem inspections in the list of safe commodities. Thus, point 2 above should be deleted.

Indeed, specifying that the meat should be derived from animals that have passed ante- and post-mortem inspection is in contradiction with the concept of safe commodities, as ante- and post-mortem inspection is a risk mitigating measure, without which the commodity itself would not be regarded as safe. The current articles of this chapter relating to recommendations for trade in meat and meat products (14.8.16. to 14.8.18.) precisely require that the meat *inter alia* be derived from animals that have passed ante- and post-mortem inspection. In addition, this would need to be certified by the Veterinary Authorities. Therefore, these articles should not be deleted.

Furthermore, PPRV – like rinderpest virus – is known to remain infective for many days in chilled meat of infected animals. Therefore, specific trade recommendations for import of meat and meat products from countries not free of PPR are justified and necessary.

Reference is made to the respective recommendations in the chapter on rinderpest, and to the previous EU comments on PPR of December 2012, available online at http://ec.europa.eu/food/international/organisations/docs/eu_comments_tahsc_sept2011_en.pdf .

Article 14.8.3.

PPR free country or zone

1) The PPR status of a country or *zone* can only be determined after considering the following criteria ~~in domestic ruminants~~, as applicable:

a) PPR should be notifiable in the whole territory, and all clinical signs suggestive of PPR should be subjected to appropriate field ~~and/~~or *laboratory* investigations;

b) an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of PPR;

EU comment

The EU suggests adding the following points, in line with requirements in point 2 below, and in analogy with another chapter in the code (African Horse Sickness):

"b bis) systematic vaccination against PPR is prohibited, and importation of domestic ruminants and their semen, oocytes or embryos are carried out in accordance with this chapter;"

c) the *Veterinary Authority* should have current knowledge of, and authority over, all domestic ~~ruminants~~ sheep and goats in the country or *zone*;

d) ~~for domestic ruminants~~ appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs, is in place; this may be achieved through a *surveillance* programme in accordance with ~~Chapter 1.4~~ Articles 14.8.25. to 14.8.31.

~~A country or *zone* may be considered free from PPR when it has been shown that PPR has not been present for at least the past three years.~~

2) To qualify for inclusion in the list of PPR free countries or *zones*, a Member Country should either:

a) declare historical freedom as described in Article 1.4.6.1.; or

b) submit to the OIE:

i) a record of regular and prompt animal disease reporting;

ii) a declaration stating that:

– there has been no *outbreak* of PPR during the past 24 months;

– no evidence of PPRV *infection* has been found during the past 24 months;

– no *vaccination* against PPR has been carried out during the past 24 months;

iii) supply documented evidence that *surveillance* in accordance with Chapter 1.4. is in operation and that regulatory measures for the prevention and control of PPR have been implemented;

iv) evidence that no *animals* vaccinated against PPR have been imported since the cessation of *vaccination*.

The Member Country will be included in the list only after the submitted evidence has been accepted by the OIE. Changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1. Retention on the list requires that the information in points b)i) to b)iv) above be re-submitted annually.

EU comment

In the paragraph above, the EU suggests inserting the words "the declaration of historical freedom or" before "the submitted evidence has been accepted by the OIE". Indeed, historical freedom status should not result from Member Country self-declaration, but be assessed by OIE, in a similar way as was recently done for African

Horse Sickness. In addition, the mechanism for retention on the list for Member Countries having historical freedom status should be stated as well.

Article 14.8.4.

PPR free compartment

A PPR free *compartment* can be established in either a PPR free country or *zone* or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.3. and 4.4. should be followed. Domestic sheep and goats in the PPR free *compartment* should be separated from any other susceptible *animals* by the application of an effective biosecurity management system.

A Member Country wishing to establish a PPR free *compartment* should:

1) have a record of regular and prompt animal *disease* reporting and if not PPR free, have an *official control programme* and a *surveillance* system for PPR in place according to Articles 14.8.25. to 14.8.31. that allows an accurate knowledge of the prevalence of PPR in the country or *zone*;

2) declare for the PPR free *compartment* that:

   a) there has been no *outbreak* of PPR during the past 24 months;

   b) no evidence of PPRV *infection* has been found during the past 24 months;

   c) *vaccination* against PPR is prohibited;

   d) no small ruminant in the *compartment* has been vaccinated against PPR within the past 24 months;

   e) *animals*, semen and embryos should only enter the *compartment* in accordance with relevant articles in this chapter;

   f) documented evidence shows that *surveillance* in accordance with Articles 14.8.25. to 14.8.31. is in place;

   g) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;

3) describe in detail the animal subpopulation in the *compartment* and the biosecurity plan for PPRV *infection*.

The *compartment* should be approved by the *Veterinary Authority*.

Article 14.8.5.

Infected country or *zone*

A country or *zone* shall be considered as PPR infected when the requirements for acceptance as a PPR free country or *zone* are not fulfilled.

Article 14.8.6.

Establishment of a containment zone within a PPR free country or zone

In the event of limited *outbreaks* within an PPR free country or *zone*, including within a *protection zone*, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimising the impact on the entire country or *zone*.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE that:

1) the *outbreaks* are 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* has been identified, and investigations on the likely source of the *outbreak* have been carried out;

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 14.8.1. 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* is clearly identifiable as belonging to the *containment zone*;

4) increased passive and targeted *surveillance* in accordance with Articles 14.8.25. to 14.8.31. in the rest of the country or *zone* has not detected any evidence of *infection*;

5) animal health measures that effectively prevent the spread of the PPRV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place;

6) ongoing *surveillance* is in place in the *containment zone*.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of these areas may be reinstated irrespective of the provisions of Article 14.8.7., once the *containment zone* is clearly established, by complying with points 1 to 6 above. It should be demonstrated that *commodities* for *international trade* have originated outside the *containment zone*.

The recovery of the PPR free status of the *containment zone* should follow the provisions of Article 14.8.7.

Article 14.8.~~4~~7.

Recovery of free status

When a PPR *outbreak* or PPRV *infection* occurs in a PPR free ~~In a newly infected~~ country or *zone* and when a *stamping-out policy* is practised with or without *vaccination*, the recovery period shall be six months after the *slaughter* of the last affected *animal* provided that Article 14.8.30. has been complied with. ~~for countries in which a *stamping-out policy* is practised with or without *vaccination* against PPR~~.

EU comment

In the paragraph above, the EU suggests deleting the words "with or without *vaccination*". Indeed, there is no mention of emergency vaccination policy in Article 14.8.6., and vaccination could mask on-going virus circulation. In addition, vaccination would not be in line with the requirements of Article 14.8.3. which requires that no vaccination against PPR has been carried for the past 2 years.

Furthermore, the words "affected *animal*" should be replaced by "*case*", for reasons of clarity.

If *stamping-out* is not applied, the provisions of Article 14.8.3. apply.

Article 14.8.~~5~~8.

Recommendations for importation from PPR free countries or zones

For domestic sheep and goats ~~small ruminants, cattle, camels and buffaloes~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

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

2) were kept in a PPR free country or *zone* since birth or for at least the past 21 days.

Article 14.8.~~6~~9.

Recommendations for importation from PPR free countries or zones

For wild ruminants

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals:*

1) showed no clinical sign suggestive of PPR *infection* on the day of shipment;

2) come from a PPR free country or *zone*;

3) if the country or *zone* of origin has a common border with a country considered infected with PPR:

   ~~a)~~ ~~have been~~ were captured at a distance from the border that precludes any contact with *animals* in an infected country, the distance should be defined according to the biology of the species exported, including home range and long distance movements;

   OR

   b) were kept in a *quarantine station* for at least the 21 days prior to shipment.

Article 14.8.~~7~~10.

Recommendations for importation from countries or zones considered infected with PPR

For domestic sheep and goats ~~small ruminants~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) showed no clinical sign suggestive of PPR *infection* for at least the 21 days prior to shipment;

2) were kept since birth, or for at least the ~~past~~ 21 days prior to shipment, in an *establishment* where no *case* of PPR was reported during that period, and that the *establishment* was not situated in a PPR *infected zone*; ~~and/~~or

3) were kept in a *quarantine station* for at least the 21 days prior to shipment;

EU comment

For clarity reasons, the EU suggests merging points 2) and 3) above into a single point, then separating the two sentences clearly with an "or" in capital letters, as done in point 4) below.

4) ~~have~~ were not ~~been~~ vaccinated against PPR and were submitted to a diagnostic test for PPR *infection* with negative result ~~at least~~ no more than 21 days prior to shipment;

   OR

   were vaccinated against PPR with live attenuated PPRV vaccine ~~not less than~~ at least 21 days prior to shipment. ~~and attested by the presence of antibodies anti PPRV~~.

~~Article 14.8.8.~~

~~**Recommendations for importation from countries or zones considered infected with PPR**~~

~~For cattle, camels and buffaloes~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *animals*:~~

~~1) showed no clinical sign suggestive of PPR *infection* at least 21 days prior to shipment;~~

~~2) were kept in a *quarantine station* for the 21 days prior to shipment.~~

Article 14.8.~~9~~11.

Recommendations for importation from countries or zones considered infected with PPR

For wild ruminants

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) showed no clinical sign suggestive of PPR *infection* for at least the 21 days prior to shipment;

2) were submitted to a diagnostic test for PPR *infection* with negative results ~~at least~~ no more than 21 days prior to shipment;

3) were kept in a *quarantine station* for ~~the~~ at least the 21 days prior to shipment.

Article 14.8.~~10~~.12.

Recommendations for importation from PPR free countries or zones

For semen of domestic sheep and goats ~~small ruminants, cattle, camels and buffaloes~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the donor *animals*:

1) showed no clinical sign of PPR on the day of collection of the semen and during the following 21 days;

2) were kept in a PPR free country or *zone* for at least the ~~not less than~~ 21 days prior to collection.

Article 14.8.~~11~~13.

Recommendations for importation from countries considered infected with PPRV

For semen of domestic sheep and goats ~~small ruminants~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the donor *animals*:

1) showed no clinical sign suggestive of PPR ~~*infection*~~ for at least the 21 days prior to collection of the semen and during the following 21 days;

2) were kept, for at least the 21 days prior to collection, in an *establishment* or *artificial insemination centre* where no *case* of PPR was reported during that period, which was not situated in a PPRV *infected zone* and to which no *animals* had been added ~~for~~ during the 21 days prior to collection;

3) ~~in the absence of vaccination against PPR with the live attenuated PPRV,~~ were not vaccinated against PPR and were submitted to a diagnostic test for PPRV *infection* with negative results at least 21 days prior to collection of the semen;

OR

4) were vaccinated against PPR with ~~the~~ live attenuated PPRV vaccines at least 21 days prior the semen collection ~~and attested by the presence of antibodies anti PPRV~~.

~~Article 14.8.12.~~

~~**Recommendations for importation from countries considered infected with PPR**~~

~~For semen of cattle, camels and buffaloes~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor *animals*:~~

~~1) showed no clinical sign suggestive of PPR *infection* at least 21 days prior semen collection;~~

~~2) were submitted to a diagnostic test for PPR with negative results at least 21 days prior to collection of the semen;~~

~~3) were kept for the 21 days prior to collection, in an *establishment* or *artificial insemination centre* where no *case* of PPR was reported during that period, which was not situated in a PPR *infected zone* and to which no *animals* had been added for the 21 days prior to collection.~~

Article 14.8.~~13~~14.

Recommendations for importation from PPR free countries or zones

For embryos of domestic sheep and goats ~~small ruminants~~ and captive wild ruminants

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor ~~females~~ animals were kept in an *establishment* located in a PPR free country or *zone* at least 21 days prior to ~~the time of collection of the~~ embryo~~s~~ collection;

EU comment

The requirements for male and female animals should be specified individually, as they differ. The EU therefore suggests reverting to "donor females" in point 1) above, and to add the following requirements for male donors, in line with Article 14.8.12.:

"1 bis) the male donor showed no clinical sign of PPR on the day of semen collection and during the following 21 days, and was kept in a PPR free country or *zone* for at least the 21 days prior to collection;"

2) the embryos were collected, processed and stored in conformity with the relevant provisions of Chapters 4.7., 4.8. and 4.9.~~, as relevant~~.

Article 14.8.~~14~~15.

Recommendations for importation from countries or zones considered infected with PPRV

For embryos of domestic sheep and goats ~~small ruminants~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor ~~females~~ animals:

   a) and all other *animals* in the *establishment* showed no clinical sign suggestive of PPRV *infection* at the time of collection and during the following 21 days;

b) were kept, for at least ~~in an *establishment* for~~ the 21 days prior to collection, in an *establishment* where no *case* of PPR was reported during that period, and to which no susceptible *animals* had been added ~~for~~ during the 21 days prior to collection;

c) ~~have~~ were not ~~been~~ vaccinated against PPR and were subjected to a diagnostic test for PPRV *infection* with negative results at least 21 days prior to collection;

OR

d) were ~~have been~~ vaccinated against PPR with ~~the~~ live attenuated PPRV vaccines ~~not less than~~ at least 21 days prior to ~~the~~ embryo collection; ~~and attested by the presence of antibodies anti-PPRV;~~

EU comment

In analogy to the EU comment on Article 14.8.14. above, the requirements for male and female animals should again be specified individually. Requirements for male donors should be added in line with Article 14.8.13.

2) the embryos were collected, processed and stored in conformity with the relevant provisions of Chapters 4.7., 4.8. and 4.9.~~, as relevant~~.

Article 14.8.~~15~~16.

Recommendations for importation from countries or zones considered infected with PPRV

For embryos of ~~cattle, camels, buffaloes and~~ captive wild ruminants

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

a) showed no clinical signs suggestive of ~~PPR~~ *infection* with PPRV for at least the 21 days prior to the embryo collection;

b) ~~have~~ were not ~~been~~ vaccinated against PPR and were subjected to a diagnostic test for PPRV *infection* with negative results at least 21 days prior to collection;

c) were kept, for at least ~~in an *establishment* for~~ the 21 days prior to collection, in an *establishment* where no *case* of PPR or of *infection* with PPRV was reported during that period, and to which no susceptible *animals* had been added ~~for~~ during the 21 days prior to collection;

2) the embryos were collected, processed and stored in conformity with the relevant provisions of Chapters 4.7., 4.8. and 4.9.~~, as relevant~~.

~~Article 14.8.16.~~

~~**Recommendations for importation from PPR free countries or zones**~~

~~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 of *meat* comes from *animals*:~~

~~1) which have been kept in a PPR free country or *zone* since birth, or for at least 21 days;~~

~~2) which have been slaughtered in an approved *abattoir* and have been subjected to ante mortem and post mortem inspections with favourable results.~~

~~Article 14.8.17.~~

~~**Recommendations for importation from countries or zones considered infected with PPR**~~

~~For fresh meat of 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) showed no clinical signs of PPR within 24 hours before *slaughter*;~~

~~2) were kept in the *establishment* of origin since birth or for at least 21 days prior to shipment to the approved *abattoir*, and did not show clinical signs suggestive of PPR *infection* in the *establishment* during that period;~~

~~3) 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;~~

~~4) were slaughtered in an approved *abattoir* in which no PPR has been detected during the period between the last *disinfection* carried out before *slaughter* and the date on which the shipment has been dispatched and have been subjected to ante-mortem and post-mortem inspections for PPR with favourable results.~~

~~Article 14.8.18.~~

~~**Recommendations for importation from countries or zones considered infected with PPR**~~

~~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 requirements in Article 14.8.17. has been used in the preparation of the *meat products*;~~

~~OR~~

~~the *meat products* have been processed to ensure the destruction of the PPRV in conformity with one of the procedures referred to in Article 8.5.34.;~~

~~2) the necessary precautions were taken after processing to avoid contact of the *meat products* with any possible source of PPRV.~~

EU comment

As stated in the comment on Article 14.8.2. above, the EU cannot accept considering meat and meat products of domestic sheep and goats that has passed ante- and post-mortem inspections as safe commodities. Therefore, the Articles 14.8.16. to 14.8.18. should not be deleted. However, the words "susceptible animals" should be replaced by "domestic sheep and goats", in line with the principles set in Article 14.8.1.

Article 14.8.~~19~~17.

Recommendations for importation from PPR free countries or zones

For milk and milk products from sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in a PPR free country or *zone* ~~since birth or~~ for at least the 21 days prior to milking.

Article 14.8.~~20~~18.

Recommendations for importation from countries or zones considered infected with PPRV

For milk from sheep and goats ~~susceptible animals~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the milk:

   a) originates from *herds* or *flocks* which were not subjected to any restrictions due to PPR at the time of *milk* collection;

   OR

   b) has been processed to ensure the destruction of the PPRV in conformity with one of the procedures referred to in Articles 8.5.~~38~~35. and 8.5.~~39~~36.;

2) the necessary precautions were taken to avoid contact of the products with any potential source of PPRV.

Article 14.8.~~21~~.19.

Recommendations for importation from countries or zones considered infected with PPRV

For milk products from ~~susceptible animals~~ sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) these products are derived from *milk* complying with the requirements of Article 14.8.18~~20~~.;

2) the necessary precautions were taken after processing to avoid contact of the *milk products* with a potential source of PPRV.

Article 14.8.~~22~~20.

Recommendations for importation from PPR free countries or zones

For products of sheep and goats ~~animal origin~~, other than milk, ~~and~~ fresh meat and their products ~~from susceptible animals~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals*:

1) which have been kept in a PPR free country or *zone* since birth or for at least the past 21 days;

2) which have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante-~~mortem~~ and post-mortem inspections with favourable results.

Article 14.8.~~23~~21.

Recommendations for importation from countries or zones considered infected with PPRV

For meal and flour from blood, meat, defatted bones, hooves, claws and horns from ~~susceptible animals~~ sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) ~~these~~ the products ~~have been~~ were processed using heat treatment to a minimum internal temperature of 70°C for at least 30 minutes;

2) the necessary precautions were taken after processing to avoid contact of the *commodities* with a potential source of PPRV.

Article 14.8.~~24~~22.

Recommendations for importation from countries or zones considered infected with PPRV

For hooves, claws, bones and horns, hunting trophies and preparations destined for museums from ~~susceptible animals~~ sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) ~~these~~ the products were completely dried and had no trace on them of skin, flesh or tendon~~; and/~~or

~~2.~~ ~~these products have been~~ were adequately disinfected; and

~~3~~2) the necessary precautions were taken after processing to avoid contact of the *commodities* with a potential source of PPRV.

~~Article 14.8.25.~~

~~**Recommendations for importation from countries or zones considered infected with PPR**~~

~~For wool and hair 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 PPR virus in conformity with one of the procedures referred to in Articles 8.5.35. and 8.5.36. in premises controlled and approved by the *Veterinary Authority* of the *exporting country*;~~

~~2) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of PPRV.~~

Article 14.8.~~26~~23.

Recommendations for importation from countries or zones considered infected with PPRV

For wool, hair, raw hides and skins from ~~susceptible animals~~ sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the products ~~have been~~ were adequately processed in conformity with one of the procedures referred to in Article 8.5.~~37~~34. in premises controlled and approved by the *Veterinary Authority* of the *exporting country*;

2) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of PPRV.

Article 14.8.~~27~~.24.

Recommendations for importation from countries or zones considered infected with PPRV

For products of animal origin from ~~susceptible animals~~ sheep and goats intended for pharmaceutical or surgical use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products:

1) come from *animals* which ~~have been~~ were slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante~~-mortem~~ and post-mortem inspections with favourable results;

2) ~~have been~~ were processed to ensure the destruction of the PPRV in conformity with one of the procedures referred to in Article 8.5.~~29~~26. or in Articles 8.5.~~34~~31. to 8.5.~~37~~34. as appropriate and in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.

Article 14.8.24bis.

Procedures for the inactivation of the PPRV in casings of sheep and goats

For the inactivation of viruses present in casings of sheep and goats, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine (Aw < 0.80), and kept at a temperature of greater than 20°C during this entire period.

EU comment

The EU suggests amending the article above, in line with the recent scientific opinion of the European Food Safety Authority (EFSA) on animal health risk mitigation treatments as regards imports of animal casings (cf. http://www.efsa.europa.eu/de/efsajournal/pub/2820.htm), as follows:

"For the inactivation of PPRV ~~viruses present~~ in casings of sheep and goats, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl a_w < 0.80), or with phosphate supplemented salt containing 86.5 percent NaCl, 10.7 percent Na_2HPO_4 and 2.8 percent Na_3PO_4 (weight/weight/weight), either dry or as a saturated brine (a_w< 0.80), and kept at a temperature of ~~greater than~~ 20°C or above during this entire period."

For PPRV, also the phosphate supplemented salt treatment should be recommended. Indeed, the EFSA opinion states that "*While they are relatively stable at a neutral pH, both viruses* [rinderpest virus and PPRV] *are rapidly inactivated at low and high pH values*" (cf. p 21 of said opinion). This indicates that the phosphate supplemented salt treatment would be at least as effective as the classical NaCl treatment, since the pH would be higher with phosphate supplemented salts than with NaCl alone.

Furthermore, EFSA recommends salting treatments to be done at a temperature of 20°C or above (cf. p 23 of said opinion).

Article 14.8.25.

Surveillance: introduction

Articles 14.8.25. to 14.8.31. define the principles and provide a guide for the *surveillance* of PPR in accordance with Chapter 1.4. applicable to Member Countries seeking recognition of country or zonal freedom from PPR. Guidance is provided for Member Countries seeking reestablishment of freedom following an *outbreak* and for the maintenance of PPR free status.

Surveillance strategies employed for demonstrating freedom from PPR at an acceptable level of confidence will need to be adapted to the local situation. *Outbreaks* of PPR may vary in severity with differing clinical presentations believed to reflect variations in host resistance and variations in the virulence of the attacking strain. Experience has shown that *surveillance* based on a predefined set of clinical signs (e.g. searching for "pneumo-enteritis syndrome") increases the sensitivity of the system. In the case of peracute *cases* the presenting sign may be sudden death. In the case of sub-acute (mild) *cases*, clinical signs are displayed irregularly and are difficult to detect.

Where they exist, susceptible domestic species, and feral populations of these species, should be included in the design of the *surveillance* strategy.

EU comment

The EU suggests also mentioning susceptible wildlife species in this introductory chapter to surveillance, as they are covered by Article 14.8.28.

Surveillance for PPR should be in the form of a continuing programme designed to establish that the whole country or *zone* is free from PPRV *infection*.

Article 14.8.26.

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 suspected *cases* to a *laboratory* for PPR diagnosis.

2) The PPR *surveillance* programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspected *cases*. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of PPR. 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 PPR, such as pneumo-enteritis syndrome, should be reported and 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 be available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in PPR 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 a PPR infected country.

An effective *surveillance* system will periodically identify *animals* with signs suggestive of PPR that require follow-up and investigation to confirm or exclude that the cause of the condition is PPRV. The rate at which such suspected *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from PPRV *infection* should, in consequence, provide details of the occurrence of suspected *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 14.8.27.

Surveillance strategies

1. Clinical surveillance

   Clinical *surveillance* aims to detect clinical signs of PPR by close physical examination. Clinical surveillance and epidemiological investigations are the cornerstone of all *surveillance* systems and should be supported by additional strategies such as virological and serological *surveillance*. Clinical *surveillance* 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 up by the collection of appropriate samples such as ocular and nasal swabs, blood or other tissues for virus isolation or virus detection by other means. Sampling units within which suspicious animals are detected should be classified as infected until fully investigated.

   Active search for clinical *disease* can include participatory disease searching, tracing backwards and forwards, and follow-up investigations. Participatory *surveillance* is a form of targeted active *surveillance* based upon methods to capture livestock owners' perceptions on the prevalence and patterns of *disease*.

   The labour requirements and the logistical difficulties involved in conducting clinical examinations should be taken into account.

   PPRV isolates may be sent to an OIE Reference Laboratory for further characterisation.

2. Virological surveillance

   Given that PPR is an acute *infection* with no known carrier state, virological *surveillance* should only be conducted as a follow-up to clinically suspected *cases*.

3. Serological surveillance

   Serological *surveillance* aims to detect antibodies against PPRV. Positive antibody test results can have four possible causes:

   a) natural *infection* with PPRV;

b) *vaccination* against PPR;

c) maternal antibodies derived from an immune dam (maternal antibodies in small ruminants can be found only up to six months of age);

d) heterophile (cross) and other non-specific reactions.

It may be possible to use serum collected for other survey purposes for PPR *surveillance*. However, the principles of survey design described in this chapter and the requirement for a statistically valid survey for the presence of PPRV 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 PPRV *infection* is not present in a country or *zone*. It is therefore essential that the survey be adequately documented.

Article 14.8.28.

Surveillance in wildlife

Where a population of a susceptible *wildlife* species may act as sentinels indicating the spill over of PPRV from domestic sheep and goats, serosurveillance data should be collected.

Obtaining meaningful data from *surveillance* in *wildlife* can be enhanced by close coordination of activities in a region. Both purposive and opportunistic samplings are used to obtain material for analysis in national or reference *laboratories*. The latter are required because many countries do not have adequate facilities to perform the full testing protocol for detecting antibodies against PPRV in *wildlife* sera.

Targeted sampling is the preferred method to provide *wildlife* data to evaluate the status of *infection* with PPRV. In reality, the capacity to perform *wildlife* sampling is minimal in most countries. However, samples can be obtained from hunted *animals*, and these may provide useful background information.

Article 14.8.29.

Additional surveillance procedures for Member Countries applying for OIE recognition of PPR free status

The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances in and around the country or *zone* and should be planned and implemented according to the conditions for status recognition described in Article 14.8.3. and methods in this chapter, to demonstrate absence of PPRV *infection* during the preceding 24 months. This requires the support of a *laboratory* able to undertake identification of PPRV *infection* through virus, antigen or viral nucleic acid detection and antibody tests.

The target population for *surveillance* aimed at identifying *disease* and *infection* should cover significant populations within the country or *zone* to be recognised as free from PPRV *infection*.

The strategy employed should be based on an appropriate combination of randomised and targeted sampling requiring *surveillance* consistent with demonstrating the absence of PPRV *infection* at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Risk-based approaches (e.g. based on the increased likelihood of *infection* in particular localities or species) may be appropriate to refine the *surveillance* strategy. The Member Country should justify the *surveillance* strategy chosen as adequate to detect the presence of PPRV *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.

Consideration should be given to the risk factors for the presence of PPRV, including:

a) historical *disease* patterns;

b) critical population size, structure and density;

c) livestock husbandry and farming systems;

d) movement and contact patterns, such as market and other trade-related movements;

e) virulence and infectivity of the strain.

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 predetermined minimum *disease* prevalence determine the level of confidence in the results of the survey. The applicant Member Country should justify the choice of design, minimum prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the minimum prevalence in particular should 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 subsequently 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* or *flocks* which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease* or *infection* are technically well defined in Chapter 1.4. The design of *surveillance* programmes to demonstrate the absence of PPRV *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.

Article 14.8.30.

Additional surveillance procedures for recovery of free status

Following an *outbreak* of PPR in a Member Country at any time after recognition of PPR 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 Country wishing to regain the free status should undertake *surveillance* according to this chapter to demonstrate the absence of PPRV *infection*.

Article 14.8.31.

The use and interpretation of serological tests for serosurveillance of PPR

Serological testing is an appropriate tool to use for PPR *surveillance* where *vaccination* has not been practised. There is only one serotype of virus and the tests will detect antibodies elicited by *infection* with all PPRV but the tests cannot discriminate between antibodies against field *infection* and those from *vaccination* with attenuated vaccines. This fact compromises serosurveillance in vaccinated populations and meaningful serosurveillance can only commence once *vaccination* has ceased for several years. Antibodies against virulent and vaccine strains of PPRV can be detected in small ruminants from about 14 days post *infection* or *vaccination* and peak around 30 to 40 days. Antibodies then persist for many years, possibly for life, although titres decline with time.

It is necessary to demonstrate that positive serological results have been adequately investigated.

Article 14.8.32.

OIE endorsed official control programme for PPR

The objective of an OIE endorsed *official control programme* for PPR is for Member Countries to progressively improve the situation in their territories and eventually attain the status of free from PPR.

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for PPR when they have implemented measures in accordance with this article.

For a Member Country's *official control programme* for PPR to be endorsed by the OIE, the Member Country should:

1) submit documented evidence on the capacity of its *Veterinary Services* to control PPR; this evidence can be provided by countries following the OIE PVS Pathway;

2) submit documentation indicating that the *official control programme* for PPR is applicable to the entire territory (even if it is on a zonal basis);

3) have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1;

4) submit a dossier on the status of PPR in the country describing the following:

   a) the general epidemiology of PPR in the country highlighting the current knowledge and gaps;

   b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all PPR *outbreaks* in order to reduce the incidence of *outbreaks* and to eliminate virus circulation in domestic sheep and goats in at least one *zone* in the country;

   c) the main livestock production systems and movement patterns of sheepand goats and their products into and within the country and, where applicable, the specific *zone(s)*;

5) submit a detailed plan of the programme to control and eventually eradicate PPR in the country or *zone* including:

   a) the timeline for the programme;

   b) the performance indicators that will be used to assess the efficacy of the control measures;

6) submit evidence that PPR *surveillance* is in place, taking into account the provisions in Chapter 1.4. and the provisions on *surveillance* in this chapter;

7) have diagnostic capability and procedures in place, including regular submission of samples to a *laboratory*;

8) where *vaccination* is practised as a part of the *official control programme* for PPR, provide evidence (such as copies of legislation) that *vaccination* of sheep and goats in the country or *zone* is compulsory;

9) if applicable, provide detailed information on *vaccination* campaigns, in particular on:

   a) the strategy that is adopted for the *vaccination* campaign;

   b) monitoring of *vaccination* coverage, including serological monitoring of population immunity;

   c) serosurveillance in other susceptible species, including *wildlife* to serve as sentinels for PPRV circulation in the country;

   d) disease *surveillance* in sheep and goat populations;

   e) the proposed timeline for the transition to the cessation of the use of *vaccination* in order to enable demonstration of absence of virus circulation;

10) provide an emergency preparedness and contingency response plan to be implemented in the case of PPR *outbreak*(s).

The Member Country's *official control programme* for PPR will be included in the list of programmes endorsed by the OIE only after the evidence submitted has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

The OIE may withdraw the endorsement of the *official control programme* if there is evidence of:

– non-compliance with the timelines or performance indicators of the programme; or

– significant problems with the performance of the *Veterinary Services*; or

– an increase in the incidence of PPR that cannot be addressed by the programme.

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— Text deleted.

Annex XXX (contd)

CHAPTER 1.6.

PROCEDURES FOR SELF DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE

EU position

The EU in general supports the adoption of this modified chapter.

Article 1.6.1.

General principles

Members may wish to make a self declaration as to the freedom of a country, *zone* or *compartment* from an OIE *listed disease*. The Member may inform the OIE of its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim. The OIE does not publish self declaration for bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), rinderpest, contagious bovine pleuropneumonia (CBPP), ~~and~~ African horse sickness (AHS), peste des petits ruminants (PPR) and classical swine fever (CSF).

Members may request official recognition by the OIE as to:

1) the risk status of a country or *zone* with regard to BSE;

2) the freedom of a country or *zone* from FMD, with or without vaccination;

3) the freedom of a country from rinderpest;

4) the freedom of a country or *zone* from CBPP;

5) the freedom of a country or *zone* from AHS;

6) the freedom of a country or *zone* from PPR;

7) the freedom of a country or *zone* from CSF.

The OIE does not grant official recognition for other diseases.

In these cases, Members should present documentation setting out the compliance of the *Veterinary Services* of the applicant country or *zone* with the provisions of Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code* and with the provisions of the relevant disease chapters in the *Terrestrial Code* and the *Terrestrial Manual*.

When requesting official recognition of disease status, the Member should submit to the OIE Scientific and Technical Department a dossier providing the information requested (as appropriate) in Articles 1.6.3. (for BSE), 1.6.4. (for FMD), 1.6.5. (for rinderpest), 1.6.6. (for CBPP), ~~or~~ 1.6.7. (for AHS), 1.6.7bis. (for PPR) or 1.6.7 ter. (for CSF).

The OIE framework for the official recognition and maintenance of disease status is described in Resolution N° XXII (administrative procedures) and Resolution N° XXIII (financial obligations) adopted during the 76th General Session in May 2008.

Article 1.6.2.

[no change]

Annex XXX (contd)

Article 1.6.2bis.

Endorsement by the OIE of an official control programme for peste des petits ruminants

Member Countries may wish to request an endorsement by the OIE of their *official control programme* for peste des petits ruminants (PPR).

When requesting endorsement by the OIE of an *official control programme* for PPR, the Member Country should submit to the OIE Scientific and Technical Department a dossier providing the information requested in Article 1.6.8 bis..

Article 1.6.7bis.

Questionnaires on peste des petits ruminants

PPR FREE COUNTRY

Report of a Member Country which applies for recognition of status, under Chapter 14.8. of the *Terrestrial Code* as a PPR free country

Please address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

   a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to PPR 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.

   b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

   a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to PPR.

   b) 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 PPR related activities. Provide maps and tables wherever possible.

   c) Role of farmers, industry and other relevant groups in PPR *surveillance* and control (include a description of training and awareness programmes on PPR).

   d) Role of private veterinary profession in PPR *surveillance* and control.

Annex XXX (contd)

3. PPR eradication

a) History. Provide a description of the PPR history in the country, date of first detection, epidemiological patterns, origin of *infection*, date of eradication (date of last *case*), lineage(s) present if available.

b) Strategy. Describe how PPR was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), provide time frame for eradication.

c) Vaccines and vaccination. Was PPR vaccine ever used? If so, when was the last *vaccination* carried out? What species were vaccinated?

d) Legislation, organisation and implementation of the PPR eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

e) 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* or *flock* 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. PPR diagnosis

Provide evidence that a system is in place for the rapid confirmation of a suspected *outbreak* i.e. that the provisions in Chapters 1.1.2., 1.1.3. and 2.7.11. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is PPR 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.

b) Provide an overview of the PPR approved laboratories in the country, in particular to address the following points:

i) 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 are planned for, the laboratory system.

ii) Give details of participation in inter-laboratory validation tests (ring tests).

iii) Is live virus handled?

iv) Biosecurity measures applied.

v) Details of the type of tests undertaken.

5. PPR surveillance

Provide documentary evidence that *surveillance* for PPR in the country complies with the provisions of Articles 14.8.25. to 14.8.31. of the *Terrestrial Code* and Chapter 2.7.11. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of PPR? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what disincentives for failure to report? Provide a summary table indicating, for the past two years, the number of suspected *cases*, the number of samples tested for PPR virus, species, type of sample, testing method(s) and results (including differential diagnosis). In particular, provide evidence of compliance with the provisions of Articles 14.8.25. to 14.8.31. of the *Terrestrial Code*.

b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design in accordance with Articles 14.8.25. to 14.8.31. of the *Terrestrial Code*. 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 PPR 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.

c) Domestic small ruminant demographics and economics. What is the population by species and production systems? How many *herds* or *flocks* of each species are in the country? How are they distributed (e.g. *herd* or *flock* density)? Provide tables and maps as appropriate.

d) Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution.

e) *Slaughterhouses/abattoirs* and markets. Where are the major domestic small ruminant marketing or collection centers? What are the patterns of domestic small ruminant movement within the country? How are the animals transported and handled during these transactions?

6. PPR prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries that should be taken into account (e.g. distance from the border to susceptible *herds*, *flocks* or *animals* in the neighbouring country)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

b) Import control procedures

From what countries or *zones* does the country authorise the import of sheep and goats and susceptible *wildlife* 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 sheep and goats and susceptible *wildlife* 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 sheep and goats and susceptible *wildlife* and their products for the past two years, specifying country or *zone* of origin, species and volume.

c) Provide a map with the number and location of ports, airports and land crossings. Is the service responsible for import controls part of the government 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.

d) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or their final destination, concerning the import and follow-up of the following:

i) small ruminants,

ii) genetic material (semen and embryos),

iii) animal products,

iv) veterinary medicinal products (i.e. biologics).

e) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

Annex XXX (contd)

7. Control measures and contingency planning

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of PPR.

b) Is quarantine imposed on premises with suspected *cases*, pending final diagnosis? What other procedures are followed regarding suspected *cases*?

c) In the event of a PPR *outbreak*:

i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

ii) describe the actions taken to control the *disease* situation in and around any holdings found to be infected with PPR;

iii) indicate the control or eradication procedures (e.g. *vaccination*, stamping-out, modified stamping-out, etc.) that would be taken;

iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled and the *disease* eradicated, including any restrictions on restocking;

v) give details and prescribed timetable of any compensation made available to owners when *animals* are slaughtered for *disease* control or eradication purposes.

8. Compliance with the *Terrestrial Code*

The Delegate of the country must submit documentary evidence that the provisions of Article 14.8.3. or point 1 of Article 1.4.6. (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 14.8.7. of the *Terrestrial Code* and provide detailed information as specified in Sections 3.a, 3.b, 3.c and 5.b of this questionnaire. Information in relation to other sections need only be supplied if relevant.

PPR FREE ZONE

Report of a Member Country which applies for recognition of status, under Chapter 14.8. of the *Terrestrial Code* as a PPR free *zone*

Please address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

a) Geographical factors. Provide a general description of the country and the *zone* including physical, geographical and other factors that are relevant to PPR 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 *protection zone* if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

b) Livestock industry. Provide a general description of the livestock industry in the country and the *zone*.

2. Veterinary system

a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to PPR.

b) 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 Chapter 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all PPR related activities. Provide maps and tables wherever possible.

c) Role of farmers, industry and other relevant groups in PPR *surveillance* and control (include a description of training and awareness programmes on PPR).

d) Role of private veterinary profession in PPR *surveillance* and control.

3. PPR eradication

a) History. Provide a description of the PPR history in the country and *zone*, date of first detection, epidemiological patterns, origin of *infection*, date of eradication (date of last *case*), lineage(s) present if available.

b) Strategy. Describe how PPR was controlled and eradicated in the *zone* (e.g. stamping-out, modified stamping-out, zoning), provide time frame for eradication.

c) Vaccines and vaccination. Was PPR vaccine ever used? If so, when was the last *vaccination* carried out? What species were vaccinated?

d) Legislation, organisation and implementation of the PPR eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

e) 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* or *flock* registration and traceability. How are animal movements controlled in and between *zones* of the same or different status? Provide evidence on the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.

4. PPR diagnosis

Provide evidence that a system is in place for the rapid confirmation of a suspected *outbreak* i.e. that the provisions in Chapters 1.1.2., 1.1.3. and 2.7.11. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is PPR 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.

b) Provide an overview of the PPR approved laboratories in the country, in particular to address the following points:

i) 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 are planned for, the laboratory system.

Annex XXX (contd)

ii) Give details of participation in inter-laboratory validation tests (ring tests).

iii) Is live virus handled?

iv) Biosecurity measures applied.

v) Details of the type of tests undertaken.

5. PPR surveillance

Provide documentary evidence that *surveillance* for PPR in the *zone* complies with the provisions of Articles 14.8.25. to 14.8.31. of the *Terrestrial Code* and Chapter 2.7.11. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of PPR? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what disincentives for failure to report? Provide a summary table indicating, for the past two years, the number of suspected *cases*, the number of samples tested for PPR virus, species, type of sample, testing method(s) and results (including differential diagnosis). In particular, provide evidence of compliance with the provisions of Articles 14.8.25. to 14.8.31. of the *Terrestrial Code*.

b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design in accordance with Articles 14.8.25. to 14.8.31. of the *Terrestrial Code*. 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 PPR 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.

c) Domestic small ruminant demographics and economics. What is the population by species and production systems? How many *herds* or *flocks* of each species are in the country and the *zone*? How are they distributed (e.g. *herd* or *flocks* density)? Provide tables and maps as appropriate.

d) Wildlife demographics. What susceptible species are present in the country and the *zone*? Provide estimates of population sizes and geographic distribution.

e) *Slaughterhouses/abattoirs* and markets. Where are the major domestic small ruminant marketing or collection centres? What are the patterns of domestic small ruminant movement within the country? How are the *animals* transported and handled during these transactions?

6. PPR prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. distance from the border to susceptible *herds, flocks* or *animals* in the neighbouring country)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*.

If the PPR free *zone* is situated in a PPR 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.

b) Import control procedures

From what countries or *zones* does the country authorise the import of sheep and goats and susceptible *wildlife* or their products into a 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 sheep and goats and susceptible *wildlife* 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 sheep and goats and susceptible *wildlife* and their products for the past two years, specifying country or *zone* of origin, species and volume.

c) Provide a map with the number and location of ports, airports and land crossings. Is the service responsible for import controls part of the government 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.

d) Describe the regulations, procedures, type and frequency of checks at the point of entry into the *zone* or their final destination, concerning the import and follow-up of the following:

i) small ruminants;

ii) genetic material (semen and embryos);

iii) animal products;

iv) veterinary medicinal products (i.e. biologics).

e) 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

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of PPR.

b) Is quarantine imposed on premises with suspected *cases*, pending final diagnosis? What other procedures are followed regarding suspected *cases*?

c) In the event of a PPR *outbreak*:

i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

ii) describe the actions taken to control the *disease* situation in and around any holdings found to be infected with PPR;

iii) indicate the control or eradication procedures (e.g. *vaccination*, stamping-out, modified stamping-out, etc.) that would be taken;

iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled and the *disease* eradicated, including any restrictions on restocking;

v) give details and prescribed timetable of any compensation made available to owners when *animals* are slaughtered for *disease* control or eradication purposes.

Annex XXX (contd)

8. Compliance with the *Terrestrial Code*

The Delegate of the country must submit documentary evidence that the provisions of Article 14.8.3. or point 1 of Article 1.4.6. (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 14.8.7. of the *Terrestrial Code* and provide detailed information as specified in Sections 3.a, 3.b, 3.c and 5.b of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.6.8bis.

Questionnaire on peste des petits ruminants

COUNTRY WITH AN OIE ENDORSED OFFICIAL CONTROL PROGRAMME FOR PPR

Report of a Member Country which applies for the OIE endorsement of its *official control programme* for PPR under Chapter 14.8. of the *Terrestrial Code*

Please address concisely the following topics. National laws, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

a) Provide a general description of geographical factors in the country and any defined *zones*, including physical, geographical and other factors that are relevant to PPR dissemination, countries or *zones* sharing common borders and other countries or *zones* that, although not adjacent, present a risk for the introduction of *disease*.

b) If the endorsed plan is being gradually implemented in specific parts of the country, the boundaries of the *zone(s)* should be clearly defined, including the *protection zone*, if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone(s)*.

c) Provide a general description of the livestock industry in the country and any *zones*.

2. Veterinary system

a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to the PPR control programme.

b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Services* 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 PPR related activities in the country and any *zones*. Provide maps and tables wherever possible.

c) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small scale producers, community animal health workers and the role of the private veterinary profession in PPR *surveillance* and control. Include a description of training and awareness programmes on PPR.

d) Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS Pathway.

3. PPR control

a) Provide a description of the PPR history in the country and any *zones*, including date of first detection, origin of *infection*, date of implementation of the control programme in the country and any *zones*, and any information available on lineages of the PPR virus present.

b) Describe the general epidemiology of PPR in the country and the surrounding countries or *zones* highlighting the current knowledge and gaps.

c) Describe how PPR is controlled in the country or any *zones*.

d) Provide a description of the legislation, organisation and implementation of the PPR control programme. Indicate if detailed operational guidelines exist and give a brief summary.

e) Provide information on the vaccine and if it is certified (If yes please provide the name of the certifying institution/body). Describe the *vaccination* programme in the country and in any *zones*, including records kept, and provide evidence to show its effectiveness, such as *vaccination* coverage, population immunity, etc. Provide details on the studies carried out to determine the population immunity, including the study design.

f) Provide a description of the methods of *animal identification* (at the individual or group level), *herd* registration and traceability; and how the movements of *animals* are assessed and controlled, including movement of infected *animals* for *slaughter*. Describe the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe measures to prevent introduction of the virus from neighbouring countries or *zones* and through trade.

4. PPR surveillance

Provide documentary evidence on whether *surveillance* for PPR in the country complies with the provisions of Articles 14.8.25. to 14.8.31. of the *Terrestrial Code* and Chapter 2.7.11. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Describe the criteria for raising a suspicion of PPR and the procedure to notify (by whom and to whom) and what penalties are involved for failure to report.

b) Describe how clinical *surveillance* is conducted, including which levels of the livestock production system are included in clinical *surveillance*, such as farms, markets, fairs, *slaughterhouse*, check points, etc. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested in diagnostic laboratories. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators. Explain whether serological surveys are conducted and, if so, how frequently and for what purpose.

c) Provide a summary table indicating, for at least the past two years, the number of samples tested for PPR diagnosis, species, type of sample, testing method(s) and results (including differential diagnosis). Provide procedural details on follow-up actions taken on suspicious and positive results.

d) Provide information on small ruminant demographics and economics, including the production systems in the country and the *zone*. Identify how many *herds*, *flocks*, etc. of each small ruminant species are in the country and how they are distributed, such as *herd* density, etc. Provide tables and maps as appropriate.

e) Identify the livestock slaughter, marketing and collection centres. Provide information on the patterns of livestock movement within the country, including how *animals* are transported and handled during these transactions.

Annex XXX (contd)

5. PPR laboratory diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.7.11. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is PPR laboratory diagnosis carried out in the country? If so, provide a list of laboratories approved by the *Competent Authority* to diagnose PPR. 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. If applicable, indicate the laboratory(ies) where samples originating from any *zone* are diagnosed. Is there regular submission of samples from the country or *zone* to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the standards and methods described in the *Terrestrial Manual*.

b) Provide an overview of the laboratory(ies) where PPR diagnosis is carried out, in particular to address the following points:

i) 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 are planned for, the laboratory system.

ii) Give details on participation in inter-laboratory validation tests (ring tests).

iii) Is live virus handled?

iv) Biosecurity measures applied.

v) Details of the type of tests undertaken.

6. PPR prevention

Describe the procedures in place to prevent the introduction of PPR into the country. In particular provide details on:

a) Coordination with neighbouring countries, trading partners and other countries within the same region. Identify relevant factors about the adjacent countries and *zones* that should be taken into account such as size, distance from adjacent borders to affected *herds* or *animals*, *surveillance* carried out in adjacent countries. Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*. Describe the measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation of the agent within the country or *zone* and through trade.

b) Provide information on countries or *zones* from which the country authorises the import of sheep and goats and susceptible *wildlife* or their products into the country or *zone*. Describe the criteria applied to approve such countries or *zones*, the controls applied on entry of such *animals*, and subsequent internal movement. Describe the import conditions and test procedures required. Advise whether imported sheep and goats and susceptible *wildlife* are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health certificates are required.

c) Describe any other procedures used. Provide summary statistics on imports of sheep and goats and susceptible *wildlife* and their products for at least the past two years, specifying country or *zone* of origin, the species and the number.

i) Provide a map with the number and location of ports, airports and land crossings. Advise whether the service responsible for import controls is part of the official services, or if it is 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.

ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and their final destination, concerning the import and follow-up of the following:

– *animals*,

– genetic material (semen and embryos),

iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports, if available.

7. Control measures and emergency response

a) Give details of any written guidelines, including emergency response plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of PPR.

b) Advise whether quarantine is imposed on premises with suspected *cases*, pending final diagnosis and any other procedures followed in respect of suspected *cases*.

c) In the event of a PPR *outbreak*:

i) provide a detailed description of procedures that are followed in *case* of an *outbreak* including forward and backward tracing;

ii) indicate the sampling and testing procedures used to identify and confirm presence of PPR virus;

iii) describe the actions taken to control the *disease* situation in and around any holdings found to be infected with PPR virus;

iv) indicate the control or eradication procedures, such as *vaccination*, *stamping-out*, partial *slaughter* or *vaccination*, movement control, pastured sheep and goats, campaign to promote awareness of farmers, etc. that would be taken;

v) describe the procedures used to confirm that an *outbreak* has been successfully controlled or eradicated, including any restrictions on restocking;

vi) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control or eradication purposes and their prescribed timetable.

8. Official control programme for PPR submitted for OIE endorsement

Submit a detailed plan on the measures, in addition to those described in point 3, for the control and eventual eradication of PPR in the country, including:

a) objectives;

b) timelines of the control programme;

c) performance indicators, including methods for measurement and verification;

d) details, if applicable, on a proposed timeline for the transition to the cessation of *vaccination* in order to enable demonstration of absence of virus circulation.

Annex XXX (contd)

9. Recovery of official endorsement of the national PPR control programme

Countries applying for recovery of the official endorsement of the national PPR control programme should provide updated information in compliance with the provisions of Article 14.8.32. of the *Terrestrial Code*.

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— Text deleted.

Annex XXXI

CHAPTER 15.2.

INFECTION WITH CLASSICAL SWINE FEVER VIRUS

EU position
The EU thanks the OIE and in general supports the adoption of this modified chapter. However, comments are inserted in the text below, one of which is important and needs to be considered before adoption.
In addition, the EU would like to ask the OIE for clarification of how this chapter will be implemented after adoption as regards the official disease status recognition and ensuring that surveillance requirements in free countries are proportionate to the risk. In particular, what will the proposed procedure be in the first 12 months following May 2013?
Furthermore, while in principle supporting the addition of this disease to the list of diseases for which the OIE officially recognises the disease status of Member Countries, the EU acknowledges and wishes to emphasise the significant increase in workload this represents for the OIE Headquarters and the Scientific Commission for the years to come. Therefore, the EU will be very interested in the implementation of the official status recognition procedure for the newly added diseases, which should be consolidated successfully before the addition of further diseases can be considered in the future.

Article 15.2.1.

General provisions

For the purposes of the *Terrestrial Code*, classical swine fever (CSF) is defined as an *infection* of pigs with classical swine fever virus (CSFV).

The following defines *infection* with CSFV:

1) A strain of CSFV (excluding vaccine strains) has been isolated from, or viral ribonucleic acid (RNA) specific to a strain of CSFV has been demonstrated to be present in, samples from a pig;

OR

2) viral antigen (excluding vaccine strains) has been identified in samples from one or more pigs epidemiologically linked to a confirmed or suspected *outbreak* of CSF, or giving cause for suspicion of previous association or contact with CSFV, with or without clinical signs consistent with CSF;

OR

3) virus specific antibodies to CSFV that are not a consequence of *vaccination* or *infection* with other pestiviruses, have been identified in samples from one or more pigs in a *herd* showing clinical signs consistent with CSF, or epidemiologically linked to a confirmed or suspected *outbreak* of CSF, or giving cause for suspicion of previous association or contact with CSFV.

EU comment
The EU cannot support point 1) above, as it implies that the mere demonstration of presence of viral ribonucleic acid using assays such as PCR on its own would be

sufficient and automatically lead to the declaration of an outbreak of CSF, without need for further investigations or links to confirmed or suspected outbreaks. However, it is well accepted and experience has shown in the recent past that false positive results in RNA detection assays cannot be excluded, e.g. due to contamination of samples at any point (i.e. not necessarily in the laboratory), with potentially devastating consequences. Therefore, the detection of viral RNA should only define CSFV infection if there is an epidemiological link to a confirmed or suspected outbreak.

Thus, the EU suggests deleting the viral ribonucleic acid clause from point 1) above and inserting it in point 2 below, as follows:

"1) A strain of CSFV (excluding vaccine strains) has been isolated from~~, or viral ribonucleic acid (RNA) specific to a strain of CSFV has been demonstrated to be present in,~~ samples from a pig;

OR

2) viral antigen (excluding vaccine strains) has been identified, or viral ribonucleic acid (RNA) specific to a strain of CSFV has been demonstrated to be present, in samples from one or more pigs epidemiologically linked to a confirmed or suspected outbreak of CSF, or giving cause for suspicion of previous association or contact with CSFV, with or without clinical signs consistent with CSF;

OR

3) virus specific antibodies to CSFV that are not a consequence of *vaccination* or *infection* with other pestiviruses, have been identified in samples from one or more pigs in a *herd* showing clinical signs consistent with CSF, or epidemiologically linked to a confirmed or suspected *outbreak* of CSF, or giving cause for suspicion of previous association or contact with CSFV."

The pig is the only natural host for CSFV. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild. For the purposes of this chapter, a distinction is made between:

– domestic and *captive wild* pigs, permanently captive or farmed free range, used for the production of *meat*, or other commercial products or use, or for breeding these categories of pigs;

– *wild* and *feral* pigs.

~~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 and wild. For the purposes of this chapter, a distinction is made between domestic pig, and wild pig (including feral pigs) populations.~~

Pigs exposed to CSFV ~~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 2-14 days, and are usually infective between post-*infection* days 5 and 14, but up to 3 months in cases of chronic *infections*.

~~For the purposes of *international trade*,~~ A Member Country should not impose ~~trade~~ bans on the trade in *commodities* of domestic and *captive wild* pigs in response to a notification of *infection* with ~~classical swine fever virus~~ CSFV in *wild* or *feral* pigs ~~according to Article 1.1.3. of the *Terrestrial Code* after~~ provided ~~the Member confirms~~ that Article 15.2.2. is ~~appropriately~~ implemented.

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

Article 15.2.2.

General criteria for the d~~D~~etermination 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) CSF should be notifiable in the whole territory, and all pigs showing clinical signs suggestive of CSF should be subjected to appropriate field ~~and/~~or *laboratory* investigations;

2) an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of CSF;

3) the *Veterinary Authority* should have current knowledge of, and authority over, all domestic and *captive wild* pig~~s~~ *herds* in the country, *zone* or *compartment*;

4) the *Veterinary Authority* should have current knowledge about the population and habitat of *wild* and *feral* pigs in the country or *zone*;

5) for domestic and *captive wild* pigs, appropriate *surveillance* in accordance with Articles 15.2.23. to 15.2.28. bis, ~~capable of detecting the presence of *infection* even in the absence of clinical signs, and the risk posed by *wild* pigs,~~ is in place; ~~this may be achieved through a *surveillance* programme in accordance with Articles 15.2.23. to 15.2.28.;~~

6) for *wild* and *feral* pigs, if present in the country or *zone*, a *surveillance* programme is in place according to Article 15.2.28., taking into account the presence of natural and artificial boundaries, the ecology of the *wild* and *feral* pig population, and an assessment of the risks of *disease* spread.

7) Based on the assessed risk of spread within the *wild* and *feral* pig population, and according to Article 15.2.26., the domestic and *captive wild* pig population should be separated from the *wild* and *feral* pig population by appropriate ~~biosecurity~~ measures ~~to prevent transmission of CSF from *wild* to domestic pigs~~.

Article 15.2.3.

CSF free country~~,~~ or zone ~~or compartment~~

A country~~,~~ or *zone* ~~or *compartment*~~ may be considered free from CSF when Article 15.2.2. is complied with ~~*surveillance* in accordance with Articles 15.2.23. to 15.2.28. has been in place for at least 12 months~~, and when:

1) *surveillance* in accordance with Articles 15.2.23. to 15.2.28.bis has been in place for at least 12 months;

~~1.~~2) there has been no *outbreak* of CSF in domestic and *captive wild* pigs during the past 12 months;

~~2.~~3) no evidence of CSFV *infection* has been found in domestic and *captive wild* pigs during the past 12 months;

~~3.~~4) no *vaccination* against CSF has been carried out in domestic and *captive wild* pigs during the past 12 months unless there are means, validated according to ~~OIE standards (~~Chapter 2.8.3. of the *Terrestrial Manual*~~)~~, of distinguishing between vaccinated and infected pigs;

~~4.~~5) imported ~~domestic~~ pigs and pig *commodities* comply with the requirements in Articles 15.2.5.~~,~~ ~~or Article 15.2.6.~~ to 15.2.12.

The country or the proposed free *zone* will be included in the list of CSF free countries or *zones* only after the submitted evidence, based on the provisions of Article 1.6.7. ter, has been accepted by the OIE.

EU comment
For clarity reasons, the EU suggests the following slight rewording of the sentence above:
"The proposed free country or ~~the proposed free~~ zone will be […]"

Retention on the list requires that the information in points 1 to 5 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 15.2.3. bis

CSF free compartment

The bilateral recognition of a CSF free *compartment* should follow the relevant requirements of this chapter and the principles laid down in Chapters 4.3. and 4.4.

Article 15.2.3. ter

Establishment of a containment zone within a CSF free country or zone

In the event of limited *outbreaks* or *cases* of CSF within a CSF free country or *zone*, including within a *protection zone*, a *containment zone*, which includes all *outbreaks*, can be established for the purpose of minimising the impact on the entire country or *zone*.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE.

In addition to the requirements for the establishment of a *containment zone* outlined in Article 4.3.3. (3), the *surveillance* programme should take into consideration the involvement of *wild* and *feral* pigs and measures to avoid their dispersion.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of these areas may be reinstated irrespective of the provisions of Article 15.2.4., once the *containment zone* is clearly established. It should be demonstrated that *commodities* for *international trade* have originated outside the *containment zone*.

In the event of the recurrence of CSF in the *containment zone*, the approval of the *containment zone* is withdrawn.

The recovery of the CSF free status of the *containment zone* should follow the provisions of Article 15.2.4.

Article 15.2.4.

Recovery of free status

Should a CSF *outbreak* occur in a free country~~,~~ or *zone* ~~or *compartment*~~, the free status may be restored where *surveillance* in accordance with Articles 15.2.23. to 15.2.28.bis has been carried out with negative results either:

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 according 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 Article 15.2.3. should be followed.

The country or *zone* will regain CSF free status only after the submitted evidence, based on the provisions of Article 1.6.7. ter, has been accepted by the OIE.

Article 15.2.5.

Recommendations for importation from countries, zones or compartments free ~~of~~ from CSF

For domestic and *captive wild* 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~~ from CSF since birth or for at least the past three months;

3) have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated according to ~~OIE standards (~~Chapter 2.8.3. of the *Terrestrial Manual~~),~~* of distinguishing between vaccinated and infected pigs.

Article 15.2.6.

Recommendations for importation from CSF infected countries or zones

For domestic and *captive wild* 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 since birth or for the past three months in a CSF free *compartment;*

3) have not been vaccinated against CSF nor are they the progeny of vaccinated sows, unless there are means, validated according to ~~OIE standards (~~Chapter 2.8.3. of the *Terrestrial Manual~~),~~* of distinguishing between vaccinated and infected pigs.

Article 15.2.7.

Recommendations for the importation of wild and feral pigs

Regardless of the CSF status of the country 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) 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 means, validated according to ~~OIE standards (~~Chapter 2.8.3. of the *Terrestrial Manual~~),~~* of distinguishing between vaccinated and infected pigs.

Article 15.2.8.

Recommendations for importation from countries, zones or compartments free ~~of~~ from CSF

For semen of domestic and *captive wild* 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~~ from CSF since birth or for at least three 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 Chapters 4.5. and 4.6.

Article 15.2.9.

Recommendations for importation from CSF infected countries or zones

For semen of domestic and *captive wild* 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~~ from CSF since birth or for at least three 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) met one of the following conditions:

i) have not been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection, with negative results; or

ii) have been vaccinated against CSF and were subjected to a serological test ~~in accordance with the *Terrestrial Manual*~~ performed at least 21 days after collection and it has been conclusively demonstrated that any antibody is due to the vaccine; or

iii) have been vaccinated against CSF and were subjected to a virological test performed ~~in accordance with the *Terrestrial Manual*~~ on a sample taken on the day of collection and it has been conclusively demonstrated that the boar is negative for virus genome;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 15.2.10.

Recommendations for importation from countries, zones or compartments free ~~of~~ from 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 Chapters 4.7. and 4.9., as relevant.

Article 15.2.11.

Recommendations for importation from CSF infected countries or zones

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 *compartment* free ~~of~~ from CSF since birth or for at least three 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) and either:

i) have not been vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection; or

ii) 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 according 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 Chapters 4.7. and 4.9., as relevant.

Article 15.2.12.

Recommendations for importation from countries, zones or compartments free ~~of~~ from CSF

For fresh meat of domestic and *captive wild* pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *animals* which:

1) have been kept in a country, *zone* or *compartment* free ~~of~~ from CSF, or which have been imported in accordance with Article 15.2.5. or Article 15.2.6.;

2) have been slaughtered in an approved *slaughterhouse/abattoir,* have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any sign suggestive of CSF.

Article 15.2.13.

Recommendations for the importation of fresh meat of wild and feral pigs

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *animals*:

1) which have been subjected to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre, and have been found free ~~of~~ from 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.

Article 15.2.14.

Recommendations for the importation of meat and meat products of pigs~~, 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

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 Article 15.2.12.;

b) in a processing establishment:

i) approved by the *Veterinary Authority* for export purposes;

ii) processing only *meat* meeting the conditions laid down in Article 15.2.12.;

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~~ CSFV in conformity with one of the procedures referred to in

Article 15.2.21. and that the necessary precautions were taken after processing to avoid contact of the product with any source of ~~CSF virus~~ CSFV.

Article 15.2.15.

Recommendations for the importation of pig products ~~of animal origin (from pigs~~, ~~but~~ not derived from fresh meat~~)~~, intended for use in animal feeding

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1) originated from domestic and *captive wild* pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; 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~~ CSFV in accordance with Article 15.2.20. and that the necessary precautions were taken after processing to avoid contact of the product with any source of ~~CSF virus~~ CSFV.

Article 15.2.16.

Recommendations for the importation of pig products ~~of animal origin (from pigs~~, ~~but~~ not derived from fresh meat~~)~~, intended for agricultural or industrial use

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1) originated from domestic and *captive wild* pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; 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~~ CSFV ~~(under study)~~ and that the necessary precautions were taken after processing to avoid contact of the product with any source of ~~CSF virus~~ CSFV.

Article 5.2.17.

Recommendations for the importation of bristles

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1) originated from domestic and *captive wild* pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; 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~~ CSFV ~~(under study)~~ and that the necessary precautions were taken after processing to avoid contact of the product with any source of ~~CSF virus~~ CSFV.

Article 15.2.18.

Recommendations for the importation of litter and manure

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1) originated from domestic and *captive wild* pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; 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~~ CSFV ~~(under study)~~ and that the necessary precautions were taken after processing to avoid contact of the product with any source of ~~CSF virus~~ CSFV.

Article 15.2.19.

Recommendations for the importation of skins and trophies

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1) originated from domestic and *captive wild* pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; 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~~ CSFV in conformity with one of the procedures referred to in Article 15.2.22. and that the necessary precautions were taken after processing to avoid contact of the product with any source of ~~CSF virus~~ CSFV.

Article 15.2.20.

Procedures for the inactivation of the ~~CSF virus~~ CSFV in swill

For the inactivation of ~~CSF viruses~~ CSFV ~~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 15.2.21.

Procedures for the inactivation of the ~~CSF virus~~ CSFV in meat

For the inactivation of ~~viruses~~ CSFV ~~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 should 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 15.2.21. bis

Procedures for the inactivation of the CSFV in casings of pigs

For the inactivation of CSFV in casings of pigs, the following procedures should be used: salting for at least 30 days either with phosphate supplemented dry salt or saturated brine (Aw < 0.80) containing 86.5% NaCl, 10.7% Na_2HPO_4 and 2.8% Na_3PO_4 (weight/weight/weight), and kept at a temperature of greater than 20°C during this entire period.

EU comment

The EU suggests amending the article above, in line with the recent scientific opinion of the European Food Safety Authority (EFSA) on animal health risk mitigation treatments as regards imports of animal casings (cf. http://www.efsa.europa.eu/de/efsajournal/pub/2820.htm), as follows:

"For the inactivation of CSFV in casings of pigs, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl a_w < 0.80), or with phosphate supplemented dry salt or saturated brine (a_w ~~Aw~~ < 0.80) containing 86.5% NaCl, 10.7% Na2HPO4 and 2.8% Na3PO4 (weight/weight/weight), and kept at a temperature of ~~greater than~~ 20°C or above during this entire period."

For CSFV, also the classical NaCl treatment should be recommended. Indeed, the EFSA opinion states that "*Salting of casings derived from experimentally infected animals with NaCl for a period of 30 days at room temperature (~20 °C) inactivated CSFV*" (cf. p 21 of said opinion).

Furthermore, EFSA recommends salting treatments to be done at a temperature of 20°C or above (cf. p 23 of said opinion).

Article 15.2.22.

Procedures for the inactivation of the ~~CSF viruses~~ CSFV in skins and trophies

For the inactivation of ~~CSF viruses~~ CSFV ~~likely to be present~~ in skins and trophies, one of the following procedures should be used:

1) boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed;

2) gamma irradiation at a dose of at least 20 kilo Gray 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 15.2.23.

Surveillance: introduction

Articles 15.2.23. to 15.2.28.bis define the principles and provide a guide on the *surveillance* for CSF, complementary to Chapter 1.4., applicable to Member Countries seeking the OIE recognition of CSF status ~~to determine their CSF status~~. This may be for the entire country, or a *zone*. Guidance is also provided for Member Countries seeking recovery of CSF status for the entire country or for a *zone*, ~~free status~~ following an *outbreak* and for the maintenance of CSF status. ~~is also provided.~~

The impact and epidemiology of CSF may vary ~~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 should ~~will need to~~ be adapted to the local situation. For example, the approach should be tailored in order to prove freedom from CSF for a country or *zone* where *wild* and *feral* pigs provide a potential reservoir of *infection,* or where CSF is present in adjacent countries. The method should 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 Member Countries 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~~ susceptible populations in a country, *zone* or *compartment* ~~is~~ are free from CSFV *infection* or to detect the introduction of CSFV into a population already defined ~~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 and the role of *wild* and *feral* pigs 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 15.2.24.

Surveillance: general conditions and methods

1) A *surveillance* system, in accordance with Chapter 1.4. and under the responsibility of the *Veterinary Authority*, should address the following aspects:. ~~A procedure should be in place for the rapid collection and transport of samples to an accredited *laboratory* as described in the *Terrestrial Manual*.~~

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

   b) a procedure should be in place for the rapid collection and transport of samples from suspected *cases* to a *laboratory* for CSF diagnosis;

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

2) The CSF *surveillance* programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspected ~~suspicious~~ *cases*. Diagnosticians and those with regular ~~Farmers and workers, who have day to day~~ contact with pigs ~~livestock, as well as diagnosticians~~, should report promptly any suspicion of CSF to the *Veterinary Authority*. ~~They~~ The *notification* system under the *Veterinary Authority* 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*.~~ Other important *diseases* such as African swine fever should also be considered in any differential diagnosis. 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~~ laboratory 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* and *feral* pigs are present).

An effective *surveillance* system will periodically identify suspected ~~suspicious~~ *cases* that require follow-up and investigation to confirm or exclude ~~that the cause of the condition is~~ *infection* with CSFV. The rate at which such suspected ~~suspicious~~ *cases* are likely to occur will differ between epidemiological situations and cannot, therefore, be reliably predicted. Applications for r~~R~~ecognition~~s~~ ~~for~~ of ~~freedom from~~ CSF~~V~~ status ~~infection~~ should, as a consequence, provide details in accordance with Article 1.6.7ter. of the occurrence of suspected ~~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 15.2.25.

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 free of CSF, *surveillance* programmes should be designed to detect the introduction of CSFV into domestic 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*.~~

The strategy employed to establish the prevalence or absence of CSFV *infection* may be based on randomised or targeted clinical investigation or sampling at an acceptable level of statistical confidence. If an increased likelihood of *infection* in particular localities or sub-populations can be identified, targeted sampling may be an appropriate strategy. ~~*Surveillance* is targeted to the~~ This may include ~~pig populations which presents the highest risk of *infection* (for example,~~

- swill fed farms,
- pigs reared outdoors,
- specific high-risk *wild* and *feral* pig sub-populations and ~~or~~ farms in their proximity ~~to infected wild pigs)~~.

~~Each Member will need to identify its individual risk factors.~~

~~These~~ Risk factors may include~~:~~ temporal and spatial distribution of past *outbreaks*, pig movements and demographics, etc.

For reasons of cost~~,~~, ~~and~~ ~~the~~ ~~longevity~~ persistence of antibody levels~~, as well as~~ and the existence of clinically inapparent *infections* ~~and difficulties associated with differential diagnosis of other *diseases*,~~, serology in unvaccinated populations is often the most effective and efficient *surveillance* methodology. In some circumstances such as ~~with~~in differential diagnosis of other *diseases*, ~~which will be discussed later,~~ clinical and virological *surveillance* may also have value.

The *surveillance* strategy chosen ~~The Member~~ should be justify~~ied~~ ~~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 routine ~~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*.~~

When applying randomised sampling, either at the level of the entire population or within targeted sub-populations ~~For random surveys,~~ the design of the sampling strategy ~~will need to~~ should incorporate epidemiologically appropriate design prevalences for the selected populations. The sample size selected for testing ~~will need to~~ should be large enough to detect *infection* if it were to occur at a ~~predetermined~~ predefined minimum rate. ~~The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey.~~ The choice of design prevalence and confidence level ~~The Member~~

should be justifyied ~~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~~ approach selected, the sensitivity and specificity of the diagnostic tests ~~employed~~ should be considered ~~are factors~~ in the survey design, the sample size determination and the 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,~~ tThe *surveillance* system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognised 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.~~

Clinical *surveillance* continues to be the cornerstone of CSF detection. However, due to the low virulence of some CSFV strains and the spread of *diseases* such as African swine fever, and those associated with porcine circovirus 2 *infection*, clinical *surveillance* should be supplemented, as appropriate, by serological and virological *surveillance*.

~~In the past, The value of clinical identification of *cases* was the cornerstone of early detection of CSF. However, emergence of *surveillance* alone is limited due to the low virulence of some strains of CSF, as well as the emergence of 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) which can mask the presence of CSF. Therefore, clinical *surveillance* should be supplemented, as appropriate, by serological and virological *surveillance*.~~

~~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, c~~Clinical signs and pathological findings ~~presentation should not be ignored as a tool~~ are useful for early detection; in particular, any *cases* where clinical signs or lesions suggestive of ~~consistent with~~ CSF are accompanied by high morbidity ~~and/~~or mortality, these should be investigated without delay. In CSFV *infections* involving low virulence strains, high mortality may only be seen in young *animals* and adults may not present clinical signs. ~~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 *feral* 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.

3. Virological surveillance

Virological *surveillance* should be conducted:

a) to monitor at risk populations;

b) to investigate clinically suspected *cases*;

c) to follow up positive serological results;

d) to investigate increased mortality.

Molecular detection methods can be applied to large-scale screening for the presence of virus. If targeted at high risk groups, they provide an opportunity for early detection that can considerably reduce the subsequent spread of *disease*. 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. Therefore, CSFV isolates should be sent to an OIE Reference Laboratory for further characterisation.

~~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~~4. 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 viruses (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.~~ One route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with BVDV.

CSFV may lead to persistently infected, sero-negative young *animals*, which continuously shed virus. CSFV *infection* may also lead to c~~C~~hronically infected pigs which may have undetectable or fluctuating antibody levels. Even though serological methods will not detect these *animals*, such *animals* are likely to be in a minority and would not confound a diagnosis based on serology as part of a *herd* investigation.

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 should 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.~~ In countries or *zones* where *vaccination* has been recently discontinued, ~~T~~targeted serosurveillance of young, unvaccinated *animals* ~~stock will indicate whether newly~~ can indicate the presence of *infection* ~~circulating virus is present, although the presence of maternal antibody will also need to be considered~~. Maternal antibodies are usually found up to 8-10 weeks of age but may occasionally last up to four and a half months and can interfere with the interpretation of serological results. ~~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.~~

Marker v~~V~~accines and accompanying DIVA tests which fulfil the requirements of the *Terrestrial Manual* ~~also exist which~~, ~~when used in conjunction with dedicated serological tests~~, may allow discrimination between vaccinal antibody and that induced by ~~field~~ natural *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,~~ The serosurveillance results using DIVA techniques may be interpreted either at *animal* or *herd* level ~~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.~~

~~The free status~~ Member Countries should ~~be~~ review~~ed~~ their *surveillance* strategies whenever an increase in the risk of incursion of CSFV is perceived. ~~evidence emerges to indicate that changes which may alter the underlying assumption of continuing freedom, has occurred~~. Such changes include but are not limited to:

a) an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;

b) ~~an increase in the volume of imports or a change in their country or *zone* of origin;~~ an increase in the prevalence of CSF in *wild* or *feral* pigs in the country or *zone*;

c) an increase in the prevalence of CSF in ~~the domestic or *wild* pigs of~~ adjacent countries or *zones*;

d) an increased entry from, or exposure to, infected *wild* or *feral* pig populations of adjacent countries or *zones*.

Article 15.2.26.

Additional surveillance procedures for Member Countries applying for OIE recognition of CSF free status

~~**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 above, 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 should be planned and implemented according to the general conditions for status recognition and methods described in Article 15.2.2. and 15.2.3. and methods described elsewhere in this chapter., The objective is to demonstrate the absence of CSFV *infection* in domestic and *captive wild* pigs during the last 12 months and to assess the *infection* status in *wild* and *feral* pig populations, as described in Article 15.2.28. 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 Chapters 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:

g. periodic clinical and serological monitoring of *herds* in the country or *zone*, and adjacent wild pig populations following these recommendations;

h. *herd* registration;

i. official accreditation of *biosecurity plans*;

j. 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 government wildlife authorities, 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 15.2.27.

Additional surveillance procedures for recovery of free status

Recovery of free status: additional surveillance procedures

In addition to the general conditions described in ~~the above-mentioned articles~~ this chapter, a Member Country seeking ~~reestablishment~~ recovery of country or *zone* ~~freedom from~~ CSF free status, including a *containment zone*, should show evidence of an active *surveillance* programme to demonstrate absence of CSFV *infection*.

Populations under this *surveillance* programme should include:

1) *establishments* in the proximity of the *outbreaks*;

2) *establishments* epidemiologically linked to the *outbreaks*;

3) *animals* moved from or used to re-populate affected *establishments*; ~~and~~

4) any *establishments* where contiguous culling ~~is~~ has been carried out;

5~~4~~) *wild* and *feral* pig populations in the area of the *outbreaks*.

~~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~~ tThe domestic and *captive wild* pig populations should undergo~~es~~ regular clinical, pathological, virological, and/~~or~~ serological examination, planned and implemented according to the general conditions and methods described in these recommendations. Epidemiological evidence of the infection status in *wild* and *feral* pigs should be compiled. ~~The *surveillance* should be based on a statistically representative sample of the populations at risk.~~ To regain CSF free status, the *surveillance* approach should provide at least the same level of confidence as within the original application for recognition of freedom.

Article 15.2.28.

Surveillance for CSFV infection in wild ~~boars~~ and feral pigs

1) The objective of a *surveillance* programme is either to demonstrate that CSFV *infection* is not present in *wild* and *feral* pigs or, if known to be present, to estimate the distribution and prevalence of the *infection*. While the same principles apply, *surveillance* in *wild* and *feral* pigs presents additional challenges including: ~~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* and *feral* pig population;

   b) relevance and practicality of assessing~~ment~~ ~~of~~ the possible presence of CSFV *infection* within the population;

   c) determination of the practicability of establishing a *zone* taking into account the degree of interaction with domestic and *captive wild* pigs within the proposed *zone*.

~~2) 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~~ estimated size of *wild* and *feral* pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information to aid in the design of a monitoring system may include governmental and non-governmental *wildlife* ~~conservation~~ organisations~~,~~ such as 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.~~

~~3) Estimates of *wild* pig populations can be made using advanced methods (e.g. 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).~~

4~~2~~) For implementation of the monitoring programme, it will be necessary to define the limits of the ~~territory~~ area over which *wild* and *feral* pigs range, in order to delineate the *epidemiological units* within the monitoring programme. It is often difficult to define *epidemiological units* for *wild* or *feral* pigs ~~*animals*~~. The most practical approach is based on natural and artificial barriers.

~~5~~3) The monitoring programme should involve serological and virological testing, ~~should also~~ includinge *animals* found dead, road kills, *animals* showing abnormal behaviour or exhibiting gross lesions during dressing.

~~6~~4) 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 large populations of *wild* and *feral* pigs;

c) border regions with CSF affected countries or *zones*;

d) interface between *wild* and *feral* pig populations, and domestic and *captive wild* pig populations;

Annex XXXI (contd)

~~e) picnic and camping areas;~~

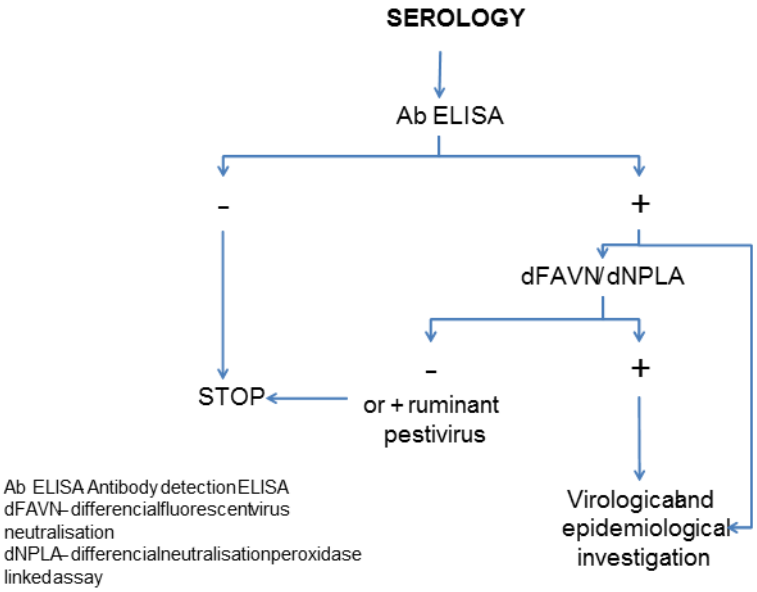
~~f~~e) farms with free-ranging pigs;

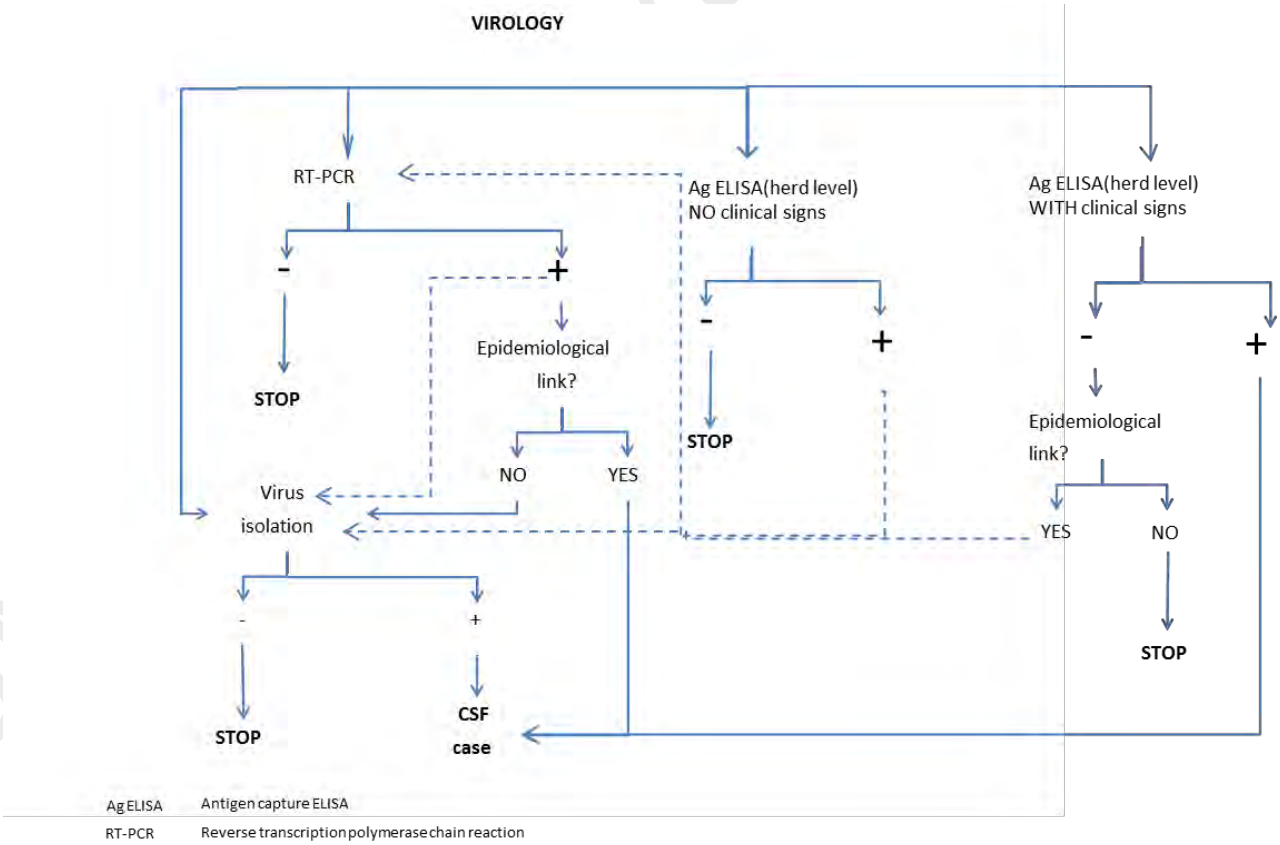
~~g) garbage dumps;~~

~~h~~f) other risk areas determined by the *Veterinary Authority* such as garbage dumps and picnic and camping areas.

Article 15.2.28. bis

The use and interpretation of diagnostic tests in surveillance




VIROLOGY
RT-PCR
Ag ELISA(herd level)
NO clinical signs
Ag ELISA(herd level)
WITH clinical signs
-
+
STOP
Epidemiological
link?
NO
YES
Virus
isolation
CSF
case
Ag ELISA Antigen capture ELISA
RT-PCR Reverse transcription polymerase chain reaction

Annex XXXI (contd)

CHAPTER 1.6.

PROCEDURES FOR SELF DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE

EU position

The EU supports the adoption of this modified chapter.

Article 1.6.7. ter

Questionnaire on classical swine fever

CSF FREE COUNTRY OR ZONE

Report of a Member Country which applies for recognition of status,
under Chapter 15.2. of the *Terrestrial Animal Health Code*, as a free country or *zone*

Please address concisely the following topics. National regulations, laws and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

   a) Geographical factors. Provide a general description of the country or *zone* including physical, geographical and other factors that are relevant to CSF dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. The boundaries of the country or *zone* must be clearly defined, including a *protection zone* if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the country or *zone*.

   b) Pig industry. Provide a general description of the domestic and *captive wild* pig industry in the country or *zone*.

2. Veterinary system

   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to CSF.

   b) *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 Chapter 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all CSF related activities. Provide maps and tables wherever possible.

   c) Role of farmers, industry and other relevant governmental and non-governmental organisations in CSF *surveillance* and control (include a description of training and awareness programmes on CSF).

   d) Role of private veterinary profession in CSF *surveillance* and control.

3. CSF eradication

   a) History. Provide a description of the CSF history in the country and *zone*, date of first detection, temporal and spatial distribution, origin of *infection*, date of last *case* in the country or *zone*.

   b) Strategy. Describe how CSF was controlled and eradicated in the country or *zone* (e.g. stamping-out, modified stamping-out, zoning), provide time-frame for eradication.

c) Vaccines and vaccination. Was CSF vaccine ever used? If so, of what type and when was the last *vaccination* carried out? If DIVA vaccine has been used, provide details of the differential tests.

d) Legislation, organisation and implementation of the CSF eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

e) Animal identification and movement control. Are pigs identified (individually or at a group level)? Provide a description of the criteria and methods for *animal identification*, *herd* registration and traceability for all sectors of pig production including free-ranging pig management systems. How are pig movements controlled in different sectors in the country or *zone*, or between *zones* of the same or different status?

4. CSF diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.1, 1.1.2., 1.1.3., and 2.8.3. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is CSF 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.

b) Provide an overview of the CSF approved laboratories, in particular to address the following points:

i) Procedures for the official accreditation of laboratories. Give details of formal quality management systems, such as Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system.

ii) Give details of participation in inter-laboratory validation tests (ring tests).

iii) Is live virus handled?

iv) Biosecurity and biosafety measures applied.

v) Details of the type of tests undertaken.

5. CSF surveillance

Provide documentary evidence that *surveillance* for CSF in the country or *zone* complies with the provisions of Articles 15.2.23. to 15.2.28.bis of the *Terrestrial Code* and Chapter 2.8.3. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of CSF? 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 12 months, the number of suspected *cases*, the number of samples tested for CSFV, type of sample, testing method(s) and results (including differential diagnosis).

b) Serological and virological surveillance. Are serological or virological surveys conducted? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are *wild* and *feral* pigs included in *surveillance*? For both serological and virological surveillance provide a summary table indicating, for the past 12 months, the number of samples tested for CSFV, 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 pigs examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

c) Domestic and captive wild pig populations and production. What is the pig population? Provide a description of the different production systems present in the country and *zone(s)* and production figures in each sector. How many *herds* are in the country and *zone(s)*? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.

Annex XXXI (contd)

d) Wild and feral pig populations. Provide estimates of population sizes, geographic distribution and, if available, population trends in the country and *zone(s)*.

e) Slaughterhouses and markets. Where are the major pig marketing or collection centres? What are the patterns of pig movement within the country or *zone*, and between *zone(s)* of the same or different status? How are the pigs sourced, transported and handled during these transactions? Is any *surveillance* carried out at *slaughterhouses*? Provide data on the number of pigs slaughtered and inspected during the past twelve months.

6. CSF prevention

a) 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 *wild* and *feral* pig populations)? Describe coordination, collaboration and information sharing activities with neighbouring countries. Are *protection zones* in place? If so, provide details on the measures that are applied (e.g. *vaccination*, intensified *surveillance*, pig density control), and provide a geo-referenced map of the *zone(s)*.

b) Import control procedures

From what countries or *zones* does the country authorize the import of pigs or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such pigs and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported pigs 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 pigs and their products for the past twelve months, specifying country or *zone* of origin and volume.

i) 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.

ii) 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 twelve months, of the quantity disposed of. Is swill feeding of pigs allowed in the country? If so, provide details on any heat inactivation procedures that are applied.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or their final destination, concerning the import and follow-up of the following:

- pigs,
- genetic material (semen and embryos),
- *fresh meat*, pig products and by-products,
- veterinary medicinal products (i.e. biologics).

iv) 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

a) What are the measures in place to prevent contact between domestic and *captive wild* pigs, and *wild* and *feral* pig populations?

b) If DIVA vaccine is used as part of risk mitigation, provide details of the vaccine and the differential tests.

c) Describe the procedures applied to ensure *disinfection* of *vehicles* and equipment, including verification methods.

d) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of CSF.

e) Is quarantine imposed on premises with suspected *cases*, pending final diagnosis? What other procedures are followed regarding suspected *cases*?

f) In the event of a CSF *outbreak*:

i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with CSF;

iii) indicate the control and eradication procedures (e.g. policies on emergency *vaccination*, stamping-out, partial *slaughter*, etc.) that would be taken. Provide details of any vaccine supply scheme and stocks. If DIVA vaccines may be used, also include details on the differential test. Include details on carcass disposal, logistics and methods;

iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled or eradicated, including any details on policy for restocking;

v) give details of any compensation payments when pigs are slaughtered for *disease* control and eradication purposes and the prescribed timetable for payments.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Articles 15.2.2. and 15.2.3. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:

a) there has been no *outbreak* of CSF or evidence of CSFV *infection* in domestic and *captive wild* pigs in the country or *zone* during the past 12 months;

b) no *vaccination* against CSF has been carried out in domestic and *captive wild* pigs in the country or *zone* during the past 12 months; or, if *vaccination* is carried out, vaccinated and infected pigs can be distinguished by a means validated according to Chapter 2.8.3. of the *Terrestrial Manual*;

c) imported pigs and pig *commodities* comply with the relevant requirements in Chapter 15.2.

Annex XXXI (contd)

9. Recovery of free status

Member Countries applying for recovery of free status of a country or *zone* should comply with the provisions of Article 15.2.4. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c), 5.b) and 7 of this questionnaire. Information in relation to other sections need only be supplied if relevant.

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— Text deleted.

Annex XXXVI

CHAPTER 7.5.

SLAUGHTER OF ANIMALS

EU comments

The EU does not support the proposed removal of the tables from this chapter.

Justification

The tables list different operations (i.e. methods of restraint, stunning etc.) - the way animals should be presented, the welfare concerns, implications and applicable species – this is not included anywhere else in the chapters and it is very relevant to basic animal welfare.

Two examples for this are:

1) Non-penetrative captive bolt, where the table includes the following information (but similar examples could be found for most rows in the tables):

"Presently available devices are not recommended for young bulls and animals with thick skull. This method should only be used for cattle and sheep when alternative methods are not available."

2) Basic concerns / requirements for bleeding by severance of blood vessels

"Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut."

"A very sharp blade or knife of sufficient length so that the point of the knife remains outside the incision during the cut."

Alternatively, if the OIE decides to remove these tables the whole chapter should undergo review to ensure that none of this detail is lost. An option could be to include sections on restraint, stunning etc. which cover the different methods/ types and list the species, advantages and disadvantages.

Article 7.5.1.

General principles

1. Object

These recommendations address the need to ensure the *welfare* of food *animals* during pre-slaughter and *slaughter* processes, until they are dead.

These recommendations apply to the *slaughter* in *slaughterhouses* of the following domestic *animals*: cattle, buffalo, bison, sheep, goats, camelids, deer, horses, pigs, ratites, rabbits and *poultry*. Other *animals*, wherever they have been reared, and all *animals* slaughtered outside *slaughterhouses* should be managed to ensure that their *transport*, *lairage*, *restraint* and *slaughter* is carried out without causing undue stress to the *animals*; the principles underpinning these recommendations apply also to these *animals*.

2. Personnel

Persons engaged in the *unloading*, moving, *lairage*, care, *restraint*, *stunning*, *slaughter* and bleeding of *animals* play an important role in the *welfare* of those *animals*. For this reason, there should be a sufficient

number of personnel, who should be patient, considerate, competent and familiar with the recommendations outlined in the present chapter and their application within the national context.

Competence may be gained through formal training and/or practical experience. This competence should be demonstrated through a current certificate from the *Competent Authority* or from an independent body accredited by the *Competent Authority*.

The management of the *slaughterhouse* and the *Veterinary Services* should ensure that *slaughterhouse* staff are competent and carry out their tasks in accordance with the principles of *animal welfare*.

3. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock, and understand the behaviour patterns of *animals* and the underlying principles necessary to carry out their tasks.

The behaviour of individual *animals* or groups of *animals* will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic *animals*, should be taken into consideration in handling and moving the *animals*.

Most domestic livestock are kept in groups and follow a leader by instinct.

Animals which are likely to harm each other in a group situation should not be mixed at *slaughterhouses*.

The desire of some *animals* to control their personal space should be taken into account in designing facilities.

Domestic *animals* will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. *Animals* reared in close proximity to humans i.e. tame have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. *Animal handlers* should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape.

Animal handlers should use the point of balance at the *animal*'s shoulder to move *animals*, adopting a position behind the point of balance to move an *animal* forward and in front of the point of balance to move it backward.

Domestic *animals* have wide-angle vision but only have limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

Although most domestic *animals* have a highly sensitive sense of smell, they react in different ways to the smells of *slaughterhouses*. Smells which cause fear or other negative responses should be taken into consideration when managing *animals*.

Domestic *animals* can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling *animals*.

4. Distractions and their removal

Distractions that may cause approaching *animals* to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

a) reflections on shiny metal or wet floors – move a lamp or change lighting;

b) dark entrances to chutes, races, stun boxes or conveyor restrainers – illuminate with indirect lighting which does not shine directly into the eyes of approaching *animals* or create areas of sharp contrast;

c) *animals* seeing moving people or equipment up ahead – install solid sides on chutes and races or install shields;

d) dead ends – avoid if possible by curving the passage, or make an illusory passage;

e) chains or other loose objects hanging in chutes or on fences – remove them;

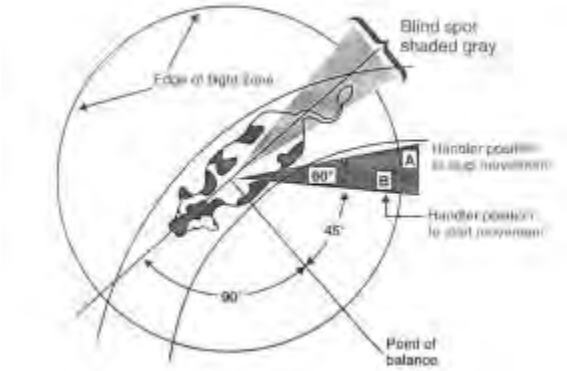
f) uneven floors or a sudden drop in floor levels at the entrance to conveyor restrainers – avoid uneven floor surfaces or install a solid false floor under the restrainer to provide an illusion of a solid and continuous walking surface;

g) sounds of air hissing from pneumatic equipment – install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;

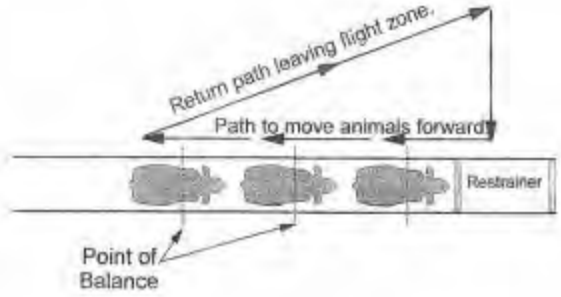
h) clanging and banging of metal objects – install rubber stops on gates and other devices to reduce metal to metal contact;

i) air currents from fans or air curtains blowing into the face of *animals* – redirect or reposition equipment.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



Article 7.5.2.

Moving and handling animals

1. General considerations

Each *slaughterhouse* should have a dedicated plan for *animal welfare*. The purpose of such plan should be to maintain good level of *animal welfare* at all stages of the handling of *animals* until they are killed. The

plan should contain standard operating procedures for each step of animal handling as to ensure that *animal welfare* is properly implemented based on relevant indicators. It also should include specific corrective actions in case of specific risks, like power failures or other circumstances that could negatively affect the *welfare* of *animals*.

Animals should be transported to *slaughter* in a way that minimises adverse animal health and *welfare* outcomes, and the transport should be conducted in accordance with the OIE recommendations for the transportation of *animals* (Chapters 7.2. and 7.3.).

The following principles should apply to *unloading animals*, moving them into *lairage* pens, out of the *lairage* pens and up to the *slaughter* point:

a) The conditions of the *animals* should be assessed upon their arrival for any *animal welfare* and health problems.

b) Injured or sick *animals*, requiring immediate *slaughter*, should be killed humanely and without delay, in accordance with the recommendations of the OIE.

c) *Animals* should not be forced to move at a speed greater than their normal walking pace, in order to minimise injury through falling or slipping. Performance standards should be established where numerical scoring of the prevalence of *animals* slipping or falling is used to evaluate whether animal moving practices and/or facilities should be improved. In properly designed and constructed facilities with competent *animal handlers*, it should be possible to move 99 percent of *animals* without their falling.

d) *Animals* for *slaughter* should not be forced to walk over the top of other *animals*.

e) *Animals* should be handled in such a way as to avoid harm, distress or injury. Under no circumstances should *animal handlers* resort to violent acts to move *animals*, such as crushing or breaking tails of *animals*, grasping their eyes or pulling them by the ears. *Animal handlers* should never apply an injurious object or irritant substance to *animals* and especially not to sensitive areas such as eyes, mouth, ears, anogenital region or belly. The throwing or dropping of *animals*, or their lifting or dragging by body parts such as their tail, head, horns, ears, limbs, wool, hair or feathers, should not be permitted. The manual lifting of small *animals* is permissible.

f) When using goads and other aids, the following principles should apply:

    i) *Animals* that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move *animals*. The use and the power output should be restricted to that necessary to assist movement of an *animal* and only when an *animal* has a clear path ahead to move. Goads and other aids should not be used repeatedly if the *animal* fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the *animal* from moving.

    ii) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.

    iii) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the *animals* without causing undue stress.

    iv) Painful procedures (including whipping, kicking, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move *animals*.

    v) Excessive shouting at *animals* or making loud noises (e.g. through the cracking of whips) to encourage them to move should not occur, as such actions may make the *animals* agitated, leading to crowding or falling.

vi) *Animals* should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young *animals* or small species, and in a manner appropriate to the species; grasping or lifting such *animals* only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where *animal welfare* or human safety may otherwise be compromised.

vii) Conscious *animals* should not be thrown, dragged or dropped.

g) Performance standards should be established to evaluate the use of such instruments. Numerical scoring may be used to measure the percentage of *animals* moved with an electric instrument and the percentage of *animals* slipping or falling at a point in the *slaughterhouse*. Any risk of compromising *animal welfare*, for example slippery floor, should be investigated immediately and the defect rectified to eliminate the problem. In addition to resource-based measures, outcome-based measures (e.g. bruises, lesions, behaviour, and mortality) should be used to monitor the level of *welfare* of the *animals*.

2. Specific considerations for poultry

Stocking density in transport crates should be optimum to suit climatic conditions and to maintain species-specific thermal comfort within *containers*.

Care is especially necessary during *loading* and *unloading* to avoid body parts being caught on crates, leading to dislocated or broken bones in conscious birds. Such injuries will adversely affect *animal welfare*, carcass and *meat* quality.

Modular systems that involve tipping of live birds are not conducive to maintaining good *animal welfare*. These systems, when used, should be incorporated with a mechanism to facilitate birds sliding out of the transport system, rather than being dropped or dumped on top of each other from heights of more than a metre.

Birds may get trapped or their wings or claws may get caught in the fixtures, mesh or holes in poorly designed, constructed or maintained transport systems. Under this situation, operators *unloading* birds should ensure gentle release of trapped birds.

Drawers in modular systems and crates should be stacked and de-stacked carefully so as to avoid injury to birds.

Birds should have sufficient space so that all can lie down at the same time without being on top of each other.

Birds with broken bones and/or dislocated joints should be humanely killed before being hung on shackles for processing.

The number of *poultry* arriving at the processing plant with broken bones and/or dislocated joints should be recorded in a manner that allows for verification. For *poultry*, the percentage of chickens with broken or dislocated wings should not exceed 2 percent, with less than 1 percent being the goal (under study).

3. Provisions relevant to animals delivered in containers

a) *Containers* in which *animals* are transported should be handled with care, and should not be thrown, dropped or knocked over. Where possible, they should be horizontal while being loaded and unloaded mechanically, and stacked to ensure ventilation. In any case they should be moved and stored in an upright position as indicated by specific marks.

b) *Animals* delivered in *containers* with perforated or flexible bottoms should be unloaded with particular care in order to avoid injury. Where appropriate, *animals* should be unloaded from the *containers* individually.

c) *Animals* which have been transported in *containers* should be slaughtered as soon as possible; mammals and ratites which are not taken directly upon arrival to the place of *slaughter* should have drinking water available to them from appropriate facilities at all times. Delivery of *poultry* for *slaughter* should be scheduled such that they are not deprived of water at the premises for longer than 12 hours.

Animals which have not been slaughtered within 12 hours of their arrival should be fed, and should subsequently be given moderate amounts of food at appropriate intervals.

4. Provisions relevant to restraining and containing animals

a) Provisions relevant to *restraining animals* for *stunning* or *slaughter* without *stunning*, to help maintain *animal welfare*, include:

i) provision of a non-slippery floor;

ii) avoidance of excessive pressure applied by *restraining* equipment that causes struggling or vocalisation in *animals*;

iii) equipment engineered to reduce noise of air hissing and clanging metal;

iv) absence of sharp edges in *restraining* equipment that would harm *animals*;

v) avoidance of jerking or sudden movement of *restraining* device.

b) Methods of *restraint* causing avoidable suffering should not be used in conscious *animals* because they cause severe pain and stress:

i) suspending or hoisting *animals* (other than *poultry*) by the feet or legs;

ii) indiscriminate and inappropriate use of *stunning* equipment;

iii) mechanical clamping of the legs or feet of the *animals* (other than shackles used in *poultry* and ostriches) as the sole method of *restraint*;

iv) breaking legs, cutting leg tendons or blinding *animals* in order to immobilise them;

v) severing the spinal cord, for example using a puntilla or dagger, to immobilise *animals* using electric currents to immobilise *animals*, except for proper *stunning*.

Article 7.5.3.

Lairage design and construction

1. General considerations

The *lairage* should be designed and constructed to hold an appropriate number of *animals* in relation to the throughput rate of the *slaughterhouse* without compromising the *welfare* of the *animals*.

In order to permit operations to be conducted as smoothly and efficiently as possible without injury or undue stress to the *animals*, the *lairage* should be designed and constructed so as to allow the *animals* to move freely in the required direction, using their behavioural characteristics and without undue penetration of their flight zone.

The following recommendations may help to achieve this.

2. Design of lairage

a) The *lairage* should be designed to allow a one-way flow of *animals* from *unloading* to the point of *slaughter*, with a minimum number of abrupt corners to negotiate.

b) In red meat *slaughterhouses*, pens, passageways and races should be arranged in such a way as to permit inspection of *animals* at any time, and to permit the removal of sick or injured *animals* when considered to be appropriate, for which separate appropriate accommodation should be provided.

c) Each *animal* should have room to stand up and lie down and, when confined in a pen, to turn around, except where the *animal* is reasonably restrained for safety reasons (e.g. fractious bulls). Fractious *animals* should be slaughtered as soon as possible after arrival at the *slaughterhouse* to avoid *welfare* problems. The *lairage* should have sufficient accommodation for the number of *animals* intended to be held. Drinking water should always be available to the *animals*, and the method of delivery should be appropriate to the type of *animal* held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces, without introducing risk of bruising and injury in *animals*, and should not hinder the movement of *animals*.

d) Holding pens should be designed to allow as many *animals* as possible to stand or lie down against a wall. Where feed troughs are provided, they should be sufficient in number and feeding space to allow adequate access of all *animals* to feed. The feed trough should not hinder the movement of *animals*.

e) Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress to the *animals* and should also allow the *animals* to stand, lie down and access any food or water that may need to be provided.

f) Passageways and races should be either straight or consistently curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race, the shared partition should allow adjacent *animals* to see each other. For pigs and sheep, passageways should be wide enough to enable two or more *animals* to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the *animals*.

g) *Animal handlers* should be positioned alongside races and passageways on the inside radius of any curve, to take advantage of the natural tendency of *animals* to circle an intruder. Where one-way gates are used, they should be of a design which avoids bruising. Races should be horizontal but where there is a slope, they should be constructed to allow the free movement of *animals* without injury.

h) In *slaughterhouses* with high throughput, there should be a waiting pen, with a level floor and solid sides, between the holding pens and the race leading to the point of *stunning* or *slaughter*, to ensure a steady supply of *animals* for *stunning* or *slaughter* and to avoid having *animal handlers* trying to rush *animals* from the holding pens. The waiting pen should preferably be circular, but in any case, so designed that *animals* cannot be trapped or trampled.

i) Ramps or lifts should be used for the *loading* and *unloading* of *animals* where there is a difference in height or a gap between the floor of the *vehicle* and the *unloading* area. Unloading ramps should be designed and constructed so as to permit *animals* to be unloaded from *vehicles* on the level or at the minimum gradient achievable. Lateral side protection should be available to prevent *animals* escaping or falling. They should be well drained, with secure footholds and adjustable to facilitate easy movement of *animals* without causing distress or injury.

3. Construction of lairage

a) *Lairages* should be constructed and maintained so as to provide protection from unfavourable climatic conditions, using strong and resistant materials such as concrete and metal which has been treated to prevent corrosion. Surfaces should be easy to clean. There should be no sharp edges or protuberances which may injure the *animals*.

b) Floors should be well drained and not slippery; they should not cause injury to the feet of the *animals*. Where necessary, floors should be insulated or provided with appropriate bedding. Drainage grids should be placed at the sides of pens and passageways and not where *animals* would have to cross them. Discontinuities or changes in floor, wall or gate colours, patterns or texture which could cause baulking in the movement of *animals* should be avoided.

Annex XXXVI (contd)

c) *Lairages* should be provided with adequate lighting, but care should be taken to avoid harsh lights and shadows, which frighten the *animals* or affect their movement. The fact that *animals* will move more readily from a darker area into a well-lit area might be exploited by providing for lighting that can be regulated accordingly.

d) *Lairages* should be adequately ventilated to ensure that waste gases (e.g. ammonia) do not build up and that draughts at animal height are minimised. Ventilation should be able to cope with the range of expected climatic conditions and the number of *animals* the *lairage* will be expected to hold.

e) Care should be taken to protect the *animals* from excessively or potentially disturbing noises, for example by avoiding the use of noisy hydraulic or pneumatic equipment, and muffling noisy metal equipment by the use of suitable padding, or by minimising the transmission of such noises to the areas where *animals* are held and slaughtered.

f) Where *animals* are kept in outdoor *lairages* without natural shelter or shade, they should be protected from the effects of adverse weather conditions.

Article 7.5.4.

Care of animals in lairages

Animals in *lairages* should be cared for in accordance with the following recommendations:

1) As far as possible, established groups of *animals* should be kept together and each *animal* should have enough space to stand up, lie down and turn around. *Animals* hostile to each other should be separated.

2) Where tethers, ties or individual stalls are used, they should allow *animals* to stand up and lie down without causing injury or distress.

3) Where bedding is provided, it should be maintained in a condition that minimises risks to the health and safety of the *animals*, and sufficient bedding should be used so that *animals* do not become soiled with manure.

4) *Animals* should be kept securely in the *lairage*, and care should be taken to prevent them from escaping and from predators.

5) Suitable drinking water should be available to the *animals* on their arrival and at all times to *animals* in *lairages* unless they are to be slaughtered without delay.

6) Waiting time should be minimised and should not exceed 12 hours. If *animals* are not to be slaughtered within this period, suitable feed should be available to the *animals* on arrival and at intervals appropriate to the species. Unweaned *animals* should be slaughtered as soon as possible.

7) In order to prevent heat stress, *animals* subjected to high temperatures, particularly pigs and *poultry*, should be cooled by the use of water sprays, fans or other suitable means. However, the potential for water sprays to reduce the ability of *animals* to thermoregulate (especially *poultry*) should be considered in any decision to use water sprays. The risk of *animals* being exposed to very cold temperatures or sudden extreme temperature changes should also be considered.

8) The *lairage* area should be well lit in order to enable the *animals* to see clearly without being dazzled. During the night, the lights should be dimmed. Lighting should also be adequate to permit inspection of all *animals*. Subdued lighting, and for example blue light, may be useful in *poultry lairages* in helping to calm birds.

9) The condition and state of health of the *animals* in a *lairage* should be inspected at least every morning and evening by a *veterinarian* or, under the *veterinarian*'s responsibility, by another competent person, such as an *animal handler*. *Animals* which are sick, weak, injured or showing visible signs of distress should be separated, and veterinary advice should be sought immediately regarding treatment or the *animals* should be humanely killed immediately if necessary.

10) Lactating dairy *animals* should be slaughtered as soon as possible. Dairy *animals* with obvious udder distension should be milked to minimise udder discomfort.

11) *Animals* which have given birth during the *journey* or in the *lairage* should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling for their *welfare* and the *welfare* of the newborn. Under normal circumstances, *animals* which are expected to give birth during a *journey* should not be transported.

12) *Animals* with horns, antlers or tusks capable of injuring other *animals*, if aggressive, should be penned separately.

13) *Poultry* awaiting *slaughter* should be protected from adverse weather conditions and provided with adequate ventilation.

14) *Poultry* in transport *containers* should be examined at the time of arrival. *Containers* should be stacked with sufficient space between the stacks to facilitate inspection of birds and air movement.

15) Forced ventilation or other cooling systems may be necessary under certain conditions to avoid build up of temperature and humidity. Temperature and humidity should be monitored at appropriate intervals.

Recommendations for specific species are described in detail in Articles 7.5.5. ~~to~~ and 7.5.~~9~~6.

Article 7.5.5.

Management of foetuses during slaughter of pregnant animals

Under normal circumstances, pregnant *animals* that would be in the final 10 percent of their gestation period at the planned time of *unloading* at the *slaughterhouse* should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that females are handled separately, and the specific procedures described below are applied. In all cases, the *welfare* of foetuses and dams during *slaughter* should be safeguarded.

Foetuses should not be removed from the uterus sooner than 5 minutes after the maternal neck or chest cut, to ensure absence of consciousness. A foetal heartbeat will usually still be present and foetal movements may occur at this stage, but these are only a cause for concern if the exposed foetus successfully breathes air.

If a live mature foetus is removed from the uterus, it should be prevented from inflating its lungs and breathing air (e.g. by clamping the trachea).

When uterine, placental or foetal tissues, including foetal blood, are not to be collected as part of the post-*slaughter* processing of pregnant *animals*, all foetuses should be left inside the unopened uterus until they are dead. When uterine, placental or foetal tissues are to be collected, where practical, foetuses should not be removed from the uterus until at least 15–20 minutes after the maternal neck or chest cut.

If there is any doubt about consciousness, the foetus should be killed with a captive bolt of appropriate size or a blow to the head with a suitable blunt instrument.

The above recommendations do not refer to foetal rescue. Foetal rescue, the practice of attempting to revive foetuses found alive at the evisceration of the dam, should not be attempted during normal commercial *slaughter* as it may lead to serious *welfare* complications in the newborn *animal*. These include impaired brain function resulting from oxygen shortage before rescue is completed, compromised breathing and body heat production because of foetal immaturity, and an increased incidence of infections due to a lack of colostrum.

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Article 7.5.6.

Summary analysis of handling and restraining methods and the associated animal welfare issues

[DELETE TABLE]

Article 7.5.~~7~~6.

Stunning methods

1. General considerations

The competence of the operators, and the appropriateness, and effectiveness of the method used for *stunning* and the maintenance of the equipment are the responsibility of the management of the *slaughterhouse*, and should be checked regularly by a *Competent Authority*.

Persons carrying out *stunning* should be properly trained and competent, and should ensure that:

a) the *animal* is adequately restrained;

b) *animals* in *restraint* are stunned as soon as possible;

c) the equipment used for *stunning* is maintained and operated properly in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the *animal*;

d) the equipment is applied correctly;

e) stunned *animals* are bled out (slaughtered) as soon as possible;

f) *animals* are not stunned when *slaughter* is likely to be delayed; and

g) backup *stunning* devices are available for immediate use if the primary method of *stunning* fails. Provision of a manual inspection area and simple intervention like captive bolt or cervical dislocation for *poultry* would help prevent potential *welfare* problems.

In addition, such persons should be able to recognise when an *animal* is not correctly stunned and should take appropriate action.

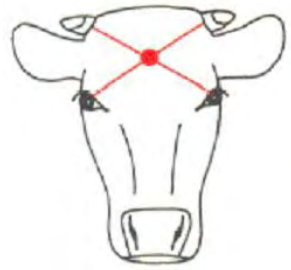
2. Mechanical stunning

A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface.

For a more detailed explanation on the different methods for mechanical *stunning*, see Chapter 7.6. and Articles 7.6.~~6~~5., 7.6.~~7~~6. and 7.6.~~8~~7. The following diagrams illustrate the proper application of the device for certain species.

Figure 1. The optimum position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Cattle



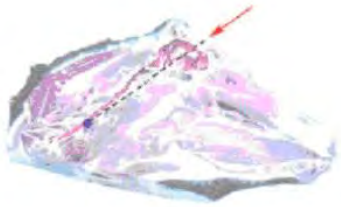


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

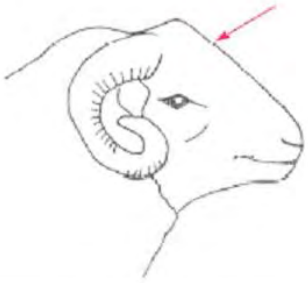
Figure 2. The optimum position for pigs is on the midline just above eye level, with the shot directed down the line of the spinal cord.

Pigs

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 3. The optimum position for hornless sheep and goats is on the midline.

Sheep



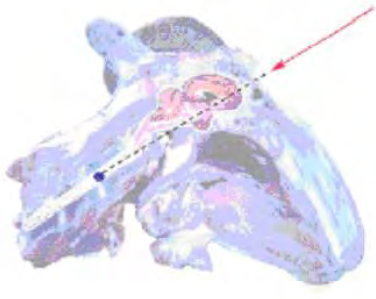


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Annex XXXVI (contd)

Figure 4. The optimum position for heavily horned sheep and horned goats is behind the poll, aiming towards the angle of the jaw.

Goats

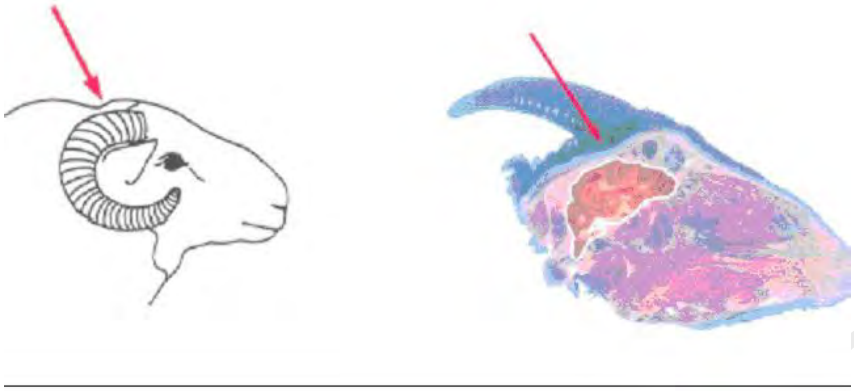


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 5. The optimum position for horses is at right angles to the frontal surface, well above the point where imaginary lines from eyes to ears cross.

Horses

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Signs of correct *stunning* using a mechanical instrument are as follows:

1) the *animal* collapses immediately and does not attempt to stand up;

2) the body and muscles of the *animal* become tonic (rigid) immediately after the shot;

3) normal rhythmic breathing stops; and

4) the eyelid is open with the eyeball facing straight ahead and is not rotated.

Figure 6. Poultry

Captive bolts powered by cartridges, compressed air or spring can be used for poultry. The optimum position for poultry species is at right angles to the frontal surface.

Firing of a captive bolt according to the manufacturers' instructions should lead to immediate destruction of the skull and the brain and, as a result, immediate death.

Poultry

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Poultry

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~~Captive bolts powered by cartridges, compressed air or spring can be used for *poultry*. The optimum position for *poultry* species is at right angles to the frontal surface.~~

~~Firing of a captive bolt according to the manufacturers' instructions should lead to immediate destruction of the skull and the brain and, as a result, immediate *death*.~~

3. Electrical stunning

a) General considerations

An electrical device should be applied to the *animal* in accordance with the following recommendations.

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Electrodes should be designed, constructed, maintained and cleaned regularly to ensure that the flow of current is optimal and in accordance with manufacturing specifications. They should be placed so that they span the brain. The application of electrical currents which bypass the brain is unacceptable unless the *animal* has been stunned. The use of a single current leg-to-leg is unacceptable as a *stunning* method.

If, in addition, it is intended to cause cardiac arrest, the electrodes should either span the brain and immediately thereafter the heart, on the condition that it has been ascertained that the *animal* is adequately stunned, or span brain and heart simultaneously.

Electrical *stunning* equipment should not be applied on *animals* as a means of guidance, movement, *restraint* or immobilisation, and shall not deliver any shock to the *animal* before the actual *stunning* or *killing*.

Electrical *stunning* apparatus should be tested prior to application on *animals* using appropriate resistors or dummy loads to ensure the power output is adequate to stun *animals*.

The electrical *stunning* apparatus should incorporate a device that monitors and displays voltage (true RMS) and the applied current (true RMS) and that such devices are regularly calibrated at least annually.

Appropriate measures, such as removing excess wool or wetting the skin only at the point of contact, can be taken to minimise impedance of the skin and facilitate effective *stunning*.

The *stunning* apparatus should be appropriate for the species. Apparatus for electrical *stunning* should be provided with adequate power to achieve continuously the minimum current level recommended for *stunning* as indicated in the table below.

In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for between one and three seconds and in accordance with the manufacturer's instructions. Minimum current levels for head-only *stunning* are shown in the following table.

Species	Minimum current levels for head-only stunning
Cattle	1.5 amps
Calves (bovines of less than 6 month of age)	1.0 amps
Pigs	1.25 amps
Sheep and goats	1.0 amps
Lambs	0.7 amps
Ostriches	0.4 amps

b) Electrical stunning of birds using a waterbath

There should be no sharp bends or steep gradients in the shackle line and the shackle line should be as short as possible consistent with achieving acceptable line speeds, and ensuring that birds have settled by the time they reach the water bath. A breast comforter can be used effectively to reduce wing flapping and calm birds. The angle at which the shackle line approaches the entrance to the water bath, and the design of the entrance to the water bath, and the draining of excess 'live' water from the bath are all important considerations in ensuring birds are calm as they enter the bath, do not flap their wings, and do not receive pre-stun electric shocks.

In the case of birds suspended on a moving line, measures should be taken to ensure that the birds are not wing flapping at the entrance of the stunner. The birds should be secure in their shackle, but there should not be undue pressure on their shanks. The shackle size should be appropriate to fit the size of the shanks (metatarsal bones) of birds.

Birds should be hung on shackles by both legs.

Birds with dislocated or broken legs or wings should be humanely killed rather than shackled.

The duration between hanging on shackles and *stunning* should be kept to the minimum. In any event, the time between shackling and *stunning* should not exceed one minute.

Waterbaths for *poultry* should be adequate in size and depth for the type of bird being slaughtered, and their height should be adjustable to allow for the head of each bird to be immersed. The electrode immersed in the bath should extend the full length of the waterbath. Birds should be immersed in the bath up to the base of their wings.

The waterbath should be designed and maintained in such a way that when the shackles pass over the water, they are in continuous contact with the earthed rubbing bar.

The control box for the waterbath stunner should incorporate an ammeter which displays the total current flowing through the birds.

The shackle-to-leg contact should be wetted preferably before the birds are inserted in the shackles. In order to improve the electrical conductivity of the water, it is recommended that salt be added in the waterbath as necessary. Additional salt should be added regularly as a solution to maintain suitable constant concentrations in the waterbath.

Using waterbaths, birds are stunned in groups and different birds will have different impedances. The voltage should be adjusted so that the total current is the required current per bird as shown in the table hereafter, multiplied by the number of birds in the waterbath at the same time. The following values have been found to be satisfactory when employing a 50 Hertz sinusoidal alternating current.

Birds should receive the current for at least 4 seconds.

While a lower current may also be satisfactory, the current shall in any case be such as to ensure that unconsciousness occurs immediately and lasts until the bird has been killed by cardiac arrest or by bleeding. When higher electrical frequencies are used, higher currents may be required.

Every effort shall be made to ensure that no conscious or live birds enter the scalding tank.

In the case of automatic systems, until fail-safe systems of *stunning* and bleeding have been introduced, a manual back-up system should be in place to ensure that any birds which have missed the waterbath stunner and/or the automatic neck-cutter are immediately stunned and/or killed immediately, and they are dead before entering scald tank.

To lessen the number of birds that have not been effectively stunned reaching neck cutters, steps should be taken to ensure that small birds do not go on the line amongst bigger birds and that these small birds are stunned separately. The height of the waterbath stunner should be adjusted according to the size of birds to ensure even the small birds are immersed in the water bath up to the base of the wings.

Waterbath *stunning* equipment should be fitted with a device which displays and records the details of the electrical key parameter.

Annex XXXVI (contd)

Minimum current for *stunning poultry* when using 50Hz is as follows:

Species	Current (milliamperes per bird)
Broilers	100
Layers (spent hens)	100
Turkeys	150
Ducks and geese	130

Minimum current for *stunning poultry* when using high frequencies is as follows:

	Minimum current (milliamperes per bird)	
Frequency (Hz)	**Chickens**	**Turkeys**
From 50 to 200 Hz	100 mA	250 mA
From 200 to 400 Hz	150 mA	400 mA
From 400 to 1500 Hz	200 mA	400 mA

4. Gas stunning (under study)

a) Stunning of pigs by exposure to carbon dioxide (CO_2)

The concentration of CO_2 for *stunning* should be preferably 90 percent by volume but in any case no less than 80 percent by volume. After entering the *stunning* chamber, the *animals* should be conveyed to the point of maximum concentration of the gas as rapidly as possible and be kept until they are dead or brought into a state of insensibility which lasts until *death* occur due to bleeding. Ideally, pigs should be exposed to this concentration of CO_2 for 3 minutes. Sticking should occur as soon as possible after exit from the gas chamber.

In any case, the concentration of the gas should be such that it minimises as far as possible all stress of the *animal* prior to loss of consciousness.

The chamber in which *animals* are exposed to CO_2 and the equipment used for conveying them through it shall be designed, constructed and maintained in such a way as to avoid injury or unnecessary stress to the *animals*. The animal density within the chamber should be such to avoid stacking *animals* on top of each other.

The conveyor and the chamber shall be adequately lit to allow the *animals* to see their surroundings and, if possible, each other.

It should be possible to inspect the CO_2 chamber whilst it is in use, and to have access to the *animals* in emergency cases.

The chamber shall be equipped to continuously measure and display register at the point of *stunning* the CO_2 concentration and the time of exposure, and to give a clearly visible and audible warning if the concentration of CO_2 falls below the required level.

Emergency *stunning* equipment should be available at the point of exit from the *stunning* chamber and used on any pigs that do not appear to be completely stunned.

b) Inert gas mixtures for stunning pigs

Inhalation of high concentration of carbon dioxide is aversive and can be distressing to *animals*. Therefore, the use of non-aversive gas mixtures is being developed.

Such gas mixtures include:

i) a maximum of 2 percent by volume of oxygen in argon, nitrogen or other inert gases, or

ii) to a maximum of 30 percent by volume of carbon dioxide and a maximum of 2 percent by volume of oxygen in mixtures with carbon dioxide and argon, nitrogen or other inert gases.

Exposure time to the gas mixtures should be sufficient to ensure that no pigs regain consciousness before *death* supervenes through bleeding or cardiac arrest is induced.

c) Gas stunning of poultry

The main objective of gas *stunning* is to avoid the pain and suffering associated with shackling conscious *poultry* under water bath *stunning* and *killing* systems. Therefore, gas *stunning* should be limited to birds contained in crates or on conveyors only. The gas mixture should be non-aversive to *poultry*.

Live *poultry* contained within transport modules or crates may be exposed to gradually increasing concentrations of CO_2 until the birds are properly stunned. No bird should recover consciousness during bleeding.

Gas *stunning* of *poultry* in their transport *containers* will eliminate the need for live birds' handling at the processing plant and all the problems associated with the electrical *stunning*. Gas *stunning* of *poultry* on a conveyor eliminates the problems associated with the electrical water bath *stunning*.

Live *poultry* should be conveyed into the gas mixtures either in transport crates or on conveyor belts.

The following gas procedures have been properly documented for chickens and turkeys but do not necessarily apply for other domestic birds. In any case the procedure should be designed as to ensure that all *animals* are properly stunned without unnecessary suffering. Some monitoring points for gas *stunning* could be the following:

– ensure smooth entry and passage of crates or birds through the system;

– avoid crowding of birds in crates or conveyors;

– monitor and maintain gas concentrations continuously during operation;

– provide visible and audible alarm systems if gas concentrations are inappropriate to the species;

– calibrate gas monitors and maintain verifiable records;

Annex XXXVI (contd)

– ensure that duration of exposure is adequate to prevent recovery of consciousness;

– make provision to monitor and deal with recovery of consciousness;

– ensure that blood vessels are cut to induce *death* in unconscious birds;

– ensure that all birds are dead before entering scalding tank;

– provide emergency procedures in the event of system failure.

i) Gas mixtures used for stunning *poultry* include:

– a minimum of 2 minutes exposure to 40 percent carbon dioxide, 30 percent oxygen and 30 percent nitrogen, followed by a minimum of one minute exposure to 80 percent carbon dioxide in air; or

– a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30 percent by volume and the residual oxygen concentration does not exceed 2 percent by volume; or

– a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2 percent residual oxygen by volume; or

– a minimum of 2 minutes exposure to a minimum of 55 percent carbon dioxide in air; or

– a minimum of one minute exposure to 30 percent carbon dioxide in air, followed by a minimum of one minute exposure to at least 60 percent carbon dioxide in air.

ii) Requirements for effective use are as follows:

– Compressed gases should be vaporised prior to administration into the chamber and should be at room temperature to prevent any thermal shock; under no circumstances, should solid gases with freezing temperatures enter the chamber.

– Gas mixtures should be humidified.

– Appropriate gas concentrations of oxygen and carbon dioxide should be monitored and displayed continuously at the level of the birds inside the chamber to ensure that anoxia ensues.

Under no circumstances, should birds exposed to gas mixtures be allowed to regain consciousness. If necessary, the exposure time should be extended.

5. Bleeding

From the point of view of *animal welfare*, *animals* which are stunned with a reversible method should be bled without delay. Maximum stun-stick interval depends on the parameters of the *stunning* method applied, the species concerned and the bleeding method used (full cut or chest stick when possible). As a consequence, depending on those factors, the *slaughterhouse* operator should set up a maximum stun-stick interval that ensures that no *animals* recover consciousness during bleeding. In any case the following time limits should be applied.

Stunning method	**Maximum stun – stick interval**
Electrical methods and non-penetrating captive bolt	20 seconds
CO_2	60 seconds (after leaving the chamber)

All *animals* should be bled out by incising both carotid arteries, or the vessels from which they arise (e.g. chest stick). However, when the *stunning* method used causes cardiac arrest, the incision of all of these vessels is not necessary from the point of view of *animal welfare*.

It should be possible for staff to observe, inspect and access the *animals* throughout the bleeding period. Any *animal* showing signs of recovering consciousness should be re-stunned.

After incision of the blood vessels, no scalding carcass treatment or dressing procedures should be performed on the *animals* for at least 30 seconds, or in any case until all brain-stem reflexes have ceased.

~~Article 7.5.8.~~

~~**Summary analysis of stunning methods and the associated animal welfare issues**~~

[DELETE TABLE]

~~Article 7.5.9.~~

~~**Summary analysis of slaughter methods and the associated animal welfare issues**~~

[DELETE TABLE]

Article 7.5.~~10~~7.

Methods, procedures or practices unacceptable on animal welfare grounds

1) The restraining methods which work through electro-immobilisation or immobilisation by injury such as breaking legs, leg tendon cutting, and severing the spinal cord (e.g. using a puntilla or dagger) cause severe pain and stress in *animals*. Those methods are not acceptable in any species.

2) The use of the electrical *stunning* method with a single application leg to leg is ineffective and unacceptable in any species.

3) The *slaughter* method of brain stem severance by piercing through the eye socket or skull bone without prior *stunning* is not acceptable in any species.

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— Text deleted.

CHAPTER 7.6.

KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES

EU comments

The EU does not support the proposed removal of the tables from this chapter.

Justification

See chapter 7.5.

Article 7.6.1.

General principles

These recommendations are based on the premise that a decision to kill the *animals* has been made, and address the need to ensure the *welfare* of the *animals* until they are dead.

1) All personnel involved in the humane *killing* of *animals* should have the relevant skills and competencies. Competence may be gained through formal training and/or practical experience.

2) As necessary, operational procedures should be adapted to the specific circumstances operating on the premises and should address, apart from *animal welfare*, aesthetics of the method of *euthanasia*, cost of the method, operator safety, biosecurity and environmental aspects.

3) Following the decision to kill the *animals*, *killing* should be carried out as quickly as possible, and normal husbandry should be maintained until the *animals* are killed.

4) The handling and movement of *animals* should be minimised and when done, it should be carried out in accordance with the recommendations described below.

5) Animal *restraint* should be sufficient to facilitate effective *killing*, and in accordance with *animal welfare* and operator safety requirements; when *restraint* is required, *killing* should follow with minimal delay.

6) When *animals* are killed for disease control purposes, methods used should result in immediate *death* or immediate loss of consciousness lasting until *death*; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive or the least aversive possible and should not cause avoidable anxiety, pain, distress or suffering in *animals*.

7) For *animal welfare* considerations, young *animals* should be killed before older *animals*; for biosecurity considerations, infected *animals* should be killed first, followed by in-contact *animals*, and then the remaining *animals*.

8) There should be continuous monitoring of the procedures by the *Competent Authorities* to ensure they are consistently effective with regard to *animal welfare*, operator safety and biosecurity.

9) When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on *animal welfare*, operator safety and biosecurity.

10) These general principles should also apply when *animals* need to be killed for other purposes such as after natural disasters or for culling animal populations.

Article 7.6.2.

Organisational structure

Disease control contingency plans should be in place at a national level and should contain details of management structure, disease control strategies and operational procedures; *animal welfare* considerations should be addressed within these disease control contingency plans. The plans should also include a strategy to ensure that an adequate number of personnel competent in the humane *killing* of *animals* is available. Local level plans should be based on national plans and be informed by local knowledge.

Annex XXXVI (contd)

Disease control contingency plans should address the *animal welfare* issues that may result from animal movement controls.

The operational activities should be led by an *official Veterinarian* who has the authority to appoint the personnel in the specialist teams and ensure that they adhere to the required *animal welfare* and biosecurity standards. When appointing the personnel, he/she should ensure that the personnel involved have the required competencies.

The *official Veterinarian* should be responsible for all activities across one or more affected premises and should be supported by coordinators for planning (including communications), operations and logistics to facilitate efficient operations.

The *official Veterinarian* should provide overall guidance to personnel and logistic support for operations on all affected premises to ensure consistency in adherence to the OIE *animal welfare* and animal health recommendations.

A specialist team, led by a team leader answerable to the *official Veterinarian*, should be deployed to work on each affected premises. The team should consist of personnel with the competencies to conduct all required operations; in some situations, personnel may be required to fulfil more than one function. Each team should contain a *veterinarian* or have access to veterinary advice at all times.

In considering the *animal welfare* issues associated with *killing animals*, the key personnel, their responsibilities and competencies required are described in Article 7.6.3.

Article 7.6.3.

Responsibilities and competencies of the specialist team

1. Team leader

   a) Responsibilities

      i) plan overall operations on affected premises;

      ii) determine and address requirements for *animal welfare*, operator safety and biosecurity;

      iii) organise, brief and manage team of people to facilitate humane *killing* of the relevant *animals* on the premises in accordance with national regulations and these recommendations;

      iv) determine logistics required;

      v) monitor operations to ensure *animal welfare*, operator safety and biosecurity requirements are met;

      vi) report upwards on progress and problems;

      vii) provide a written report at the conclusion of the *killing*, describing the practices adopted and their effect on the *animal welfare*, operator safety and biosecurity outcomes.

   b) Competencies

      i) appreciation of normal animal husbandry practices;

ii) appreciation of *animal welfare* and the underpinning behavioural, anatomical and physiological processes involved in the *killing* process;

iii) skills to manage all activities on premises and deliver outcomes on time;

iv) awareness of psychological effects on farmer, team members and general public;

v) effective communication skills;

vi) appreciation of the environmental impacts caused by their operation.

2. Veterinarian

a) Responsibilities

i) determine and supervise the implementation of the most appropriate *killing* method to ensure that *animals* are killed without avoidable pain and distress;

ii) determine and implement the additional requirements for *animal welfare*, including the order of *killing*;

iii) ensure that confirmation of the *death* of the *animals* is carried out by competent persons at appropriate times after the *killing* procedure;

iv) minimise the risk of disease spread within and from the premises through the supervision of biosecurity procedures;

v) continuously monitor *animal welfare* and biosecurity procedures;

vi) in cooperation with the leader, prepare a written report at the conclusion of the *killing*, describing the practices adopted and their effect on *animal welfare*.

b) Competencies

i) ability to assess *animal welfare*, especially the effectiveness of *stunning* and *killing* and to correct any deficiencies;

ii) ability to assess biosecurity risks.

3. Animal handlers

a) Responsibilities

i) review on-site facilities in terms of their appropriateness;

ii) design and construct temporary animal handling facilities, when required;

iii) move and restrain *animals*;

iv) continuously monitor *animal welfare* and biosecurity procedures.

b) Competencies

i) animal handling in emergency situations and in close confinement is required;

ii) an appreciation of biosecurity and containment principles.

Annex XXXVI (contd)

4. Animal killing personnel

a) Responsibilities

Humane *killing* of the *animals* through effective *stunning* and *killing* should be ensured.

b) Competencies

i) when required by regulations, licensed to use necessary equipment;

ii) competent to use and maintain relevant equipment;

iii) competent to use techniques for the species involved;

iv) competent to assess effective *stunning* and *killing*.

5. Carcass disposal personnel

a) Responsibilities

An efficient carcass disposal (to ensure *killing* operations are not hindered) should be ensured.

b) Competencies

The personnel should be competent to use and maintain available equipment and apply techniques for the species involved.

6. Farmer/owner/manager

a) Responsibilities

i) assist when requested.

b) Competencies

i) specific knowledge of his/her *animals* and their environment.

Article 7.6.4.

Considerations in planning the humane killing of animals

Many activities will need to be conducted on affected premises, including the humane *killing* of *animals*. The team leader should develop a plan for humanely *killing animals* on the premises which should include consideration of:

1) minimising handling and movement of *animals*;

2) *killing* the *animals* on the affected premises; however, there may be circumstances where the *animals* may need to be moved to another location for *killing*; when the *killing* is conducted at an *abattoir*, the recommendations in Chapter on the *slaughter* of *animals* should be followed;

3) the species, number, age and size of *animals* to be killed, and the order of *killing* them;

4) methods of *killing* the *animals*, and their cost;

5) housing, husbandry, location of the *animals* as well as accessibility of the farm;

6) the availability and effectiveness of equipment needed for *killing* of the *animals*, as well as the time necessary to kill the required number of *animals* using such methods;

7) the facilities available on the premises that will assist with the *killing* including any additional facilities that may need to be brought on and then removed from the premises;

8) biosecurity and environmental issues;

9) the health and safety of personnel conducting the *killing*;

10) any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment;

11) the presence of other nearby premises holding *animals*;

12) possibilities for removal, disposal and destruction of carcasses.

The plan should minimise the negative *welfare* impacts of the *killing* by taking into account the different phases of the procedures to be applied for *killing* (choice of the *killing* sites, *killing* methods, etc.) and the measures restricting the movements of the *animals*.

Competences and skills of the personnel handling and *killing animals*.

In designing a *killing* plan, it is essential that the method chosen be consistently reliable to ensure that all *animals* are humanely and quickly killed.

~~Article 7.6.5.~~

~~**Table summarising killing methods described in Articles 7.6.6.–7.6.18.**~~

~~The methods are described in the order of mechanical, electrical and gaseous, not in an order of desirability from an *animal welfare* viewpoint.~~

[DELETE TABLE]

Article 7.6.~~6~~5.

Free bullet

1. Introduction

a) A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.

b) The most commonly used firearms for close range use are:

i) humane killers (specially manufactured/adapted single-shot weapons);

ii) shotguns (12, 16, 20, 28 bore and .410);

iii) rifles (.22 rimfire);

iv) handguns (various calibres from .32 to .45).

Annex XXXVI (contd)

c) The most commonly used firearms for long range use are rifles (.22, .243, .270 and .308).

d) A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the *animals* (high neck shot) and to cause irreversible concussion and *death* and should only be used by properly trained and competent marksmen.

2. Requirements for effective use

a) The marksman should take account of human safety in the area in which he/she is operating. Appropriate vision and hearing protective devices should be worn by all personnel involved.

b) The marksman should ensure that the *animal* is not moving and in the correct position to enable accurate targeting and the range should be as short as possible (5–50 cm for a shotgun) but the barrel should not be in contact with the head of the *animals*.

c) The correct cartridge, calibre and type of bullet for the different species age and size should be used. Ideally, the ammunition should expand upon impact and dissipate its energy within the cranium.

d) Shot *animals* should be checked to ensure the absence of brain stem reflexes.

3. Advantages

a) Used properly, a free bullet provides a quick and effective method for *killing*.

b) It requires minimal or no *restraint* and can be use to kill from a distance by properly trained and competent marksmen.

c) It is suitable for *killing* agitated *animals* in open spaces.

4. Disadvantages

a) The method is potentially dangerous to humans and other *animals* in the area.

b) It has the potential for non-lethal wounding.

c) Destruction of brain tissue may preclude diagnosis of some *diseases*.

d) Leakage of bodily fluids may present a biosecurity risk.

e) Legal requirements may preclude or restrict use.

f) There is a limited availability of competent personnel.

5. Conclusion

The method is suitable for cattle, sheep, goats and pigs, including large *animals* in open spaces.

Figure 1. The optimum shooting position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 2. The optimum position for hornless sheep and goats is on the midline.

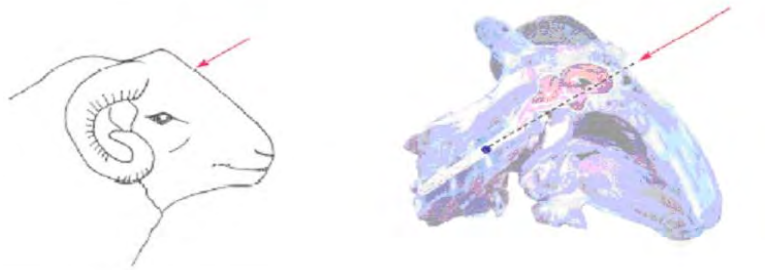

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using

Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead,

Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 3. The optimum shooting position for heavily horned sheep and horned goats is behind the poll aiming towards the angle of the jaw.

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Annex XXXVI (contd)

Figure 4. The optimum shooting position for pigs is just above eye level, with the shot directed down the line of the spinal cord.

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Article 7.6.~~7~~6.

Penetrating captive bolt

1. Introduction

A penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The captive bolt should be aimed on the skull in a position to penetrate the cortex and mid-brain of the *animal*. The impact of the bolt on the skull produces unconsciousness. Physical damage to the brain caused by penetration of the bolt may result in *death*; however, pithing or bleeding should be performed as soon as possible after the shot to ensure the *death* of the *animal*. Shooting *poultry* species with the captive bolts results in immediate destruction of the skull and brain, causing *death*. For a detailed description on the use of this method, see Chapter 7.5. of the *Terrestrial Code*.

2. Requirements for effective use

a) For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of *animal*, in accordance with the recommendations of the manufacturer.

b) Captive bolt guns should be frequently cleaned and maintained in good working condition.

c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.

d) *Animals* should be restrained; at a minimum, they should be penned for cartridge powered guns and in a race for compressed air guns.

e) The operator should ensure that the head of the *animal* is accessible.

f) The operator should fire the captive bolt at right angles to the skull in the optimal position (see figures 1, 3 & 4. The optimum shooting position for hornless sheep is on the highest point of the head, on the midline and aim towards the angle of the jaw).

g) To ensure the *death* of the *animal*, pithing or bleeding should be performed as soon as possible after *stunning*.

h) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

a) Mobility of cartridge powered equipment reduces the need to move *animals*.

b) The method induces an immediate onset of a sustained period of unconsciousness.

4. Disadvantages

a) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.

b) Post stun convulsions may make pithing difficult and hazardous.

c) The method is difficult to apply in agitated *animals*.

d) Repeated use of a cartridge powered gun may result in over-heating.

e) Leakage of bodily fluids may present a biosecurity risk.

f) Destruction of brain tissue may preclude diagnosis of some *diseases*.

5. Conclusions

The method is suitable for *poultry*, cattle, sheep, goats and pigs (except neonates), when followed by pithing or bleeding.

Article 7.6.~~8~~7.

Non-penetrating captive bolt

1. Introduction

A non-penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The gun should be placed on the front of the skull to deliver a percussive blow which produces unconsciousness in cattle (adults only), sheep, goats and pigs, and *death* in poultry and neonate sheep, goats and pigs. Bleeding should be performed as soon as possible after the blow to ensure the *death* of the *animal*.

2. Requirements for effective use

a) For cartridge powered and compressed air guns, the bolt velocity should be appropriate to the species and type of *animal*, in accordance with the recommendations of the manufacturer.

b) Captive bolt guns should be frequently cleaned and maintained in good working condition.

c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.

d) *Animals* should be restrained; at a minimum mammals should be penned for cartridge powered guns and in a race for compressed air guns; birds should be restrained in cones, shackles, crushes or by hand.

Annex XXXVI (contd)

e) The operator should ensure that the head of the *animal* is accessible.

f) The operator should fire the captive bolt at right angles to the skull in the optimal position (figures 1–4).

g) To ensure *death* in non-neonate mammals, bleeding should be performed as soon as possible after *stunning*.

h) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

a) The method induces an immediate onset of unconsciousness, and *death* in birds and neonates.

b) Mobility of equipment reduces the need to move *animals*.

4. Disadvantages

a) As consciousness can be regained quickly in non-neonate mammals, they should be bled as soon as possible after *stunning*.

b) Laying hens in cages have to be removed from their cages and most birds have to be restrained.

c) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.

d) Post stun convulsions may make bleeding difficult and hazardous.

e) Difficult to apply in agitated *animals*; such *animals* may be sedated in advance of the *killing* procedure.

f) Repeated use of a cartridge powered gun may result in over-heating.

g) Bleeding may present a biosecurity risk.

5. Conclusions

The method is suitable for *killing* poultry, and neonate sheep, goats and pigs up to a maximum weight of 10 kg.

Article 7.6.~~9~~8.

Maceration

1. Introduction

Maceration, utilising a mechanical apparatus with rotating blades or projections, causes immediate fragmentation and *death* in day-old *poultry* and embryonated eggs.

2. Requirements

a) Maceration requires specialised equipment which should be kept in excellent working order.

b) The rate of introducing the birds should not allow the equipment to jam, birds to rebound from the blades or the birds to suffocate before they are macerated.

3. Advantages

a) Procedure results in immediate *death*.

b) Large numbers can be killed quickly.

4. Disadvantages

a) Specialised equipment is required.

b) Macerated tissues may present biosecurity or human health risks.

c) The cleaning of the equipment can be a source of contamination.

5. Conclusion

The method is suitable for *killing* day-old poultry and embryonated eggs.

Article 7.6.~~10~~9.

Electrical – two-stage application

1. Introduction

A two-stage application of electric current comprises firstly an application of current to the head by scissor-type tongs, immediately followed by an application of the tongs across the chest in a position that spans the heart.

The application of sufficient electric current to the head will induce 'tonic/clonic' epilepsy and unconsciousness. Once the *animal* is unconscious, the second stage will induce ventricular fibrillation (cardiac arrest) resulting in *death*. The second stage (the application of low frequency current across the chest) should only be applied to unconscious *animals* to prevent unacceptable levels of pain.

2. Requirements for effective use

a) The stunner control device should generate a low frequency (AC sine wave 50 Hz) current with a minimum voltage and current as set out in the following table:

Animal	Minimum voltage (V)	Minimum current (A)
Cattle	220	1.5
Sheep	220	1.0
Pigs over 6 weeks of age	220	1.3
Pigs less than 6 weeks of age	125	0.5

b) Appropriate protective clothing (including rubber gloves and boots) should be worn.

c) *Animals* should be restrained, at a minimum free-standing in a pen, close to an electrical supply.

d) Two team members are required, the first to apply the electrodes and the second to manipulate the position of the *animal* to allow the second application to be made.

Annex XXXVI (contd)

e) A *stunning* current should be applied via scissor-type *stunning* tongs in a position that spans the brain for a minimum of 3 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 3 seconds.

f) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.

g) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

h) Electrodes should be applied firmly for the intended duration of time and pressure not released until the stun is complete.

3. Advantages

a) The application of the second stage minimises post-stun convulsions and therefore the method is particularly effective with pigs.

b) Non-invasive technique minimises biosecurity risk.

4. Disadvantages

a) The method requires a reliable supply of electricity.

b) The electrodes should be applied and maintained in the correct positions to produce an effective stun and kill.

c) Most stunner control devices utilise low voltage impedance sensing as an electronic switch prior to the application of high voltages; in unshorn sheep, contact impedance may be too high to switch on the required high voltage (especially during stage two).

d) The procedure may be physically demanding, leading to operator fatigue and poor electrode placement.

5. Conclusion

The method is suitable for calves, sheep and goats, and especially for pigs (over one week of age).

Figure 5. Scissor-type tongs.

Article 7.6.~~11~~10.

Electrical — single application

1. Method 1

Method 1 comprises the single application of sufficient electrical current to the head and back, to simultaneously stun the *animal* and fibrillate the heart. Provided sufficient current is applied in a position that spans both the brain and heart, the *animal* will not recover consciousness.

a) Requirements for effective use

i) The stunner control device should generate a low frequency (30–60 Hz) current with a minimum voltage of 250 volts true RMS under load.

ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.

iii) *Animals* should be individually and mechanically restrained close to an electrical supply as the maintenance of physical contact between the *stunning* electrodes and the *animal* is necessary for effective use.

iv) The rear electrode should be applied to the back, above or behind the heart, and then the front electrode in a position that is forward of the eyes, with current applied for a minimum of 3 seconds.

v) Electrodes should be cleaned regularly between *animals* and after use, to enable optimum electrical contact to be maintained.

vi) Water or saline may be necessary to improve electrical contact with sheep.

vii) An effective stun and kill should be verified by the absence of brain stem reflexes.

b) Advantages

i) Method 1 stuns and kills simultaneously.

ii) It minimises post-stun convulsions and therefore is particularly effective with pigs.

iii) A single team member only is required for the application.

iv) Non-invasive technique minimises biosecurity risk.

c) Disadvantages

i) Method 1 requires individual mechanical animal *restraint*.

ii) The electrodes should be applied and maintained in the correct positions to produce an effective stun and kill.

iii) Method 1 requires a reliable supply of electricity.

d) Conclusion

Method 1 is suitable for calves, sheep, goats, and pigs (over one week of age).

2. Method 2

Method 2 stuns and kills by drawing inverted and shackled poultry through an electrified waterbath stunner. Electrical contact is made between the 'live' water and earthed shackle and, when sufficient current is applied, poultry will be simultaneously stunned and killed.

Annex XXXVI (contd)

a) Requirements for effective use

i) A mobile waterbath stunner and a short loop of processing line are required.

ii) A low frequency (50–60 Hz) current applied for a minimum of 3 seconds is necessary to stun and kill the birds.

iii) Poultry need to be manually removed from their cage, house or yard, inverted and shackled onto a line which conveys them through a waterbath stunner with their heads fully immersed.

iv) The required minimum currents to stun and kill dry birds are:

– Quails – 100 mA/bird

– Chickens – 160 mA/bird

– Ducks & geese – 200 mA/bird

– Turkeys – 250 mA/bird.

A higher current is required for wet birds.

v) An effective stun and kill should be verified by the absence of brain stem reflexes.

b) Advantages

i) Method 2 stuns and kills simultaneously.

ii) It is capable of processing large numbers of birds reliably and effectively.

iii) This non-invasive technique minimises biosecurity risk.

c) Disadvantages

i) Method 2 requires a reliable supply of electricity.

ii) Handling, inversion and shackling of birds are required.

d) Conclusion

Method 2 is suitable for large numbers of poultry.

3. Method 3

Method 3 comprises the single application of sufficient electrical current to the head of poultry in a position that spans the brain, causing unconsciousness; this is followed by a *killing* method (see Article 7.6.~~17~~16.).

a) Requirements for effective use

i) The stunner control device should generate sufficient current (more than 600 mA/duck and more than 300 mA/bird) to stun.

ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.

iii) Birds should be restrained, at a minimum manually, close to an electrical supply.

iv) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.

v) Birds should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

b) Advantages

Non-invasive technique (when combined with cervical dislocation) minimises biosecurity risk.

c) Disadvantages

i) Method 3 requires a reliable supply of electricity and is not suitable for large-scale operations.

ii) The electrodes should be applied and maintained in the correct position to produce an effective stun.

iii) Birds should be individually restrained.

iv) It should be followed by a *killing* method.

d) Conclusion

Method 3 is suitable for small numbers of poultry.

Article 7.6.~~12~~11.

CO_2 / air mixture

1. Introduction

Controlled atmosphere killing is performed by exposing *animals* to a predetermined gas mixture, either by placing them in a gas-filled *container* or apparatus (Method 1) or by placing transport modules or crates containing birds in a gas tight *container* and introducing a gas mixture (Method 2) or by the gas being introduced into a poultry house (Method 3). Method 3 should be used whenever possible, as it eliminates *welfare* issues resulting from the need to manually remove live birds. Although Method 2 requires handling and crating of the birds, it benefits bird *welfare* overall in comparison with Method 1 as it reduces the risk of *death* by smothering or suffocation.

Inhalation of carbon dioxide (CO_2) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, *death*. Exposure to carbon dioxide does not induce immediate loss of consciousness, therefore the aversive nature of gas mixtures containing high concentrations of CO_2 and the respiratory distress occurring during the induction phase are important considerations for *animal welfare*.

2. Method 1

The *animals* are placed in a gas-filled *container* or apparatus.

a) Requirements for effective use in a *container* or apparatus

i) *Containers* or apparatus should allow the required gas concentration to be maintained and accurately measured.

ii) When *animals* are exposed to the gas individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.

iii) *Animals* can also be introduced to low concentrations (as low concentrations are not aversive) and the concentration could be increased afterwards and the *animals* then held in the higher concentration until *death* is confirmed.

iv) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.

v) *Containers* or apparatus should not be overcrowded and measures are needed to avoid *animals* suffocating by climbing on top of each other.

b) Advantages

i) CO_2 is readily available.

ii) Application methods are simple.

iii) The volume of gas required can be readily calculated.

iv) As the units are operated outdoor, the gas is dispersed quickly at the end of each cycle by opening the door, improving operator's health and safety.

v) The system uses skilled catching teams and equipment in daily use by the industry.

vi) Metal *containers* can be readily cleansed and disinfected.

c) Disadvantages

i) The need for properly designed *container* or apparatus.

ii) The aversive nature of high CO_2 concentrations.

iii) No immediate loss of consciousness.

iv) The risk of suffocation due to overcrowding.

v) Difficulty in verifying *death* while the *animals* are in the *container* or apparatus.

d) Conclusion

Method 1 is suitable for use in poultry, and neonatal sheep, goats and pigs.

3. Method 2

In this method, the crates or modules holding the birds are loaded into a chamber into which gas is introduced. ~~As illustrated in the example below, a~~ A containerised gassing unit (CGU) typically comprises a gas-tight chamber designed to accommodate poultry transport crates or a single module. The chamber is fitted with gas lines and diffusers, with silencers that are connected via a system of manifolds and gas regulators to gas cylinders. There is a hole at the top to permit displaced air to escape when the *container* is filling with gas.

The procedures for the operation of CGU include (a) position the *container* on level, solid, open ground; (b) connect the gas cylinder to the *container* (c) load birds into the *container* (d) shut and secure the door, (e) deliver the gas until a concentration of 45 percent by volume of carbon dioxide has been achieved at the top of the *container*, (f) allow time for the birds to become unconscious and die (g) open the door and allow gas to be dispersed in the air (h) remove the module (i) check each drawer for survivors (j) humanely kill any survivors; and (k) dispose of carcasses appropriately.

a) Requirements for effective use of containerised gassing units (CGU)

i) The birds should be caught gently and placed in crates or modules of appropriate size and at appropriate *stocking densities* to allow all birds to sit down.

ii) The crates or module full of birds should be placed inside the *container* and the door shut only when the operator is ready to administer the gas.

iii) Ensure the *container* door is locked and administer the gas until a minimum concentration of 45 percent carbon dioxide is achieved at the top of the crates.

iv) An appropriate gas meter should be used to ensure the appropriate concentration of carbon dioxide is achieved and maintained until it can be confirmed that the birds have been killed.

v) Sufficient exposure time should be allowed for birds to die before the door is opened. In the absence of a viewing window that allows direct observation of birds during killing, cessation of vocalisation and convulsive wing flapping sounds, which can be listened to by standing near the *container*, can be used to determine that the birds are unconscious and that *death* is imminent. Remove the crates or modules from the *container* and leave them in the open air.

vi) Each crate or module should be examined and birds checked to ensure they are dead. Dilated pupils and absence of breathing indicate *death*.

vii) Any survivors should be humanely killed.

viii) Ducks and geese are resilient to the effects of carbon dioxide and therefore require a minimum of 80 percent CO_2 and a longer period of exposure to die.

b) Advantages

i) The gas is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.

ii) Gradual increase in the concentration of CO_2 minimises the aversive nature of this method for inducing unconsciousness.

iii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house.

iv) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.

v) CO_2 is readily available.

vi) Birds are exposed to gas more uniformly and they do not smother each other when compared with Method 1.

Annex XXXVI (contd)

vii) The volume of gas required can be readily calculated.

viii) As the units are operated outdoors, the gas is dispersed quickly at the end of each cycle by opening the door, improving operator's health and safety.

ix) The system uses skilled catching teams and equipment in daily use by the industry.

x) Metal *containers* can be readily cleansed and disinfected.

c) Disadvantages

i) Requires trained operators, trained catchers, transport modules and fork lift. However, this equipment and suitable areas with hard surfaces are usually available.

ii) The main limiting factors are speed of catching birds.

iii) In the absence of a viewing window, visual confirmation of *death* while the birds are still in the *container* is difficult. However, cessation of vocalisation and convulsive wing flapping sounds can be used to determine onset of *death*.

d) Conclusion

i) Method 2 is suitable for use in a wide range of poultry systems, providing there is access to *vehicles* to carry the *containers* and equipment.

ii) Birds should be introduced into the *container* or apparatus, which is then sealed and filled as quickly as possible with the required gas concentrations, i.e. more than 40 percent CO_2. Birds are held in this atmosphere until *death* is confirmed.

iii) Method 2 is suitable for use in poultry, and neonatal sheep, goats and pigs. However, CO_2 is likely to cause a period of distress in the *animals* before they lose consciousness.

4. Method 3

The gas is introduced into a poultry house.

a) Requirements for effective use in a poultry house

i) Prior to introduction of the CO_2, the poultry house should be appropriately sealed to allow control over the gas concentration. The interval between sealing and gas administration should be kept to the minimum so as to avoid overheating.

Forced ventilation systems, where fitted, should only be switched off immediately prior to gas administration.

The main water supply to the poultry house may have to be turned off and water drained to avoid freezing and bursting of water pipes.

Feeders and water troughs should be lifted to avoid obstruction of the gas entry and prevent injury to birds.

ii) Gas delivery pipes or lancets should be positioned appropriately such that birds are not hit directly by very cold gas delivered at high pressures. It may be necessary to exclude birds from the area in front of the delivery pipes, for a distance of about 20 meters, by partitioning the house with nets, wire mesh or similarly perforated materials.

iii) The house should be gradually filled with CO_2 so that all birds are exposed to a concentration of >40 percent until they are dead; a vaporiser may be required to prevent freezing.

iv) Devices should be used to accurately measure the gas concentration at the maximum height accommodation of birds.

b) Advantages

i) Applying gas to birds *in situ* eliminates the need to manually remove live birds.

ii) CO_2 is readily available.

iii) Gradual raising of CO_2 concentration minimises the aversiveness of the induction of unconsciousness.

c) Disadvantages

i) It is difficult to determine volume of gas required to achieve adequate concentrations of CO_2 in some poultry houses.

ii) It is difficult to verify *death* while the birds are in the poultry house.

The extremely low temperature of liquid CO_2 entering the house and formation of solid CO_2 (dry ice) may cause concern for bird *welfare*.

d) Conclusion

Method 3 is suitable for use in poultry in closed-environment sheds. This method could be developed for killing pigs. However, CO_2 is likely to cause a period of distress in the birds before they lose consciousness.

Article 7.6.~~13~~12.

Nitrogen and/or inert gas mixed with CO2

1. Introduction

CO_2 may be mixed in various proportions with nitrogen or an inert gas (e.g. argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and *death* when the oxygen concentration by volume is <2 percent, or <5 percent for chickens. Various mixtures of CO_2 and nitrogen or an inert gas can be administered to kill birds using Methods 1 and 2 described under Article 7.6.~~12~~11. Whole house gassing with mixtures of CO_2 and nitrogen, or an inert gas, has not been tested owing to the complex issues presented by mixing gases in large quantities. Such mixtures however do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO_2 and the respiratory distress occurring during the induction phase, are important *animal welfare* considerations.

Pigs and poultry appear not to find low concentrations of CO_2 strongly aversive, and a mixture of nitrogen or argon with <30 percent CO_2 by volume and <2 percent O_2 by volume can be used for *killing* poultry, neonatal sheep, goats and pigs.

2. Method 1

The *animals* are placed in a gas-filled *container* or apparatus.

Annex XXXVI (contd)

a) Requirements for effective use

i) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O_2 and CO_2 concentrations accurately measured during the *killing* procedure.

ii) When *animals* are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.

iii) *Animals* should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with <2 percent O_2), and held in this atmosphere until *death* is confirmed.

iv) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.

v) *Containers* or apparatus should not be overcrowded and measures are needed to avoid *animals* suffocating by climbing on top of each other.

b) Advantages

Low concentrations of CO_2 cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.

c) Disadvantages

i) A properly designed *container* or apparatus is needed.

ii) It is difficult to verify *death* while the *animals* are in the *container* or apparatus.

iii) There is no immediate loss of consciousness.

iv) Exposure times required to kill are considerable.

d) Conclusion

The method is suitable for poultry, and for neonatal sheep, goats and pigs.

3. Method 2

In this method, the crates or modules holding the birds are loaded into a *container* and gas is introduced into the *container* ~~(refer to Figures under Article 7.6.12.)~~. As shown in the example below, each containerised gassing unit (CGU) typically comprises a gas-tight chamber designed to accommodate poultry transport crates or a module. The *container* or chamber is fitted with gas lines and diffusers, with silencers, which in turn are connected via a system of manifolds and gas regulators to gas cylinders. There is a hole at the top of the unit to permit displaced air to escape when filling the *container* with gas.

Procedures involved in the operation of CGU includes (a) position the *container* on a level, solid, open ground; (b) connect gas cylinder to the *container* (c) load a module of birds into the *container*, (d) shut and secure the door, (e) deliver the gas to the point where less than 2 percent by volume of oxygen is found at the top of the *container*, (f) allow time for the birds to become unconscious and die, (g) open the door and allow the gas to be dispersed in air, (h) remove the module, (i) check each drawer for survivors; (j) humanely kill survivors, if any; and (k) dispose carcasses appropriately.

a) Requirements for effective use of containerised gassing units (CGU)

i) The birds should be caught gently and placed in crates or modules of appropriate size and at appropriate *stocking densities* to allow all birds to sit down.

ii) The crates or module of birds should be placed inside the *container* and the door shut only when the operator is ready to administer the gas mixture.

iii) Ensure the *container* door is locked and administer the gas mixture until <2 percent residual oxygen is achieved at the top of the crates.

iv) An appropriate gas meter should be used to ensure a concentration of oxygen <2 percent is achieved and maintained until it can be confirmed that the birds have been killed.

v) Sufficient exposure time should be allowed for birds to die before the door is opened. In the absence of a viewing window, which allows direct observation of birds during killing, cessation of vocalisation and wing flapping sounds can be observed by standing close to the *container* and used to determine the onset of *death* in birds. Remove the crates or modules from the *container* and leave them in the open air.

vi) Each crate or module should be examined and birds checked to ensure they are dead. Dilated pupils and absence of breathing movements indicate *death*.

vii) Any survivors should be humanely killed.

viii) Ducks and geese do not appear to be resilient to the effects of a mixture of 20 percent carbon dioxide and 80 percent nitrogen or argon.

b) Advantages

i) The gas mixture is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.

ii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house.

iii) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.

iv) Mixtures containing up to 20 percent carbon dioxide in argon are readily available as welding gas cylinders.

v) Birds are exposed to gas in a more uniform manner and they do not smother each other when compared with Method 1.

vi) Two CGU can be operated in tandem and throughputs of up to 4,000 chickens per hour are possible.

vii) The volume of gas required can be readily calculated.

viii) As the units are operated outdoor the gas is dispersed quickly at the end of each cycle by opening the door, improving operators' health and safety.

ix) The system uses skilled catching teams and equipment in daily use by the industry.

x) Metal *containers* can be readily cleansed and disinfected.

Annex XXXVI (contd)

c) Disadvantages

i) Requires trained operators, trained catchers, transport modules and a fork lift. However, such equipment and suitable outdoor areas with a hard surface are usually available.

ii) The main limiting factors are speed of catching birds and availability of gas mixtures.

iii) In the absence of a viewing window, visual confirmation of *death* while the birds are still in the *container* is difficult. However, cessation of vocalisation and convulsive wing flapping can be used to determine the onset of *death*.

iv) CGU could be used to kill poultry on small to medium farms, e.g. up to 25 thousand birds on a single farm.

d) Conclusion

i) Method 2 is suitable for use in poultry and in neonatal sheep, goats and pigs.

ii) Method 2 is suitable for use in poultry in a wide range of poultry systems providing that these have access to *vehicles* to carry *containers* and equipment.

iii) *Animals* should be introduced into the *container* or apparatus, which is then sealed and filled as quickly as possible with the gas mixture. A residual oxygen concentration of less than 2 percent should be achieved and maintained and birds should be held in this atmosphere until *death* is confirmed.

[DELETE THREE PICTURES]

Article 7.6.~~14~~13.

Nitrogen and/or inert gases

1. Introduction

This method involves the introduction of *animals* into a *container* or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and *death* from hypoxia.

Research has shown that hypoxia is not aversive to pigs and poultry, and it does not induce any signs of respiratory distress prior to loss of consciousness.

2. Requirements for effective use

a) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O_2 concentration accurately measured.

b) When *animals* are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.

c) *Animals* should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with <2 percent O_2), and held in this atmosphere until *death* is confirmed.

d) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.

e) *Containers* or apparatus should not be overcrowded, and measures are needed to avoid *animals* suffocating by climbing on top of each other.

3. Advantages

Animals are unable to detect nitrogen or inert gases, and the induction of hypoxia by this method is not aversive to *animals*.

4. Disadvantages

a) A properly designed *container* or apparatus is needed.

b) It is difficult to verify *death* while the *animals* are in the *container* or apparatus.

c) There is no immediate loss of consciousness.

d) Exposure times required to kill are considerable.

5. Conclusion

The method is suitable for poultry and neonatal sheep, goats and pigs.

Article 7.6.~~15~~14.

Lethal injection

1. Introduction

A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and *death*. In practice, barbiturates in combination with other drugs are commonly used.

2. Requirements for effective use

a) Doses and routes of administration that cause rapid loss of consciousness followed by *death* should be used.

b) Prior sedation may be necessary for some *animals*.

c) Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating.

d) *Animals* should be restrained to allow effective administration.

e) *Animals* should be monitored to ensure the absence of brain stem reflexes.

3. Advantages

a) The method can be used in all species.

b) *Death* can be induced smoothly.

Annex XXXVI (contd)

4. Disadvantages

a) *Restraint* and/or sedation may be necessary prior to injection.

b) Some combinations of drug type and route of administration may be painful, and should only be used in unconscious *animals*.

c) Legal requirements and skill/training required may restrict use to veterinarians.

d) Contaminated carcasses may present a risk to other *wild animals* or domestic *animals*.

5. Conclusion

The method is suitable for *killing* small numbers of cattle, sheep, goats, pigs and poultry.

Article 7.6.~~16~~15.

Addition of anaesthetics to feed or water

1. Introduction

An anaesthetic agent which can be mixed with poultry feed or water may be used to kill poultry in houses. Poultry which are only anaesthetised need to be killed by another method such as cervical dislocation.

2. Requirements for effective use

a) Sufficient quantities of anaesthetic need to be ingested rapidly for effective response.

b) Intake of sufficient quantities is facilitated if the birds are fasted or water is withheld.

c) Should be followed by *killing* (see Article 7.6.~~17~~16.) if birds are anaesthetised only.

3. Advantages

a) Handling is not required until birds are anaesthetised.

b) There may be biosecurity advantages in the case of large numbers of diseased birds.

4. Disadvantages

a) Non-target *animals* may accidentally access the medicated feed or water when provided in an open environment.

b) Dose taken is unable to be regulated and variable results may be obtained.

c) *Animals* may reject adulterated feed or water due to illness or adverse flavour.

d) The method may need to be followed by *killing*.

e) Care is essential in the preparation and provision of treated feed or water, and in the disposal of uneaten treated feed/water and contaminated carcasses.

5. Conclusion

The method is suitable for *killing* large numbers of poultry in houses. However, a back-up method should be available to kill birds that are anaesthetized but not killed.

Article 7.6.~~17~~16.

Cervical dislocation and decapitation

1. Cervical dislocation (manual and mechanical)

a) Introduction

Unconscious poultry may be killed by either manual or mechanical cervical dislocation (stretching the neck). This method results in *death* from cerebral anoxia due to cessation of breathing and/or blood supply to the brain.

When the number of birds to be killed is small, and other methods of *killing* are not available, conscious birds of less than 3 kilograms may be killed using cervical dislocation in such a way that the blood vessels of the neck are severed and *death* is instantaneous.

b) Requirements for effective use

i) *Killing* should be performed either by manually or mechanically stretching the neck to sever the spinal cord with consequent major damage to the spinal cord.

ii) Consistent results require strength and skill so team members should be rested regularly to ensure consistently reliable results.

iii) Birds should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

i) It is a non-invasive *killing* method.

ii) It can be performed manually on small birds.

d) Disadvantages

i) Operator fatigue.

ii) The method is more difficult in larger birds.

iii) Requires trained personnel to perform humanely.

iv) Human health and safety concerns due to handling of the birds.

v) Additional stress to the *animals* from handling.

2. Decapitation

a) Introduction

Decapitation results in *death* by cerebral ischaemia using a guillotine or knife.

b) Requirements for effective use

The required equipment should be kept in good working order.

c) Advantages

The technique is effective and does not require monitoring.

d) Disadvantages

i) The working area is contaminated with body fluids, which increases biosecurity risks.

ii) Pain if consciousness is not lost immediately.

Article 7.6.~~18~~17.

Pithing and bleeding

1. Pithing

a) Introduction

Pithing is a method of *killing animals* which have been stunned by a penetrating captive bolt, without immediate *death*. Pithing results in the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the bolt hole.

b) Requirements for effective use

i) Pithing cane or rod is required.

ii) An access to the head of the *animal* and to the brain through the skull is required.

iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

The technique is effective in producing immediate *death*.

d) Disadvantages

i) A delayed and/or ineffective pithing due to convulsions may occur.

ii) The working area is contaminated with body fluids, which increases biosecurity risks.

2. Bleeding

a) Introduction

Bleeding is a method of *killing animals* through the severance of the major blood vessels in the neck or chest that results in a rapid fall in blood pressure, leading to cerebral ischaemia and *death*.

b) Requirements for effective use

i) A sharp knife is required.

ii) An access to the neck or chest of the *animal* is required.

iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

The technique is effective in producing *death* after an effective *stunning* method which does not permit pithing.

d) Disadvantages

i) A delayed and/or ineffective bleeding due to convulsions may occur.

ii) The working area is contaminated with body fluids, which increases biosecurity risks.

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DRAFT CHAPTER 7.X.

ANIMAL WELFARE AND DAIRY CATTLE PRODUCTION SYSTEMS

EU comments

The EU thanks the OIE for its work on this new chapter which in general is based on the adopted chapter on beef cattle. However, some changes have been proposed for the beef cattle and these should also be proposed here. The EU has several comments as indicated in the text below.

Article 7.X.1.

Definition

Dairy cattle production systems are defined as all commercial cattle production systems where the purpose of the operation includes some or all of the breeding, rearing and management of cattle intended for production of milk.

EU comment

The term "temporo-spatial patterns" is used in Article 7.x.4. number 3 and the EU asks the OIE to consider including a definition of it.

Justification:

Temporo-spatial pattern is a phrase that is not easily understandable and to ensure the proper application of the standard it should be defined.

Article 7.X.2.

Scope

This chapter addresses the welfare aspects of dairy cattle production systems.

Article 7.X.3.

Commercial dairy cattle production systems

Commercial dairy cattle production systems include:

1. Housed or confined

   These are systems where cattle are in confinement and are fully dependent on humans to provide for basic animal needs such as food, shelter and water on a daily basis.

EU comment

The EU asks the OIE to consider the following rephrasing:

"Permanently housed ~~or confined~~

These are systems where cattle are ~~in confinement~~ kept permanently housed and are fully dependent on humans to provide for basic animal needs such as food, shelter and water on a daily basis. The animals may be loose housed or tethered, within this housing system."

Justification

The word "confinement" for dairy cows suggests housed cows that are tethered which is different to a loose housed system and this needs better clarification.

2. Pastured

These are systems where cattle have the freedom to roam outdoors, and where the cattle have some autonomy over diet selection (through grazing), water consumption and access to shelter.

3. Combination systems

These are systems where cattle are exposed to any combination of housing, confinement or pasture husbandry methods, either simultaneously, or varied according to changes in climatic conditions or physiological state of the cattle.

Article 7.X.4.

Criteria (or measurables) for the welfare of dairy cattle

The following outcome-based criteria, specifically animal-based criteria, can be useful indicators of *animal welfare*. The use of these indicators and their appropriate thresholds should be adapted to the different situations where dairy cattle are managed. Consideration should also be given to the design of the system. These criteria can be considered as a tool to monitor the efficiency of design and management, given that *animal welfare* will be affected by both system design and stockmanship.

1. Behaviour

Certain behaviours could indicate an *animal welfare* problem. These include decreased feed intake, locomotory behaviour and posture, altered lying time, human-animal relationship, altered respiratory rate and panting, and the demonstration of stereotypic, aggressive, depressive or other abnormal behaviours (Wiepkema *et al.*, 1983; Moss, 1992; Desire *et al.*, 2002; Appleby, 2006; Mason and Latham, 2004; Lawrence, 2008; Chapinel *et al.*, 2009).

EU comment

The EU asks the OIE to consider the following insertion of words in the second sentence so that the text reads:

"These include decreased feed intake, locomotory behaviour and posture, altered lying time, human-animal relationship, altered respiratory rate and panting (assessed by panting score), and the demonstration of stereotypic, aggressive, depressive or other abnormal behaviours."

Justification

To align the text with that of the beef cattle chapter.

2. Morbidity rates

Morbidity rates, including for *diseases* such as mastitis and metritis, lameness, metabolic diseases, parasitic diseases, post-procedural complication and injury rates, above recognised thresholds, may be direct or indirect indicators of the *animal welfare* status of the whole *herd*. Understanding the aetiology of the *disease* or syndrome is important for detecting potential *animal welfare* problems (Blecha, 2000). Scoring systems, such as lameness scoring, can provide additional information (Sprecher *et al.*, 1997).

EU comment

The EU asks the OIE to consider the using the term "post-partum complication" rather than "post-procedural" in the first sentence and to insert body condition in the final sentence of the above paragraph:

"Morbidity rates, including for diseases such as mastitis and metritis, lameness, metabolic diseases, parasitic diseases, post-partum ~~procedural~~ complication and injury

rates, above recognised thresholds, may be direct or indirect indicators of the animal welfare status of the whole *herd*. … Scoring systems, such as lameness and body condition scoring, can provide additional information."

Justification

Post-partum complications are more pertinent to the issue in this case. Body condition within accepted norms for the environment / situation is a key tool in welfare assessment for dairy cows and is reflected in number 4 below.

Both clinical examination and pathology should be utilised as an indicator of *disease*, injuries and other problems that may compromise *animal welfare*. *Post-mortem* examination is useful to establish causes of *death* in cattle.

3. Mortality rates

Mortality rates, like morbidity rates, may be direct or indirect indicators of the *animal welfare* status (Moss, 1992). Depending on the production system, estimates of mortality rates can be obtained by analysing causes of *death* and the rate and temporo-spatial pattern of mortality. Mortality rates can be reported daily, monthly, annually or with reference to key husbandry activities within the production cycle.

EU comment

The EU askes the OIE to consider rephrasing the text of this point as follows:

"Mortality and culling rates

Mortality and culling rates, like morbidity rates, may be direct or indirect indicators of the animal welfare status (Moss, 1992). Depending on the production system, estimates of mortality and culling rates can be obtained by analysing causes of death and culling and the rate and temporo-spatial pattern of mortality and culling. Mortality and culling rates should ~~can~~ be recorded regularly, i.e. ~~reported~~ daily, monthly, annually or with reference to key husbandry activities within the production cycle."

Justification:

The term "mortality" is normally understood as meaning both animals that have died and those that are culled for different reasons. It seems appropriate to differ between these, especially because the reason for culling can be other than animal welfare, such as reproductive failure ~~or the occurrence of lameness~~. The change in the final sentence is to align with text already adopted or proposed for the beef cattle.

4. Changes in milk yield, body weight and body condition

In growing *animal*s, body weight gain (failure to achieve appropriate growth curve) may be an indicator of animal health and *animal welfare*.

EU comment

The EU asks the OIE to consider the following rephrasing of the above sentence so that the text reads:

"In growing animals, body weight ~~gain (failure to achieve appropriate~~ changes outside the expected growth rate ~~curve)~~ may be an indicator of poor animal health and animal welfare. Future performance, including milk yield and fertility, of heifer replacements can be affected by under or over-nutrition at different stages of rearing."

Justification

Better clarification of what is being explained here. Poor growth is bad, but so may excessive growth be for heifer replacements and this should be emphasised. Using the term "expected" growth allows for those Member countries where growth may not be optimum but is what is expected for the current environmental situation e.g. severe drought / lack of feed for animals and humans alike.

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Le Cozler, Y (Le Cozler, Y.); Peyraud, JL (Peyraud, J. L.); Troccon, JL (Troccon, J. L.)[1] LIVESTOCK SCIENCE Volume: 124 Issue: 1-3 Pages: 72-81 DOI: 10.1016/j.livsci.2008.12.011 SEP 2009 Effect of feeding regime, growth intensity and age at first insemination on performances and longevity of Holstein heifers born during autumn

Terre, M (Terre, Marta); Tejero, C (Tejero, Carolina); Bach, A (Bach, Alex) JOURNAL OF DAIRY RESEARCH Volume: 76 Issue: 3 Pages: 331-339 DOI: 10.1017/S0022029909004142 AUG 2009 Long-term effects on heifer performance of an enhanced-growth feeding programme applied during the preweaning period

Wathes, DC (Wathes, D. C.); Brickell, JS (Brickell, J. S.); Bourne, NE (Bourne, N. E.); Swali, A (Swali, A.); Cheng, Z (Cheng, Z.)ANIMAL Volume: 2 Issue: 8 Pages: 1135-1143 DOI: 10.1017/S1751731108002322 : AUG 2008 Factors influencing heifer survival and fertility on commercial dairy farms

In lactating *animals*, body condition score outside an acceptable range, significant body weight change and significant decrease in milk yield may be indicators of compromised welfare (Roche *et al.*, 2004; Roche *et al.*, 2009).

In non-lactating *animals*, including bulls, body condition score outside an acceptable range and significant body weight change may be indicators of compromised welfare.

5. Reproductive efficiency

Reproductive efficiency can be an indicator of animal health and *animal welfare* status. Poor reproductive performance can indicate *animal welfare* problems. Examples may include:

– prolonged post-partum anoestrus,

– low conception rates,

– high abortion rates,

– high rates of dystocia,

– loss of fertility in breeding bulls.

6. Physical appearance

Physical appearance may be an indicator of animal health and *animal welfare*, as well as the conditions of management. Attributes of physical appearance that may indicate compromised welfare include:

– presence of ectoparasites,

– abnormal coat colour, texture or hair loss,

– excessive soiling with faeces, mud or dirt (cleanliness),

– abnormal swellings and lesions,

– feet abnormalities,

– emaciation.

EU comment

The EU asks the OIE to consider add "dehydration" to the above list.

Justification

This state is not uncommon in a weakened dairy cow.

7. Handling responses

Improper handling can result in fear and distress in cattle. Indicators could include:

– evidence of poor human-animal relationship, such as excessive flight distance,

– negative behaviour at milking time, such as reluctance to enter to the milking parlour, kicking, vocalisation,

– percentage of *animals* striking restraints or gates,

– percentage of *animals* injured during handling, such as bruising, lacerations, broken horns and fractured legs,

– percentage of *animals* vocalising during restraint and handling,

– chute or race behaviour,

– percentage of *animals* slipping or falling.

EU comment

The EU asks the OIE to consider deleting the words "percentage of" from the third, fourth, fifth and seventh indent of the above paragraph so that the text read as follows:

"Improper handling can result in fear and distress in cattle. Indicators could include:

- evidence of poor human-animal relationship, such as excessive flight distance

- negative behaviour at milking time, such as reluctance to enter the milking parlour, kicking, vocalisation,

- ~~percentage of~~ *animals* striking restrains or gates,

- ~~percentage of~~ *animals* injured during handling, such as bruising, lacerations, broken horns and fractured legs,

- ~~percentage of~~ *animals* vocalising during restraint or handling,

- chute or race behaviour,

- ~~percentage of~~ animals slipping or falling."

Justification:

From an animal welfare point of view it should not be accepted that indicators of improper handling are given as a percentage. This indicates an acceptance that these indicators can occur in a certain number before action is taken. This is especially the case for indicators of serious animal welfare problems, such as lacerations, broken horns and fractured legs.

8. Complications due to routine procedure management

Surgical and non-surgical procedures may be performed in dairy cattle for improving *animal* performance, facilitating management, and improving human safety and *animal welfare*. However, if

these procedures are not performed properly, *animal welfare* can be compromised. Indicators of such problems could include:

EU comment

The EU asks the OIE to consider revising the first sentence of the above paragraph:

"Surgical and non-surgical procedures may be performed in dairy cattle for ~~improving *animal* performance,~~ facilitating management, and improving human safety and animal welfare."

Justification

Such procedures should only be done if they may benefit the animals.

– post procedure infection and swelling,

– body condition and weight loss,

– mortality.

Article 7.X.5.

Provisions for good animal welfare

Ensuring high welfare of dairy cattle is contingent on several management factors, including system design and stockmanship which includes responsible husbandry and appropriate care. Serious problems can arise in any system if one or more of these elements are lacking.

Each recommendation includes a list of relevant outcome-based measurables derived from Article 7.X.4. This does not exclude other measures being used where appropriate.

1. Recommendations on system design including physical environment

When new facilities are planned or existing facilities are modified, professional advice on design in regards to animal health and welfare, should be sought (e.g. Milk Development Council, 2006).

Many aspects of the environment can impact on the health and welfare of dairy cattle. These include heat and cold, air quality, noise, etc.

a) Thermal environment

Although cattle can adapt to a wide range of thermal environments particularly if appropriate breeds are used for the anticipated conditions, sudden fluctuations in weather can cause heat or cold stress.

i) Heat stress

The risk of heat stress for cattle is influenced by environmental factors including air temperature, relative humidity and wind speed, and animal factors including breed, age, body condition, metabolic rate and coat colour and density (West, 2003; Bryant *et al.*, 2007).

EU comment

The EU asks the OIE to consider revising the above sentence as follows:

"The risk of heat stress for cattle is influenced by environmental factors including air temperature, relative humidity and wind speed, and animal factors including stocking density, breed, age, body condition, metabolic rate and coat colour and density."

Justification:

A high stocking density reduces the possibility for the animals to get rid of excess body heat.

Animal handlers should be aware of the risk that heat stress poses to cattle and of the thresholds in relation to heat and humidity that may require action. As conditions change, routine daily activities that require moving cattle should be amended appropriately. If the risk of heat stress reaches very high levels the *animal handlers* should institute an emergency action plan that could include provision of shade, fans, easy access to additional drinking water, and provision of cooling systems as appropriate for the local conditions (Igono *et al.*, 1987; Kendall *et al.*, 2007; Blackshaw and Blackshaw, 1994).

EU comment

The EU asks the OIE to consider revising the third sentence of the above paragraph as follows:

"If the risk of heat stress reaches very high levels the animal handlers should institute an emergency action plan that could include provision of shade, fans, free ~~easy~~ access to additional drinking water, reduction of stocking density, and provision of cooling systems as appropriate for the local conditions."

Justification:

The possibility for the animals to get rid of excess body heat and unrestricted water intake is crucial if heat stress reaches very high levels. Please also refer to the revised chapter on welfare recommendations for beef cattle (chapter 7.9.)

Outcome-based measurables: feed and water intake, behaviour, including respiratory rate and panting, morbidity rate, mortality rate, changes in milk yield.

ii) Cold stress

Protection from extreme weather conditions should be provided when these conditions are likely to create a serious risk to the welfare of cattle, particularly in neonates and young cattle and others that are physiologically compromised. This could be provided by extra bedding and natural or man-made shelters (Manninen *et al.*, 2002).

During extreme cold weather conditions, *animal handlers* should institute an emergency action plan to provide cattle with shelter, adequate feed and water.

Outcome-based measurables: mortality and morbidity rates, physical appearance, behaviour including abnormal postures, shivering and huddling, growth curve, body condition and weight loss.

b) Lighting

Confined cattle that do not have access to natural light should be provided with supplementary lighting which follows natural periodicity sufficient for their health and welfare, to facilitate natural behaviour patterns and to allow adequate inspection of the cattle (Arab *et al.*, 1995; Dahl *et al.*, 2000; Phillips *et al.*, 2000).

EU comment

The EU asks the OIE to consider rephrasing the above paragraph and to add two new sentences so that it reads:

"Housed ~~Confined~~ cattle ~~that do not~~ should have access to natural light. Confinement units should also be provided with ~~supplementary~~ permanently installed lighting which follows natural periodicity sufficient for ~~their~~ the animals' health and welfare, to facilitate natural behaviour patterns and to allow inspection of each animal without difficulty. The lighting must not cause discomfort to the animals. Housed dairy cows should be provided with subdued night time lighting."

Justification:

Subdued night time lighting reduces the impact of sudden movements and noises. This has proved to reduce the risk of teat tramp injuries in dairy cattle.

Outcome-based measurables: behaviour, morbidity, physical appearance, mobility.

c) Air quality

Good air quality is an important factor for the health and welfare of cattle. It is affected by air constituents such as gases, dust and micro-organisms, and is influenced strongly by management and building design in housed systems. The air composition is influenced by the stocking density, the size of the cattle, flooring, bedding, waste management, building design and ventilation system.

Proper ventilation is important for effective heat dissipation in cattle and preventing the build-up of effluent gases (e.g. ammonia and hydrogen sulphide) and dust in the confinement unit. Poor air quality and poor ventilation are risk factors for respiratory discomfort and *disease*s.

EU comment

The EU asks the OIE to consider amending the above paragraph by adding the following text:

"It is important to prevent air flow from manure store systems into the compartment in order to keep low levels of gases such as ammonia and hydrogen sulphide. Proper ventilation is important for effective heat dissipation in cattle and preventing the build-up of effluent gases (e.g. ammonia and hydrogen sulphide) and dust in the confinement unit. Poor air quality and poor ventilation are risk factors for respiratory discomfort and diseases. The ammonia level in enclosed housing should not exceed 25 ppm."

Justification

Ammonia has been shown to cause irritation to the respiratory tract. A threshold value for permanent exposure should therefore be recommended in this document.

Outcome-based measurables: morbidity rate, behaviour, mortality rate, respiratory rate or panting, changes in weight and body condition score, growth curve.

d) Noise

Cattle are adaptable to different levels and types of noise. However, exposure of cattle to sudden and unexpected noises should be minimised where possible to prevent stress and fear reactions. Ventilation fans, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in a manner that minimises sudden and unexpected noise.

EU comment

The EU asks the OIE to consider the following rephrasing of the above paragraph:

"Although cattle are adaptable to different levels and types of noise, constant noise in housed systems should not exceed 65 dBA. ~~However,~~ Exposure of cattle to sudden and unexpected noises should be minimised where possible to prevent stress and fear reactions. Ventilation fans, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in a manner that minimises ~~sudden and unexpected~~ noise."

Justification:

Both constant and sudden noise is shown to cause stress to the animals. The threshold value of 65 dBA for constant noise is e.g. motivated by Algers, Ekesbo & Strömberg 1978a and Algers, Ekesbo, Strömberg 1978b.

Outcome-based measurables: behaviour, changes in milk yield.

e) Flooring, bedding, resting surfaces and outdoor areas

In all production systems cattle need a well-drained and comfortable place to rest (Baxter *et al.*, 1983; Baxter, 1992; Moberg and Mench, 2000; Bell and Huxley, 2009; O'Driscoll *et al.*, 2007). All cattle in a group should have sufficient space to lie down and rest at the same time (Kondo *et al.*, 2003).

Particular attention should be given to the provisions for calving areas. The environment in such areas (e.g. floors, bedding, temperature and hygiene) should be appropriate to ensure the welfare of calving cows and new born calves.

EU comment

The EU asks the OIE to consider adding the following text to the above paragraph:

"Calving areas should be thoroughly cleaned and provided with fresh bedding between each calving. Group pens for calving should be managed based on the principle «all in - all out». The group calving pen should be thoroughly cleaned and provided with fresh bedding between each animal group. The time interval between first and last calving of cows kept in the same group calving pen should be minimized."

Justification:

The suggested management of calving areas lowers the risk of infections in both calf and cow, and thereby increases animal health and welfare.

Floor management in housed production systems can have a significant impact on cattle welfare (Ingvartsen *et al.*, 1993; Rushen and de Passillé, 1992; Barkema *et al.*, 1999; Drissler *et al.*, 2005). Areas that compromise welfare and are not suitable for resting (e.g. places with excessive water and faecal accumulation) should not be included in the calculation of the area available for cattle to lie down.

Slopes of pens should be maintained to allow water to drain away from feed troughs and not pool excessively in the pens.

Facilities should be cleaned as conditions warrant, to ensure good hygiene and minimise disease risk.

EU comment

The EU asks the OIE to consider the following rephrasing:

"To ensure good hygiene and minimise disease risk, facilities should be cleaned on a daily basis as conditions warrant, and more thoroughly at least once a year~~, to ensure good hygiene and minimise disease risk~~."

Justification:

A thorough cleaning once a year is an important tool to improve biosecurity.

In straw, sand or other bedding systems, the bedding should be maintained to provide cattle with a dry and comfortable place in which to lie (Bell, 2007; Bell and Huxley, 2009; Fisher *et al.*, 2003; Zdanowicz *et al.*, 2004).

The design of a standing, or cubicle, or free stall, should be such that the *animal* can stand and lie comfortably on solid surface (e.g. length, width and height should be appropriate for the size of the animal) (; Anderson, 2010; Bell 2007; Bernardi *et al.*, 2009; Cook *et al.*, 2008; Tucker *et al.*, 2003; Tucker *et al.*, 2004; Tucker *et al.*, 2009). Where possible, this design should allow for the *animal* to move its head freely as it stands up. Where individual spaces are provided for cows to rest, there should be one space per cow (Fregonesi *et al.*, 2007).

EU comment

The EU asks the OIE to consider amending in the first and second sentences of the above paragraph:

"The design of a standing, or cubicle, or free stall, should be such that the *animal* can stand and lie comfortably on solid surface (e.g. length, width and height should be appropriate for the size of the animal) There should be sufficient room for them to rest, to adopt sleeping postures and freely to stretch their limbs and to rise and also with sufficient freedom of movement to be able to groom themselves without difficulty. ~~Where possible, t~~This design should allow for the *animal* to move its head freely as it stands up."

Justification:

Being able to freely move its head is essential for a bovine animal trying to stand up. The movements carried out when cattle lie down and get up are important physical activities of cattle. The head and body of an adult cow move 0.60 -0.70 meters forward both during the natural lying down and the getting up process. If the cow is prevented in carrying out her natural movements, there is a higher risk of injuries. Specifying the degree of space required for lying and grooming is pertinent for their welfare.

Alleys and gates should be designed and operated to allow free movement of cattle. Slippery surfaces should be avoided (e.g. grooved concrete; metal grating, not sharp; rubber mats or deep sand) to minimise slipping and falling (Haufe *et al.*, 2009; Rushen and de Passilé, 2006).

If a housing system includes areas of slatted floor, cattle, including replacement stock, should have access to a solid lying area. The slat and gap widths should be appropriate to the hoof size of the cattle to prevent injuries (Hinterhofer *et al.*, 2006; Telezhenko *et al.*, 2007).

If cattle have to be tethered, they should, as a minimum, be able to lie down and stand up unimpeded. *Animal handlers* should be aware of the higher risks of welfare problems where cattle are tethered (Loberg *et al.*, 2004; Tucker *et al.*, 2009).

EU comment

The EU asks the OIE to consider inserting a new second and third sentence in above paragraph:

"Tethering of male cattle should be avoided. If tethered outdoors, they should be able to turn around, walk and maintain a normal position."

Justification:

Tethering of male animals means a higher risk of soiling in the cubicle, primarily by urine. To align text with the one proposed for the beef cattle chapter.

Where breeding bulls are in housing systems, care should be taken to ensure that they have sight of other cattle with sufficient space for resting and exercise. If used for natural mating, the floor should not be slatted or slippery.

Outcome-based measurables: morbidity rates (e.g. lameness, pressure sores), behaviour, changes in weight and body condition score, physical appearance (e.g. hair loss, cleanliness score), growth curve.

EU comment

The EU asks the OIE to consider including "grooming" as one of the measurable. In addition "body condition score" should be amended to "body condition" and "growth curve" to "growth rate" throughout the text of this chapter.

Justification:

Grooming is an important behavioural need and the other changes are in line with the wording in the beef cattle chapter and the draft broiler chapter.

f) Location, construction and equipment

Farms for dairy cattle should be situated in an appropriate geographical location for the health, welfare and productivity of the cattle.

All facilities for dairy cattle should be constructed, maintained and operated to minimise the risk to the welfare of the cattle (Grandin, 1980).

Equipment for milking, handling and restraining dairy cattle should only be used in a way that minimises the risk of injury, pain or distress.

Electrified equipment (e.g. cow trainer, electrified gate) has been associated with increased incidence of welfare problems and should not be used.

EU comment

The EU asks the OIE to consider the following rephrasing:

"Electrified equipment which is designed to control animal behaviour (e.g. cow trainer, electrified gate) has been associated […]"

Justification:

Clarifies and improves the understanding of the text.

Cattle in housed or pastured production systems should be offered adequate space for comfort and socialisation (Kondo *et al.*, 2003).

In all production systems, feed and water provision should allow all cattle to have unimpeded access to feed and water (DeVries and Keyserlingk, 2005; DeVries *et al.*, 2005, DeVries *et al.*, 2004; Endres *et al.*, 2005). Feeders and water providers should be clean and free of spoiled, mouldy, sour, unpalatable feed and faecal contamination.

Milking parlour, free stalls, standings, cubicles, races, chutes and pens should be free from sharp edges and protrusions to prevent injury to cattle.

Where possible, there should be a separated area to closely examine individual *animals*, which should have restraining facilities.

A hospital area for sick and injured *animals* should be provided so the *animals* can be treated away from healthy *animals*.

EU comment

The EU asks the OIE to consider adding a second sentence to the above paragraph:

"A hospital area for sick and injured animals should be provided so the animals can be treated away from healthy animals. The hospital area should fulfil, as a minimum, all requirements met elsewhere on the farm and should enable individual and loose housing."

Justification:

Sick and injured animals need more care and attention than healthy fit animals. Hospital pens therefore must provide at least the same level of comfort and access for feed and water as the rest of the farm. Because sick or injured animals may be unable to move or reach food or water additional provision for these may be required. Additional bedding or alternative floors may be required to prevent recumbent animals suffering

injury while in the hospital pen. Furthermore, treatment and rehabilitation of most conditions in cattle is facilitated by loose housing of the animal.

Hydraulic, pneumatic and manual equipment should be adjusted, as appropriate, to the size of cattle to be handled. Hydraulic and pneumatic operated restraining equipment should have pressure limiting devices to prevent injuries. Regular cleaning and maintenance of working parts is imperative to ensure the system functions properly and safe for the cattle.

Mechanical and electrical devices used in facilities should be safe for cattle.

Dipping baths and spray races are sometimes used in dairy cattle production for ectoparasite control. Where these are used, they should be designed and operated to minimise the risk of crowding and to prevent injury and drowning.

Collecting yards (e.g. entry to the milking parlour) should be operated to minimise crowding and prevent injuries and lameness.

EU comment

The EU asks the OIE to consider also including minimising stress so that the sentence reads:

"Collecting yards (e.g. entry to the milking parlour) should be operated to minimise crowding and stress, and prevent injuries and lameness."

Justification:

Improperly designed collecting yards makes management complicated for the handler and stressful for the animals.

The loading areas and ramps should be designed to minimise stress and injuries for the *animals* and ensure the safety of the *animal handlers*, accordingly to Chapters 7.2., 7.3. and 7.4.

EU comment

The EU asks the OIE to consider the following amendment to the above sentence:

"The loading areas and ramps, including the slope of the ramp, should be designed to minimise stress and prevent injuries for the *animals* and ensure the safety of the *animal handlers*, accordingly to Chapters 7.2., 7.3. and 7.4."

Justification:

It is not acceptable that loading areas and ramps cause injuries to the animals. Many studies have shown that loading is stressful, and the slope of the ramp is an important aspect when stress is to be minimised and injuries prevented.

Outcome-based measurables: handling response, morbidity rate, mortality rate, behaviour, changes in weight and body condition score, physical appearance, lameness, growth curve.

g) Emergency plans

Where the failure of power, water and feed supply systems could compromise *animal welfare*, dairy producers should have contingency plans to cover the failure of these systems. These plans may include the provision of fail-safe alarms to detect malfunctions, back-up generators, access to maintenance providers, ability to store water on farm, access to water cartage services, adequate on-farm storage of feed and alternative feed supply.

EU comment

The EU asks the OIE to consider deleting "where" so that the first sentence reads:

"~~Where t~~The failure of power, water and feed supply systems could compromise animal welfare and dairy producers should have contingency plans to cover the failure of these systems."

Justification:

These kinds of failures are likely to compromise animal welfare.

Dairy producers should have contingency plans to cover the evacuation of animals in case of emergency (e.g. fire, flooding).

Outcome-based measurables: mortality, morbidity, behaviour, vocalization.

2. Recommendations on stockmanship and animal management

Good management and stockmanship are critical to providing an acceptable level of *animal welfare*. Personnel involved in handling and caring for dairy cattle should be competent and receive appropriate training to equip them with the necessary practical skills and knowledge of dairy cattle behaviour, health, physiological needs and welfare. There should be a sufficient number of *animal handlers* to ensure the health and welfare of the cattle.

a) Biosecurity and animal health

i) Biosecurity and disease prevention

Biosecurity means a set of measures designed to maintain a *herd* at a particular health status and to prevent the entry or spread of infectious agents.

Biosecurity plans should be designed and implemented, commensurate with the desired *herd* health status and current *disease* risk and, for OIE *listed diseases* in accordance with relevant recommendations found in the *Terrestrial Code*.

EU comment

The EU asks the OIE to consider rephrasing the above sentence:

"Biosecurity plans should be designed and implemented, commensurate with the best possible ~~desired~~ *herd* health status and current disease risk (endemic and exotic or transboundary) that is specific to each epidemiological group of dairy cows and~~, for OIE listed diseases~~ in accordance with relevant recommendations found in the Terrestrial Code."

Justification:

To align the requirements with the text proposed for the broiler chapter.

These biosecurity plans should address the control of the major sources and pathways for spread of pathogens:

– cattle,

EU comment

The EU asks the OIE to consider the insertion of the words "especially those introduced into the herd" in the above indent so that it reads as follows:

"– cattle, especially those introduced into the herd."

Justification:

Cattle introduced into a herd may institute a major source of spread of pathogens compared to cattle already in the herd. This is especially the case if animals are in the incubation phase of a disease, and do not yet show clinical signs of disease.

– other domestic animals and *wildlife*,

– people,
– equipment,
– *vehicles*,
– air,
– water supply,
– feed,
– semen.

EU comment

The EU asks the OIE to consider the following addition to the above indent the so that it reads as follows

"– semen, embryos and ova."

Justification:

The use of semen, embryos and ova equally affects biosecurity. For example, embryo transfer can transmit EBL, or TSE. Some references to support this are indicated below.

References

Sutmoller P, Wrathall AE. The risks of disease transmission by embryo transfer in cattle. Rev Sci Tech. 1997 Apr;16(1):226-39

Le Tallec B, Ponsart C, Marquant-Le Guienne B, Guérin B. Risks of transmissible diseases in relation to embryo transfer. Reprod Nutr Dev. 2001 Sep-Oct;41(5):439-50

Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, changes in weight and body condition score, changes in milk yield.

EU comment

The EU asks the OIE to consider including the following measurable in the above listing:

"herd disease status (for endemic diseases) and changes in milk yield and composition"

Justification:

The first is an animal based measurable at the herd level in relation to certain endemic diseases (some of which may also be OIE listed diseases, others may not). Maintenance of immunological naivety or controlled disease exposure can impact significantly on animal health and welfare if the disease status of existing herd/ incoming animals is not fully understood.

In cases of acidosis milk fat drops before cows show clinical signs.

ii) Animal health management

Animal health management means a system designed to optimise the physical and behavioural health and welfare of the dairy *herd*. It includes the prevention, treatment and control of *diseases* and conditions affecting the *herd*.

There should be an effective programme for the prevention and treatment of *diseases* and conditions, formulated in consultation with a *veterinarian*, where appropriate. This programme should include the recording of production data (e.g. number of lactating cows, animal movements in and out of the *herd*, milk yield), morbidities, mortalities, culling rate and medical treatments. It should be kept up to date by the *animal handler*. Regular monitoring of records aids management and quickly reveals problem areas for intervention.

For parasitic burdens (e.g. endoparasites, ectoparasites and protozoa), a programme should

be implemented to monitor, control and treat, as appropriate.

Lameness is a problem in dairy *herds*. *Animal handlers* should monitor the state of feet and claws and maintain foot health (Chapinal *et al.*, 2009; Sprecher *et al.*, 1997).

EU comment

The EU asks the OIE to consider the following rephrasing of the above paragraph:

"Lameness is a problem in dairy cattle ~~herds~~. Animal handlers should take measures to prevent lameness, and monitor the state of feet and claws in order to maintain foot health. Standardised locomotor scoring systems are available (Dairyco 2009, Welfare Quality 2009)."

Justification:

The cause of lameness is not always attributed to feet and claws, but may also involve limbs and joints and have aetiology in the housing environment. Where standardised systems for measuring "outcome measurable" are currently available these have been quoted in other OIE welfare texts.

Those responsible for the care of cattle should be aware of early specific signs of *disease* or distress (e.g. coughing, ocular discharge, changing locomotion score), and non-specific signs such as reduced feed and water intake, reduction of milk production, changes in weight and body condition, changes in behaviour or abnormal physical appearance (FAWC, UK, 1993; Ott *et al.*, 1995; Anonymous, 1997; Blecha, 2000; EU-SCAHAW, 2001; Webster, 2004; Mellor and Stafford, 2004; Millman *et al.*, 2004; OIE, 2005; Appleby, 2006; Broom, 2006; Gehring *et al.*, 2006; Fraser, 2008; Blokhuis *et al.*, 2008; Mench, 2008; Fraser, 2009; Ortiz-Pelawz *et al.*, 2008; FAWAC, Ireland; Hart, 1987; Tizard, 2008; Weary *et al.*, 2009).

EU comment

The EU asks the OIE to consider the following addition to the sentence:

"Those responsible for the care of cattle should be aware of early specific signs of *disease* or distress (e.g. coughing, ocular discharge, clots in the milk, changing locomotion score), and non-specific signs such as reduced feed and water intake, reduction of milk production, changes in weight and body condition, changes in behaviour or abnormal physical appearance. "

Justification:

A common specific sign of mastitis.

Cattle at higher risk of *disease* or distress will require more frequent inspection by *animal handlers*. If *animal handlers* suspect the presence of a *disease* or are not able to correct the causes of *disease* or distress, they should seek advice from those having training and experience, such as *veterinarians* or other qualified advisers, as appropriate. In the event of an *OIE listed disease* being suspected or diagnosed, the official veterinary services should be notified (see Chapter 1.1. of the *Terrestrial Code*).

Vaccinations and other treatments administered to cattle should be undertaken by people skilled in the procedures and on the basis of veterinary or other expert advice.

Animal handlers should have experience in managing chronically ill or injured cattle, for instance in recognising and dealing with non-ambulatory cattle, especially those that have recently calved. Veterinary advice should be sought as appropriate.

Non-ambulatory cattle should have access to water at all times and be provided with feed at least once daily. They should not be transported or moved except for treatment or diagnosis. Such movements should be done carefully using methods avoiding excessive lifting.

EU comment

The EU asks the OIE to consider the following rephrasing of this paragraph:

"Non-ambulatory cattle should have access to water at all times and be provided with feed at least once daily. They should not be transported or moved unless absolutely necessary ~~except~~ for treatment or diagnosis. Such movements should be done carefully using methods avoiding dragging or excessive lifting. "

Justification:

To align with the text proposed for the beef cattle chapter.

Animal handlers should also be competent in assessing fitness to transport.

EU comment

The OIE may wish to reference OIE transport chapter 7.3.

In case of chronic *disease* or injury, when treatment has been attempted and recovery deemed unlikely (e.g. cattle that are unable to stand up, unaided or refuse to eat or drink), the *animal* should be humanely killed (AABP, 1999; AVMA, 2007) and in accordance to Chapter 7.6.

EU comment

The OIE may wish to reference OIE chapter 7.5 as well so that the sentence ends:

"[…] and in accordance to Chapter 7.5 or 7.6 as applicable"

Justification:

Slaughter is defined as the killing of animals for human consumption. Some of the animals with chronic injuries may be fit for human consumption and as a result be slaughtered rather than killed.

Animals suffering from photosensitisation should be offered shade.

EU comment

The EU asks the OIE to consider the following addition to the sentence:

"Animals suffering from photosensitisation should be ~~offered~~ provided with shade in the acute phase of the disease, and, where appropriate, identification and removal of the primary cause of the photosensitisation should occur."

Justification:

According to current scientific knowledge the treatment of photosensitization is always the same anyway (removal from direct sunlight) and establishing primary cause – by getting veterinary advice / further treatment /investigation etc.

Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, behaviour, physical appearance and changes in weight and body condition score, changes in milk yield.

iii) Emergency plans

Emergency plans should cover the management of the farm in the face of an emergency *disease outbreak*, consistent with national programmes and recommendations of *Veterinary Services* as appropriate.

b) Nutrition

The nutrient requirements of dairy cattle have been well defined. Energy, protein, mineral and vitamin content of the diet are major factors determining milk production and growth, feed efficiency, reproductive efficiency, and body condition (National Research Council, 2001).

Cattle should be provided with access to an appropriate quantity and quality of balanced nutrition that meets their physiological needs. Where cattle are maintained in outdoor conditions, short term exposure to climatic extremes may prevent access to nutrition that meets their daily physiological needs. In such circumstances the *animal handler* should ensure that the period of reduced nutrition is not prolonged and that extra food and water supply are provided if welfare would otherwise be compromised.

Animal handlers should have adequate knowledge of appropriate body condition scores for their cattle and should not allow body condition to go outside an acceptable range according to breed and physiological status (Roche *et al.*, 2004; Roche *et al.*, 2009).

Feedstuffs and feed ingredients should be of satisfactory quality to meet nutritional needs. Where appropriate, feed and feed ingredients should be tested for the presence of substances that would adversely impact on animal health (Binder, 2007).

The relative risk of digestive upset in cattle increases as the proportion of grain increases in the diet or if quality of silage is poor. *Animal handlers* should understand the impact of cattle size and age, weather patterns, diet composition and sudden dietary changes in respect to digestive upsets and their negative consequences (displaced abomasum, sub-acute ruminal acidosis, bloat, liver abscess, laminitis) (Enemark, 2008; Vermunt and Greenough, 1994). Where appropriate, dairy producers should consult a cattle nutritionist for advice on ration formulation and feeding programmes.

Particular attention should be paid to nutrition in the last month of pregnancy, with regards to energy balance, roughage and micronutrients, in order to minimise calving and post-calving diseases and body condition loss (Drackley, 1999; Bertoni *et al.*, 2008; Huzzey *et al.*, 2005).

Dairy producers should become familiar with potential micronutrient deficiencies or excesses for housed and pastured production systems in their respective geographical areas and use appropriately formulated supplements where necessary.

All cattle, including unweaned calves, need an adequate supply and access to palatable water that meets their physiological requirements and is free from contaminants hazardous to cattle health (Lawrence *et al.*, 2004b; Cardot *et al.*, 2008).

Outcome-based measurables: mortality rates, morbidity rates, behaviour, changes in weight and body condition score, reproductive efficiency, changes in milk yield, growth curve.

c) Social environment

Management of cattle should take into account their social environment as it relates to *animal welfare*, particularly in housed systems (Le Neindre, 1989; Jóhannesson and Sørensen, 2000; Bøe and Færevik, 2003; Bouissou *et al.*, 2001; Kondo *et al.*, 2003; Sato *et al.*, 1993). Problem areas include: agonistic and oestrus activity, mixing of heifers and cows, feeding cattle of different size and age in the same pens, high stocking density, insufficient space at the feeder, insufficient water access and mixing of bulls.

Management of cattle in all systems should take into account the social interactions of cattle within groups. The *animal handler* should understand the dominance hierarchies that develop within different groups and focus on high risk *animals*, such as very young, very old, small or large size for cohort group, for evidence of bullying and excessive mounting behaviour. The *animal handler* should understand the risks of increased agonistic interactions between *animals*, particularly after mixing groups. Cattle that are suffering from excessive agonistic activity should be removed from the group (Bøe and Færevik, 2003; Jensen and Kyhn, 2000; von Keyserlingk *et al.*, 2008).

EU comment

The EU asks the OIE to consider the following amendment to the final sentence of the above paragraph:

"Cattle that are suffering from excessive agonistic activity or excessive mounting behaviour should be removed from the group."

Justification:

A logical conclusion of the previous text in the paragraph.

Animal handlers should be aware of the *animal welfare,* problems that may be caused by mixing of inappropriate groups of cattle, and provide adequate measures to minimise them (e.g. introduction of heifers in a new group, mixing of *animals* at different production stages that have different dietary needs) (Grandin, 1998; Grandin, 2003; Grandin, 2006; Kondo *et al.*, 2003).

Horned and non-horned cattle should not be mixed because of the risk of injury (Menke *et al.*, 1999).

EU comment

The EU asks the OIE to consider the following additional wording:

"Horned and non-horned cattle should not be mixed in loose housed systems because of the risk of injury (Menke *et al.*, 1999)."

Justification:

Menke et al 1999 was a study of a loose housed system and therefore statement should refer to system type where such evidence has been provided. OR evidence should be provided for extensive / pastured systems requirement to separate such animals.

Outcome-based measurables: behaviour (e.g. lying times), physical injuries, changes in weight and body condition score, physical appearance (e.g. cleanliness), lameness scores, changes in milk yield, morbidity rate, mortality rate, growth curve.

EU comment

The EU asks the OIE to consider adding vocalisation to the list of outcome-based measurables.

Justification:

Vocalisation is an important and easy measurable indicator of animal welfare for cattle.

d) Stocking density

High stocking densities may increase injuries and have an adverse effect on growth curve, feed efficiency, and behaviour such as locomotion, resting, feeding and drinking (Martin and Bateson, 1986; Kondo *et al.*, 2003).

EU comment

The EU asks the OIE to consider the following rephrasing:

"High stocking densities may increase the occurrence of injuries and have an adverse effect on growth rate ~~curve~~, feed efficiency, and behaviour such as locomotion, resting, feeding and drinking."

Justification:

To align text with the one proposed for beef cattle.

Stocking density should be managed such that crowding does not adversely affect normal behaviour of cattle (Bøe and Færevik, 2003). This includes the ability to lie down freely without the risk of injuries, move freely around the pen and access feed and water. Stocking density should also be managed such that weight gain and duration of time spent lying is not adversely affected by crowding (Petherick and Phillips, 2009a). If abnormal behaviour is seen, measures

should be taken such as reducing stocking density.

EU comment

The EU asks the OIE to consider the following amendment of the three final sentences:

"This includes the ability to lie down freely without the risk of injuries, move freely around when loose housed ~~the pen~~ and access feed and water. Stocking density should also be managed such that ~~weight gain~~ body condition and duration of time spent lying is not adversely affected by crowding If abnormal behaviour (e.g. excessive fighting, animals not daring to lie down or to eat/drink because of disturbing other dominant animals) is seen, measures should be taken such as reducing stocking density."

Justification:

Tethered animals will not be able to move freely around. In adult cows you cannot expect weight gain, but body condition may be affected by impaired access to feed due to crowding. Examples of abnormal behaviour would help understanding.

In pastured systems, stocking density should depend on the available feed and water supply and pasture quality (Stafford and Gregory, 2008).

Outcome-based measurables: behaviour, morbidity rate, mortality rate, changes in weight and body condition score, physical appearance, changes in milk yield, parasite burden, growth curve.

e) Protection from predators

Cattle should be protected as much as possible from predators.

Outcome-based measurables: mortality rate, morbidity rate (injury rate), behaviour, physical appearance.

f) Genetic selection

Welfare and health considerations, in addition to productivity, should be taken into account when choosing a breed or subspecies for a particular location or production system (Lawrence *et al.*, 2001; Lawrence *et al.*, 2004a; Boissy and Le Neindre, 1997; Boissy *et al.*, 2007; Jensen *et al.*, 2008; Veissier *et al.*, 2008; Dillon *et al.*, 2006; Macdonald *et al.*, 2008). Examples of these include nutritional maintenance requirement, ectoparasite resistance and heat tolerance.

Individual *animals* within a breed should be selected to propagate offspring that exhibit traits beneficial to animal health and welfare by promoting robustness and longevity. These include resistance to infectious and production related *diseases*, ease of calving, fertility, body conformation and mobility, and temperament.

EU comment

The EU asks the OIE to consider inserting a new paragraph here:

"In breeding programs at least as much attention shall be paid to criteria conducive to the improvement of cattle welfare, including health, as to production criteria. Therefore, the conservation or development of breeds or strains of cattle, which would limit or reduce animal welfare problems, shall be encouraged."

Justification:

The EU supports that welfare and health considerations, in addition to productivity should be taken into account when choosing a breed or subspecies, as stated in the first paragraph. However, in order to be able to do this it is important that those deciding on breeding programs are encouraged to be aware of this.

Outcome-based measurables: morbidity rate, mortality rate, behaviour, physical appearance,

reproductive efficiency, lameness, human-animal relationship, growth curve, body condition score outside an acceptable range.

g) Artificial insemination, pregnancy diagnosis and embryo transfer

Semen collection should be carried out by a trained operator in a manner that does not cause pain or distress to the bull and in accordance with Chapter 4.6.

EU comment

The EU asks the OIE to consider the following rephrasing of the above sentence:

"Semen collection should be carried out by a trained operator in a manner that does not cause pain or distress to the bull and any teaser animal used during collection and in accordance with Chapter 4.6."

Justification:

No animal should be subject to pain or distress during semen collection.

Artificial insemination and pregnancy diagnosis should be performed by a competent operator.

Embryo transfer should be performed under an epidural or other anesthesia by a trained operator, preferably a *veterinarian* or a *veterinary para-professional*.

Outcome-based measurables: behaviour, morbidity rate, reproductive efficiency

h) Sire selection and calving management

Dystocia can be a welfare risk to dairy cattle. Heifers should not be bred before they are at stage of physical maturity sufficient to ensure the health and welfare of both dam and calf at birth. The sire has a highly heritable effect on final calf size and as such can have a significant impact on ease of calving. Sire selection for embryo implantation, insemination or natural mating, should take into account the maturity and size of the female.

EU comment

The EU asks the OIE to consider rephrasing the first and second sentences as follows:

"Dystocia is ~~can be~~ a welfare risk to dairy cattle. Heifers should not be bred before they are at the stage of physical maturity sufficient to ensure the health and welfare of both dam and calf at birth."

Justification:

Every case of dystocia is an obvious welfare risk. Grammatical correction.

Pregnant cows and heifers should be managed during pregnancy so as to achieve an appropriate body condition range for the breed. Excessive fatness increases the risk of dystocia and metabolic disorders during late pregnancy or after parturition.

Cows and heifers should be monitored when they are close to calving. *Animals* observed to be having difficulty in calving should be assisted by a competent handler as soon as possible after they are detected.

Outcome-based measurables: morbidity rate (rate of dystocia), mortality rate (cow and calf), reproductive efficiency, body condition score.

i) New born calves

Receiving adequate immunity from colostrum generally depends on the volume and quality of colostrum ingested, and how soon after birth the calf receives it.

Animal handlers should ensure that calves receive sufficient colostrum within 24 hours of birth to provide passive immunity. Where possible, calves should continue to receive colostrum or

equivalent for at least 5 days after birth.

EU comment

The EU asks the OIE to consider inserting a new sentence after the first sentence of the above paragraph:

"It is most beneficial during the first 6 hours after birth."

Justification:

Immunoglobulin absorption drops off rapidly in the calf. Optimal absorption occurs at about 6 hours post partum. Ability to actively take up immunoglobulin effectively drops to about 12% by 24 hours, 7% by 36 hours, 6% at 48 hours etc. i.e. the intestinal barrier is pretty much closed to absorbing further immunoglobulins between 24-36 hours of age and it is uptake within the first 6 hours that is key to getting effective immunoglobulin levels in the calf that can protect it for future weeks, even months. Continued feeding of spare milk in the first days and indeed weeks of life may have a beneficial effect in a number of ways: highly digestible nutrients which maximize absorption of essential nutrients but additionally a local protective effect within the gut itself (not by active absorption) by the immunoglobulins present in the milk. (Note milk contains Ig too, just not at such high concentrations).

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Where new born calves need to be transported, this should be carried out according to Chapter 7.3.

EU comment

The above sentence does not seem to be quite in line with Chapter 7.3 and the EU asks the OIE to consider amending the text as follows:

"After the healing of the navel, ~~Where new born~~ if calves need to be transported, this should be carried out according to Chapter 7.3."

Justification:

According to 7.3.7.3.c new born animals with an unhealed navel are unfit to travel. The proposed text seems to indicate that transporting new born animals may be permissible. This is not the case as new born calves are highly susceptible to infections before the navel is healed (according to Hides & Hannah 2005 the umbilical cord in most calves has dried in the range of 1 to 8 days), and before their own immune system is active (according to Stadler et al. 2002, the transition from maternal Ig dominance to endogenous Ig dominance occurs between weeks two to six of life). Transportation is a stress factor that adds to this sensitivity. It should therefore not be carried out during the first two weeks of a calf's life.

Calves should be handled and moved in a manner which minimises distress and avoids pain and injury.

Outcome-based measurables: mortality rate, morbidity rate, growth curve.

j) Cow-calf separation and weaning

Different strategies to separate the calf from the cow are utilised in dairy cattle production systems. These include early separation (usually within 48 hours of birth) or a more gradual separation (leaving the calf with the cow for a longer period so it can continue to be suckled). Separation can be stressful for both cow and calf (Newberry and Swanson, 2008; Weary *et al.*, 2008).

EU comment

The EU asks the OIE to consider amending the last sentence in the above paragraph as follows:

"Separation ~~can be~~ is stressful for both cow and calf."

Justification:

The moment of separation is indeed stressful for both cow and calf.

For the purposes of this chapter, weaning means the change from a milk-based diet to a fibrous diet. This change should be done gradually and calves should be weaned only when their ruminant digestive system has developed sufficiently to enable them to maintain growth, health and welfare (Roth *et al.*, 2009).

EU comment

The EU asks the OIE to consider rephrasing the first sentence of the above paragraph as follows:

"For the purposes of this chapter, weaning means the change from a milk-based diet to a fibrous diet and a weaned animal does not any longer receive milk in its diet."

Justification:

It is true that weaning is a gradual process. However, for a definition there needs to be a clear point when animals are considered weaned to ensure uniform application of the standard.

If necessary, dairy cattle producers should seek expert advice on the most appropriate time and

method of weaning for their type of cattle and production system.

Outcome-based measurables: morbidity rate, mortality rate, behaviour, physical appearance, changes in weight and body condition score, growth curve.

k) Rearing of replacement stock

Young calves are at particular risk of thermal stress. Special attention should be paid to management of the thermal environment (e.g. provision of additional bedding, nutrition or protection to maintain warmth and appropriate growth).

Where possible, replacement stock should be reared in groups. Animals in groups should be of similar age and physical size (Bøe and Færevik, 2003; Jensen and Kyhn, 2000).

When in pens, each calf should have enough space to be able to turn around, rest, stand up and groom comfortably.

EU comment

The EU asks the OIE to consider rephrasing the above sentence as follows:

"When in pens, each calf should have enough space to be able to turn around, rest, stand up, ~~and~~ groom comfortably and see and touch other animals."

Justification:

Calves are very social animals, interacting frequently with other calves after one week of age and developing normal social behaviour only if they can interact freely with other calves, cf. conclusion no 13 in Report of the Scientific Veterinary Committee, Animal Welfare Section on the Welfare of Calves (November 1995). Having contact with other animals of its species is essential for a calf, at least after the first two weeks of life. According to Warnick et al. 1977, calves given the opportunity to have social contact with other calves e.g. started eating concentrates earlier than calves housed separately.

Replacement stock should be monitored for cross-sucking and appropriate measures taken to prevent this occurring (e.g. provision of sucking devices, use of nose guards or temporary separation).

EU comment

The EU asks the OIE to consider rephrasing the above paragraph as follows:

"Replacement stock should be monitored for cross-sucking and appropriate measures taken to prevent this occurring (e.g. provision of sucking devices, ~~use of nose guards~~ revise or modify feeding practices ~~or temporary separation~~)."

Justification:

According to Nielsen 2008, the calves' behavioural motivation to suckle is high, and cross-sucking is a sign that this need is not met at feeding.

Particular attention should be paid to the nutrition, including trace elements, of growing replacement stock to ensure good health and that they achieve an appropriate growth curve for the breed and farming objectives.

Outcome-based measurables: morbidity rate, mortality rate, behaviour, physical appearance, changes in weight and body condition score, growth curve, reproduction efficiency.

l) Milking management

Milking should be carried out in a calm and considerate manner in order to avoid pain and distress. Special attention should be paid to the hygiene of the udder and milking equipment (Barkema *et al.*, 1999; Breen *et al.*, 2009).

A regular milking routine should be established relevant to the stage of the lactation and system (e.g. female in full lactation may need more frequent milking to relieve udder pressure). All milking cows should be checked for abnormal milk at all milking times.

Where a milking machine is used, it should be maintained, according to the recommendations of the manufacturer, in order to minimise teat and udder damage.

EU comment

The EU asks the OIE to consider rephrasing the above sentence as follows:

"Where a milking machine or robot is used, the recommendations of the manufacturer should be obtained and the equipment ~~it should be~~ maintained, according to these recommendations ~~of the manufacturer~~, in order to minimise teat and udder damage."

Justification:

Robots are also commonly used and there should be an obligation to obtain from the manufacturer the user manual. In our experience user manuals are not always available and it needs to be more strongly emphasized that such information needs to be collected.

Special care should be paid to *animals* being milked for the first time. If possible, they should be familiarised with the milking facility prior to giving birth.

Long waiting times before and after milking can lead to health and welfare problems (e.g. lameness, reduced time to eat). Management should ensure that waiting times are minimised.

Outcome-based measurables: morbidity rate (e.g. udder health), behaviour, changes in milk yield, physical appearance (e.g. lesions).

m) Painful husbandry procedures

Husbandry practices are routinely carried out in cattle for reasons of management, *animal welfare* and human safety. Those practices that have the potential to cause pain should be performed in such a way as to minimise any pain and stress to the *animal*.

Alternative procedures that reduce or avoid pain should be considered.

EU comment

The EU asks the OIE to consider inserting the following paragraph here:

"Future options for enhancing *animal welfare* in relation to these procedures include: ceasing the procedure and addressing the current need for the operation through management strategies; breeding cattle that do not require the procedure; or replacing the current procedure with a non-surgical alternative that has been shown to enhance *animal welfare.*"

Justification:

To align requirements with those already adopted for beef cattle.

Example of such interventions include: dehorning, tail docking and identification.

i) Dehorning (including disbudding)

Dairy cattle that are naturally horned are commonly dehorned in order to reduce animal injuries and hide damage, improve human safety, reduce damage to facilities and facilitate transport and handling (Laden *et al.*, 1985; Petrie *et al.*, 1996; Singh *et al.*, 2002; Sutherland *et al.*, 2002; Stafford *et al.*, 2003; Stafford and Mellor, 2005). Where practical and appropriate for the production system, the selection of polled cattle is preferable to dehorning.

Where it is necessary to dehorn dairy cattle, producers should seek guidance from

veterinary advisers as to the optimum method, use of anesthesia and analgesia, and timing for their type of cattle and production system.

EU comment

The EU asks the OIE to consider amending the above text as follows:

"Where it is necessary to dehorn dairy cattle, producers should seek guidance from *veterinarians* ~~veterinary advisers~~ as to the optimum method, use of anaesthesia and analgesia, and timing for their type of cattle and production system."

Justification:

To align requirements with those already adopted for beef cattle.

Performing dehorning or disbudding at an early age, where practicable, and the use of anaesthesia or analgesia, under the supervision of a *veterinarian*, are strongly recommended.

Thermal cautery of the horn bud by a trained operator with proper equipment is the recommended method in order to minimise post-operative pain. This should be at an appropriate age before the horn bud has attached to the skull. Other methods of dehorning include: removal of the horn buds with a knife and the application of chemical paste to cauterise the horn buds. Where chemical paste is used, special attention should be paid to avoid chemical burns to other parts of the calf or to other calves.

EU comment

The EU asks the OIE to consider amending the third and fourth sentences of the above text as follows:

"~~Other methods of dehorning include:~~ The removal of the horn buds with a knife and the application of chemical paste to cauterise the horn buds should be discouraged, because of the risk of too much pain and~~. Where chemical paste is used, special attention should be paid to avoid~~ chemical burns to other parts of the calf or to other calves."

Justification:

Chemical burns due to chemical cauterization paste are very painful. The evidence indicates that caustic paste disbudding causes distress for at least 3 hours and that local anaesthesia is efficient in controlling pain for the first hour but discomfort returns after the nerve blocking subsides. It is difficult to avoid the paste in spreading to sensitive parts around the horn bud due to the exudation caused by the paste, and to the grooming behaviour of the calf. If kept in groups there will be a high risk that other calves touch the bud resulting in a chemical burn.

References

Stilwell, George; de Carvalho, Rita Campos; Lima, Miguel S.; et al. 2009. **Effect of caustic paste disbudding, using local anaesthesia with and without analgesia, on behaviour and cortisol of calves** APPLIED ANIMAfnL BEHAVIOUR SCIENCE Volume: **116** Issue: **1** Pages: **35-44**

Stafford, KJ; Mellor, DJ 2005. **Dehorning and disbudding distress and its alleviation in calves**. VETERINARY JOURNAL Volume: **169** Issue: **3** Pages: **337-349**

Methods of dehorning when horn development has commenced involve the removal of the horn by cutting or sawing through the base of the horn close to the skull. Operators removing developed horns from dairy cattle should be trained and competent in the procedure used, and be able to recognise the signs of complications (e.g. excessive bleeding, sinus infection).

ii) Tail docking

Research shows that tail docking does not improve the health and *welfare of animals*, therefore it is not recommended, as a routine procedure, to dock the tails of dairy cattle. As an alternative, trimming of tail hair should be considered where maintenance of hygiene is a problem.

iii) Identification

Ear-tagging, ear-notching, tattooing, freeze branding and radio frequency identification devices (RFID) are preferred methods of permanently identifying dairy cattle from an *animal welfare* standpoint. In some situations however hot iron branding may be required or be the only practical method of permanent identifying dairy cattle. If cattle are branded, it should be accomplished quickly, expertly and with the proper equipment. Identification systems should be established also according to Chapter 4.1.

EU comment

The EU asks the OIE to consider amending the first sentence in the above paragraph.

"Ear-tagging, ~~ear-notching,~~ tattooing, ~~freeze branding~~ and radio frequency identification devices (RFID) are preferred methods of permanently identifying dairy cattle from an *animal welfare* standpoint. Other methods such as ear-notching and freeze branding are in use but they should only be used if none of the preferred methods are available."

Justification:

The listed methods have different welfare implications and the two methods proposed removed from the category of preferred methods are known to be painful and to have more negative welfare implications than the others, e.g. ear notching is painful in pigs and is considered more painful than ear tagging by some researchers.

References

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Schwartzkopf-Genswein, K.S., Stookey, J.M., Crowe, T.G. and Genswein, B.M.A. (1998). Comparison of image analysis, exertion force, and behaviour measurements for use in the assessment of beef cattle responses to hot-iron and freeze branding. *J. Anim. Sci.* 76: 972-979.

Outcome-based measurables: postprocedural complication rate, morbidity rate, behaviour, physical appearance, changes in weight and body condition score.

n) Inspection and handling

Dairy cattle should be inspected at intervals appropriate to the production system and the risks to the health and welfare of the cattle. In most circumstances, cattle should be inspected at least once a day. Some *animals* may benefit from more frequent inspection for example: neonatal calves (Larson *et al.*, 1998; Townsend, 1994), cows in late gestation (Boadi and Price, 1996; Mee, 2008; Odde, 1996), newly weaned calves, cattle experiencing environmental stress and those that have undergone painful husbandry procedures or veterinary treatment.

EU comment

The EU asks the OIE to consider rephrasing the third sentence in the above paragraph as follows:

"Some animals ~~may benefit from~~ need more frequent inspection for example: [...]"

Justification:

The listed conditions undoubtedly put the animals in need of frequent inspections.

Dairy cattle identified as sick or injured should be given appropriate treatment at the first available opportunity by competent and trained *animal handlers*. If *animal handlers* are unable to provide appropriate treatment, the services of a *veterinarian* should be sought.

Recommendations on the handling of cattle are also found in Chapter 7.5. In particular handling aids that may cause pain and distress (e.g. sharp prods, electric goads) should be used only in extreme circumstances. Dairy cattle should not be prodded in sensitive areas including the udder, eyes, nose or ano-genital region.

EU comment

The EU asks the OIE to consider rephrasing the second sentence in the above paragraph as follows:

"In particular handling aids that may cause pain and distress (e.g. sharp prods, electric goads) should be used only in extreme circumstances, and only when the animal can move freely forward."

Justification:

The use of handling aids such as sharp prods or electric goads when all escape routes are closed causes extreme stress to the animal.

Where dogs are used, as an aid for cattle herding, they should be properly trained. *Animal handlers* should be aware that presence of dogs can cause fear and should keep them under control at all times. The use of dogs is not appropriate in housed systems.

EU comment

The EU asks the OIE to consider rephrasing the final sentence in the above paragraph as follows:

"The use of dogs is not appropriate in housed systems or in small outdoor enclosures."

Justification:

In a small, fenced outdoor space, the use of a dog may be equally stressful.

Cattle are adaptable to different visual environments. However, exposure of cattle to sudden or persistent movement or visual contrasts should be minimised where possible to prevent stress and fear reactions.

Electroimmobilisation should not be used.

Outcome-based measurables: human-animal relationship, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight and body condition score, changes in milk yield.

o) Personnel training

All people responsible for dairy cattle should be competent according to their responsibilities and should understand cattle husbandry, animal handling, milking routines, behaviour, biosecurity, signs of *disease*, and indicators of poor *animal welfare* such as stress, pain and discomfort, and their alleviation.

Competence may be gained through formal training or practical experience.

Outcome-based measurables: human-animal relationship, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight and body condition score, changes in milk yield.

p) Disaster management

Plans should be in place to minimise and mitigate the effects of natural disasters or extreme climatic conditions, such as heat stress, drought, blizzard and flooding. Humane *killing* procedures for sick or injured cattle should be part of the emergency action plan. In times of drought, animal management decisions should be made as early as possible and these should include a consideration of reducing cattle numbers.

Reference to emergency plans can also be found in points 1 g) and 2a) iii) of Article 7.X.5.

q) Humane killing

For sick and injured cattle a prompt diagnosis should be made to determine whether the animal should be treated or humanely killed.

The decision to kill an *animal* humanely and the procedure itself should be undertaken by a competent person.

Reasons for humane killing may include:

– severe emaciation, weak cattle that are non-ambulatory or at risk of becoming downers;

– non-ambulatory cattle that will not stand up, refuse to eat or drink, have not responded to therapy;

– rapid deterioration of a medical condition for which therapies have been unsuccessful;

– severe, debilitating pain;

– compound (open) fracture;

– spinal injury;

– central nervous system *disease*;

– multiple joint *infections* with chronic weight loss; and

– premature calves that are unlikely to survive, or calves that have debilitating congenital defect.

For a description of acceptable methods for humane *killing* of dairy cattle see Chapter 7.6.

FUTURE WORK PROGRAMME FOR THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

EU comments

The EU thanks the Code Commission for providing its updated and detailed work programme, which it supports.

The EU would like to suggest reviewing Chapter 12.8. "Equine rhinopneumonitis" in light of the proposed delisting of EHV-4 and the amendment to the listing of this disease, in case these changes are adopted at the 81st General Session.

Furthermore, as scrapie is not being proposed for delisting, the EU would like to reiterate its comments as to this disease submitted on the work programme of the Code Commission attached to the February 2012 meeting report (cf. http://ec.europa.eu/food/international/organisations/docs/annex%201_eu%20position_052012_en.pdf, p. 297).

In addition, in Chapter 5.2. "Certification procedures", more specifically Article 5.2.4. "Electronic certification", the EU suggests including a reference to the use of international standards for data exchange, as is the case in the relevant standards of IPPC and Codex. A text proposal to that effect is attached (see appendix to this Annex).

Finally, the EU notes the proposal by the Biological Standards Commission to include a case definition for dourine in Chapter 2.5.3. of the Terrestrial Manual. While this is acceptable for now as there currently is no case definition in the *Terrestrial Code* chapter on this disease, the EU is of the opinion that it would be preferable to have a clear case definition in the disease specific chapters of the *Terrestrial Code*, as this is important in view of notification obligations of members and for reasons of international trade. Consequently, case definitions in the *Terrestrial Manual* should in future be replaced by references to the *Terrestrial Code*, so as to avoid contradictions (reference is made to the EU's comment under item 1 of this report). Therefore, the EU invites the Code Commission to review Chapter 12.3. "Dourine" of the *Terrestrial Code* by adding a case definition in Article 12.3.1.

Topic		
Action	**How to be managed**	**Status (Feb 2013)**
Restructuring of the *Terrestrial Code*, including Harmonisation of the *Terrestrial* and *Aquatic Codes*		
1. Work with AAHSC towards harmonisation, as appropriate, of the Codes 2. CH rename by disease agents 3. Revision and formatting of Section 7 4. Revision of the Users' guide 5. OIE policy on wildlife	TAHSC & ITD3.TAHSC & AWWG 4. TAHSC & SCAD 5. TAHSC with WG on Wildlife & SCAD	1. Ongoing, revised CH 1.1. for adoption 2. Ongoing 3. Revised 7.5 and 7.6. for MC 4 Revised User's Guide for MC 5. Ongoing
Notification of 'emerging disease'		
Clarification of definition, criteria for	SCAD & TAHSC	Ongoing

notification, etc.		
Listed diseases		
1. Criteria for listing 2. List of diseases	TAHSC & SCAD	1. Revised CH 1.2. for adoption 2. Revised list for adoption
CWD		
Decision on listing (new CH)	TAHSC & SCAD & AHG	AHG to be convened
PRRS		
New CH	SCAD/AHG	AHG to be convened
Evaluation of VS and OIE PVS pathway		
Veterinary education aspect	TAHSC & AHG & ITD	Ongoing
CSF		
Official recognition CSF	SCAD/AHG & TAHSC	Revised CH 15.2. for adoption
AHS		
Official recognition - zones	SCAD & TAHSC	Revised CH 12.1. for adoption
PPR		
Update CH on PPR including official recognition	SCAD & TAHSC	Revised CH 14.8. for adoption
FMD		
Revise chapter including wildlife	SCAD & TAHSC	Revised CH 8.5. for MC
RP		
Global freedom era	SCAD & TAHSC	Revised CH 8.12 for adoption
New horizontal chapter on disease control		
Draft new chapter	SCAD & TAHSC	Draft new CH for MC
Horse diseases		
1. International movement of competition horses 2. Update horse disease chapters	AHG/SCAD & TAHSC	AHG to be convened
Veterinary products (AMR)		
1. Updating CH 6.9. 2. Updating CH 6.10.	TAHSC & SCAD & AHG	1. Revised CH 6.9. for adoption 2. Revised CH 6.10. for MC
Other *Terrestrial Code* texts on diseases in need of revision		
Pet food certificate CH	TAHSC	On hold
Update BT and EHD in line with AHS	SCAD & AHG	AHG to be convened
Update CH on Brucellosis	AHG/SCAD & TAHSC	Revised CH 8.X. for MC
Update CH on Rabies (article on control of rabies in dog)	SCAD & TAHSC	Revised CH 8.10. for adoption
Update CH on Bee diseases	AHG/SCAD & TAHSC	Revised CHs for adoption
CH on EHD	SCAD & TAHSC	Revised new chapter for MC
Update CH on SVD	SCAD & TAHSC	Delisting proposed for adoption
Update CH on ASF (SURV)	SCAD	Pending SCAD revision
CH on Paratuberculosis	BSC (diagnostic test) & STD (guidance document)	Ongoing

Update CH on tuberculosis	AHG/SCAD & TAHSC	AHG to be convened
Update CH on Avian Mycoplasmosis	SCAD and TAHSC	Pending SCAD revision

Animal production food safety		
2. Zoonotic parasitic diseases a. *Trichinella* spp. b. Echinococcosis c. *Taenia solium* (Porcine cysticercosis)	AHG & TAHSC	a. Revised CH 8.13 for adoption b. Revised CH8.4 and X.X. for adoption c. On hold pending delisting
Animal welfare		
New texts: 1. Broiler production systems 2. Dairy cattle production systems	AWWG & AHGs TAHSC supervision	1. New CH 7.X for adoption 2. New CH for MC

Note: MC; Member comments, CH: chapter, Q: questionnaire, SURV: surveillance, ITD: International Trade Department, S&T Dept: Scientific & Technical Department

ITEM, ANNEX, CHAPTER NUMBERS AND CURRENT STATUS

Item	Annex	Chapter	Title	Provided for comments	GS81
1			General comments		
2	XXXII		User's Guide	Feb. 13	C
3	IV		Glossary	Sep. 12	A
4	V	1.1.	Notification of diseases and epidemiological information	Sep. 12	A
5	VI	1.2.	Criteria for listing diseases		A
		8.15.	Vesicular stomatitis		
		15.4.	Swine vesicular disease		
	XXXIII		Report of electronic *ad hoc* Group on listing *Taenia solium*		I
6	VII	3.2.	Evaluation of veterinary services	Sep. 12	A
	VIII	3.4.	Veterinary legislation	Sep. 11	A
	XXXIV		Report of *ad hoc* Group on Veterinary Legislation		I
7	IX	4.6.	Collection and processing of bovine, small ruminant and porcine semen	Sep. 12	A
		4.7.	Collection and processing of *in vivo* derived embryos from livestock and horses		
8	X	6.4.	Biosecurity procedures in poultry production	Sep. 12	A
9		6.6.	Introduction to the recommendations for controlling antimicrobial resistance	Sep. 12	D
		6.7.	Harmonisation of national antimicrobial resistance surveillance and monitoring programmes	Sep. 12	D
	XI	6.9.	Responsible and prudent use of antimicrobial	Sep. 11	A
	XXXV	6.10	Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals	Feb. 12	C
10	XII	6.11.	Zoonoses transmissible from non-human primates	Sep. 12	A
11	XIII	NEW	Broiler chicken production systems	Sep. 10	A
	XIV	7.1.	Introduction to the recommendation for AW (General principle for production system)	Sep. 11	A
	XV	7.9.	Beef cattle production systems	Sep. 12	A
	XVI	7.8.	Use of animals in research and education	Sep. 12	A
	XXXVI	7.5 & 7.6.	Revision of AW chapters	Feb. 13	C
	XXXVII	NEW	Dairy cattle production systems	Feb. 13	C
			Report of *ad hoc* Group on AW and Dairy cattle production systems		I
	XXXVIII		AWWG work programme	Feb. 13	I
12		8.3.	Bluetongue	Sep. 11	D
13	XVII	8.4.	Echinococcosis (*E. granulosus*)	Feb. 11	A
		NEW	Echinococcosis (*E. multilocularis*)	Feb. 11	
	XVIII	8.13.	*Trichinella* infection	Feb. 11	A

Annex XLIV (contd)

Item	Annex	Chapter	Title	Provided for comments	GS81
14	XXXIX	8.5.	Foot and mouth disease	Feb. 13	C
15	XIX	8.10.	Rabies		A
16	XX	8.12.	Rinderpest	Sep. 11	A
17	XXI	4.14.	Official health control of bee diseases	Sep. 12	A
	XXII	9.1. 9.2. 9.3. 9.4. 9.5. 9.6.	Acarapisosis of honey bees American foulbrood of honey bees European foulbrood of honey bees Small hive beetle infestation (*Aethina tumida*) *Tropilaelaps* infestation of honey bees Varroosis of honey bees	Sep. 09	A
18	XXIII	10.4.	Infection with avian influenza viruses	Sep. 12	A
19	XXIV	10.9.	Newcastle disease		A
20	XL	11.3.	Brucellosis	Sep. 11	C
21	XXV	1.6.	Procedure for self declaration and for official recognition by the OIE	Sep. 12	A
		11.5.	Bovine spongiform encephalopathy		
22	XXVI	11.8.	CBPP	Sep. 12	A
23	XXVII	12.1.	Infection with African horse sickness virus		A
	XXVIII	12.9.	Infection with equine arteritis virus		A
24	XXIX	14.5.	Infection with *Chlamydophila abortus*	Sep. 12	A
25	XXX	1.6.	Procedure for self declaration and for official recognition by the OIE		A
		14.8.	Peste des petits ruminants	Sep. 11	
26	XXXI	1.6.	Procedure for self declaration and for official recognition by the OIE		A
		15.2.	Classical swine fever	Sep. 10	
27	XLI	New	Epizootic haemorrhagic disease	Sep. 12	C
28	XLII	New	Disease control	Feb. 13	C
29	XLIII		Report of APFSWG		I
30	XLIV		Work programme		C
31			Review of application for recognition as an OIE collaboration centre		
32			Inactivation of pathogen in casings		
33		11.12.	Lumpy skin disease		E

A: proposed for adoption at 81th General Session, C: For Member comments, E: under expert consultation (*ad hoc* Groups, Specialist Commissions etc.), D: deferred to Sep 2013 meeting, I: For Member information.

List of abbreviations	
AAHSC	Aquatic Animal Health Standards Commission
AHS	African horse sickness
APFSWG	Animal Production Food Safety Working Group
AWWG	Animal Welfare Working Group
EHD	Epizootic haemorrhagic disease
FMD	Foot and mouth disease
PPR	Peste des petits ruminants
PRRS	Porcine reproductive and respiratory syndrome
SCAD	Scientific Commission for Animal Diseases
TAHSC	Terrestrial Animal Health Standards Commission
VE	Veterinary Education

Appendix to EU comment on Annex XLIV

OIE terrestrial code

Artice 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 should have access to all information such as laboratory results and animal identification data.~~

    a. Systems providing electronic certificates normally provide an interface with the commercial organisation marketing the *commodity* for provision of information to the certifying authority. The certifying *veterinarian* should have access to all information such as *laboratory* results and *animal identification* data.

    b. When exchanging electronic certificates and in order to fully utilise electronic data exchange the Veterinary Authorities should use internationally standardized language, message structure and exchange protocols. Guidance for electronic certification in standardized World Wide Web Consortium (WC3) Extensible Markup Language (XML schemas) as well as secure exchange mechanisms between Veterinary Authorities is provided by the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT).

2) Electronic certificates may be in a different format but should carry the same information as conventional paper certificates.

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

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