



EUROPEAN UNION

Brussels
SANCO G2/MMK/kh (2012)1708715



Subject: EU comments on the report of the September 2012 Code Commission meeting

Dear Director General,

Please find here attached the comments of the European Union (EU) on the report of the September 2012 meeting of the Terrestrial Animal Health Standards Commission for consideration in its next meeting of February 2013.

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

Yours sincerely,

<p>Dr. Georgios Kyriakides Chief Veterinary Officer Cyprus</p>	<p>Bernard Van Goethem Director Veterinary and International affairs DG Health and Consumers European Commission</p>
	

Annex: 1

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

Dr. B. Vallat
Directeur général OIE
12 rue de Prony
F-75017 Paris



Organisation
Mondiale
de la Santé
Animale

World
Organisation
for Animal
Health

Organización
Mundial
de Sanidad
Animal

ANNEX

Original: English
September 2012

REPORT OF THE MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION Paris, 4–13 September 2012

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 September 2012 meeting of the Code Commission are inserted in the text below, while specific comments are inserted in the text of its respective annexes.

The EU would like to stress 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 4 to 13 September 2012. The members of the Code Commission are listed in [Annex I](#).

Dr Monique Eloit, on behalf of Dr Bernard Vallat, Director General of the OIE, opened the Code Commission meeting with a particular welcome to Members attending for the first time. Dr Monique Eloit recalled the contribution of Dr Stuart Hargreaves to the OIE and the Commission marked a minute of silence in his memory.

The Code Commission reviewed the documents identified in the agenda, addressing comments that Member Countries had submitted by 3 August 2012 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. In Annexes XVIII (Chapter 6.9.) and XXIV (Chapters on bee diseases), the amendments made at this meeting (September 2012) are shown with **coloured highlight** to distinguish them from those made prior to the 80th OIE General Session in May 2012.

Member Countries should note that, unless stated otherwise, texts submitted for comment may be proposed for adoption at the 81st OIE General Session in May 2013. Depending on the comments received on each text, the Code Commission will identify the texts proposed for adoption in May 2013 in the report of its February 2013 meeting.

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

indicated in 'strikethrough' and proposed additions with 'double underline'. Member Countries should not use the automatic 'track-change' function provided by word processing software as such changes are lost in the process of collating Member Countries' submissions into the Code Commission's working documents. Comments on this report must reach OIE Headquarters by 18 January 2013 to be considered at the February 2013 meeting of the Code Commission.

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

A. MEETING WITH THE DIRECTOR GENERAL

In the second week of the meeting, Dr Vallat joined the Commission to discuss some key topics, as follows:

1. Clarification of the role of the OIE *Terrestrial Animal Health Code*

Dr Alejandro Thiermann informed Dr Vallat that the Code Commission proposed to adapt the text of the *Terrestrial Code* User Guide to clarify this point, as requested by Members. Dr Vallat advised to be very prudent with this topic and to avoid wording that would limit the scope of the *Terrestrial Code*. According to our practices, all texts in the *Terrestrial Code* and the *Aquatic Code* are standards; all other material published by the OIE is considered to be a guideline or a recommendation. Dr Vallat also considered that the use of equivalence should be promoted. Regarding a Member's comment on the consistency of nomenclature used in the *Terrestrial Code* and the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *Terrestrial Manual*), Dr Vallat emphasised the importance of ongoing collaboration between the elected commissions.

2. Proposed delisting of animal diseases

Dr Thiermann outlined the approach that the Code Commission proposed to take to the proposed delisting of certain animal diseases (see discussion in Part D, Item 5). Dr Vallat agreed that Member Countries should be asked to offer expert comment on the proposed new list of notifiable diseases.

3. Diseases of honey bees

Dr Thiermann commended the *ad hoc* Group's work and recommended that the Group be reconvened, as appropriate, annually to monitor developments in global bee health and diagnostic advances, to ensure that the recommendations in the *Terrestrial Code* were always up to date.

4. Distribution of documents to OIE Members

Dr Thiermann recalled the difference in approach between the distribution of reports of the Scientific Commission for Animal Diseases (SCAD) and those of the Code Commission. He asked Dr Vallat to consider the possibility that the OIE distribute SCAD reports as MSWord documents, consistent with the format of the Code Commission reports, to facilitate review and comment by Member Countries. Dr Vallat supported this proposal, which had been endorsed already by the SCAD.

5. *Ad hoc* Group on Peste des petits ruminants and *ad hoc* Group on Classical swine fever

Dr Thiermann summarised the work of the Code Commission on these important topics and informed Dr Vallat that the Commission looked forward to seeing the reports of the *ad hoc* Groups.

6. Proposed new chapter on disease control

Dr Thiermann advised that the Commission had received from the Scientific Department a report from the *ad hoc* Group on Epidemiology containing a proposed new chapter in the *Terrestrial Code* on disease control, which had been endorsed by the SCAD. The document had not been received by the Trade Department prior to the Code Commission meeting, and the Commission did not have sufficient time to give this document proper consideration. However, the Code Commission recommended that the document be placed on the OIE internet site and that Members be invited to review the SCAD report and provide comments.

7. Joint meetings between the Code Commission and the Scientific Commission for Animal Diseases

Dr Thiermann indicated that the International Trade Department and the Scientific Department were taking steps to ensure an overlap between the meetings of the two Commissions. Dr Vallat recalled that the dates of meetings were prerogative of the OIE administration and agreed that if it was not possible for the meetings to overlap, the SCAD meeting should take place before the Code Commission meeting.

8. Rinderpest

Dr Vallat highlighted the importance of continuing to work on rinderpest global freedom, including the new obligation in the *Terrestrial Code* for countries to provide annual notification of the holding of rinderpest virus or material containing rinderpest virus.

B. ADOPTION OF THE AGENDA

Annex II contains the adopted agenda.

A list of abbreviations used in the report is in Annex III.

C. REPORT ON JOINT MEETING OF THE CODE COMMISSION BUREAU AND THE PRESIDENT OF THE SCIENTIFIC COMMISSION

The Bureau of the Code Commission met Dr Gideon Brückner, the President of the SCAD, on 3rd September 2012. The meeting report is in Annex IV.

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

Item 1. General comments of OIE Members

The Code Commission reviewed comments from the European Union (EU), New Zealand and South Africa.

The Code Commission discussed Members' recommendations for the inclusion of an introductory text explaining the various purposes of the *Terrestrial Code* – e.g. trade, disease control and management, animal production food safety. It was agreed to adapt the *Terrestrial Code* user's guide (between the foreword and the glossary) to make this clear. A revised text will be considered by the Code Commission at its meeting in February 2013 and the views of Members will be sought.

EU comment

The EU thanks the OIE for having considered its request, strongly supports this proposal to adapt the User's Guide to clarify the purpose of the OIE Code in international trade and encourages the Code Commission to embark on this important work.

The Code Commission noted the comments of a Member who called for greater consistency in the terminology used in the *Terrestrial Manual* and the *Terrestrial Code*, and asked the Trade Department to forward the comments to the OIE Scientific Department for action.

The Code Commission discussed the concerns of a Member about the WAHIS with the Head of the OIE Sanitary Information Department, who agreed to clarify the matter directly with the Member.

Item 2. Horizontal issues

(a) Development of the *Terrestrial Code* to address wildlife

Comments on the document on OIE policy as regard wildlife were received from Argentina, Australia, the EU, New Zealand, South Africa, the USA and the African Union Interafrican Bureau for Animal Resources (AU-IBAR).

The Code Commission restated its intention to deal with updates to the *Terrestrial Code* in a measured, disease-by-disease manner, with the incorporation of references to wildlife primarily based on the epidemiological significance of the wildlife species to the disease, as outlined in the document.

The Code Commission noted the extensive comments of Members on this important, cross cutting topic and referred these to the OIE Working Group on Wildlife (WWG) and the SCAD for review. The Code Commission recommended that this topic be discussed by the relevant OIE Departments (International Trade, Scientific and Sanitary Information) and the two Elected Commissions (SCAD and Code Commission) with a view to finalising OIE policy on the incorporation of wildlife in the *Terrestrial Code*. The Code Commission looked forward to receiving advice from the WWG and the SCAD for consideration in February 2013.

Item 3. Glossary

Comments were received from the OIE *ad hoc* Group on Epidemiology, the *ad hoc* Group on Evaluation of Veterinary Services and *ad hoc* Group on Antimicrobial resistance.

The Code Commission reviewed the recommendations in the report of the *ad hoc* Group on Epidemiology's meeting of 6–8 March 2012. The Code Commission accepted the proposed modification of 'surveillance' in the glossary but did not see a need to modify the term 'specific surveillance' as the current text is adequate and appropriate.

The Code Commission did not accept a proposal to replace the current term 'targeted surveillance' with 'risk based surveillance', noting that the latter term is not used in the Code and had not been endorsed by the SCAD.

On the advice of the *ad hoc* Group on Antimicrobial Resistance, with support of the SCAD (see Part D, Item 9), the Code Commission proposed to add two new definitions in the Glossary, as follows:

'Veterinary medicinal products means any product with approved claim(s) to having a protective, therapeutic or diagnostic effect or to alter physiological functions when administered or applied to an animal.' and

'Good manufacturing practice means a production and testing practice that helps to ensure a quality product.'

The Code Commission also proposed to modify the definition of Veterinary Statutory Body as proposed by the *ad hoc* Group on Evaluation of Veterinary Services (see Part D, Item 6.)

The amended Glossary is attached as [Annex V](#) for Member comments.

EU comments

The EU in general supports the proposed changes to the Glossary but has some specific comments that are inserted in the text of Annex V.

Item 4. Notification of diseases and epidemiological information (Chapter 1.1.)

OIE Headquarters presented a proposal to modify the text in Chapter 1.1. with the goal of improving consistency between the *Terrestrial Code* and the *Aquatic Animal Health Code* (the *Aquatic Code*). The Code Commission accepted several proposed modifications. Some modifications were not accepted, because the Code Commission considered that the existing text in the *Terrestrial Code* was correct, even if the text was slightly different from that in the *Aquatic Code*.

In point 2 of Article 1.1.3., the Code Commission proposed to delete 'by fax or e-mail'. Also in this point, the Code Commission discussed and agreed with a proposal to replace 'it becoming endemic' with 'the situation has become sufficiently stable'.

In Article 1.1.4., the Code Commission modified 'territory' to 'country' and 'OIE' to 'Headquarters'.

The Code Commission proposed to delete Articles 1.1.5. and 1.1.6. as some of the text was obsolete and, in any case, these articles relate to the organisation of work at the OIE Headquarters.

The Code Commission invited the Aquatic Animal Health Standards Commission to consider further text amendments with a view to improved harmonisation of the two Codes.

The amended Chapter 1.1. is attached as Annex VI for Member comments.

EU comments

The EU in general supports the proposed changes to this chapter but has some specific comments that are inserted in the text of Annex VI.

The EU would like to reiterate the need for clarifications on the concept of "emerging disease" and its notification requirements, as was discussed during the 25th Conference of the OIE Regional Commission for Europe in September 2012 in Fleesensee, Germany.

Item 5. Criteria for listing diseases (Chapter 1.2.)

(a) Revised disease list proposed by the *ad hoc* Group on Notification of animal diseases and pathogenic agents

The Code Commission reviewed the *ad hoc* Group's draft decision tree and proposed a revised version to clarify the pathways to disease listing.

The Code Commission noted that the international spread of a disease by vectors is not taken into account in making a decision to list a disease, in contrast to the spread of the agent via live animals, their products and fomites (see point 1 of Article 1.2.2.).

The Code Commission considered each proposal on disease listing that had been made by the *ad hoc* Group. Noting the advice of the SCAD regarding the zoonotic importance of Crimean-Congo haemorrhagic fever, the Code Commission questioned the proposal to delist the disease.

The Code Commission also noted the objection of the SCAD to delisting Nipah virus encephalitis. Based on the fact that the virus had been known to spread internationally via trade in pigs for slaughter, and on at least one occasion had caused human infections via occupational exposure, the Code Commission questioned the proposal to delist the disease.

With respect to the proposal to delist porcine cysticercosis (*Taenia solium*), which is a major neglected zoonosis, the Code Commission considered that the rationale for listing trichinellosis would apply equally to cysticercosis and questioned if the approaches to these two diseases were consistent.

On scrapie, the Code Commission noted that the quoted range of morbidity (2-30%) was very wide. If 30% of a flock was affected, this would be significant. There are free countries and the disease can readily be transmitted via trade in sheep. The Code Commission considered that the proposal to delist the disease should be the subject of further advice from OIE Members.

On leptospirosis, the Code Commission noted an advice from an OIE Reference Laboratory supporting the listing of certain serovars but considered that the criterion that at least one country be free from the disease is not met. The Code Commission has referred this advice back to the *ad hoc* group.

With respect to haemorrhagic septicaemia, the Code Commission noted that international spread via live animals occurred and the disease is listed by FAO as a trans-boundary disease (FAO website: <http://www.fao.org/ag/againfo/programmes/en/empres/diseases.asp>). The Code Commission questioned the proposal to delist this disease.

Dr Karim Ben Jebara, Head of the Sanitary Information Department, joined the Code Commission for a discussion on the proposed revision of the listed diseases.

In conclusion, the Code Commission decided to ask Members with experience of any of the diseases proposed for delisting to advise on the proposals of the *ad hoc* Group and, if the proposal to delist the diseases is not supported, to provide scientific information relevant to the OIE criteria to justify continued listing.

The Code Commission invited Member Countries to review the report of the *ad hoc* Group as attached in [Annex VII](#) and to provide their comments on it. The Commission will present revised Chapter 1.2. with a revised disease list after reviewing those comments in February 2013.

EU comments

The EU supports the procedure proposed by the Code Commission. Specific comments on the report of the *ad hoc* group are inserted in the text of Annex VII.

(b) Listed bee diseases

The Code Commission agreed with the recommendations of the *ad hoc* Group on Bee Diseases, which reviewed the listing of bee diseases according to the revised criteria and concluded that the list should not be modified.

EU comment

The EU agrees with the *ad hoc* group on bee diseases and the Code Commission.

Item 6. Support for Veterinary Services

(a) Evaluation of Veterinary Services (Chapter 3.2.)

Comments were received from the EU, the FAO, the OIE *ad hoc* Group on Evaluation of Veterinary Services (*ad hoc* Group on PVS) and the OIE *ad hoc* Group on Veterinary Education.

The Code Commission accepted the proposal of the *ad hoc* Group on Evaluation of Veterinary Services to modify the definition of Veterinary Statutory Body, as follows:

Veterinary Statutory Body means the autonomous regulatory body for *veterinarians* and *veterinary para-professionals*.

Members' comments on Article 3.2.6. subpoint 3 (b) were accepted and the text modified accordingly. Article 3.2.14. subpoint 5 (a) (v) was also amended, consistent with the modification of Article 3.2.6. subpoint 3 (b).

The Code Commission did not agree with the recommendations to move parts of the text in Chapter 3.2. to Chapter 3.4. and instead referred the FAO comments to the *ad hoc* Group on Veterinary Legislation with a request to ensure that the points raised by the FAO have been addressed appropriately in Chapter 3.4.

On Article 3.2.12., the Code Commission accepted most of the text modifications recommended by the *ad hoc* Group on PVS, with some editorial amendments to make the text shorter and clearer.

On Article 3.2.14., the Code Commission agreed with the recommendations of the *ad hoc* Group on Veterinary Education, insofar as the addition of 'and the post-graduate and continuing education topics' in sub-point 2 (a) (vi) but did not agree to include additional text, such as the internet addresses of documents on the OIE website, as this was not consistent with established practice.

The revised Chapter 3.2. is attached as [Annex VIII](#) for Member comments.

EU comment

The EU thanks the OIE and supports the proposed changes to this chapter.

(b) Veterinary legislation (Chapter 3.4.)

Comments were received from the EU and the Food and Agriculture Organization of the United Nations (FAO).

Noting that the *ad hoc* Group on Veterinary Legislation would hold its next meeting on 25–27 September, the Code Commission referred the comments of FAO and the EU to the Group for consideration. The *ad hoc* Group's advice will be reviewed by the Code Commission at its February 2013 meeting.

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

(i) Sixth edition of OIE *Tool for the Evaluation of Performance of Veterinary Services*

The Code Commission noted the updated edition of the OIE *Tool for the Evaluation of Performance of Veterinary Services*.

(ii) Chapter 6.3. Control of hazards of animal health and public health importance in animal feed

A proposal of the *ad hoc* Group on PVS was not accepted, as the Code Commission did not agree with the rationale provided.

The report of the *ad hoc* Group is attached as Annex XXXII for information of Member Countries.

Item 7. Semen and embryos

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

Comments were received from Australia, South Africa and the USA. The Code Commission also received comments from an expert.

The Code Commission noted the support of a Member for the development of a new chapter on equine semen. The Code Commission sought advice from an expert for consideration at the next meeting in February.

A Member's comments on point 2 of Article 4.6.3. has been sent to an expert for advice.

The modifications proposed by a Member to points 3 and 4 of Article 4.6.7. were accepted, with an editorial amendment.

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

Comments were received from Australia.

A proposal to move sheep scrapie from Category 1 to Category 4 in Article 4.7.14. was not accepted, as the list reflects the International Embryo Transfer Society categorisation, which is developed by that organisation on the basis of a rigorous peer-reviewed process.

The revised Chapters 4.6. and 4.7. are attached as Annex IX for Member comments.

EU comments

The EU in general supports the proposed changes to Chapters 4.6. and 4.7. and has a comment inserted in the text of Annex IX.

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

Comments were received from the EU.

In response to one comment, the Code Commission moved the sentence on antimicrobial resistance from Article 6.4.5. Point 2 sub-point (o) to Point 1, new sub-point (f).

Also see Agenda item 1 for the answer to the general comment.

The revised Chapter 6.4. is attached as Annex X for Member comments.

EU comment

The EU thanks the OIE and supports the proposed change to this chapter.

Item 9. Antimicrobial resistance

(a) Work of the OIE on antimicrobial resistance

Dr Elisabeth Erlacher-Vindel, Deputy Head of the OIE Scientific Department, outlined current OIE activities relevant to the issue of antimicrobial resistance (AMR). She reminded the Code Commission that the revised Chapters 6.7. and 6.8. had been adopted at the General Session in May 2012 and a revised Guideline on Laboratory Methodologies for bacterial antimicrobial susceptibility testing added to the latest edition of the *Terrestrial Manual*. At the fourth meeting of the *ad hoc* Group on Antimicrobial resistance, in July 2012, the Group had addressed OIE Members' comments on Chapter 6.9. The Group also started to update the List of Antimicrobials of Veterinary Importance (http://10.0.0.112/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/OIE_list_antimicrobials.pdf). The next meeting of this Group will take place in December 2012. At this meeting, the Group will address Members' comments on risk assessment and finalise the updating of Chapter 6.10., and complete its work on the List.

Dr Erlacher-Vindel informed the Code Commission that the OIE is working in collaboration with World Health Organization (WHO) and Food and Agriculture Organization (FAO) on the topic of AMR, which is a priority in the OIE/FAO/WHO Tripartite Strategy.

The Scientific Department of the OIE has nearly completed a 2nd cycle of Focal Point training, with an emphasis on the VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) and AMR.

Dr Elisabeth Erlacher-Vindel informed the Code Commission that the OIE had sent out a questionnaire to OIE Members on monitoring of the quantities of antimicrobial agents used in animals. The high response rate (133 countries) was very pleasing. The results of the questionnaire will be analysed and presented at the OIE Global Conference on the Responsible and Prudent Use of Antimicrobials for Animals, 'International Solidarity to Fight against Antimicrobial Resistance', which will take place on 13–15 March 2013 in Paris (see http://www.oie.int/eng/A_AMR2013/introduction.htm).

The OIE is hosting an International Symposium on Alternatives to Antibiotics, which is organised by the International Alliance for Biological Standardisation (IABS) and the United States Department of Agriculture, on 25–28 September 2012 (<http://www.alternativestoantibiotics.org/>).

Dr Erlacher-Vindel drew to the Commission's attention the recently published Volume 31(1) of the OIE Scientific and Technical Review on 'Antimicrobial resistance in animal and public health'.

The Code Commission encouraged OIE Members to review information on AMR, which is addressed in a new dedicated place on the OIE website (<http://www.oie.int/en/our-scientific-expertise/veterinary-products/antimicrobials/>) which also links to this topic on the WHO website.

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

Following recommendations of the *ad hoc* Group on Antimicrobial Resistance, endorsed by the SCAD, the Code Commission proposed to add:

'These chapters should be read in conjunction with the standards, codes of practice and guidelines on antimicrobial resistance developed by the Codex Alimentarius Commission.'

In addition, the word 'entire' was added before 'animal sector' to make it clear that the OIE recommendations on antimicrobial use and resistance apply to all animals covered in the *Terrestrial Code*, not only those used for the production of food.

The Code Commission did not accept several definitions of ‘therapeutic use’ and ‘non-therapeutic use’ that were proposed by the *ad hoc* Group, because they were not considered to be necessary at this time.

The Code Commission agreed to add a definition, as follows, in the glossary: ‘Good manufacturing practice means a production and testing practice that helps to ensure a quality product.’

The revised Chapter 6.6. is attached as Annex XI for Member comments.

EU comment

The EU thanks the OIE and supports the proposed changes to this chapter.

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

Comments were received from the EU.

The first comment was the subject of advice from the SCAD, which considered that the comment should be addressed by a specifically convened *ad hoc* Group at a later stage.

Following Members’ comments, a new point 6 was added to Article 6.7.2. and a new sub-point (e) was added to Article 6.7.3. point 1.

The revised Chapter 6.7. is attached as Annex XII for Member comments.

EU comments

The EU thanks the OIE and in general supports the proposed changes to this chapter. A few comments are inserted in the text of Annex XII.

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

The Code Commission reviewed the reports of the December 2011 and July 2012 meetings of the *ad hoc* Group on Antimicrobial Resistance, which had been endorsed by the SCAD.

The OIE had received comments from Australia, Canada, Chile, Mexico and the USA (considered at the December meeting of the *ad hoc* Group) and from Argentina, China (People’s Republic of), Cuba, the EU, New Zealand, Switzerland and the AU-IBAR (considered at the July meeting).

The Code Commission noted that the report of the *ad hoc* Group’s July 2012 meeting would be provided to Members as an annex to the report of the August 2012 meeting of the SCAD.

The Commission did not agree to modify the definition of *Competent Authority* as proposed by the *ad hoc* Group because the current definition (and also the definition of Veterinary Authority) makes reference to all matters covered in the *Terrestrial Code*; there is no need for an explicit reference to marketing authorisation of veterinary medicinal products.

The following definition of ‘veterinary medicinal products’ was proposed for inclusion in the glossary: ‘any medicinal product with approved claim(s) to having a protective, therapeutic or diagnostic effect or to alter physiological functions when administered or applied to an animal.’ The Code Commission noted that this definition is used by the VICH and had been endorsed by the SCAD.

Several amendments were made to the text of Article 6.9.3., reflecting the correct use of concepts and defined terms in the *Terrestrial Code*. This included the replacement of ‘regulatory authorities’ by ‘Competent Authority’ in this article and elsewhere in the chapter. In addition, the Code Commission deleted several references to VICH guidelines, as the reference in point 4 of Article 6.9.3. was considered to be sufficient.

Following Members’ comments, the Code Commission made several text amendments to clarify aspects relating to the use of antimicrobial agents in food producing animals.

The revised Chapter 6.9. is attached as [Annex XIII](#) for Member comments.

EU comments

The EU thanks the OIE and in general supports the changes proposed to this chapter. However, a few specific comments are inserted in the text of Annex XIII.

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

Comments were received from Argentina, Chinese Taipei, the EU, Norway, New Zealand, the USA and the African Union-Interafrican Bureau for Animal Resources (AU-IBAR).

All comments were referred to the *ad hoc* Group for consideration at its December 2012 meeting. The Group's report and SCAD advice will be reviewed by the Code Commission in February 2013.

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

Comments were received from the EU.

The Code Commission proposed to insert new text reading 'sourcing in accordance with Article 7.8.7.' in Article 6.11.1.

The revised Chapter 6.11. is attached as [Annex XIV](#) for Member comments.

EU comments

The EU thanks the OIE and supports the proposed changes in this chapter. Some further comments are inserted in the text of Annex XIV.

Item 11. Animal welfare

(a) Animal Welfare Working Group – meeting report June 2012

The Code Commission noted the Animal Welfare Working Group (AWWG) work programme for 2012–2013, as revised at the June 2012 meeting.

The Commission considered animal production systems to be the top priority topic for the development of standards in 2012–2013 and invited OIE Members to comment on the AWWG proposal to develop a standard on the welfare of working animals.

The report of the AWWG is attached as [Annex XXXIII](#) for information of Member Countries.

(b) Draft new chapter on Animal Welfare and Broiler Chicken Production Systems (Chapter 7.X.)

The Code Commission reviewed a revised draft chapter resulting from an electronic consultation undertaken in July and August 2012 by the *ad hoc* Group on Animal Welfare and Broiler Chicken Production Systems.

The Code Commission cross checked the text with that of the recently adopted (in May 2012) Chapter 7.9. on Animal Welfare and Beef Cattle Production Systems, to ensure a consistent approach to like concepts, as appropriate.

The text in Annex XV shows, in marked up text, the modifications made to the document since it was presented to the World Assembly of Delegates in May 2011.

The key definition, of broilers, was amended to 'means birds of the species *Gallus gallus* kept for commercial meat production. Poultry in backyard and village flocks are not included.'

The definitions of ‘cage housing system’, ‘deep litter system’ and ‘slatted floor housing system’ were deleted as none of these terms was used in the text.

In Article 7.X.3., the text explaining the terms ‘completely housed systems’, ‘partially housed systems’ and ‘completely outdoors systems’ was modified for greater clarity and precision and all three points were moved into Article 7.X.2 Scope. The Code Commission made several amendments to the text of chapter to remove overly detailed explanations about types of broiler housing.

The Code Commission discussed the importance of retaining, for the information of Members, the scientific references, which will be removed from this chapter after it has been adopted. Scientific references could be included in a document entitled ‘Scientific references for Chapter 7.X’ and placed on the Animal Welfare page on the OIE website.

In Article 7.X.5 Recommendations, the Code Commission made several text amendments to improve clarity and coherence of the text.

The title ‘Social environment’ was replaced with ‘Prevention of feather pecking and cannibalism’, to better reflect the content of sub-point 2.7. The Code Commission also modified the text to clarify that therapeutic beak trimming is a last resort, to be used only when other management strategies are not effective, consistent with sub-point 2.12, which states that painful procedures, including beak trimming, should not be performed routinely.

The revised draft Chapter 7.X. is attached as [Annex XV](#) for Member comments.

EU comments

The EU thanks the OIE for redrafting this chapter. The EU can in general support many of the proposed changes in the text, but has comments to a majority of the specific provisions as inserted in the text of Annex XV.

(c) Member comments on Chapters 7.1., 7.8. and 7.9.

Chapter 7.1. Introduction to the recommendations for Animal Welfare

Comments were received from Canada, the OIE Animal Welfare Working Group (AWWG), and the International Coalition for Animal Welfare (ICFAW).

Following comments of the AWWG, the Code Commission added a new point in Article 7.1.1.: ‘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.’

Following a Member’s comment, the Commission clarified point 5 of Article 7.1.1., by replacing ‘in confined spaces’ with ‘For housed animals’.

Proposals of an organisation to add to the core principles were referred to the AWWG with a request for advice to be Commission for consideration at its meeting in February 2013.

The revised Chapter 7.1. is attached as [Annex XVI](#) for Member comments.

EU comments

The EU supports most of the proposed changes in this chapter. The EU has only commented on text that has been revised since the 80th General Session in May 2012.

Chapter 7.8. Use of animals in research and education

Comments were received from Canada and the EU.

In Article 7.8.10. ‘Transportation’, the Code Commission did not accept the addition of ‘transport of animals should be kept to the minimum (, etc.)’ as this is already covered in Article 7.8.7. point 8.

Following Members’ recommendations during the 80th General Session (2012), the Code Commission added new text to the first paragraph, making reference to the general provisions in Chapters 7.3. and 7.4. The Commission also added text reflecting the fact that animals used in research and education may at times be transported even though their welfare is compromised as a consequence of their use, or intended use, in scientific research.

The revised Chapter 7.8. is attached as Annex XVII for Member comments.

EU comments

The EU thanks the OIE and supports the proposed changes to Article 7.8.10.

Chapter 7.9. Animal Welfare and Beef Cattle Production Systems

Comments were received from Australia, Canada, the EU and the International Coalition for Animal Welfare (ICFAW).

The Code Commission reviewed comments received and, noting that this chapter was recently adopted (in May 2012), cross checked the text with that of the draft new chapter on broiler chickens (Chapter 7.X.), to ensure a consistent approach to like concepts, as appropriate.

The Code Commission replaced ‘reported’ with ‘recorded’ in point 3 of Article 7.9.4., as it did not recognise a need to report mortalities in this context, nor was it clear to whom they should be reported. Following the comments of a Member and an international organisation, the phrase ‘unless absolutely necessary’ was added to Article 7.9.5. sub-point 1 (b).

Following the comment of a Member and an international organisation, the Code Commission included the sentence: ‘Where possible, cattle on slatted floors should have access to a bedded area’ in Article 7.9.5. sub-point 2 (f).

The reference for this text is the Scientific Opinion on the welfare of cattle kept for beef production and the welfare in intensive calf farming systems. EFSA Journal 2012;10(5):2669. 166 pp. doi:10.2903/j.efsa.2012.2669 (www.efsa.europa.eu/efsajournal).

Following the comments of a Member and an international organisation calling for the addition of recommendations on tethering, the Code Commission discussed the various tethering systems that occur around the world. These vary between intensive farming systems, which are discussed in the EFSA Scientific Opinion (<http://www.efsa.europa.eu/de/efsajournal/doc/2669.pdf>), and some traditional farming systems, where individual animals are restrained on a long tether and can graze relatively freely. In conclusion, the Code Commission proposed to add the following text to Article 7.9.5. point 3, sub-point (i):

‘Cattle that are tethered should, as a minimum, be able to lie down, turn around and walk.’

The Code Commission did not add a reference to Article 7.1.4., as requested by Members, as it considered that Chapter 7.1. is generally relevant to all subsequent chapters in Section 7.

Following a Member’s comment, the Code Commission added ‘fire’ to sub-point (h) on Emergency plans.

Noting a Member’s request to include tables in this chapter (e.g. on husbandry and identification methods), the Code Commission confirmed its intention to review all chapters in Section 7 and to remove tables containing detailed information, as it considered that these would be more appropriately placed on the OIE internet site in the context of guidelines or recommendations, rather than being included in the Code.

The revised Chapter 7.9. is attached as Annex XVIII for Member comments.

EU comments

The EU thanks the OIE and in the main supports the proposed changes in this chapter. The EU does however have some comments as indicated below.

(d) Chapters 7.3., 7.5. and 7.6.

Comments were received from the EU and Canada (on Chapter 7.3.); the EU, Peru, Switzerland, the USA and the International Coalition for Animal Welfare (on Chapter 7.5.); and the EU and USA (Chapter 7.6).

The Code Commission deferred consideration of these comments to the February 2013 meeting, at which time it would also review the work to be undertaken by the International Trade Department with the objective of removing excessively detailed information from the *Terrestrial Code* and relocating it to the OIE internet site in the form of guidelines and recommendations.

(e) Update on proposal of the International Organization for Standardization to develop technical specifications on animal welfare

Dr Sarah Kahn updated the Code Commission on the decision of the International Organization for Standardization (ISO) to develop technical specifications on animal welfare based on the provisions of the *Terrestrial Code*. This work was undertaken under the aegis of the official agreement between the OIE and the ISO, which aims to facilitate and strengthen cooperation and collaboration in all fields of mutual interest, including in the field of international standards and recommendations on animal health and welfare.

In preliminary discussions between the OIE and ISO on the proposal to develop ISO technical specifications on animal welfare, the following objectives were identified:

- to encourage food chain operators to conform with the OIE animal welfare standards in relation to international trade in food of animal origin;
- to encourage governments to implement the OIE animal welfare standards in relation to international trade in foods of animal origin;
- to promote international harmonisation of animal welfare standards for food-producing animals; and
- by providing global ISO specifications based on OIE standards, to help to prevent the multiplication of private schemes and certification systems, with their associated costs.

This work would take place under the auspices of the ISO Technical Committee 34 (Food Products), following the ISO procedures for standards development. Dr Sarah Kahn indicated that the ISO would convene a first meeting of a technical working group in Paris, during October 2012. The International Trade Department will attend the meeting and will provide an update to the Code Commission at its next meeting.

The Code Commission discussed this development. Noting that ISO standards are references under the World Trade Organization Agreement on Technical Barriers to Trade (TBT Agreement), the Commission considered that technical specifications produced might have legal status in the context of a WTO dispute under the TBT Agreement.

Item 12. Aujeszky's disease (Chapter 8.2.)

Comments were received from South Africa.

The Code Commission reviewed these comments but considered that the treatment of Aujeszky's disease (AD) in Chapter 8.2. was appropriate to the disease epidemiology and management and that the differences between the provisions in this chapter and others (e.g. FMD, classical swine fever) were scientifically warranted. On the proposal to make provisions for compartmentalisation of AD, the Commission recalled that Chapters 4.3. and 4.4. apply to AD, as to all diseases. While some disease chapters contain specific provisions on the establishment of compartments, reflecting specific risk factors, the Code Commission did not see a need for such provisions in Chapter 8.2.

Item 13. Bluetongue (Chapter 8.3.)

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

The Code Commission moved the paragraph ‘for the purposes of international trade...’ from Article 8.3.17. to Article 8.3.1.

In response to Members’ comments on Articles 8.3.1. and 2., the Code Commission considered that the term ‘adjacent’ did not need any explanation beyond the standard dictionary definition.

The Code Commission did not see a valid rationale for accepting a Member’s proposal to re-insert the words ‘of the establishment or facility’ in Article 8.3.15. point 1.

On the recommendation of Members, supported by SCAD, the phrase ‘and other susceptible herbivores of epidemiological significance’, was included in the first paragraph of Article 8.3.19., under the title ‘Surveillance strategies’.

The Code Commission noted a Member’s comment regarding surveillance by sampling and testing of bulk milk but considered that no text amendment was warranted because the current text already covers this possibility.

The revised Chapter 8.3. is attached as Annex XIX for Member comments.

EU comments

The EU thanks the OIE and in general supports the proposed changes to this chapter.

However, the title should be amended to read "[...] virus" (singular), to be consistent with other chapters where several serotypes of the pathogen species exist (e.g. AHS, EHD). Indeed, the causative agent of bluetongue disease is bluetongue virus, i.e. a single virus species. This is also correctly stated in the case definition (cf. first sentence of Article 8.3.1) and should be used consistently throughout the text.

A further comment is inserted in the text of Annex XIX.

Item 14. Zoonotic parasites**(a) Infection with *Echinococcus granulosus* (revised Chapter 8.4.)**

Comments were received from the EU, Japan, New Zealand, Norway and the African Union-Interafrican Bureau for Animal Resources (AU-IBAR).

The Code Commission reviewed Members’ comments in conjunction with the report of the December 2011 meeting of the *ad hoc* Group on Zoonotic Parasites and made several modifications to the draft text, following Members’ recommendations.

The Code Commission noted that, in the course of revision of this chapter, several parts of the text had previously been inserted or deleted at the request of OIE Members. For this reason, the Code Commission did not accept a number of proposed text modifications on these parts.

As the word ‘hydatid’ is a noun, not an adjective, the Code Commission replaced the term ‘hydatid cyst’ with ‘hydatid’ throughout the chapter. The Commission noted that in French and Spanish, the correct terminology is ‘kyste hydatique’ and ‘cisto hidatico’.

For clarification of the phrase ‘good food and personal hygiene’, the Code Commission added the word ‘hygiene’ after ‘good food’ in Article 8.4.1. At Members’ request the Code Commission agreed to add processed fat to the list of safe commodities in Article 8.4.2. In addition, the term ‘offal’ was defined, to clarify the provisions of the chapter.

A Member’s proposal to make an article on the importation of sheep was not accepted, because as the proposed measures would have the effect of limiting international trade in a manner that is not

commensurate with the measures applied for the purposes of domestic control by most countries of the world.

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

Comments were received from the EU, Japan, New Zealand, Norway and the African Union-Interafrican Bureau for Animal Resources (AU-IBAR).

Bearing in mind the modifications made to Chapter 8.4., the Code Commission reviewed comments on the new draft chapter.

In response to a Member's comments, the Code Commission noted that the *ad hoc* Group on Notification of Animal Diseases and Pathogenic Agents had considered the listing of echinococcosis/hydatidosis and had concluded that listing was justified for both *E. granulosus* and *E. multilocularis* but not for other *Echinococcus* species.

Following Members' comments, the Code Commission removed references to cats in the draft chapter and clarified that the purpose of surveillance for *E. multilocularis* in pig livers (Article X.X.3. point 2) is as an indicator of the parasite's presence in the environment. The text on the use of information on human cases of infection was also clarified.

The Code Commission noted that the distinct epidemiology of the two diseases should be respected, even though the approach to the two chapters was similar.

The revised Chapter 8.4. and the revised draft Chapter X.X. are attached as Annex XX for Member comments.

EU comments

The EU thanks the OIE and in general supports the proposed changes to these chapters. However, the EU cannot support the proposed treatment time period for canids imported from infected countries. A specific comment to this effect as well as some further comments is inserted in the text of Annex XX.

(c) Meeting report of the *ad hoc* Group on Zoonotic parasites (Infection with *Trichinella* spp., Chapter 8.13.)

The Code Commission noted the report of the *ad hoc* Group on Zoonotic parasites, which met on 23–25 July 2012 and reviewed comments provided by Argentina, Australia, Canada, the EU, Japan, New Zealand, Norway, Switzerland, the USA and the Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA).

The Code Commission greatly appreciated the work of this Group, notably the care taken to align the work of Codex and the OIE on this topic and commended the Group on the novel approach taken in the drafting of the chapter, taking into account the unique aspects of this infection. The Commission agreed with the revised text proposed by the Group and provided the revised Chapter 8.13. to Members for comment, with a view to possible adoption in May 2013.

The revised Chapter 8.13., as a clean text, is attached as Annex XXI for Member comments.

The report of the *ad hoc* Group is attached as Annex XXXIV for information of Member Countries.

EU comments

The EU would like to thank the OIE for the progress made in the draft Chapter 8.13 of the OIE Terrestrial Animal Health Code and for inviting the European Commission to participate as observer to the OIE ad hoc group meeting of 23 to 25 July 2012.

The EU would like to remind the OIE that it is co-chairing the development of Codex Alimentarius guidelines on parasites in meat and fully supports consistency between both OIE and Codex Alimentarius draft proposals. In order to further develop the Codex guidelines, while taking into account the OIE guidance, and in view of the on-going revision of EU pig meat inspection rules, the EU would support the adoption of the OIE guidance at its earliest convenience.

The EU considers that significant progress has been made with this chapter. In line with the objective of ensuring consistency with the Codex guidelines, the EU would like to make the following comments:

1. The Codex Committee for Food Hygiene (CCFH) at its meeting in New Orleans from 12 to 16 November 2012 discussed several pathways to consider the public health concern including the one proposed in the OIE draft Chapter 8.13. The CCFH, however, also supported an alternative pathway to the one described in Chapter 8.13 and encouraged Members to collaborate with their national OIE Delegates to ensure alignment of Codex and OIE work on Trichinella. Based on the outcome of the CCFH meeting and considering pre-harvest control options and the development of a negligible risk compartment as an OIE competence, the EU requests the OIE to address the pre-harvest control options for an alternative pathway leading to a negligible risk compartment. In particular, more flexibility should be given as regards the verification of the on-farm conditions. Specific suggestions have been made in the text of Annex XXI to address this.

2. The EU accepts the current limitation to a negligible risk status for herds or compartments in order to reach adoption of the guidelines as soon as possible. However, it would like to know the reason for the deletion of the notion of negligible risk status for countries by the OIE. Several EU Member States have made huge efforts to successfully achieve this status in accordance with former guidance of the OIE.

Item 15. Foot and mouth disease (FMD)

Comments were received on Chapter 1.6. from Australia and an EFSA report on the inactivation of pathogens in animal casings was received from the European Commission.

The Code Commission did not review the comments on FMD, as a complete revision of the chapter is under way and the questionnaire may need to be revised consistent with this review. The EFSA report was referred to the OIE Scientific Department for discussion with SCAD and determination if a new article on a model veterinary certificate for international trade in casings would be warranted.

Item 16. Rabies (Chapter 8.10.)

Comments were received from Japan and Norway.

The Code Commission was not convinced of the need to make provisions for rabies free regions for the purpose of dealing with overseas territories and therefore did not propose any text amendments.

The recommendation (waiting period between test and export) of a Member was referred to an expert of an OIE Reference Laboratory for rabies. The Commission noted that the expert had advised to modify the current procedure for better efficiency of the test, and decided to review this advice in collaboration with the SCAD in February 2013.

Item 17. Rinderpest (Chapter 8.12.)

Comments were received from Australia, the EU, Japan, New Zealand, Switzerland, the SCAD, the Joint FAO/OIE Advisory Committee on Rinderpest (JAC), the African Union-Interafrican Bureau for Animal Resources (AU-IBAR) and the Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA).

The Code Commission noted the general support expressed by Members for the revised chapter, and made a number of text amendments in light of comments submitted. The advice provided by the JAC, at times, included some recommendations that were not compatible. In these cases, the Code Commission mainly took into account the advice of the SCAD.

Throughout the chapter, 'RP' was replaced with 'rinderpest' and 'rinderpest virus' with 'RPV'.

The Code Commission changed the title of Article 8.12.2. to 'Definitions and general provisions' and replaced 'for the purpose of this article' with 'for the purpose of the *Terrestrial Code*' or 'for the purpose of this chapter', as appropriate.

In response to a question from a Member, the Code Commission noted that, for rinderpest, reference laboratories must be approved by both OIE and FAO. Some reference laboratories are also *appointed* for the purpose of holding live rinderpest virus.

Following comments of Members, the Code Commission modified the text in Article 8.12.5. The addition of an 'e-link' to the international contingency plan was not supported, as the inclusion of internet addresses for documents is not accepted practice in the *Terrestrial Code*.

The word 'shall' was changed to 'should' in the sentence 'in the event of the confirmation of rinderpest, the entire country shall be considered infected..', on the basis that the word 'shall' is only used in the *Terrestrial Code* when speaking of the legal obligations of Members, which are set out in the OIE Organic Rules.

Article 8.12.7, point 3, was modified in line with the SCAD recommendation, except that the word 'quarantine' was removed from the new text as the concept of quarantine is covered by 'movement controls'.

The Code Commission modified texts in Article 8.12.8. (Surveillance for recovery of free status of a country), as appropriate, taking into consideration comments from JAC and SCAD's review of them. The Code Commission encouraged SCAD and the JAC to develop new provisions on regaining **global** rinderpest freedom in the case where a country, or group of countries, loses and then regains free status.

In Article 8.12.9., the Code Commission proposed amendments to the 'Model Annual Report on RPV containing material', based on JAC and SCAD recommendations. Based on Members' comments, the Code Commission included some new text concerning the provision of a final report following the destruction of all RPV containing material.

The revised Chapter 8.12. is attached as [Annex XXII](#) for Member comments.

EU comments

The EU is of the opinion that this proposed modified chapter still needs substantial revision and is not ready for adoption as it stands.

As a general comment, it would be desirable to have this draft chapter adopted at the same time as the international contingency plan. As the international contingency plan is currently being prepared by the JAC and its contents are thus not yet known to Member Countries, it will otherwise be difficult to support the adoption of the respective changes to the chapter.

The OIE should consider renaming the chapter into "Infection with Rinderpest virus", for consistency with other chapters.

Some further specific comments are inserted in the text below.

Item 18. Chapters on bee diseases

A general comment was received from the Philippines.

(a) Hygiene and disease security procedures in apiaries (Chapter 4.14.)

The Code Commission added the term ‘or other Competent Authority’ after ‘Veterinary Authority’ in the entire text, as appropriate, to address the comment of a Member Country, which advised that the Veterinary Authority was not responsible for bees in that country.

The revised Chapter 4.14. is attached as Annex XXIII for Member comments.

EU comment

The EU thanks the OIE and supports the proposed changes to this chapter.

(b) Background information for the *Terrestrial Code* chapters on bee diseases

The Code Commission considered that the paper ‘Background to the *Terrestrial Code* chapters on bee diseases’ contained very useful background information. While the document was not considered to be appropriate for inclusion in the Code, the Code Commission encouraged the OIE to publish it on the internet website, in The *Bulletin* or in other OIE publications.

(c) Bee diseases (Chapters 9.1.-9.6. inclusive)

Following comments of a Member and consistent with the amendment of Chapter 4.14., the Code Commission added the term ‘or other Competent Authority’ after ‘Veterinary Authority’ in all chapters, as appropriate.

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

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

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

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

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

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

Chapter 9.4. (Infestation with *Aethina tumida*/small hive beetle)

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

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

Comments were received from Chile, China (People’s Republic), the EU and Switzerland.

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

Comments were received from Chile, China (People’s Republic), the EU, Norway and Switzerland.

Dr François Diaz, of the OIE Scientific Department, joined the Code Commission for discussion on Item 18. The Code Commission reviewed the reports of meetings of the *ad hoc* Group on Honeybee diseases that were held in January and July 2012. The Commission greatly appreciated the work of this *ad hoc* Group and generally endorsed its recommendations. Given the global importance of honeybees and the rapid development of scientific knowledge on pest and disease management in apiculture, the Commission recommended that the Group be reconvened annually to monitor developments in global bee health and diagnostic advances, to ensure that the recommendations in the *Terrestrial Code* were always up to date.

Some modifications were made to the text in individual chapters, as shown in [Annex XXIV](#) for Member Country comments.

EU comments

The EU thanks the OIE and in general supports the proposed changes to these chapters. However, some comments are included in the text of Annex XXIV for consideration by the Code Commission.

The Code Commission noted that the rationales of modifications made by the *ad hoc* Group were detailed in the report of the SCAD meeting in August 2012.

Item 19. Avian infectious laryngotracheitis (Chapter 10.3.)

Comments were received from New Zealand.

These comments were not reviewed as the disease has been proposed for delisting and the Code Commission considered that revision of Chapter 10.3. was not a priority at this time.

Item 20. Avian influenza (Chapter 10.4.)

Comments were received from Australia, the EU, India and South Africa.

The Code Commission proposed some text amendments throughout Chapter 10.4., with the goal of clarifying the requirements to address Members' comments. The Commission emphasised that these modifications do not change the provisions in the chapter; rather they present them more clearly.

These text modifications clarify the distinction between highly pathogenic avian influenza viruses, the presence of which should be reported for all avian species in which the infection occurs, and low pathogenic avian influenza viruses of subtype H5 and H7 (low pathogenic notifiable AI viruses), the presence of which in poultry should be reported.

The Code Commission highlighted the importance of Article 10.4.4., which sets out the conditions for a country, zone or compartment that is free from infection with highly pathogenic AI viruses in poultry as the basis for safe international trade in poultry and poultry products, regardless of the presence of avian influenza viruses in wild birds.

This revision also took into account a Member's recommendation, on the basis that wild birds carry avian influenza viruses, to delete the concept of a zone in this chapter. However, the Code Commission rejected this recommendation because the treatment of zoning in the chapter reflects the Code definition of notifiable avian influenza as a disease of poultry. Hence, zoning is a practical option regardless of the presence of avian influenza viruses in wild birds. The Code Commission noted Members' comments and modified Article 10.4.33 paragraph 2, as follows: 'The use of antigen detection systems... should be limited to screening clinical field cases...'. In Figure 2, the line between [-] and [S] under [Antigen detection (screening of clinical cases)] will be changed from a solid to a dotted line, to indicate that the result should be interpreted.

The revised Chapter 10.4. is attached as [Annex XXV](#) for Member comments.

EU comments

The EU in general supports the proposed changes to this chapter but has some comments inserted in the text of Annex XXV.

Item 21. Brucellosis (Chapters 11.3., 14.1. and 15.3.)

The Code Commission noted that a new *ad hoc* Group has been convened to review these chapters.

Item 22. Contagious bovine pleuropneumonia (Chapter 11.8.)

On a suggestion from the International Trade Department, the Code Commission modified Chapter 11.8. to clarify the situation with compartments for contagious bovine pleuropneumonia (CBPP). The OIE does not provide official recognition for compartments for CBPP (or for any other disease).

The Code Commission relocated and modified Article 11.8.16 and renumbered it as Article 11.8.5 *bis* and modified the text of Articles 11.8.3., 4, 6, 8, 9, 10, 11, 12 and 14 to reflect the distinction between official OIE recognition of free countries and zones and the national declaration of a CBPP free compartment.

The revised Chapter 11.8. is attached as Annex XXVI for Member comments.

EU comments

The EU supports the proposed changes to this chapter and has one comment.

Item 23. Equine diseases

(a) African horse sickness (Chapter 12.1.)

Comments were received from China (People's Republic of) and from the African Union- Interafrican Bureau for Animal Resources (AU-IBAR).

The Code Commission noted that the SCAD will shortly review Chapter 12.1. and Chapter 8.3. (Bluetongue) for consistency and, on this basis, did not review the text of Chapter 12.1. in detail.

(b) Equine influenza (Chapter 12.6.)

Comments were received from South Africa, calling for a more consistent approach to equine influenza and avian influenza. The Code Commission did not propose to modify the text of Chapter 12.6., as it considered that the text in these two chapters was appropriate to the significant differences in the epidemiology of the respective diseases.

(c) Equine viral arteritis (Chapter 12.9.)

Comments were received from the USA.

An expert advice was sought with respect to a Member's comment on the transmission of the virus by embryo transfer, to be addressed in the next meeting of the Code Commission.

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

Comments were received from the OIE Biological Standards Commission and from an expert.

The Code Commission noted that peer reviewed scientific references (Storz et al., 1976; Appleyard et al., 1985; Suri et al., 1986; Domeika et al., 1994; Amin 2003) refer to the excretion of *C. abortus* in bull and ram semen and to venereal transmission, even if this route of transmission was not regarded as an important method of spread of the disease (Aitken, 1983., Appleyard et al., 1985).

Noting the conclusions of an import risk assessment carried out by an OIE Member Country (MAF New Zealand, October 2005) and following the advice of the Biological Standards Commission, the Code Commission amended Article 14.5.4. and proposed a new Article (14.5.5.) on the importation of sheep embryos.

With respect to a Member who requested consistent use of the nomenclature of *C. abortus* in the *Terrestrial Code* and the *Terrestrial Manual*, the Code Commission noted that the name *Chlamydophila abortus* had been adopted in the *Terrestrial Manual* by the World Assembly of Delegates in May 2012.

The revised Chapter 14.5. is attached as Annex XXVII for Member comments.

EU comment

The EU supports the proposed changes to this chapter.

Item 25. Peste des petits ruminants (Chapter 14.8.)

The Code Commission noted that an *ad hoc* Group will be convened to conduct a further review on Peste des petits ruminants (PPR). The Code Commission asked the OIE to ensure that the terms of reference for the new Group include taking into account the comments already provided by the Commission on the report presented by a previous *ad hoc* Group on PPR.

Item 26. Scrapie (Chapter 14.9.)

Comments were received from Australia and from the EU.

As scrapie has been proposed for delisting, the Code Commission decided to do no further work on Chapter 14.9. until the decision on listing has been finalised.

Item 27. Classical swine fever (Chapter 15.2.)

The Code Commission noted that the OIE would convene a new *ad hoc* Group on official disease status recognition of classical swine fever.

The Commission made some suggestions on the terms of reference of the Group, for consideration by OIE Headquarters and SCAD.

Item 28. Epizootic hemorrhagic disease – new chapter

The Code Commission reviewed the report of the March 2011 meeting text of the OIE *ad hoc* Group on epizootic hemorrhagic disease (EHD) and a draft new chapter for the Code. In reviewing the draft chapter, the Commission noted that there was insufficient evidence to list bovine embryos as a safe commodity, nor were there relevant recommendations from the IETS.

The Code Commission presented the new draft chapter to Members for a first round of comments (Annex XXVIII).

EU comments

The EU thanks the OIE for its work and welcomes this new chapter on EHD. A number of comments are inserted in the text of Annex XXVIII.

Item 29. Report of the *ad hoc* Group on Veterinary Education

Comments on the report of the *ad hoc* Group meeting of January 2012 were received from Argentina and Chinese Taipei.

The Code Commission noted the report of the *ad hoc* Group and added an appropriate reference in Chapter 3.2. referring to the Group's report on Continuing Education.

The Code Commission noted that, in the documents prepared by the *ad hoc* Group, the use and presentation of 'Veterinary Services' and 'Veterinary Authority' were not always consistent and asked the Group to check these carefully against the OIE definitions.

In reviewing the draft Guidelines on the OIE Model Core Veterinary Curriculum Guidelines (August 27 2012 Draft), the Code Commission had some difficulty interpreting the following statement:

'The model Core Veterinary Curriculum assumes that the level of competence required of the day 1 graduate in medicine, surgery, diagnostic imaging, theriogenology, and anaesthesiology **are minimal** as related to the functions of National Veterinary Services.'

As the National Veterinary Services include both the public and the private sector veterinarians, the Commission felt that this statement could give rise to confusion and recommended that it be modified by the *ad hoc* Group along the following lines:

'The model Core Veterinary Curriculum assumes that there is less need for the OIE to make specific recommendations on the competence of the day 1 graduate in medicine, surgery, diagnostic imaging, theriogenology, and anaesthesiology than in matters relating directly to the OIE mandate.'

The report of the ad hoc Group is attached for information as Annex XXIX.

E. OTHER ISSUES

Item 30. Update of Code Commission work programme

Taking into account current on-going activities and Member comments, the Commission updated its work programme for 2012–2013 (Annex XXX).

Item 31. Invasive alien species

(a) Draft OIE Guidelines for assessing the risk of non-native animal species becoming invasive

Although comments had not been solicited, a Member provided comments on the Guidelines. The Code Commission did not have time to address the comments at this meeting and decided to wait for 12 months before addressing any comments that may be received.

(b) Update on OIE activities

(i) WTO/STDF workshop on invasive alien species and international trade

The workshop was attended by Dr S. MacDiarmid and Dr M. Okita. The Code Commission waits to see the final recommendations of this event.

(ii) Update on proposed OIE/CBD Agreement

The OIE Headquarters is discussing with the Secretariat of the Convention on Biological Diversity (CBD) an official agreement between the OIE and the CBD.

Item 32. Review of applications for recognition as an OIE collaborating centre

The Code Commission noted that two of the applications received appear to cover subjects outside the OIE mandate – i.e. the proposed CC on Animal Welfare and Sustainable Livestock Production and the proposed CC on Laboratory Animal Science, Medicine and Welfare. The Commission considered that the names of OIE Collaborating Centres should clearly reflect subjects and disciplines that fall within the OIE mandate. Accordingly, it recommended that these two applications should be renamed as shown below.

(a) The Universidad nacional autónoma de Mexico (UNAM) proposal to join Chile/Uruguay Collaborating Centre (CC) on Animal Welfare

The Code Commission noted this application, which had been endorsed by the OIE Animal Welfare Working Group (AWWG) and the OIE Regional Commission for the Americas. The Commission recommended that the combined CC be called: OIE CC on Animal Welfare and Livestock Production Systems.

The Code Commission recommended that OIE Members approve this application.

(b) Australia/NZ and Malaysia twinning proposal on animal welfare

The Code Commission noted that the OIE is waiting to receive a revised application.

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

The Code Commission noted this application and recommended that the title be modified to CC on Laboratory Animal Welfare. The Commission sought advice from the AWWG (out of session) and asked the OIE to seek endorsement from the Regional Commission for the Americas, with a view to possible approval of this proposal by OIE Members at the General Session in 2013.

(d) Other applications

The Code Commission noted that the OIE had received an application for recognition as an OIE Collaborating Centre on Animal Quarantine, from Brazil, and an application for a Collaborating Centre on Veterinary Education from the Middle East Centre for Veterinary Education and Training, Egypt. The Commission will review the application when full applications are submitted to the OIE.

Item 33. Generic checklist on the practical application of compartmentalisation

The Code Commission noted that the final version of this document had been sent to the SCAD and looked forward to seeing the document on the OIE internet page.

Item 34. Replacement of ‘release’ with ‘entry’, to align with the revision of Chapter 2.1.

The Code Commission proposed appropriate modifications to Chapters 1.6. and 11.5., based on the revision of Chapter 2.1. that was adopted by the World Assembly in May 2012.

The revised Chapters 1.6. and 11.5. are attached as Annex XXXI for Member comments.

EU comment

The EU supports the proposed changes to Chapters 1.6. and 11.5.
--

Item 35. Publication on the history of development of the OIE standards on avian influenza

The Code Commission noted that the International Trade Department is working with experts from OIE Reference Laboratories on Avian Influenza to produce a report for the information of Members.

The Code Commission looked forward to receiving a copy of the report.

Item 36. Proposed dates for meetings in 2013

The Code Commission proposed to hold meetings on 19–28 February and 17–26 September 2013.

.../Annexes

GLOSSARY

EU comments

The EU in general supports the proposed changes to the Glossary but has some specific comments.

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 to ensure a quality product.

EU comment

The EU is of the opinion that this definition is too vague. Indeed, anyone could define "good manufacturing practices" according to his own specific needs and be in line with that definition, without consensus by the sector concerned or prior recognition by an authoritative body.

Therefore, the EU suggests the following alternative wording:

"means a production and testing practice, that helps developed by the public or private sector concerned and recognised by the competent authorities, to ensure a quality 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.

Veterinary medicinal product

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

EU comment

The EU is of the opinion that vaccines should be covered by this general definition. As it is not clear what is meant by "protective" and whether this refers to vaccines, the EU suggests replacing the word "protective" by the word "preventative".

Veterinary statutory body

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

— Text deleted.

CHAPTER 1.1.

**NOTIFICATION OF DISEASES, INFECTIONS,
INFESTATIONS AND EPIDEMIOLOGICAL
INFORMATION**

EU comments

The EU in general supports the proposed changes to this chapter but has some specific comments.

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*.

EU comment

The EU supports the insertion of the words "and their aetiological agents" above, However, for reasons of consistency, the OIE should consider adding these throughout the chapter whenever the word "*diseases*" is used.

- 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* is constantly developing and that the presence of an infectious 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 of an infectious agent, even in the absence of clinical *disease*, should be reported.

EU comment

The EU is of the opinion that the proposed new sentence above goes too far in expanding the OIE member's notification obligations. Indeed, the mere presence of any infectious agent in the country (e.g. in a diagnostic or research laboratory setting) should not be covered by this obligation (unless specified elsewhere in the Code, e.g. rinderpest virus containing material). Thus, for clarity reasons, only the detection of infectious agents of any significance, i.e. that are aetiological agents of important animal diseases, in consistency with point 1 above (to which this point 4 refers to), should be covered by the

notification obligation, and only if these are detected in an animal (i.e. *animal* as defined in the glossary, which does not cover e.g. insect vectors). Furthermore, the EU is of the opinion that the live vaccine strains of these aetiological agents should explicitly be excluded from the scope.

Therefore, the EU proposes to amend the new sentence to read as follows:

"This means that the detection of the aetiological agent (excluding vaccine strains) of an important disease in an animal, even in the absence of clinical disease, should be reported".

- 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*; including quarantine measures and restrictions on the movement of *animals*, animal products, ~~and~~ biological products and other miscellaneous objects which could by their nature be responsible for transmission of *disease*. In the case of *diseases* transmitted by *vectors*, the measures taken against such *vectors* shall also be specified.

Article 1.1.3.

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:

EU comment

The use of the term *notification* throughout the chapter should be coherent with the definition in the glossary. Indeed, according to the definition, all information on the occurrence of an *outbreak* of a *disease* or *infection* sent to *Headquarters* by the *Veterinary Authority* and vice-versa according to the provisions of this chapter is considered as *notification*. This would include *notification* within 24 hours (which is referred to as "immediate notification" in WAHIS), weekly, 6-monthly and annual reports.

Therefore, the EU does not support the insertion of the word "immediate" in the above point or elsewhere in the Code, as it would be confusing and would not add anything to improve the existing text. Indeed, the word "immediate" is less precise and would contradict the concept of "within 24 hours".

Furthermore, perhaps a review of the definition of *notification* in the glossary should be considered, to add the word "infestation".

- a) first occurrence of a *listed disease* and/or *infection* in a country, a *zone* or a *compartment*;
- b) re-occurrence of a *listed disease* and/or *infection* 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* 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* prevalent within a country, a *zone* or a *compartment*;
- e) an *emerging disease* with significant morbidity or mortality, or zoonotic potential;

EU comment

The EU would like to reiterate the need for clarifications on the concept of "emerging disease" and its notification requirements, as discussed during the 25th Conference of the OIE Regional Commission for Europe in September 2012 in Fleesensee, Germany.

- f) evidence of change in the epidemiology of a *listed disease* (including host range, pathogenicity, strain) in particular if there is a zoonotic impact;
- 2) weekly reports ~~by fax or e-mail~~ subsequent to a *notification* under point 1 above, to provide further information on the evolution of an event incident which justified ~~urgent immediate notification~~; ~~these~~ These reports should continue until ~~the situation has been resolved through either the disease 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;

EU comment

The EU supports these proposed amendments.

Furthermore, in addition to the comment above on the need for clarifications on "emerging diseases", these clarifications should also pertain to when an "emerging disease" should no longer be considered as "emerging", and include guidance and a mechanism for the closing of cases of emerging diseases in WAHIS, e.g. when the Delegate declares his country has regained freedom of an emerging disease.

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

EU comment

In the point above, the EU suggests replacing "*listed disease*" by "*listed diseases*".

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

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*.
- 2) An *infected zone or compartment* for a particular *disease* 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* 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

As the situation with compartments differs substantially from that of zones, the EU would suggest that the Code Commission, if at all necessary, drafts a separate article for compartments, instead of adding compartments to the scope of the article above.

However, the listing of compartments by the OIE, and how notifications of disease in such compartments and their eventual freedom are handled will need careful

consideration. Indeed, the situation as to compartments is different for Terrestrial animals when compared to the Aquatic Code. Furthermore, providing maps indicating the location of compartments might prove difficult.

Alternatively, the OIE could consider including a cross-reference in this chapter to the compartment requirements already included in Chapters 4.3 and 4.4.

~~Article 1.1.5.~~

1. ~~The Headquarters shall send by fax, e-mail or Disease Information to the Veterinary Authorities concerned, all notifications received as provided in Articles 1.1.2. to 1.1.4.~~
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.~~

EU comment

While accepting that Article 1.1.6. should be deleted as it is obsolete, the EU questions the necessity to delete Article 1.1.5. as it not only deals with internal procedures at Headquarters but also specifies the notification obligations of the OIE towards its Member Countries (cf. definition of *notification* in the glossary), which should be kept in this chapter.

 — Text deleted.



Organisation
Mondiale
de la Santé
Animale

World
Organisation
for Animal
Health

Organización
Mundial
de Sanidad
Animal

Annex VII

Original: English

July 2012

**REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP
ON NOTIFICATION OF ANIMAL DISEASES AND PATHOGENIC AGENTS**

Paris 24–26 July 2012

EU comments

The EU supports the procedure proposed by the Code Commission for the review of Chapter 1.2.

Specific comments on the *ad hoc* group report are inserted in the text below.

The OIE *ad hoc* Group on Notification of Animal Diseases and Pathogenic Agents met at the OIE Headquarters from 24 to 26 July 2012.

The members of the Group and other participants are listed in [Appendix I](#). The meeting was chaired by Dr Franck Berthe and Dr Steve Weber acted as rapporteur.

Dr Karim Ben Jebara, Head of the OIE Animal Health Information Department, welcomed the participants on behalf of the Director General, Dr Bernard Vallat, and thanked them for having accepted the OIE's invitation. He explained why a single list of diseases had been established to replace the previous classification in Lists A and B. The aim in drawing up a single list in 2004 was to be in line with the terminology of the Sanitary and Phytosanitary Agreement (SPS) of the World Trade Organization (WTO), by classifying diseases as specific hazards and giving all listed diseases the same degree of importance in international trade. In creating a single list of notifiable diseases, the OIE defined criteria for including a disease on the list that would be acceptable to the majority of Member Countries, respected the criteria set out in the relevant resolutions of the International Committee (and especially Resolution No. XXIII of May 2001) and were in accordance with the OIE's other goals and missions. A new list of diseases meeting the OIE criteria to be listed was proposed for adoption by the OIE World Assembly of Delegates of the OIE in May 2005 and had come into force on 1 January 2006.

Dr Karim Ben Jebara presented the objectives of the meeting: to evaluate each OIE-listed disease and candidate disease according to the amended listing criteria adopted by the World Assembly of Delegates of the OIE in May 2012 and suggest those that should be listed/delisted. The Group was requested to propose a listing nomenclature that references the pathogenic agent. The Group was also asked for input on new or emerging diseases to be included in the discussion. Chronic wasting disease and infection with Schmallenberg virus were identified as candidates. The terms of reference were reviewed and agreed to; they are listed in [Appendix II](#).

The timeliness of input from the Group was linked to the desire to have information for consideration by the Specialist Commissions in late summer 2012 and potential adoption in 2013.

The Group discussed the main objectives of the OIE in establishing an OIE list of diseases. They agreed that the primary purpose was to identify the correct pathogens (diseases, infection and infestations) to be listed and therefore reported in order to minimise their spread and allow countries to prevent their introduction through trade of animals and animal products. Limiting the number of diseases listed by the OIE to those that are the most

relevant would reduce the notification burden for Member Countries while still achieving this primary purpose.

1. Decision tree for listing of diseases

A decision tree was developed in accordance with the newly adopted criteria for listing diseases contained in Chapter 1.2. of the OIE *Terrestrial Animal Health Code (Terrestrial Code)*. The text in the decision tree reflects the wording of Article 1.2.2. A separate decision tree was developed in accordance with Chapter 1.2. of the *Terrestrial Code*, for listing emerging diseases, given that emerging diseases may not yet have a precise case definition or reliable diagnostics tests. The proposed decision tree is shown in [Appendix III](#).

EU comment

The EU supports the new decision tree developed by the *ad hoc* group.

As regards emerging diseases, the EU reiterates its comment that clarification is needed on the concept of "emerging disease" and its notification requirements, as discussed during the 25th Conference of the OIE Regional Commission for Europe in September 2012 in Fleesensee, Germany.

The Group agreed that requests for diseases to be considered for listing should come from Member Countries.

The Group discussed possible interpretation of the criteria defined in Chapter 1.2. of the *Terrestrial Code* and agreed on the points described below:

With regard to Article 1.2.2. point 1 (international spread), the Group considered that:

- The notion of proven international spread of an agent does not include a time limit and should be based on historical evidence;
- International spread does not include natural spread via migratory animals but focuses on anthropogenic activities and 'trade-related' movement of animals and products of animal origin.

With regard to Article 1.2.2. point 2 (freedom or impending freedom from the disease), the Group considered that:

- Freedom or impending freedom of countries should be demonstrated according to the provisions of *Terrestrial Code* Chapter 1.4. (Animal health surveillance) and implies that eradication is achievable;
- For certain diseases, such as bovine spongiform encephalopathy, 'negligible risk' could be equivalent to 'freedom'.

With regard to Article 1.2.2. point 3 b) and c) (morbidity and mortality), the Group considered that:

- The level of morbidity and mortality are considered at country or zone level. Data available from the World Animal Health Information System/World Animal Health Information Database Interface (WAHIS/WAHID) as well as from other external sources (e.g. scientific opinions of the European Food Safety Authority [EFSA]) were used to assess the level of morbidity. Interpretation of the level of morbidity and mortality took into account the worst case scenario in a naive population of susceptible animals. Morbidity was also associated with respect to presence of clinical signs.

The Group recognised that criteria needed to be developed to determine when an 'emerging disease' should no longer be considered as 'emerging'. West Nile fever and Nipah virus, both of which emerged several years ago, were cited as examples. The Group recommended that the OIE develop guidance on this.

The Group had difficulty in identifying evidence of 'proven international spread' for certain diseases, because spread 'via live animals, their products or fomites' had not always been demonstrated and documented, despite the apparent international spread. This was particularly the case with vector-borne diseases.

During the discussions, the Group recognised difficulties in deciding whether diseases known to be widespread and for which an effective vaccine existed should be listed (e.g. transmissible gastroenteritis). The Group noted the removal of Marek's disease from the list and recommended that for the sake of consistency these types of diseases should be delisted.

The Group raised concerns about the reporting of *Brucella* species because some countries do not differentiate infection at the species level. The Group discussed the fact that the lack of specificity in reporting may lead to confusion between the species of *Brucella* and the host species. To improve the specificity of reporting when the species is differentiated, the Group suggested adding next to the name of the disease (brucellosis) the names of the pathogen: *B. abortus*, *B. melitensis* or *B. suis*. If the specific species is not identified, then the infection should just be reported as *Brucella* spp.

The Group also raised concerns about the reliability of the information used to ascertain whether a disease meets the listing criteria of Article 1.2.2. Since extensive use is made of the data provided by Member Countries in WAHIS when diseases are assessed against the listing criteria, the Group also proposed the creation of a tool to evaluate the reliability of information provided by countries, along similar lines to the World Health Organization (WHO) score for the reliability of information submitted by countries.

2. Disease names using the name of the pathogenic agent

With respect to the names of diseases, the Group agreed to use the wording “infection with” followed by the pathogen name. However, it was difficult to apply this principle to all diseases. Moving away from the current terminology could indeed create confusion in reporting some diseases and also lead to a lack of consistency in terminology between public health and animal health services.

The Group therefore agreed on the need to adopt an *ad hoc* approach to changing the names of listed diseases. The Group proposed to keep the existing names of the following: i) diseases with commonly accepted names, such as foot and mouth disease (FMD) and contagious bovine pleuropneumonia (CBPP); ii) diseases where the pathogen name is associated with the disease name (e.g. Bovine Babesiosis) but that include several species in the genus; and iii) diseases where the taxonomy of the pathogen is not yet well established and stabilised. [Appendix V](#) lists the newly suggested names for listed diseases.

To keep track of the proposed changes, the Group proposed that the list of diseases should comprise the new name followed by the current name in parentheses. This would facilitate the transition to the new terminology. The Group also recommended that as soon as the names of listed diseases are changed they should be consistently changed in all relevant chapters of the *Terrestrial Code* and the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *Terrestrial Manual*).

For diseases with multiple pathogens, the Group proposed that the reporting system should provide the opportunity to report at the species level (e.g. *Brucella* spp.), and that for Member Countries unable to differentiate the pathogen at the species level, an option be provided to enable them to continue reporting data at the genus level.

The Group recognised the importance of having clear case definitions for listed diseases including for the specific purpose of reporting details and notification. It noted that there were several instances in the *Terrestrial Code* where case definitions were lacking. The Group recognised that the development of a *Terrestrial Code* chapter may take time but recommended that a case definition be specified for reporting purposes for each OIE-listed disease in the *Terrestrial Code* and/or in the *Terrestrial Manual*. This would help Members to correctly report diseases through WAHIS. This could be done gradually for diseases not having case definitions. The Group cited the example of the change from *Brucella* diagnosed in sheep/goats to diagnosis of *B. melitensis* in each susceptible species.

EU comments

The EU supports the view that case definitions – including susceptible domestic species and susceptible wildlife species of epidemiological relevance – should be specified for disease notification purposes for all listed diseases.

However, the EU strongly suggests that these case definitions respectively be kept or gradually be included in the disease specific chapters of the *Terrestrial Code*, and not in the *Terrestrial Manual*.

The Group did not review bee diseases as the *ad hoc* Group on Diseases of Honey Bees, at its meeting held in Paris from 10 to 12 July 2012, had already evaluated the diseases according to the new criteria for listing.

3. Summary of key discussions on OIE-Listed diseases

The Group worked through all of the entries on the current list and applied the criteria for the inclusion of a disease or infection on the OIE list. The outcome of the detailed evaluation of criteria by disease is provided in [Appendix IV](#). In some cases the Group made its decisions based on currently available statistics for morbidity and mortality using public domain information and WAHID data.

Avian chlamydiosis – The disease has proven international spread. There are countries reporting freedom from the disease. It is an occupational zoonosis. The Group recommended that the disease be kept on the list; however, reporting should be done on the basis of genotype.

Avian infectious bronchitis – The disease is widespread. There are no countries claiming freedom. There is only one country that has never reported the disease. The Group recommended that the disease be delisted.

Avian infectious laryngotracheitis – The disease is widespread. There are no countries claiming freedom. There is only one country that has never reported the disease. The Group recommended that the disease be delisted.

Bovine genital campylobacteriosis – The disease is widespread. There is only one country that claims freedom but it does not have a control programme to justify this declaration. The Group recommended that the disease be delisted.

Bovine babesiosis – The Group concluded that, on the basis of the criteria, the disease should be retained on the list. The Group recommended that for reporting purposes important species that meet the criteria should be listed, namely *Babesia bovis*, *B. bigemina*, *B. divergens*, *B. major*, and *Babesia* sp.

Bovine tuberculosis – The Group concluded that, on the basis of the criteria, the disease should be retained on the list. The name of pathogen was discussed as several species of *Mycobacterium* were relevant to infection in bovidae. The Group recognised that the two most important species were *M. bovis* and *M. caprae*. The Group recommended using the term ‘infection with *Mycobacterium tuberculosis* complex’.

Contagious agalactia – The disease is widespread, there are countries considered free of the disease, morbidity could be significant (between 30% and 60%) and laboratory diagnosis is available as a means of confirmation. The Group recommended retaining the disease on the list. It was also decided that notifications for contagious agalactia should be made only on the basis of *Mycoplasma agalactiae*, as this is the cause of the disease, and not for *M. capricolum* subsp. *capricolum* (Mcc), *M. mycoides* subsp. *capri* (Mmc) or *M. putrefaciens*.

*Crimean-Congo haemorrhagic fever*¹ – The Group assessed the international spread of this disease solely in terms of the decision tree criteria, namely via live animals, their products or fomites, and not via migratory wild birds or wild mammals. It was noted that a reliable serological test to assess the presence of the infection in animals was not currently available. The disease did not therefore meet the criteria. The Group recommended that the disease be delisted.

Echinococcosis/hydatidosis – The Group recommended retaining the disease on the list. The Group discussed the importance of the different pathogen species and proposed that, among the five existing species, only *E. granulosus* and *E. multilocularis* should remain notifiable and that further expert opinion should be sought on the other three species. The Group recommended naming the disease “echinococcosis” and listing only the two species that meet the criteria for listing, namely *E. multilocularis* and *E. granulosus*.

Enzootic bovine leukosis – The disease is widespread and does not show significant morbidity. The Group recommended that the disease be delisted.

EU comment

The EU informs the OIE Code Commission that it reserves its comments on the proposal by the *ad hoc* group to delist Enzootic bovine leukosis to a later stage as it has not finalised gathering of relevant data.

Equine piroplasmiasis – The Group recommended renaming it as “infection with *Babesia caballi* and *Theileria equi*” and adding the disease *Babesia* sp. to the reporting system list for Member Countries unable

¹ Scientific opinion of EFSA – 2010 CCHF – Link to the report <http://www.efsa.europa.eu/en/efsajournal/pub/1703.htm>

to identify the species.

Equine rhinopneumonitis – This disease can be caused by equid herpesvirus-1 (EHV-1) and equid herpesvirus-4 (EHV-4). Equine rhinopneumonitis caused by EHV-1 virus seems to be a potential emerging disease; however, the Group recognised that insufficient information was currently available and requested further expert opinion. In the case of equine rhinopneumonitis caused by EHV-4, the Group recommended delisting as the disease does not show significant morbidity.

Fowl typhoid and pullorum disease – These two diseases have many similarities. They have shown international spread. There are countries reporting freedom. Their mortality rates vary but can be as high as 100%. The Group recommended that these diseases be kept on the list and that reporting should be on the basis of genotype, or “spp” for countries not differentiating them. The Group recommended renaming the first as “Infection with *Salmonella gallinarum* (fowl typhoid); and using *Salmonella* sp. and *Salmonella gallinarum* for reporting purposes. For pullorum disease, the Group recommended renaming it as “Infection with *Salmonella pullorum* (pullorum disease)” and adding *Salmonella* sp. and *Salmonella pullorum* to the reporting system list.

Haemorrhagic septicaemia – The disease is widespread but the Group did not find any arguments that supported international spread through movement of live animals or their products. Therefore, the first criterion was not met. The Group recommended that the disease be delisted.

Infectious bursal disease (Gumboro disease) – Though widespread, the disease has low morbidity/mortality due to effective control measures (i.e. vaccine). The disease has no zoonotic potential and does not show significant mortality/morbidity in wildlife populations. The Group recommended that the disease be delisted.

Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis – The disease has proven international spread and significant morbidity (20%). The Group recommended that the disease be retained as listed, with the name “Infection with bovine herpesvirus type 1 (IBR)”.

Leishmaniosis – International spread has been proven. Free countries exist and the disease has zoonotic potential. The Group recommended keeping leishmaniosis as a listed disease for *L. infantum*, which meets the criteria. The proposed new name is “Infection with *Leishmania infantum*”.

Myxomatosis – Morbidity can be as high as 100% and mortality is between 36% and 68%. The Group recommended that the disease be kept on the list, renamed as “Infection with myxoma virus”.

Nairobi sheep disease – The Group recognised this as a very important disease and expressed concern that Member Countries where the disease is believed to occur may not be notifying it. The Group noted that there were discrepancies between scientific assessments and the number of countries reporting it. The disease has zoonotic potential. A reliable diagnostic test is available for the purpose of trade of live animals. The Group recommended keeping the disease on the list in order to monitor Member Countries perception of its importance.

Nipah virus encephalitis – The disease is zoonotic with significant mortality in humans. International spread via live animals, their products or fomites has not been proven. The Group recommended delisting the disease.

Paratuberculosis – The disease is widely distributed. Several countries have eradication programmes in place. The disease shows significant morbidity and may have zoonotic potential. The lack of an accurate diagnostic test makes diagnosis difficult in subclinically infected animals. The Group recommended that the disease be delisted.

EU comment

The EU informs the OIE Code Commission that it reserves its comments on the proposal by the *ad hoc* group to delist paratuberculosis to a later stage as it has not finalised gathering of relevant data.

Porcine cysticercosis – The Group recognised that the disease is a zoonosis. International spread of the disease by movement of live animals has not been proven. The disease does not show significant morbidity in infected animals. Diagnosis is by post-mortem inspection since there are no reliable diagnostic tests for use in live animals. The disease is an important zoonosis but there have been no estimates of the disease burden and

reporting the disease to the OIE would not prevent its spread. The Group recommended that the disease be delisted but that provisions in the relevant *Terrestrial Manual* chapter should continue to be updated.

EU comment

The EU does not support the delisting of porcine cysticercosis, as this would seem inconsistent with the approach for Trichinellosis, for which there is also no reliable test for use in live animals. However, consideration should be given to limiting the listed disease to zoonotic species only (*Taenia solium* and *Taenia asiatica*).

Porcine reproductive and respiratory syndrome – The Group recognised the lack of a good case definition for the disease and the need for a specific *ad hoc* Group to evaluate the genotype that should be notified. The Group recommended that, with this additional information, the disease should remain listed.

Q fever – International spread has been proven and the disease is zoonotic. The disease may cause massive abortions in small ruminants and cows. New Zealand has claimed freedom from the disease. The Group recommended that the disease remain on the list. The Group also recommended that a *Terrestrial Code* chapter on the disease, containing a case definition, be developed in order to differentiate infection with *Coxiella burnetii* from the clinical disease, including the occurrence of abortion storms.

Rabbit haemorrhagic disease – The disease shows morbidity of up to 90% and mortality of between 70% and 80%. The Group recommended that the disease be retained on the list.

Rinderpest – The Group discussed the question of whether diseases that have been eradicated should remain on the list. The Group considered that in the case of rinderpest the criteria for listing were still met and therefore recommended that the disease be kept on the list.

Salmonellosis (S. abortusovis) – The disease is sporadic but it might show significant morbidity/mortality (60% of all ewes), may cause abortion and mortality in ewes and newborn lambs may be significant. The Group recommended that the disease be kept in the list.

Scrapie – The disease does not show significant morbidity (2-30% within-flock morbidity) or mortality and is not zoonotic. However, the Group noted the difficulty in evaluating the level of morbidity for diseases with a long incubation period such as scrapie. The Group recommended that the disease be delisted.

EU comment

The EU disagrees with the *ad hoc* group and strongly opposes the proposal to delist scrapie (i.e. classical scrapie) from the OIE list, for the following reasons:

1. Scrapie is a transmissible disease. As such it can be spread through international trade of live animals in particular. As laid down in chapter 2.7.1 3. of the OIE Terrestrial Manual, "Classical scrapie is endemic in many parts of the world, where it has often been introduced by importation" (e.g. Cyprus, where the disease was unknown before 1985).

2. There are already countries in the world that have claimed scrapie freedom according to the provisions of Article 14.9.3. of the OIE Terrestrial Code (e.g. Australia and New Zealand). Several EU Member States are currently considering a similar self-declaration in the near future (e.g. Denmark, Sweden and Austria). Others will certainly follow.

3. The overall impact of scrapie can be very high in a given zone or country, in relation with some very specific characteristics of this disease, including:

- a possible recycling and amplification (and potential export) of the infectious agent through feed in the absence of a very stringent feed ban;

- a very long incubation period (2 to 5 years, sometimes as long as 7 years), resulting in the fact the disease is already well established when the first clinical cases are detected.

These characteristics contribute to explain why scrapie is presently the primary animal

health concern in Cyprus, where more than 22% of the small ruminant holdings are infected.

In the context of such a high proportion of infected holdings, and considering that the in-flock/in-herd morbidity rate can be as high as 32% of the adult animals, scrapie has clearly the potential of being a seriously damaging disease.

4. Several different diagnostic techniques are described in chapter 2.7.1 3. of the OIE Terrestrial Manual that allow the identification and confirmation of scrapie cases.

Swine vesicular disease^{2,3} – The disease does not show significant morbidity, does not result in significant mortality and is not zoonotic. The Group recommended that the disease be delisted.

Theileriosis – The Group recommended listing for reporting purposes important theileriosis that meet the criteria to be listed, namely *Theileria annulata* and *T. parva*, and *Theileria* sp. for countries not differentiating individual species.

Transmissible gastroenteritis – International spread has been proven. In piglets, mortality can be up to 100%, but in adults the disease is only a cause for concern when animals are infected with other primary pathogens. A reliable diagnostic test is not available but the existence of an effective vaccine means that the disease can easily be controlled. The Group recommended that the disease be delisted.

Vesicular stomatitis – The disease does not cause significant morbidity or mortality and the prevalence of clinical signs is low (10-20%)^{4,5} The disease has minor zoonotic potential. The Group recommended that the disease be delisted.

Western equine encephalomyelitis – International spread of the disease has not been proven. The virus has been isolated from wild birds, which can act as reservoirs, but transmission is mainly by mosquitoes^{6,7}. Horses are dead-end hosts for the Western equine encephalomyelitis virus and clinical cases are rare. The disease is reported in WAHIS/WAHD by only Bolivia and the United States of America. The Group recommended that the disease be delisted.

EU comment

The *ad hoc* group proposes to delist Western equine encephalomyelitis (WEE), whereas Venezuelan equine encephalomyelitis (VEE) (and Eastern equine encephalomyelitis) are proposed to be retained. This seems a bit inconsistent, as for both WEE and VEE, international spread seems not to have been proven, and horses are true dead-end hosts (viraemia seems not to be significant).

Whereas clinical cases of WEE in horses may now be sporadic and rare since vaccines are available, morbidity and mortality rates are not insignificant (even if lower than for epizootic subtypes of VEE). Furthermore, international spread of WEE via trade in game and ornamental birds seems possible.

Therefore, the EU disagrees with the *ad hoc* group – WEE should remain listed, but perhaps could be moved to the multiple species section.

http://www.cfsph.iastate.edu/Factsheets/pdfs/easter_wester_venezuelan_equine_encephalomyelitis.pdf

² Scientific Opinion of EFSA on Swine Vesicular Disease and Vesicular Stomatitis, EFSA Journal 2012;10(4):2631 – Link to the report <http://www.efsa.europa.eu/en/efsajournal/pub/2631.htm>

³ On line version of The Merck Veterinary Manual: <http://www.merckvetmanual.com/mvm/index.jsp?cfile=htm/bc/54400.htm>

⁴ Scientific Opinion of EFSA on Swine Vesicular Disease and Vesicular Stomatitis, EFSA Journal 2012;10(4):2631– Link to the report <http://www.efsa.europa.eu/en/efsajournal/pub/2631.htm>

⁵ On line version of The Merck Veterinary manual:

<http://www.merckvetmanual.com/mvm/index.jsp?cfile=htm/bc/52500.htm&word=vesicular%2cstomatitis>

⁶ [William K. Reisen, Sarah S. Wheeler, Sandra Garcia, and Ying Fang](#). 2010. Migratory Birds and the Dispersal of Arboviruses in California. *Am J Trop Med Hyg.* 5; 83(4): 808–815. doi: [10.4269/ajtmh.2010.10-0200](https://doi.org/10.4269/ajtmh.2010.10-0200)

⁷ CFSPH: http://www.cfsph.iastate.edu/Factsheets/pdfs/easter_wester_venezuelan_equine_encephalomyelitis.pdf

West Nile fever – International spread of the disease has been proven. The disease can show high morbidity and high mortality. The Group discussed the fact that clinical cases in horses are often concomitant with clinical cases in humans, and that, since horses are dead-end hosts, the disease should continue to be listed in the ‘multiple species’ disease category or be moved to the avian disease category. Finally, the Group recommended that it should remain listed in the ‘multiple species’ category. The Group also recommended that work be done to improve the usefulness of the information that the Veterinary Services provide the public health services for the management of the disease.

4. Leptospirosis

Leptospirosis – The Group discussed the need to obtain an expert opinion on the disease. The Group recommended that guidance be developed to better address this issue. The OIE requested Reference Laboratories for leptospirosis to provide views on listing specific pathogenic serovars.

5. Summary of key discussions on non-listed diseases

Chronic wasting disease – Evidence that the disease has the potential for international spread was obtained when deer imported into the Republic of Korea were found to have the disease. Many countries are free. Morbidity, based on clinical disease, cannot be considered significant either in captive or in wild cervid populations and there is no proven zoonotic potential. The Group therefore believes that chronic wasting disease does not meet the criteria for listing.

Infection with Schmallenberg virus – There is evidence of international spread, many countries are free, and there is no proven zoonotic impact (ref. ECDC⁸ assessment) according to the available information. There is no demonstration of significant mortality/morbidity when the entire epizootic period is considered. According to an EFSA report, the maximum proportion of reported sheep holdings in Europe with Schmallenberg virus (SBV) confirmed was 4% per country and 7.6% per region, while for cattle, less than 1.3 % of holdings were reported as SBV confirmed, at both country and regional level. The Group also discussed whether the criterion of rapid spread was met and felt that this would be rather difficult to calculate because clinical disease occurs mainly in offspring (the clinical disease in adults is transient and usually mild). The Group recognised that at present there was evidence of spread to other locations/territories. Should the disease occur outside its currently known geographical range or if its behaviour were to change, it should be reported immediately to the OIE under the provisions of *Terrestrial Code* Article 1.1.3.

EU comment

The EU does not agree with the last sentence of the paragraph above, as this statement is clearly outside of the scope of this ad hoc group. Reference is made to the EU comments in Annex VI on the need for clarifications on the concept of "emerging disease" and its notification requirements.

6. Summary of key discussions on Trypanosomiasis

The Group was requested to identify *Trypanosoma* species that meet the listing criteria, with a view to their being listed in place of trypanosomiasis.

A presentation on the most pathogenic animal trypanosomes ([Appendix VI](#)) and their geographical distribution was made. The Group examined OIE-listed diseases caused by trypanosomes, both non-tsetse-transmitted and tsetse-transmitted. It was decided not to take the vector into consideration when listing a pathogen. Specifically, the Group recognised that many significant trypanosomoses are transmitted by vectors other than tsetse flies and that emphasis on tsetse-transmitted trypanosomoses could thus be misleading. The example of trypanosomoses caused by *T. vivax* was used to illustrate the case where the parasite is not strictly bound to a specific vector.

The Group recommended that the following pathogens be listed: infection with *T. congolense*; infection with *T. vivax*, infection with *T. brucei*, infection with *T. evansi* (surra), and infection with *T. equiperdum* (dourine). The criteria for listing of these pathogens are described in [Appendix IV](#).

⁸ ECDC: European Centre for Disease Prevention and Control

Annex VII (contd)

Some discussions on Chagas disease (*T. cruzi*) took place to determine whether this disease should be included on the OIE list since, according to WHO, it is a zoonotic disease. Dogs might play a sentinel role. The disease has been documented in the United States of America since 1916 but a comprehensive review has not yet been published. The Group considered that reliable epidemiological surveys should be conducted to determine the exact role of domestic animals in the transmission of the disease. The Group recommended that the disease be examined in the future when more scientific information has been made available.

7. Summary of the diseases proposed for delisting

The Group evaluated the current OIE-listed terrestrial animal diseases against the new criteria for inclusion (Article 1.2.2. of Chapter 1.2. in the *Terrestrial Code*). Bee diseases were not reviewed as the *ad hoc* Group on Diseases of Honey Bees, recommended that the list remain unchanged. Out of the 85 terrestrial animal diseases currently listed, the Group proposed delisting the 16 diseases mentioned in Table 1, which were considered not to meet the new criteria.

Table 1: Diseases proposed for delisting

	Disease name
1	Avian infectious bronchitis
2	Avian infectious laryngotracheitis
3	Bovine genital campylobacteriosis
4	Crimean Congo haemorrhagic fever
5	Enzootic bovine leukosis
6	Equine rhinopneumonitis (caused by EHV-4)
7	Haemorrhagic septicaemia
8	Infectious bursal disease (Gumboro disease)
9	Nipah virus encephalitis
10	Paratuberculosis
11	Porcine cysticercosis
12	Scrapie
13	Swine vesicular disease
14	Transmissible gastroenteritis
15	Vesicular stomatitis
16	Western equine encephalomyelitis

Annex VII (contd)Appendix I

**OIE AD HOC GROUP ON
NOTIFICATION OF ANIMAL DISEASES AND PATHOGENIC AGENTS
Paris, 24–26 July 2012**

List of participants

MEMBERS**Dr Franck Berthe**

Senior Scientific Officer
Animal Health and Animal Welfare Unit -
AHAW
European Food Safety Authority – EFSA
Largo N. Palli 5/A
43100 Parma
ITALY
Tel.: (39) 0521 036 870
Fax: (39) 0521 036 970
E-mail: Franck.Berthe@efsa.europa.eu

Prof. Mohammed Bouslikhane

Département de microbiologie-
immunologie et des maladies
infectieuses
Institut Agronomique et Vétérinaire
Hassan II
B.P. 6202 – Instituts
10101 Rabat
MOROCCO
Tel.: (212) 666292764
E-mail: bouslikhanemed@yahoo.fr

Dr Paolo Calistri

Istituto Zooprofilattico Sperimentale
Dell'Abruzzo e del Molise "G. Caporale"
Via Campo Boario
64100 Teramo
ITALY
Tel: (39) 0861 33 21
Fax : (39) 0861 33 22 51
E-mail: p.calistri@izs.it

Dr Bruno Garin-Bastuji

Agence Nationale de Sécurité Sanitaire de
l'alimentation, de l'environnement et du travail
(ANSES)
Laboratoire de santé animale
Unité zoonoses bactériennes
23 avenue du Général de Gaulle
94706 Maisons-Alfort Cedex
FRANCE
Tel.: (33) (0)1 49 77 13 00
Fax: (33) (0)1 49 77 13 44
E-mail : bruno.garin-bastuji@anses.fr

Dr Francisco Javier Reviriego-Gordejo

Head of Sector
Health & Consumers Directorate-General
DG SANCO/D1
European Commission
Rue Froissart 101-3/72
1040 Brussels
BELGIUM
Tel.: (32)2 298 47 99
Fax: (32) 2 295 31 44
E-mail: francisco.reviriego-
gordejo@ec.europa.eu

Dr Louis Touratier

228 Bld du Président Wilson
33000 Bordeaux
FRANCE
Tel.: (33) (0)5 56 44 89 29
Fax: (33) (0)5 57 57 48 03
E-mail: louistier@aol.com

Dr Steve Weber

Centers for Epidemiology and Animal
Health
USDA-APHIS-VS-CEAH
2150 Centre Ave.
Fort Collins, Co. 80526
UNITED STATES OF AMERICA
Tel.: (1) 970 494 7271
Fax: (1) 970 494 72 28
E-mail : Steve.Weber@aphis.usda.gov

OTHER PARTICIPANTS**Dr Caryl Lockhart**

Veterinary Epidemiologist
Animal Health Service
Food and Agriculture Organization of the
United Nations
Viale delle Terme di Caracalla
00153 Roma
ITALY
E-mail : caryl.lockhart@fao.org

Annex VII (contd)

Appendix I (contd)

OIE HEADQUARTERS

Dr Bernard Vallat
Director General
12 rue de Prony
75017 Paris
FRANCE
Tel.: 33 - (0)1 44 15 18 88
Fax: 33 - (0)1 42 67 09 87
E-mail: oie@oie.int

Dr Karim Ben Jebara
Head
Animal Health Information Department
E-mail: k.benjebara@oie.int

Dr Simona Forcella
Chargée de Mission
Animal Health Information Department
E-mail: s.forcella@oie.int

Dr Alessandro Ripani
Chargé de Mission
Scientific and Technical Department
E-mail: a.ripani@oie.int

Dr Masatsugu Okita
Chargé de Mission
International Trade Department
E-mail: m.okita@oie.int

Annex VII (contd)

Appendix II

**TERMS OF REFERENCE OF THE AD HOC GROUP ON
NOTIFICATION OF ANIMAL DISEASES AND PATHOGENIC AGENTS
Paris, 24–26 July 2012**

The *ad hoc* Group is kindly requested to:

- a) On the basis of the adopted amended listing criteria during the OIE World Assembly of May 2012, assist the OIE in addressing the following points:
 1. Establish a new decision tree reflecting the newly amended Chapter 1.2. entitled criteria for the inclusion of diseases and infections on the OIE List (the previous decision tree is available in this Appendix II).
 2. Based on the newly adopted article 1.2.2. providing listing criteria and the newly proposed decision tree by the Group, evaluate each actual OIE-listed disease/infection according to the new criteria and propose to change the name of diseases that meet the new criteria using the name of the pathogenic agent. For each disease to be listed or delisted, a rationale of few lines should corroborate the decision of the Group.

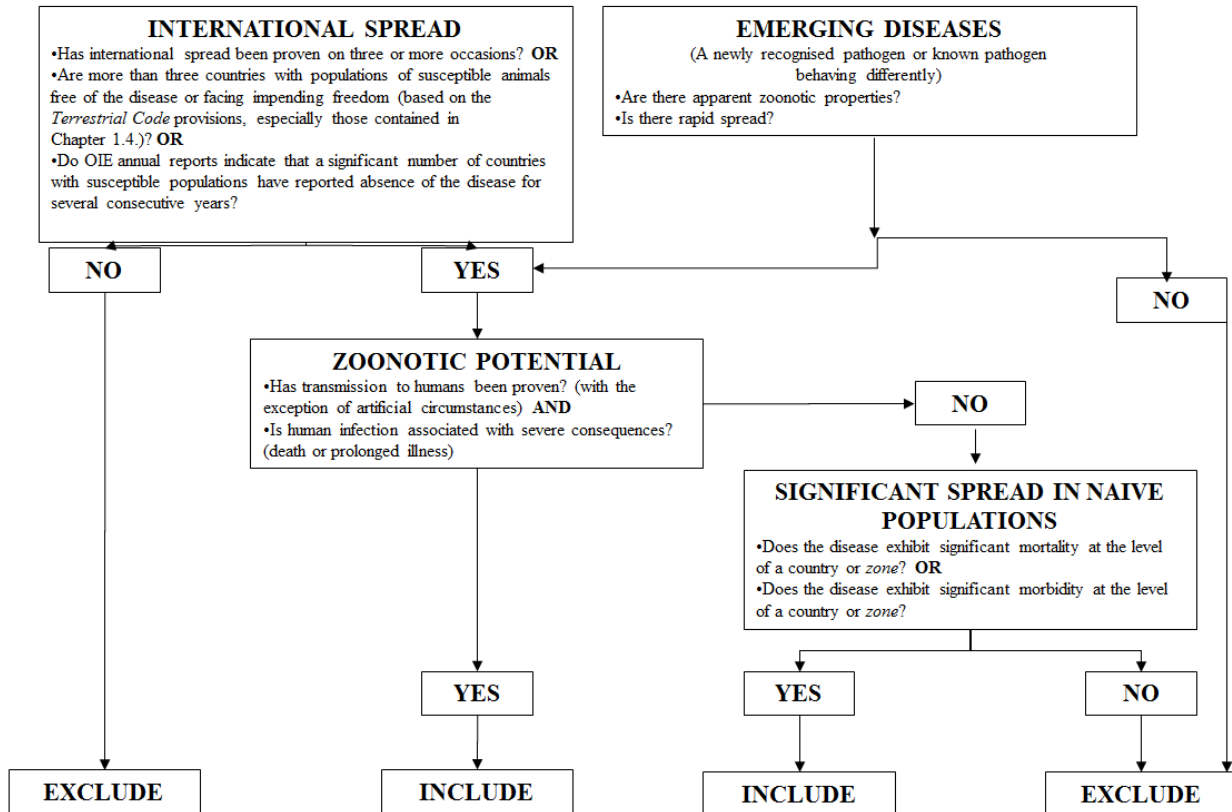
For the following diseases:

- a) Vesicular stomatitis and swine vesicular diseases: while analysing them against the new criteria, take into account the report provided by the EU on the Scientific opinion of EFSA on SVD and VS, EFSA Journal 2012, 10(4):261;
 - b) For leptospirosis, determine those strains that meet the new criteria as per the recommendation of the *ad hoc Group* on Notification of Animal Diseases and Pathogenic Agents Report of the meeting held 29 June to 1 July 2010;
 - c) For trypanosomosis, identify pathogenic agent taxonomy in replacement of trypanosomosis, including for non-tsetse transmitted, many significant trypanosomoses being transmitted by other vectors than tsetse flies;
 - d) Examine new emerging diseases and other non-listed disease that are behaving differently as candidates for listing, according to the new listing criteria.
- b) Any other business.

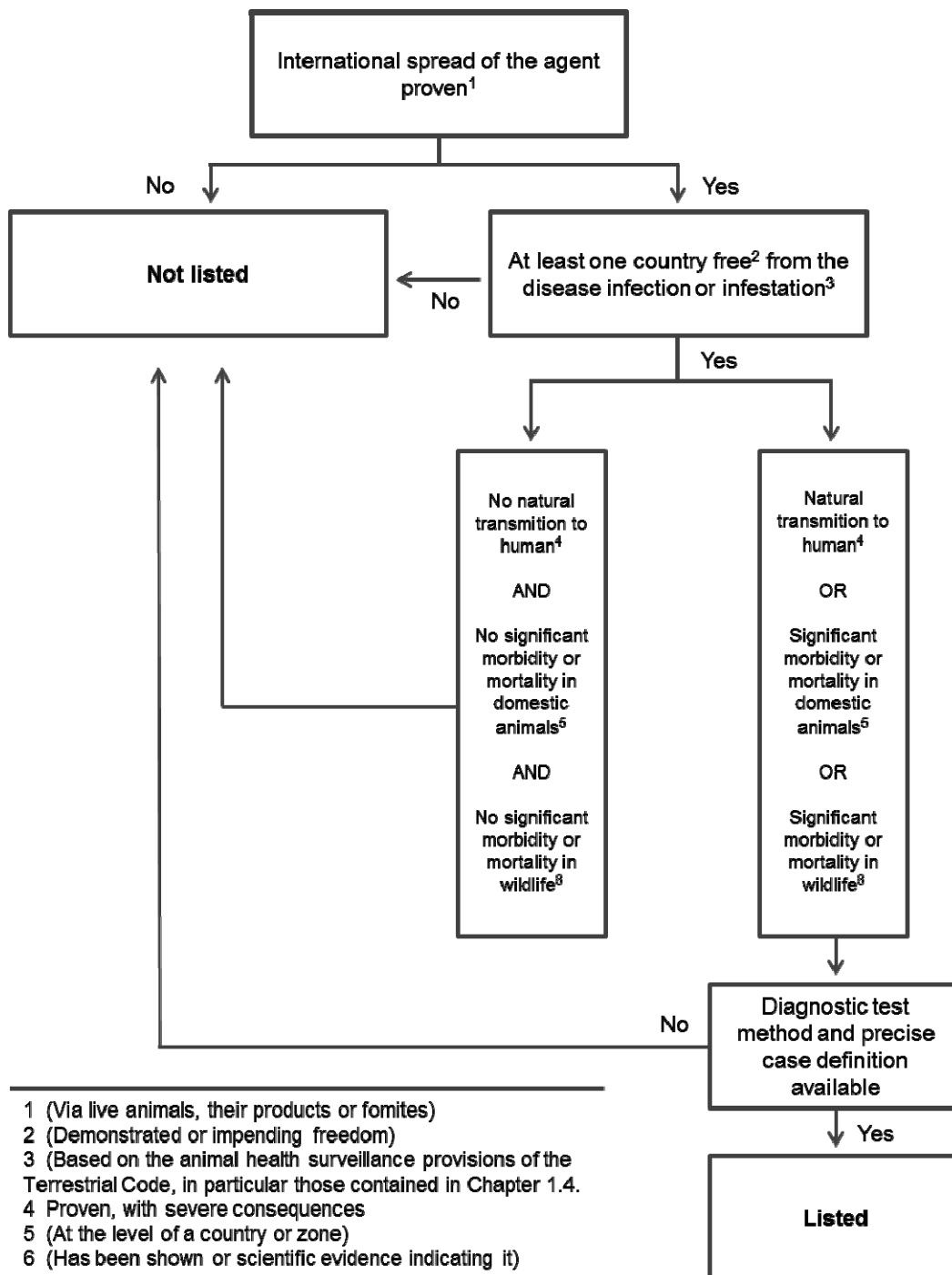
Annex VII (contd)

Appendix II (contd)

PREVIOUS DECISION TREE

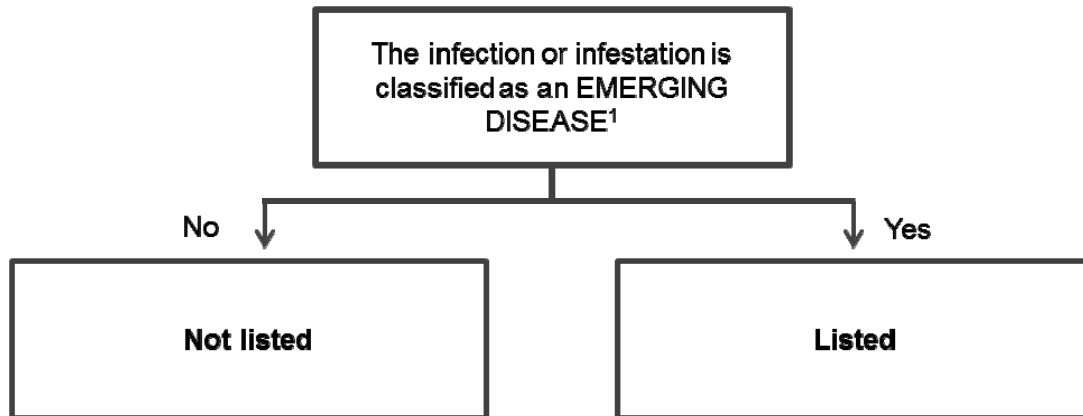


PROPOSED DECISION TREE TO BE ADDED TO ARTICLE 1.2.2



Annex VII (contd)

Appendix III (contd)



¹ (With evidence of zoonotic properties, rapid spread or significant morbidity or mortality and with case definition available)

Annex VII (contd)
Appendix IV

Detailed evaluation of criteria by disease

Disease Name / Pathogen name	International Spread	Pending/ Free Country	Significant Zoonotic (Natural)	Significant Mbty/Mtly* Domestic animals	Significant Mbty/Mtly* Wild animals	Diagnostics Reliable Case definition	Emerging zoonotic rpd sprd**	List Y or N	Comments
Multiple species									
Anthrax / <i>Bacillus anthracis</i>	y	y / New Zealand	y	y	y	y		y	
Aujeszky's disease / Suid alphaherpes virus (SHD-1)	y	y / Australia / Canada		y	y	y		y	Checking on level of morbidity from last 3 yrs data in WAHIS, there are not major changes
Bluetongue / Bluetongue virus	y	y	n	y	y	y		y	
Brucella/ <i>Brucella abortus</i>	y	y	y	y	y	y		y	Concern that some countries don't differentiate the species of brucella - how should they report (possibility to report only <i>Brucella</i> spp. if the diagnosis is only serological)
Brucella/ <i>B. melitensis</i>	y	y	y	y	y	y		y	
Brucella/ <i>B. suis</i>	y	y	y	y	y	y		y	
Crimean Congo haemorrhagic fever (Nairovirus)	n							n	No proof of international spread, reliable, specific diagnostics test not available. Lack of clinical signs. Countries don't do surveillance in animals and vectors. Reference EFSA scientific opinion 2010.
Echinococcosis / <i>Echinococcus multilocularis</i>	y	y	y			y		y	
Echinococcosis / <i>E. granulosus</i>		United Kingdom / Sweden							
Epizootic Haemorrhagic Disease (EHD) / EHD virus	y / North Africa	y / Europe		y / 18% Morocco	y	y		y	EFSA scientific opinion 2009, WAHID
Eastern Equine Encephalitis (EEE)/ EEE virus	y	y	y	y	y	y		y	
Western Equine Encephalitis (WEE)/ WEE virus	?	y	y	y / 8-15% case fatality in 1941		y		n	Comment on the need to prevent international spread of diseases through the control of game birds and ornamental birds
Venezuelan Equine Encephalitis (VEE)/ VEE virus	?	y	y	y		y		y	Retain as disease of equine
Foot and Mouth Disease (FMD)/ FMD virus	y	y	n	y	y	y		y	
Heartwater / <i>Ehrlichia ruminantium</i>	y	y	n	y / mortality (6-90%)	y	y		y	Emerging and Exotic Diseases of Animals Fourth Edition, 2009, Edited by: A. Rovid Spickler et al. published by the Centre for Food Security and Public Health

<u>Disease Name / Pathogen name</u>	<u>International Spread</u>	<u>Pending/ Free Country</u>	<u>Significant Zoonotic (Natural)</u>	<u>Significant Mbty/Mtly* Domestic animals</u>	<u>Significant Mbty/Mtly* Wild animals</u>	<u>Diagnostics Reliable Case definition</u>	<u>Emerging zoonotic rpd sprd**</u>	<u>List Y or N</u>	<u>Comments</u>
Japanese Encephalitis / Japanese encephalitis virus	y / Asian countries	y	y	y / 50-60% morbidity in swine		y		y	
New World Screwworm / <i>Cochliomyia hominivorax</i>	y	y	y	y	y	y		y	
Old World Screwworm / <i>Chrysomya bezziana</i>	y	y	y	y	y	y		y	
Paratuberculosis / <i>Mycobacterium avium</i> sbsp. <i>paratuberculosis</i>	y	y / Sweden	?	y	y	?		n	It is possible to have Manual chapter for important diseases that are not in the OIE list. diagnostics/freedom from disease were questioned
Q Fever / <i>Coxiella burnetti</i>	y	y / New Zealand	y	y	y	y		y	Initial discussion - widespread disease without clear case definition. If New Zealand is free needs to be kept on list. Need to harmonize between animal and human definition. Need an OIE Code chapter especially focusing on international trade. A case definition is needed
Rabies / Rabies virus	y	y / United Kingdom / Ireland	y	y	y	y		y	
Rift Valley Fever (RVF)/ RVF virus	y / Yemen - Saudi Arabia		y	y	y	y		y	
Rinderpest / Rinderpest virus	y	y	n	y	y	y		y	Once eradicated should remain on list
Trichinella / <i>Trichinella</i> spp.	y	y / Denmark (1930) / Uruguay (1924) / Brazil / (never reported, many other countries)	y		y	y		y	Animals - swine/wild boars, 11 species mentioned in Code, widespread, but several countries never reported, Denmark is considered negligible risk
Trypanosomoses / <i>Trypanosoma congolense</i> / <i>T. brucei</i>	y / spread via tsetse	y		y	Wild animals are natural reservoirs of <i>Trypanosoma</i> spp with the exception of <i>T. equiperdum</i> which is alone without known wild animal reservoir	y		y	Need to convene ad hoc group to determine importance of other species. Concept of Tsetse transmitted is not included because could be misleading (e.g. <i>T. vivax</i> is tsetse and not tsetse transmitted)
Trypanosomoses / <i>T. vivax</i>	y / From Africa to South America	y		y		y		y	

Disease Name / Pathogen name	International Spread	Pending/ Free Country	Significant Zoonotic (Natural)	Significant Mbty/Mtly* Domestic animals	Significant Mbty/Mtly* Wild animals	Diagnostics Reliable Case definition	Emerging zoonotic rpd sprd**	List Y or N	Comments
Trypanosomoses / <i>T. evansi</i> (Surra)	y	y		y		y		y	
Trypanosomoses / <i>T. equiperdum</i> (dourine)	y	y		y		y		y	
Tularemia / <i>Francisella tularensis</i>	y	y	y	y	y	y		y	
Vesicular stomatitis (VS)/ VS virus	y	y	n	n	n	y		n	Discussion that diagnostics are better for differential diagnosis of FMD; minor zoonotic, EFSA scientific opinion2012, Merck manual indicates low prevalence of clinical signs (10-20%); discussion on how to interpret significance of morbidity/mortality, perhaps other criteria need to be considered for historical diseases of significance to trade
West Nile fever / West Nile Fever virus	y	y	y	y	y	y		y	
Cattle diseases									
Anaplasmosis / <i>Anaplasma marginale</i>	y	y	n	y	y	y		y	Spread with tick-infected animals. The other two species of Anaplasma are very rare
Bovine babesiosis / <i>Babesia bovis</i> , <i>B. bigemina</i> , <i>B. divergens</i> & <i>B. major</i> (Sp)	y	y	n	y	y	y		y	
Theileriosis / <i>Theileria annulata</i> , <i>T. parva</i> (Sp)	y	y	n	y	n	y		y	
Bovine genital campylobacteriosis / <i>Campylobacter fetus</i>	y	Y / Latvia	n	y	n	y		n	Is not enough that a country "never reported" a disease to claim freedom from that disease
Bovine Spongiform encephalopathy	y	y	y	y	n	y		y	Official status recognised for certain countries
Bovine tuberculosis / <i>Mycobacterium bovis</i>	y	y	y	y	y	y		y	
Bovine viral diarrhoea (BVD)/ BVD virus (Pestivirus)	y	Y / Iceland	n	y	n	y		y	
Contagious bovine pleuropneumonia / <i>Mycoplasma mycoides</i> subsp <i>mycoides</i>	y	y	n	y	n	y		y	
Enzootic bovine leucosis / Delta-Retrovirus	y	y / New Caledonia & Iceland	n	y	n	y		n	
Haemorrhagic septicemia / <i>Pasteurella multocida</i>	?	y / New Zealand / Canada	n	y	n	y		n	Wide spread
Infectious bovine rhinotracheitis / infectious pustular vulvovaginitis / Bovine herpes virus type-1 (BHV1)	y	y	n	y	n	y		y	
Lumpy skin disease / Capripoxvirus	y	y	n	y	n	y		y	
Trichomonosis / <i>Trichomonas faetus</i>	y	y	n	y	n	y		y	
Sheep and goat diseases									
Caprine Arthritis/Encephalitis CAE and Maedi-Visna / Small ruminant Lentivirus	y	y		y		y		y	

<u>Disease Name / Pathogen name</u>	<u>International Spread</u>	<u>Pending/ Free Country</u>	<u>Significant Zoonotic (Natural)</u>	<u>Significant Mbty/Mtly* Domestic animals</u>	<u>Significant Mbty/Mtly* Wild animals</u>	<u>Diagnostics Reliable Case definition</u>	<u>Emerging zoonotic rpd sprd**</u>	<u>List Y or N</u>	<u>Comments</u>
Contagious agalactia / <i>Mycoplasma agalactiae</i>	y	y		y		y		y	
Contagious agalactia / <i>M. capricolum</i> subsp. capricolum								n	
Contagious agalactia / <i>M. mycoides</i> subsp. capri								n	
Contagious agalactia / <i>M. putrefaciens</i>								n	
Contagious caprine pleuropneumonia (/ <i>Mycoplasma capricolum</i> subsp. <i>capripneumoniae</i>)	y	y		y	y	y		y	
Enzootic abortion of ewes (ovine chlamydiosis) / <i>Chlamydomphila abortus</i>	y	y / New Zealand / Japan / Denmark / Finland	y	y		y		y	
Nairobi Sheep Disease (NSD)/ NSD virus (Nairovirus)	y	y	y	y		y		y	
Ovine epididymitis / <i>Brucella ovis</i>	y	y		y		y		y	
Ovine salmonellosis / <i>S. abortusovis</i>	y	y / New Zealand / Australia		y. 60% of all ewes may abort and mortality in ewes and newborn lambs may be significant		y		y	OIE disease card
Peste des petits ruminants (PPR) / PPR virus	y	y		y		y		y	
Scrapie	y	y / New Zealand / Australia		low within flock mortality 2-30% (one study)		y		n	
Sheep pox (SP) and goat pox (GP) / SP virus/ and GP virus	y/ Sri Lanka/ Netherlands	y		y/ 80% mortality in experimental, low in natural - ISU		y		y	
Equine diseases									
Equine Influenza / Equine influenza viruses (<i>Orthomyxoviridae</i>)	y / Japan to Australia	y / Belarus / Greenland		y / morbidity rate: Australia report 50%, Japan 16%		y		y	
Equine piroplasmosis / <i>Babesia caballi</i> , <i>T. equi</i>	y	y / China / Bangladesh / Japan		y / up to 20% morbidity - ISU	y	y		y	

<u>Disease Name / Pathogen name</u>	<u>International Spread</u>	<u>Pending/ Free Country</u>	<u>Significant Zoonotic (Natural)</u>	<u>Significant Mbty/Mtly* Domestic animals</u>	<u>Significant Mbty/Mtly* Wild animals</u>	<u>Diagnostics Reliable Case definition</u>	<u>Emerging zoonotic rpd sprd**</u>	<u>List Y or N</u>	<u>Comments</u>
Equine rhinopneumonitis / Equine Herpes Virus 4	y/ worldwide	y / Bolivia/ Costa Rica/ Iceland	y	n/ mild respiratory disease of young horses - ISU	n	y		n	
Equine viral abortion (also named Equine rhinopneumonitis) / Equine Herpes Virus 1	y	y	n	n / significant economic losses Australia	y			y	No enough information / may be difficult to differentiate EhV1, EhV4, incubation period 2-10 days
Equine viral arteritis (EVA)/ EVA virus	y	y / Paraguay/ Iceland/ Japan	n	y / abortion rates vary from <10% to as high as 50% (Merck)	n / little evidence of infection in zebras	y		y	
Glanders / <i>Burkholderia mallei</i>	y	y	y	y / 46% morbidity, 100% mortality		y		y	
Swine diseases									
African swine fever (ASF) / ASF virus	y	y		y	y	y		y	
Classical swine fever (CSF)/ CSF virus	y	y		y	y	y		y	
Nipah virus encephalitis / Nipah virus	n	y	y	y	n	y		n	
Porcine cysticercosis / <i>Taenia solium</i>	n	y/ Scandinavia	y	y	n	n (post-mortem meat inspection)		n	Applying strictly the criteria with the objective to prevent transboundary spread it does not meet them
Porcine reproductive respiratory syndrome (PRRS)/ PRRS virus	y	y/South America / Australia	n	y	n	y		y	
Swine vesicular disease (SVD)/ Swine vesicular disease virus	y	y	n	n	n	y		n	Low morbidity, no mortality - ref Merck, EFSA reports 2012, OIE disease card
Transmissible gastroenteritis (TGE)/ TGE virus	y	y / Australia	n	y	?	y		n	The OIE manual says that this is not an important primary pathogen
Avian Diseases									
Avian chlamydiosis / <i>Chlamydia psittaci</i>	y	Y/Central America	y (occupational)	y	y	y		y	Morbidity varies depending species. Pathogenicity is genotype dependent
Avian infectious bronchitis / coronavirus infectious bronchitis virus (IBV)	y	n / worldwide	n	y	?	y		n	Only Mongolia never reported
Avian infectious laryngotracheitis / Herpesviridae alpha herpesvirinae gallid herpesvirus 1	y	n / worldwide	n	y		?		n	Worldwide. No added value of notification for preventing transboundary spread
Avian mycoplasmosis / <i>Mycoplasma sinoviae</i>	y	y	n	y		y		y	
Avian mycoplasmosis / <i>Mycoplasma gallisepticum</i>	y	y	n	y		y		y	
Duck viral hepatitis / duck hepatitis virus (DHV) type I	y	y	n	y / up to 95-100%		y		y	

<u>Disease Name / Pathogen name</u>	<u>International Spread</u>	<u>Pending/ Free Country</u>	<u>Significant Zoonotic (Natural)</u>	<u>Significant Mbty/Mtly* Domestic animals</u>	<u>Significant Mbty/Mtly* Wild animals</u>	<u>Diagnostics Reliable Case definition</u>	<u>Emerging zoonotic rpd sprd**</u>	<u>List Y or N</u>	<u>Comments</u>
Fowl typhoid / Infection with <i>Salmonella gallinarum</i>	y	y	n	y		y		y	Data on morbidity indicate that it does meet the criteria. Fowl typhoid and pullorum disease two very closely related organisms, recently been classified as two biovars of <i>Salmonella enterica</i> subsp. <i>enterica</i> .
Highly Pathogenic Avian influenza (HPAI) / HPAI Viruses	y	y	y	y		y		y	
Infectious bursal disease (Gumboro disease) / Avibirnavirus	y	y / worldwide	n	n	?	y		n	The broad distribution and apparent low morbidity with not accurate data on mortality (9% in WAHID) do not meet criteria
Newcastle disease / avian paramyxovirus	y	y	minor	y	y	y		y	
Pullorum disease / Infection with <i>Salmonella pullorum</i>	y	y	n	y		y		y	
Turkey rhinotracheitis / Turkey rhinotracheitis virus	y	y	n	y / up to 95 %	y	y		y	
Lagomorph diseases									
Myxomatosis / Myxoma virus	y	y	n	y / morbidity up to 100% and mortality 36-38%	y	y		y	
Rabbit haemorrhagic disease / Calicivirus	y	y	n	y/morbidity >90% and mortality > 70%	y	y		y	
Other species									
Camelpox / Orthopoxvirus	y		y	y		y		y	
Leishmaniosis / <i>Leishmania infantum</i>	y	y	y	y	y	y		y	
New disease considerations									
Chronic Wasting Disease	y/ Canada / Republic of Korea	y / Australia / New Zealand	n / not proven	n / mortality (within flock) 2-30% (one study)				n	Don't fulfil criteria as listing as an emerging disease, but need to keep awareness clinical signs less than 3%; concerns about chronicity of the disease and therefore may not have high prevalence of clinical signs, infection without clinical signs is key to spread of diseases, diagnostic test is only applicable to dead animals
Schmallenberg / Schmallenberg virus	y	y	n	n	y			n	

* Mbty/Mtly: Morbidity/Mortality

** rpd sprd: Rapid spread

Annex VII (contd)

Appendix V

Annex VII (contd)

Appendix VI

MOSTLY PATHOGENIC ANIMAL TRYPANOSOMES

TSETSE ANIMAL TRANSMITTED (TTAT)

- *Trypanosoma congolense* (to be added in the OIE list)
- *Trypanosoma vivax* (to be added in the OIE list)
- *Trypanosoma brucei brucei* (to be added in the OIE list)

- *Trypanosoma brucei gambiense* (zoonotic)
- *Trypanosoma brucei rhodesiense* (zoonotic)

TSETSE and NON TSETSE TRANSMITTED

- *Trypanosoma vivax*

NON TSETSE ANIMAL TRANSMITTED (NTTAT)

(Worldwide possible extension)

- *Trypanosoma evansi* (Surra)
- *Trypanosoma equiperdum* (Dourine)
- *Trypanosoma vivax*
- *Trypanosoma cruzi* (zoonotic)

© **World Organisation for Animal Health (OIE), 2012**

This document has been prepared by specialists convened by the OIE. Pending adoption by the World Assembly of Delegates of the OIE, the views expressed herein can only be construed as those of these specialists.

All OIE (World Organisation for Animal Health) publications are protected by international copyright law. Extracts may be copied, reproduced, translated, adapted or published in journals, documents, books, electronic media and any other medium destined for the public, for information, educational or commercial purposes, provided prior written permission has been granted by the OIE.

The designations and denominations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the OIE concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers and boundaries.

The views expressed in signed articles are solely the responsibility of the authors. The mention of specific companies or products of manufacturers, whether or not these have been patented, does not imply that these have been endorsed or recommended by the OIE in preference to others of a similar nature that are not mentioned.

CHAPTER 3.2.

EVALUATION OF VETERINARY SERVICES

EU comment

The EU thanks the OIE and supports the proposed changes to this 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*.

Annex VIII (contd)

- 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.

- 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.
- 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.

Annex VIII (contd)

- 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.
- 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 resources1. 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.

Annex VIII (contd)

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 capabilities1. 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.

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.

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 body1. 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*, autonomy and functional capacity;
- c) the composition ~~and representation~~ of the *veterinary statutory body's* membership and the representativeness of its governing organs;
- d) accountability and transparency of decision-making;
- e) sources and management of funding;
- f) administration of training programmes and continuing professional development for *veterinarians* and *veterinary para-professionals*.

2. Evaluation of objectives and functions

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

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 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 ~~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 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*;~~
- e) ~~*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.

Annex VIII (contd)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.

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 *exporting country* as part of a *risk analysis* process, which is necessary to determine the sanitary or zoonosanitary 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.

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 to these private veterinarians.*];
- other *veterinarians*.

iii) Animal health:

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

Annex VIII (contd)

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.

3. Financial management informationa) 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.

Annex VIII (contd)

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 official or 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) Details of collaboration with external *laboratories* including international reference laboratories and details on numbers of samples submitted.
- viii) Details of quality control and assessment (or validation) programmes operating within the veterinary laboratory service.
- ix) Recent published reports of the official veterinary laboratory service which should include details of specimens received and foreign animal disease investigations made.
- x) 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*;
 - 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;

Annex VIII (contd)

- 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*.
- 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.

Annex VIII (contd)

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.

— Text deleted.

CHAPTER 4.6.

COLLECTION AND PROCESSING OF BOVINE,
SMALL RUMINANT AND PORCINE SEMEN**EU comments**

The EU in general supports the proposed changes to this chapter and has a comment.

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.

Annex IX (contd)

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.

Annex IX (contd)

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.

Annex IX (contd)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.

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.

Annex IX (contd)

- 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:

- 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*.

Annex IX (contd)

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.

Annex IX (contd)

- 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 semen**EU comment**

For clarity reasons, the EU suggests inserting the word "frozen" before the word "semen" in the title of paragraph 3 of this article.

Indeed, since the word "straws" is added and the word "pellets" is deleted below, it should be clarified that this Article refers to frozen semen only, as other receptacles such as bottles are generally used for fresh or chilled 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.

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.

— Text deleted.

CHAPTER 4.7.

COLLECTION AND PROCESSING OF *IN VIVO*
DERIVED EMBRYOS FROM LIVESTOCK AND EQUIDS**EU comment****The EU supports the proposed changes to this 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.

Annex IX (contd)

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.

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 animals1. 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^a. 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^a.
 - 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.

~~[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⁺ (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.

Annex IX (contd)

Article 4.7.6.

Conditions applicable to the collection and storage of embryos1. 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 Manual² 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 Manual².

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 Manual².
- 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 Manual²) 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 Manual² 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.

Annex IX (contd)

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 Manual². 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 Manual².
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.

Annex IX (contd)

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.

Article 4.7.14.

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

Based on the conclusions of the IETS¹, 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 Manual².
- 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 Manual², 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 Manual², 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)
 - 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 Manual² between collection and transfer.

Annex IX (contd)

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.

CHAPTER 6.4.

BIOSECURITY PROCEDURES IN POULTRY PRODUCTION

EU comment

The EU thanks the OIE and supports the proposed change to this 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., 6.10., 6.11.
- g) *Establishments* should be free from unwanted vegetation and debris that could attract or harbour pests.
- h) 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) Access to the *establishment* should be controlled to ensure only authorised persons and *vehicles* enter the site.
- j) 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) 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) 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.
- 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.

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.

— Text deleted.

CHAPTER 6.6.

INTRODUCTION TO THE RECOMMENDATIONS FOR
CONTROLLING ANTIMICROBIAL RESISTANCE**EU comment****The EU thanks the OIE and supports the proposed changes to this chapter.**

Article 6.6.1.

Objective

The purpose of Chapters 6.7., 6.8., 6.9. and 6.10. is to provide methodologies for OIE Members to appropriately address the emergence or spread of resistant bacteria from the use of *antimicrobial agents* in animal husbandry and to contain antimicrobial resistance through controlling the use of *antimicrobial agents*.

These chapters should be read in conjunction with the standards, codes of practice and guidelines on antimicrobial resistance developed by the Codex Alimentarius Commission.

Antimicrobial agents are essential drugs for human and animal health and welfare. The OIE recognises the need for access to *antimicrobial agents* in veterinary medicine: *antimicrobial agents* are essential for treating and controlling infectious *diseases* in *animals*. The OIE therefore considers that ensuring continued access to effective *antimicrobial agents* is important.

The OIE recognises that antimicrobial resistance is a global public and animal health concern that is influenced by the usage of *antimicrobial agents* in humans, *animals* and elsewhere. Those working in the human, animal and plant sectors have a shared responsibility to prevent or minimise pressures for the selection of antimicrobial resistance factors in humans and *animals*. Arising from its mandate for the protection of animal health and food safety, the OIE developed these chapters to provide guidance to Members in regard to risks in the entire animal sector.

The application of *risk assessment* measures should be based on relevant international standards on *risk analysis* and supported by sound data and information when available. The methodologies provided in these chapters should be consulted as part of the standard approach to prevent and reduce antimicrobial resistance.

CHAPTER 6.7.

**HARMONISATION OF
NATIONAL ANTIMICROBIAL RESISTANCE
SURVEILLANCE AND MONITORING PROGRAMMES**

EU comments

The EU thanks the OIE and in general supports the proposed changes to this chapter. A few comments are inserted in the text below.

Article 6.7.1.

Objective

This chapter provides criteria for the:

- 1) development of national antimicrobial resistance surveillance and monitoring programmes,
 - 2) harmonisation of existing national antimicrobial resistance surveillance and monitoring programmes,
- in food producing animals and in products of animal origin intended for human consumption.

Article 6.7.2.

Purpose of surveillance and monitoring

Active (targeted) surveillance and monitoring are as core parts of national antimicrobial resistance surveillance programmes. Passive surveillance and monitoring may offer additional information (refer to Chapter 1.4.). Regional cooperation between Members conducting antimicrobial resistance surveillance should be encouraged.

Surveillance and monitoring of antimicrobial resistance is necessary to:

- 1) assess and determine the trends and sources of antimicrobial resistance in bacteria;
- 2) detect the emergence of new antimicrobial resistance mechanisms;
- 3) provide the data necessary for conducting *risk analyses* as relevant to animal and human health;
- 4) provide a basis for policy recommendations for animal and human health;
- 5) provide information for evaluating antimicrobial prescribing practices and, for prudent use recommendations;
- 6) assess and determine effects of actions to combat antimicrobial resistance.

Article 6.7.3.

The development of antimicrobial resistance surveillance and monitoring programmes1. General aspects

Surveillance of antimicrobial resistance at targeted intervals or ongoing monitoring of the prevalence of resistance in bacteria from *animals*, food, environment and humans, constitutes a critical part of animal

health and food safety strategies aimed at limiting the spread of antimicrobial resistance and optimising the choice of *antimicrobial agents* used in therapy.

Annex XII (contd)

Monitoring of bacteria from products of animal origin intended for human consumption collected at different steps of the food chain, including processing, packing and retailing, should also be considered.

National antimicrobial resistance monitoring and surveillance programmes should be scientifically based and may include the following components:

- a) statistically based surveys;
- b) sampling and testing of food producing animals on the farm, at live animal market or at *slaughter*;
- c) an organised sentinel programme, for example targeted sampling of food producing animals, *herds, flocks, and vectors* (e.g. birds, rodents);
- d) analysis of veterinary practice and diagnostic *laboratory records*;
- e) sampling and testing of food products of animal origin.

2. Sampling strategies

- a) Sampling should be conducted on a statistical basis. The sampling strategy should ensure:
 - the sample is representative of the population of interest;
 - the robustness of the sampling method.
- b) The following criteria are to be considered:
 - sample source such as food producing animal, food, animal feed;
 - animal species;
 - category of *animal* within species such as age group, production type;
 - health status of the *animals* such as healthy, diseased;
 - sample selection such as targeted, systematic random;
 - type of sample (e.g. faecal, carcass, food product);
 - sample size.

3. Sample size

The sample size should be large enough to allow detection of existing and emerging antimicrobial resistance phenotypes.

Sample size estimates for prevalence of antimicrobial resistance in a large population are provided in Table 1 below.

Table 1. Sample size estimates for prevalence of antimicrobial resistance in a large population

	90% Level of confidence			95% Level of confidence		
Expected prevalence	Desired precision			Desired precision		
	10%	5%	1%	10%	5%	1%
10%	24	97	2,429	35	138	3,445
20%	43	173	4,310	61	246	6,109
30%	57	227	5,650	81	323	8,003
40%	65	260	6,451	92	369	9,135
50%	68	270	6,718	96	384	9,512
60%	65	260	6,451	92	369	9,135
70%	57	227	5,650	81	323	8,003
80%	43	173	4,310	61	246	6,109
90%	24	97	2,429	35	138	3,445

4. Sample sources

Members should examine their livestock production systems on basis of available information and assess which sources are likely to contribute most to a potential risk to animal and human health.

a) Animal feed

Members should consider including animal feed in surveillance and monitoring programmes as they may become contaminated with antimicrobial resistant bacteria, e.g. *Salmonella*.

b) Food producing animals

Categories of food producing animals considered for sampling should be relevant to the country's production system.

c) Food

Members should consider including relevant food products originating from food producing animals in surveillance and monitoring programmes as foodborne transmission is considered to be an important route for the transfer of antimicrobial resistance.

5. Type of sample to be collected

Feed samples should be collected in amounts sufficient for isolation of resistant bacteria of concern (at least 25 g) and should be linked to pathogen surveillance programmes.

Annex XII (contd)

Faecal samples should be collected in amounts sufficient for isolation of the resistant bacteria of concern (at least 5 g from bovine and porcine and whole caeca from *poultry*).

Sampling of carcasses at the *abattoir* provides information on *slaughter* practices, *slaughter* hygiene and the level of microbiological contamination and cross-contamination of *meat*. Further sampling of the product at retail sales level may provide additional information on the overall microbiological contamination from *slaughter* to the consumer.

Existing food processing microbiological monitoring, risk-based management and other food safety programmes may provide useful samples for surveillance and monitoring of resistance in the food chain after *slaughter*.

Table 2 provides examples of sampling sources, sample types and monitoring outcomes.

Table 2. *Examples of sampling sources, sample types and monitoring outcomes*

Source	Sample type	Outcome	Additional information required or additional stratification
Herd or flock of origin	Faecal or bulk milk	Prevalence of resistant bacteria originating from animal populations (of different production types) Relationship resistance – antimicrobial use	Age categories, production types, etc. Antimicrobial use over time
Abattoir	Faecal	Prevalence of resistant bacteria originating from animals at <i>slaughter</i>	
	Caeca or intestine	As above	
	Carcass	Hygiene, contamination during <i>slaughter</i>	
Processing, packing	Food products	Hygiene, contamination during processing and handling	
Point of sales (Retail)	Food products	Prevalence of resistant bacteria originating from food, exposure data for consumers	
Various origins	Animal feed	Prevalence of resistant bacteria originating from animal feed, exposure data for <i>animals</i>	

6. Bacterial isolates

The following categories of bacteria could be monitored:

a) Animal bacterial pathogens relevant to the countries' priorities

Monitoring of antimicrobial resistance in animal pathogens is important, both to:

- i) detect emerging resistance that may pose a concern for animal and human health;
- ii) guide *veterinarians* in their prescribing decisions.

Annex XII (contd)

Information on the occurrence of antimicrobial resistance in animal pathogens is in general derived from routine clinical material sent to veterinary diagnostic *laboratories*. These samples, often derived from severe or recurrent clinical cases including therapy failure, may provide biased information.

b) Zoonotic bacteria

i) *Salmonella*

Salmonella should be sampled from animal feed, food producing animals and animal derived food products. For the purpose of consistency and harmonisation, samples should be preferably taken at the *abattoir*.

Surveillance and monitoring programmes may also include bacterial isolates obtained from designated national *laboratories* originating from other sources.

Isolation and identification of bacteria and bacterial strains should follow nationally or internationally standardised procedures.

Serovars of public health importance such as *S. Typhimurium* and *S. Enteritidis* should be included. The inclusion of other relevant serovars will depend on the epidemiological situation in each country.

EU comment

The EU suggests adding the words "including the monophasic *S. Typhimurium* variants" after "*S. Typhimurium*" in the point above.

All *Salmonella* isolates should be serotyped and, where appropriate, phage-typed according to standard methods used at the nationally designated *laboratories*. For those countries that have the capabilities, *Salmonella* could be genotyped using genetic finger-printing methods.

ii) *Campylobacter*

Campylobacter jejuni and *C. coli* should be isolated from food producing animals and associated food products (primarily from *poultry*). Isolation and identification of these bacteria should follow nationally or internationally standardised procedures. *Campylobacter* isolates should be identified to the species level.

iii) Other emerging bacterial pathogens

Other emerging bacterial pathogens such as methicillin resistant *Staphylococcus aureus* (MRSA), *Listeria monocytogenes* or others which are pathogenic to humans, may be included in resistance surveillance and monitoring programmes.

EU comment

The EU suggests adding the words "*Enterobacteriaceae* carrying resistance to extended spectrum cephalosporins or carbapenems, or" before "methicillin resistant" in the point above. Indeed, *Enterobacteriaceae* carrying resistance to these classes of antibiotics, usually on transferable genes, should also be included in the surveillance.

c) Commensal bacteria

E. coli and *enterococci* (*Enterococcus faecium* and *E. faecalis*) may be sampled from animal feed, food producing animals and animal-derived food products.

These bacteria are commonly used in surveillance and monitoring programmes as indicators, providing information on the potential reservoir of antimicrobial resistance genes, which may be

transferred to pathogenic bacteria. It is considered that these bacteria should be isolated from healthy *animals*, preferably at the *abattoir*, and be monitored for antimicrobial resistance.

7. Storage of bacterial strains

If possible, isolates should be preserved at least until reporting is completed. Preferably, appropriate isolates should be permanently stored. Bacterial strain collections, established by storage of all isolates from certain years, will provide the possibility of conducting retrospective studies.

8. Antimicrobial susceptibility testing

Clinically important *antimicrobial agents* or classes used in human and veterinary medicine should be included in antimicrobial resistance surveillance programmes. Member Countries should refer to the OIE list of *antimicrobials* of veterinary importance for monitoring purposes. However, the number of tested *antimicrobial agents* may have to be limited according to financial resources.

EU comment

Since the first sentence of the paragraph above refers also to important antimicrobial agents or classes used in human medicine, the EU invites the OIE to consider making a reference also to the WHO list of critically important antimicrobials. This reference could be inserted as follows:

"Member Countries should refer to the WHO list of critically important antimicrobials for human medicine and to the OIE list of antimicrobial agents of veterinary importance for monitoring purposes".

Appropriately validated antimicrobial susceptibility testing methods should be used in accordance with Chapter 1.1.6. of the *Terrestrial Manual*, concerning laboratory methodologies for bacterial antimicrobial susceptibility testing. Antimicrobial susceptibility data should be reported quantitatively (minimum inhibitory concentrations [MICs] or inhibition zone diameters), rather than qualitatively.

9. Recording, storage and interpretation of data

- a) Because of the volume and complexity of the information to be stored and the need to keep these data available for an undetermined period of time, careful consideration should be given to database design.
- b) The storage of raw (primary, non-interpreted) data is essential to allow the evaluation in response to various kinds of questions, including those arising in the future.
- c) Consideration should be given to the technical requirements of computer systems when an exchange of data between different systems (comparability or compatibility of automatic recording of laboratory data and transfer of these data between and within resistance monitoring programmes) is envisaged. Results should be collected in a suitable national database. They should be recorded quantitatively:
 - i) as distributions of MICs in milligrams per litre;
 - ii) or inhibition zone diameters in millimetres.
- d) The information to be recorded should include, where possible, the following aspects:
 - i) sampling programme;
 - ii) sampling date;
 - iii) animal species or type;
 - iv) type of sample;

- v) purpose of sampling;
 - vi) type of antimicrobial susceptibility testing method used;
 - vii) geographical origin (geographical information system data where available) of *herd, flock or animal*;
 - viii) *animal* factors (e.g. age, condition, health status, identification, sex).
- e) The reporting of laboratory data should include the following information:
- i) identity of *laboratory*,
 - ii) isolation date,
 - iii) reporting date,
 - iv) bacterial species,
- and, where relevant, other typing characteristics, such as:
- v) serotype or serovar,
 - vi) phage type,
 - vii) antimicrobial susceptibility result or resistance phenotype,
 - viii) genotype.
- f) The proportion of isolates regarded as resistant should be reported, including the defined interpretive criteria used.
- g) In the clinical setting, breakpoints are used to categorise bacterial strains as susceptible, intermediate or resistant. These clinical breakpoints may be elaborated on a national basis and may vary between Members.
- h) The antimicrobial susceptibility testing standards and guidelines used should be recorded.
- i) For surveillance purposes, use of the microbiological breakpoint (also referred to as epidemiological cut-off point), which is based on the distribution of MICs or inhibition zone diameters of the specific bacterial species tested, is preferred. When using microbiological breakpoints, only the bacterial population with acquired resistance that clearly deviates from the distribution of the normal susceptible population will be designated as resistant.
- j) Ideally, data should be collected at the individual isolate level, allowing antimicrobial resistance patterns to be recorded.

10. Reference laboratory and annual reports

- a) Members should designate a national reference centre that assumes the responsibility to:
- i) coordinate the activities related to the antimicrobial resistance surveillance and monitoring programmes;
 - ii) coordinate and collect information from participating surveillance laboratories within the country;
 - iii) produce an annual report on the antimicrobial resistance situation in the country.

Annex XII (contd)

- b) The national reference centre should have access to the:
- i) raw data;
 - ii) complete results of quality assurance and inter-laboratory calibration activities;
 - iii) inter-laboratory proficiency testing results;
 - iv) information on the structure of the monitoring system;
 - v) information on the chosen laboratory methods.
-

CHAPTER 6.9.

**RESPONSIBLE AND PRUDENT USE OF
ANTIMICROBIAL AGENTS IN VETERINARY
MEDICINE**

EU comments

The EU thanks the OIE and in general supports the changes proposed to this chapter. However, a few specific comments are inserted in the text below.

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 Prudent~~ use is principally determined by the outcome of the specifications detailed in the marketing authorisation procedure and by their implementation of specifications when antimicrobials agents are administered to animals and are part of good veterinary and good agricultural practice.

EU comment

As the paragraph above gives a too narrow idea of what responsible and prudent is, the EU suggests slightly amending the sentence and including a reference to the veterinary professional judgement, 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 Responsible and prudent use of antimicrobial agents activities should need to involve all 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 Prudent~~ use includes a set of 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 to:

- 1) ensure 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) comply with the ethical obligation and economic need to keep *animals* in good health;
- 3) prevent, or reduce, 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;~~
- 64) contribute to 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);~~
- 85) ~~protect 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

~~The national~~ 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.

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.

EU comment

The EU supports the addition of the sentence above on unlicensed and counterfeit products. However, this sentence does not seem to relate well with the title of point 1 and the contents of its first paragraph. Therefore, the EU suggests moving that sentence

directly under the title of the Article 6.9.3. or creating a new separate point under this Article.

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, dosage regimens, ranges of withdrawal period and different durations of treatment that are proposed.~~

EU comments

The EU suggests the following amendments to the paragraph above:

"Marketing authorisation is granted on the basis of the data submitted by the pharmaceutical industry or other applicant and only if the set criteria of safety, quality and efficacy are met. 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 be performed for on each individual antimicrobial agents product and the findings should not be generalised to the active ingredient or antimicrobial class to which the particular active ingredient belongs. Guidance on usage should be provided for all target species, and dosage regimens claimed, taking into consideration the route of administration, 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.~~

EU comments

For consistency reasons, the word "approval" should be replaced by "authorisation" also in the text of the point above.

Furthermore, the title of point 3 is confusing as it does not seem to relate well to the content of that point and is very similar to the title of point 1. Therefore, the EU suggests merging points 1 and 3.

What's more, the EU does not support the deletion of the words "VMPs containing" in the paragraph above. Indeed, it is important to note that the VMP is what is to be considered for approval. A competent authority may not approve an antimicrobial agent as such. A VMP is linked to information about dose, indication, species etc. whereas an antimicrobial agent is merely the active ingredient.

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.~~

EU comment

The EU would like to reiterate its previous comment and suggest replacing the word "registration" by "authorisation" throughout the text. This is necessary to avoid confusion, as

1. the process of "registration" is different from the process of "authorisation" of VMP in the relevant EU legislation on veterinary medicinal products (cf. Directive 2001/82): whereas "registration" does not entail an assessment procedure and is used for mere administrative acts of listing of certain products such as traditional homeopathic medicinal products which are placed on the market without therapeutic indications, "authorisation" does entail a full evaluation of safety and efficacy and the formal legislative decision to approve a product or substance;

2. the terminology in the Code and within this chapter should be consist (e.g. point 1 above refers to "authorisation").

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;

EU comment

The EU suggests replacing the word "efficacy" by the word "effectiveness" in the above point.

Furthermore, the words "containing antimicrobial agents" should be added after "VMP", as only these are targeted in the context of this chapter. This term should preferably be used consistently throughout the text.

- 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 Countries 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.

5. 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;

EU comment

With reference to the comment above, the EU suggests replacing the words "marketed dosage form(s)" by the word "VMP" in the above point.

- d) to ensure the stability of *antimicrobial agent(s)* when mixed with feed or drinking water;

EU comment

With reference to the comment above, the EU suggests replacing the words "antimicrobial agents" by the words "the VMP containing antimicrobial agents" in the above point.

- 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.

6. 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:

- 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*.

EU comment

As they cover essentially the same thing, the EU suggests merging point i) and ii) above, as follows:

" i) Preclinical trials should:

- [...];
- [...];
- [...] ~~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:~~

- ~~— spectrum of activity and mode of action;~~
- ~~— investigate the minimum inhibitory and bactericidal concentrations against recent isolates;~~
- ~~— investigate the time- or concentration-dependent activity or co-dependency;~~
- ~~— investigate the 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:

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.

- 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.

7. 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) ~~p~~ Pathway 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".

- 8. 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.

EU comment

The EU suggests the following clarification and extension for the point above:

"b) The establishment of an ADI for each *the antimicrobial agent*, and an MRL for each animal-derived food, should be undertaken before a VMP containing the antimicrobial agent in question could be considered for marketing authorisation."

- c) For all VMP containing *antimicrobial agent(s)*, withdrawal periods should be established for each animal species in order to ensure produce feed 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 provide methods for regulatory testing of residues in food based on the established marker residues.
9. 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. Establishment of a summary of product characteristics for each veterinary medicinal products containing antimicrobial agent(s) product

The summary of product characteristics contains the information necessary for the appropriate use of VMPs 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;
- 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.

11. 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. 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 VAMPs containing antimicrobial agent(s). VMP labels should have appropriate instructions for disposal and destruction.

13. Control of advertising

All advertising of antimicrobials agents should be compatible with the principles of responsible and prudent use and should be controlled by a codes of advertising standards, and. The relevant authorities must ensure that the advertising of antimicrobial these products:

EU comment

In the point above, the EU suggests adding the words "including on the internet," 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. Training on the usage of antimicrobial agents users

The training on the usage of users of antimicrobials 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 animal feed manufacturers. This training should focus on preserving the effectiveness of antimicrobial agents and include:

EU comment

The EU suggests replacing "animal feed manufacturers" by "manufacturers of medicated animal feeds" throughout the text. Indeed, not all animal feed manufacturers would be concerned by this standard, as only part of them are licenced for the manufacturing of medicated feeds in the EU.

- a) information on disease prevention, and management and mitigation strategies;
- b) the ability of antimicrobials agent(s) to select for resistant 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 condition, proper disposal of unused or expired VMP;

e) record keeping.

15 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:

- supply all the information requested by the national Competent Authority regulatory authorities;
- guarantee the quality of this information in compliance with the provisions of good manufacturing, laboratory and clinical practices;
- 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 VMPs containing antimicrobial agent(s) VAPs:

- only licensed and officially approved VMPs containing antimicrobial agent(s) VAPs should be sold and supplied, and then only through licensed/authorised distribution systems;
- the pharmaceutical industry should provide quality certificates prepared by the *Competent Authority* of the exporting and/or manufacturing countries to the *importing country*;
- 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:

- distribute ~~disseminate~~ information in compliance with the provisions of the granted authorisation;
- discourage ~~ensure that~~ the advertising of VMPs 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 VAMPs 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 ~~All~~ products should be appropriately labelled.
2. The recommendations on the responsible and prudent use of VMPs containing antimicrobials 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 treatment 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~~ prescribe antimicrobial agent(s) only when necessary and taking into consideration the OIE list of antimicrobial agents of veterinary importance;

EU comment

The EU suggests 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. For example, antimicrobials such as 3rd generation cephalosporins and fluoroquinolones should only be chosen in situations where no other antimicrobial can be expected to be effective, preferably based on results of diagnostic tests including antimicrobial susceptibility testing.

- 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 *veterinarian*, 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) known pharmacokinetics and/ tissue distribution to ensure that the selected therapeutic agent is active effective at the site of infection;
 - v) 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.~~

On certain occasions, 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*.

EU comment:

In the paragraph above, the words "On certain occasions" are not very clear; a more specific wording should be used.

The EU therefore suggests replacing "On certain occasions" with the following:

"If, after clinical assessment by a veterinarian, in case of emergencies or in cases where poor disease prognosis is expected, [...]"

- b) Use of combinations of *antimicrobials agents* should be scientifically supported. Combinations of *antimicrobials agents* may be used for their synergistic effect to increase therapeutic efficacy or to broaden the spectrum of activity.

EU comment

The EU would like to reiterate its previous comment and suggest deleting the words "or to broaden the spectrum of activity", as this is in complete contradiction with the concept of prudent use of antimicrobials.

3. Appropriate use of the VMPs containing antimicrobial agent(s) chosen

A prescription for VMPs 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 VMPs 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~~ VMPs 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 VMPs containing veterinary antimicrobial agent(s) drugs should be kept in conformity with the national legislation. Information records should include the following:

- a) quantities of VMPs medication used per animal species;
- b) a list of all VMPs 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 susceptibilities 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 VMPs 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 VMAPs 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 VMAPs 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 VMAPs 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 VMAPs 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;
- jk) 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 VMPs containing antimicrobial agent(s).

Article 6.9.8.

Responsibilities of animal feed manufacturers

1. Animal feed manufacturers preparing medicated feeds should do so only 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. All products should be appropriately labelled.

EU comments

In the interest of responsible and prudent use of antimicrobial agents in veterinary medicine, the EU is of the opinion that the use of VMP containing antimicrobial agents, including in the form of medicated feed, should only be on prescription by a veterinarian. Albeit it is acknowledged that this may not currently be the case in all OIE member countries, point 1 should be drafted in such a way as to encourage OIE members to use veterinary prescription exclusively.

What's more, according to current EU legislation, it is not the manufacturing of medicated feed itself that requires a veterinary prescription, but rather the supply of medicated feed to farmers keeping food producing animals that is allowed only upon presentation of a veterinary prescription. The text should take this legal situation into account.

Furthermore, it is unclear whether the "supervision of a veterinarian" is required for the prescription by another suitably trained person or for the manufacture of the medicated feeds. Indeed, the manufacturing of medicated feed should not necessarily require veterinary supervision. However, the manufacturing of medicated feeds should be performed 1) in premises which have been previously approved by the competent authority and 2) according to HACCP principles, in order to prevent adverse effects with respect to antimicrobial resistance linked e.g. to carry over and cross contamination (see also comment on point 5 of this Article).

Finally, it is unclear what is meant by the word "products" in the second sentence. This should be specified.

Therefore, the EU suggests the following wording:

"The production of medicated feeds containing antimicrobial agents or its supply to farmers keeping food producing animals by manufacturers of medicated animal feeds should be allowed only on the prescription by a veterinarian. Alternatively, such medicated feeds may be prescribed by other suitably trained persons 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 feeds should do so only in premises which have been previously approved for that purpose by the *Competent Authority*. All medicated feeds and medicated premixes 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 feeds should ensure that only approved sources of medications are added to feeds 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 feeds should ensure that medicated animal feeds 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 feeds should implement appropriate production practices to avoid unnecessary carry over and unsafe cross contamination of unmedicated feeds.

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".

— Text deleted.

CHAPTER 6.11.

**ZOONOSES TRANSMISSIBLE
FROM NON-HUMAN PRIMATES**

EU comments

The EU thanks the OIE and supports the proposed changes in this chapter. Some further comments are inserted in the text below.

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.).

Annex XIV (contd)

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.

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 (<i>Mycobacterium tuberculosis</i> 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.	

Annex XIV (contd)

Disease/agent	Animal groups	Schedule	Methods
Other bacterial pathogens (<i>Salmonella</i> , <i>Shigella</i> , <i>Yersinia</i> 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 have to be cultured immediately or to be placed immediately in the 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.

EU comment

As to "other bacterial pathogens", the EU suggests clarifying the requirement to use the most suitable test method, by amending the text in column "method" as follows:

Faecal culture. The testing method to be used should be the method described in the OIE Terrestrial Manual or the relevant ISO method as appropriate. If appropriate, the fresh faeces or rectal swabs have to be cultured immediately or to be placed immediately in the transportation medium, placed immediately in the transportation medium appropriate for the target organism, sample type, holding and transportation temperature in event of an anticipated delay between sampling and testing.

Veterinary Authorities of importing countries should recognise the public health importance of zoonoses listed in the table below 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.

EU comment

In the paragraph above, please replace the words "in the table below" by "in the table above" (editorial).

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;

Annex XIV (contd)

- 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 (<i>Salmonella</i> , <i>Shigella</i> , <i>Yersinia</i> 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	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 (<i>Salmonella</i> , <i>Shigella</i> , <i>Yersinia</i> 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.

EU comment

In the table above, the EU suggests amending the first column of the entry for "Tuberculosis" as follows:

"Tuberculosis (*Mycobacterium tuberculosis complex*)"

Rationale: consistency with the amendment proposed in the table of article 6.11.4., as

also here the whole *M. tuberculosis* complex should be included (i.e. *M. tuberculosis*, *M. bovis*, *M. africanum*, *M. microti*, *M. canetti*, *M. pinnipedi*, *M. caprae* and the Bacillus Calmette-Guérin vaccine strain) since they all are possible causative agents of tuberculosis and may be harbored by non-human primates.

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.

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.

DRAFT CHAPTER 7.X.

**ANIMAL WELFARE AND
BROILER CHICKEN PRODUCTION SYSTEMS**

EU comments

The EU thanks the OIE for redrafting this chapter. The EU can in general support many of the proposed changes in the text, but has comments to a majority of the specific provisions as inserted in the text below.

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 flocks are not included.

EU comment

The EU asks the OIE to consider the following rephrasing of the second sentence of the definition of broiler, as follows:

"Poultry kept in ~~village or~~ backyard flocks are not included."

Justification

The notion of "poultry kept in village flocks" is not clearly defined and it is difficult to understand the difference between this production system and that of backyard flocks. The EU considers it more appropriate to retain the definition below of backyard flocks (see comment below). This would make it quite clear what production systems are covered by the scope of the chapter and which are not.

Harvesting

means the catching and loading of birds on farm for transportation to the *slaughterhouse/abattoir*.

EU comment

As the EU has asked the OIE to consider including sentences which include the terms "temporo-spatial patterns" or "day old chicks" there is a need to define these two terms.

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. Day old chicks can be up to 72 hours old.

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.~~

EU comment

The EU does not support the deletion of this definition and asks the OIE to keep the initially proposed definition of backyard flocks.

Justification

The definition provides an exact description of the production systems that are not covered by the scope of this chapter. For this reason it is important to retain that definition.

Article 7.X.2.

Scope

These recommendations cover the production period from arrival of the 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, regardless of scale, 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.~~

EU comment

The EU asks the OIE to consider the following rewording of the first two sentences of the paragraph above:

"These recommendations cover the production period from arrival of the day old 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.~~"

Justification

"Day old chicks" is the phrase used by the industry. "Day-old birds" is used in other articles and the text should be consistent throughout. The second sentence should be amended for linguistic reasons.

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 confined in a poultry house but provided with access to a restricted outdoor area.

3. Completely outdoor system

At no time during the production period are broilers confined in a poultry house. 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.4.

EU comment

As Article 7.x.3 has been deleted the number of this article should be amended to read:

"Article 7.X.4.3."

Similarly, the numbering of the following articles and references to articles within the chapter need to be amended accordingly.

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.

EU comment

The EU would ask the OIE to consider replacing the paragraph above with the same paragraph on this topic from the beef cattle chapter and adding a sentence on design based outcomes, as follows:

"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 broilers are managed,

also taking into account the strain of bird concerned. The design of the housing system and the resources that are provided will influence the potential for good bird welfare for example by facilitating important innate behaviours"

Justification:

Wherever possible the chapters should be consistent. Outcome-based measurables alone are not always best for welfare as certain measures are more difficult or time consuming to measure at a practical level and thus resource based or design requirements are still important, in certain circumstances, for setting minimum or baseline requirements.

Some measurables can be measured in the farm setting (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 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. 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 is of the opinion that this paragraph provides much guidance. The OIE has stated that the references to scientific papers in this chapter would be put on the OIE website. The EU would ask the OIE to consider whether the paragraph above also should be placed on the OIE website while at the same time elaborating more on each measurable thus providing even more guidance on how to use and interpret the measurables.

Justification:

This would be of added value in the implementation of the standard once adopted.

The following outcome based measurables are useful indicators of broiler welfare:

1. Mortality (dead, culled) and morbidity

Daily, weekly and cumulative mortality (dead or culled) and morbidity rates should be within expected ranges. Any unforeseen increase in the daily mortality or morbidity rate could reflect an animal welfare problem.

EU comments

The word "culled" is used throughout this chapter. However, in the recently adopted chapter on beef cattle the word "killed" is used. The EU therefore suggests replacing the word "cull" in this chapter by the word "kill". The EU also asks the OIE to consider moving the first sentence to Article 7.X.5 section 1b.

Furthermore, the EU suggests using the wording from the beef cattle chapter to describe mortality. Thus, the following sentences should be added to the existing text:

"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 be recorded regularly."

This would necessitate the definition of the word "temporo-spatial pattern".

Justification:

This Article describes the measurables and should therefore not include recommendations such as the first sentence and this sentence should therefore be moved to the relevant Article. The terminology used in the Code should be consistent in all chapters, as well as the wording used to describe the same phenomena. Furthermore "kill" is more easily understood than "cull".

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.

EU comments

The EU does not support the deletion of humanely in the final sentence in the paragraph above and would ask the OIE to consider the following rephrasing so that the sentence reads:

"Regardless if the scoring or assessment system used, broilers that are unable to access feed or water should be humanely killed euthanized as soon as possible after they have been observed."

Furthermore, two of the sentences in this paragraph do not merely describe the measurable but are rather a requirement to be placed in Article 7.X.5. section 1 b. The two sentences are "*Broilers in commercial flocks should be assessed for gait abnormalities, and corrective actions identified to reduce the incidence of problems in subsequent flocks.*" and the final sentence in the paragraph proposed rephrased by the EU. We would ask the OIE to consider moving these two sentences to said article.

Justification:

Terminology and structure should be consistent throughout the chapter.

3. Contact dermatitis

Contact dermatitis affects skin surfaces ~~which~~ that have prolonged contact with litter or other flooring surfaces, ~~including the foot pad, rear surface of the hock and, when severe, the breast area.~~ The conditions ~~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 sScoring systems for contact dermatitis have been developed (see Welfare Quality®, 2009).

EU comments

The EU would ask the OIE to consider rephrasing the first sentence in the above paragraph as follows:

"Contact dermatitis affects skin surfaces that have ~~prolonged~~ contact with wet litter or other wet flooring surfaces."

Furthermore, the EU asks the OIE to consider the following rephrasing of the final sentence in the paragraph above:

"Validated scoring systems for contact dermatitis have been developed for use in the slaughterhouse/abattoir (see Welfare Quality®, 2009)."

Justification

The first sentence does not correctly address the relation between litter and ensuing contact dermatitis as according to the Report of the Scientific Committee on Animal Health and Welfare from 21 March 2000 on the Welfare of Chickens Kept for Meat Production (Broilers), page 38, contact dermatitis is thought to be caused by a combination of wet litter and unspecified chemical factors in the litter. Furthermore current scientific knowledge indicates that such dermatitis may develop quickly.

Such scoring systems in welfare quality were developed for use in slaughterhouses. In addition other broiler welfare evaluation systems at the slaughterhouse exist.

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 both hock burns and lameness for individual birds (Arnould and Colin, 2009). Plumage dirtiness can be assessed as part of on-farm inspections, when the broilers are caught for *transport* to the *slaughterhouse/abattoir* and 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 would ask the OIE to consider adding the following to paragraphs under number 5:

"Metabolic disorders - Ascites occurs when there is less oxygen than normal (e.g. poor ventilation) or there is a higher demand for oxygen (e.g. increased exercise at harvesting). The post mortem changes can be identified at abattoir level as an indicator of poor welfare. Sudden death syndrome has little obvious post mortem change but can

be used as an on farm welfare indicator, since stress has been identified as the key cause. Parasitism and other disorders - There are a number of serious diseases that affect poultry but some can be reduced or avoided by effective vaccine and treatment protocols. The presence or absence of such diseases and/or effective control plans can be used as an indicator of welfare as well as flock health status.

Respiratory and digestive diseases – These may reflect poor management and production practices, as well as ineffective health control."

Justification:

The sentence remaining under this heading does not seem to reflect a definition of a disease or disorder measurable. This also expands on the measurables described as examples in the introductory paragraphs of 7.X.4. on measurable.

If examples of certain disorders / diseases are available then these should be provided. For example, whilst ascites is an issue that has on the whole been resolved by appropriate management of growth and environmental conditions in broilers in the last 10 years in many countries, when ascites is detected at high levels on an individual farm it indicates that there has been a significant welfare problem with that flock that needs to be evaluated and where possible rectified for future flocks / remaining birds

(Olkowski AA, Wojnarowicz C, Nain S, Ling B, Alcorn JM, Laarveld B. Olko; Res Vet Sci. 2008 Aug;85(1):131-40. Epub 2007 Sep 27. A study on pathogenesis of sudden death syndrome in broiler chickens.

Baghbanzadeh A, Decuypere E: Avian Pathol. 2008 Apr;37(2):117-26. Ascites syndrome in broilers: physiological and nutritional perspectives.)

6. Normal Behaviour

Broiler behaviour can be a sensitive indicator of welfare problems.

EU comment

The EU would ask the OIE to consider to not delete the above sentence, but to alter the phrasing as follows:

"Broiler behaviour can be a sensitive indicator of ~~welfare problems~~ the birds' affective state and can indicate how well the animals are coping in their rearing environment."

Justification:

It is always helpful to introduce the concept of what behaviour can tell us about how a bird is feeling and coping.

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).

EU comment

The EU would ask the OIE to consider inserting the following two sentences in the above paragraph before and after the final sentence:

"It may also lead to increased metabolic disorders such as ascites and sudden death."

"Validated methods have been developed for evaluating fearfulness (Welfare Quality 2009)"

Justification:

There are also impacts on health. Welfare Quality protocols are included elsewhere in the text.

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

Panting and wing spreading ~~may~~ indicates heat stress ~~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 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.~~

78. Water and feed consumption

Monitoring daily water consumption can be 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.

89. Performance

EU comment

The EU would ask the OIE to consider inserting the following as a general statement on performance:

"Performance criteria need not necessarily be an indicator of good welfare as for example high growth rates are associated with an increased risk of among other leg problems."

Justification:

There is a need to emphasise that performance criteria need to be used with caution as they do not always provide adequate information on the welfare of the animals.

- 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 liveweight harvested, expressed as a the weight of feed required to produce 1 kg of broiler bodyweight.
- 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.~~).

EU comment

The EU would ask the OIE to consider including an additional performance criteria as follows:

"d) Large variation in bird weight/size within a single age flock - This may indicate either disease issues or a lot of small (runt) birds which can indicate a poor approach to prompt killing of birds. They may not be able to access water and food easily and may not be suitable for processing at the slaughterhouse."

Justification:

Commercial strains of poultry used globally for large scale production have a very consistent and even growth rate, for which the industry provides guidance on ideal growth rates for each strain. Consequently large scale indoor housing systems are designed such that water access is moved to an average bird head height. Small birds (runts) will struggle to access these water points and their health and well-being will be negatively affected and so these birds should be killed (Or removed from the system to

where they can access water if killing is not an option). Large variations in bird size in the first weeks again can also indicate issues with parent flock or hatchery hygiene/ health and again this size variation should be used as an indicator of health and well-being and a trigger for action (either on farm if the issue is on-farm or feedback to the supplier if parent flock / hatchery is a concern).

940. 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 (e.g. skin lesions) and those due to human intervention, e.g. catching. The most ~~frequency~~ prevalent injuries seen during catching are bruises, broken limbs 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 prevalent ~~common~~ traumatic injury.

EU comment

The EU would ask the OIE to consider including "contact dermatitis" among the listed conditions so that the second sentence in the paragraph above reads as follows:

"Injuries include those due to other broilers (scratches, feather loss or wounding due to feather pecking and cannibalism) and those due to environmental conditions (e.g. skin lesions, contact dermatitis) and those due to human intervention, e.g. catching."

Justification:

This is another common condition which it is pertinent to mention here.

104. 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).

112. Vocalisation

Vocalisation can indicate emotional states, both positive and negative and distress in chickens (Jeon et al., 2005).

Article 7.X.5.

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 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 *Terrestrial Code* chapters on OIE listed diseases.

EU comment

The EU would ask the OIE to consider a slight rephrasing of the sentence above as follows:

"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 Terrestrial Code chapters on OIE listed diseases."

Justification:

Producers should be encouraged to aim for a high health status for their flocks.

These programmes should address the control of the major routes for disease and pathogen transmission:

- a) direct transmission from other *poultry*, domesticated and wild animals and humans,
- b) fomites, such as equipment, facilities and *vehicles*,
- c) vectors (e.g., arthropods and rodents),
- d) aerosols,
- e) water supply,
- f) feed.

EU comment

The EU would ask the OIE to consider including a new paragraph on the approach chosen on addressing this issue:

"Programmes should pay particular attention to critical control points in broiler production, for example procedures for partial depopulation (thinning) and final depopulations where there will be movement of vehicles, equipment and people onto and off the production unit when other flocks may be present on the unit. Complete cleansing and disinfection of each housing system between flocks (and where necessary environmental sampling for certain diseases) should be considered necessary to meet higher biosecurity standards."

Justification:

There is a need to mention broiler specific issues rather than a generic list if we know where the key risks are.

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*.

EU comment

The EU asks the OIE to consider the following rephrasing of the first sentence:

"If persons in charge are not able to identify the causes of disease, ill-health or distress, or to correct these, or if they suspect the presence of a reportable disease, they should seek advice from poultry veterinarians or other qualified advisers in order to remedy the situation."

Justification:

It is important to emphasise that action needs to be taken in order to correct the situation. Also veterinarians not specialised in poultry can be competent for detecting diseases.

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 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 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.

EU comment

The EU would ask the OIE to consider including also "lameness" as one of the measurables in the listing.

Justification:

Lameness is a major health problem in broiler production among other because of foot pad dermatitis.

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 the Thermal Heat Index (THI) can assist in identifying the comfort zones for the broilers at varying temperature and relative humidity levels.

EU comment

The EU asks the OIE to consider including a reference to the Thermal Heat Index.

Justification:

Not everyone will know of this index and a reference should be available if the chapter refers to it.

When environmental conditions move outside these zones, various strategies can be used in different production systems to mitigate the adverse effects on the broilers: e.g. high 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.

Management ~~system~~ of the thermal environment should be checked at least twice a day.

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.

EU comment

The EU asks the OIE to consider rephrasing the first sentences of the above paragraph as follows:

"There should be an adequate period of darkness – preferably at least 6 hours, of which at least 4 hours of continuous darkness – during each 24 hour period to allow the birds to rest."

Justification:

The term "an adequate period" is vague and the intention of the provisions should be clarified. There is scientific documentation of the number of hours proposed in Sanotra et al., 2002; Prescott et al., 2003.

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.

EU comment

The EU asks the OIE to consider rephrasing the above sentence as follows:

"The light intensity during the light period should be sufficient – preferably at least 20 lux at bird level – 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."

Justification:

The word "sufficient" is vague and the intention of the provision needs to be clarified. There is scientific documentation of the lux level proposed in Prescott *et al.*, 2003.

There should be a period for gradual adjustment Broilers should be gradually adjusted to lighting changes.

EU comment

The EU asks the OIE to consider adding the following paragraph:

"Lighting patterns should be adjusted at flock level in response to specific welfare problems and on the advice of poultry specialists and veterinarians. For example, metabolic problems such as sudden death syndrome and ascites maybe alleviated by changing light intensities, increasing dark periods and by simulating dawn to dusk light patterns. Outbreaks of cannibalism may also need to be controlled by changes to the lighting programme."

Justification:

Manipulation of lighting programme in response to specific health and welfare problems is an important management tool.

Outcome based measurables: gait₃; metabolic disorders₃; performance₃; ~~normal and abnormal~~ behaviour₃; ~~eye condition~~ and injury rate.

EU comment

The EU does not support the deletion of "eye condition".

Justification:

Eye conditions are often a result of inappropriate lighting.

- c) Air quality

Adequate ventilation is required at all times to provide fresh air.

EU comment

The EU asks the OIE to consider adding the following text to the sentence above:

"Adequate ventilation is required at all times to provide fresh air, to remove waste gases (such as carbon dioxide and ammonia) and to remove excess moisture content from the environment, including the litter."

Justification:

It is equally important to remove waste gases etc. and it furthermore links in with following sentence on ammonia levels.

Ammonia concentration should not routinely exceed 25 ppm at broiler level (Kristensen and Wathes, 2000; Jones et al., 2005).

EU comment

The EU asks the OIE to consider also including a requirement on the level of carbon dioxide:

"The concentration of carbon dioxide (CO₂) should not routinely exceed 3,000 ppm at broiler level."

Justification:

According to the EFSA opinion of 16 May 2012 on the welfare of broilers and broiler breeders "*CO₂ levels of 1% do not cause, by itself, any harm for animals. However an increase in CO₂ levels is usually accompanied by increased levels of other detrimental air pollutants such as ammonia, dust and micro-organisms*". It is thus equally relevant to mention this waste gas, particularly as it is only removed by ventilation.

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 depends 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

Exposure of broilers to sudden or loud noises should be minimised where possible to prevent stress and fear reactions (e.g. piling).

EU comment

The EU asks the OIE to consider amending the provision on noise to be more in line with the beef cattle chapter. The EU proposes the following text for consideration:

"Broilers are adaptable to different levels and types of noise. However, Exposure of broilers to sudden or loud noises should be minimised where possible to prevent stress and fear reactions (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."

Justification:

Consistency of Code chapters while also addressing the issue of agricultural equipment that can generate a considerable 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.

EU comment

The EU asks the OIE to consider the following rephrasing of the sentence above:

"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."

Justification:

Competition for feed and composition of feed have an impact on the welfare of the animals. It is therefore equally appropriate to mention good welfare in this context.

Feed and water should be palatable and free from contaminants 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 provisions should be made to enable young chicks to access to appropriate feed and water.

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 material is desirable in order to encourage dust bathing and foraging.

EU comment

The EU asks the OIE to consider the following rephrasing of the sentence above:

"The provision of loose and dry bedding material in the form of litter, which is dry and friable at the surface, is the preferred substrate for meeting the broiler's behavioural needs for activities such as dust bathing and foraging. However it is important that litter quality is maintained in order to ensure welfare is not compromised by increased levels of disease or contact dermatitis."

Justification:

There is a need to explain more clearly why litter is the preferred substrate to meet specific behavioural needs.

Litter should be managed to minimise any detrimental effects on welfare and health. Poor litter quality can lead to foot pad 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 the following rephrasing of the third sentence in the paragraph above:

"Litter should be replaced ~~or adequately treated~~ when required to prevent disease in the next flock."

Justification:

Treating litter is in contradiction with the stipulation that the floor should have a bedding of uncontaminated substrate.

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.

Slatted floors, often used where a very humid climate precludes the use of other flooring substrates, 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, day-old birds should be placed on an appropriate type of flooring suitable for their size ~~to prevent injury.~~

If housed on litter based systems, before day-old birds enter the poultry house, the floor should have a bedding of uncontaminated substrate (e.g. wood shavings, straw, rice husk, shredded paper, treated used litter) of sufficient depth to elicit normal behaviour and to separate ~~protect~~ them from the floor.

EU comment

The EU asks the OIE to consider the following rephrasing of the sentence above:

"If housed on litter, before day-old birds chicks enter the poultry house, the floor should have a bedding of uncontaminated substrate (e.g. wood shavings, straw, rice husk, shredded paper, ~~treated used litter~~) of sufficient depth to elicit normal behaviour and for insulation to separate them from the floor."

Justification:

The meaning "separate them from the floor" is not quite clear, therefore an alternative wording is suggested in line with the perceived intention of this requirement. The expression "day-old chicks" is used by the industry. As mentioned earlier, treating litter is in contradiction with the stipulation that the floor should have a bedding of uncontaminated substrate.

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.

EU comment

The EU asks the OIE to consider adding "litter quality" to the measurables listed. In addition "metabolic disorders" is mentioned twice.

Justification:

There are a number of defined litter quality assessment protocols (e.g. welfare quality). (This is an outcome based measure effect on the litter but if the OIE wants to separate from an outcome based measure on the bird then list separately.)

- g) Prevention of feather pecking and cannibalism Social environment

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 an appropriate stocking density.

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, production systems, litter quality, ventilation, biosecurity strategy, genetic stocks, and market age and weight ~~of broilers~~.

EU comment

The EU asks the OIE to consider the following rephrasing of the above sentence:

"To determine 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 and be able to move normally, the following factors should be taken into account: management capabilities, ambient conditions, housing systems, production systems, litter quality, ventilation, biosecurity strategy, genetic stocks, and market age and weight."

Furthermore, the EU asks the OIE to consider adding "level of activity and movement" to the list of measurables below.

Justification:

It is important that the birds are able to move to prevent leg disorders. It needs to be borne in mind that the level of activity and movement may not only reflect on the stocking density but also be an expression of e.g. foot pad dermatitis, thus necessitating the elucidation of causation.

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 are old enough to range safely. There should be sufficient exit areas to allow them broilers to enter and leave the poultry house freely.

Management of outdoor areas is important in ~~extensive and semi-intensive partially housed and completely outdoor~~ 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 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 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 outdoor systems.~~

Outcome based measurables: ~~normal and abnormal~~ behaviour; incidence of parasitic infestations; performance; contact dermatitis; feather condition; 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

EU comment

The EU asks the OIE to consider changing the title of this section to "Broiler strain selection"

Justification:

Genetic selection is not addressed in this section.

Welfare and health considerations, in addition to productivity, should be taken into account when choosing a strain for a particular location or production system.

EU comment

The EU asks the OIE to consider the following addition to the above sentence:

"Welfare and health considerations, in addition to productivity, should be taken into account when choosing a strain for a particular location or production system. In particular broilers selected with faster growth rates may have greater risks of poor welfare, including metabolic disorders and contact dermatitis which could be mitigated by the application of certain management procedures."

Furthermore the EU asks the OIE to include among the measurables below "contact dermatitis".

Justification:

More specific advice is provided on birds selected for rapid growth and on managing them. Contact dermatitis is relevant as a measurable for this issue.

Outcome based measurables: gait; metabolic disorders; 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.

EU comment

The EU asks the OIE to consider adding the following text to the above sentence:

"Beak trimming should usually be unnecessary in broilers as they rarely exhibit feather pecking and cannibalism due to their young age."

Justification:

As stated above due to age this intervention should be unnecessary.

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 castration 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.

m) Handling and inspection

Broilers should be inspected at least 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.

EU comment

The EU asks the OIE to consider rephrasing the above second sentence as follows:

"Inspection should have ~~three~~ four main objectives: to identify sick or injured broilers to treat or cull them; to detect and correct any welfare or health problem in the flock; ~~and to pick up dead broilers;~~ and to reduce fearfulness (therefore reducing the risk of panic, smothering and sudden death)"

Justification:

The change is in line with earlier comments on fearfulness.

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 acceptable 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*.~~

EU comment

The EU asks the OIE to consider the following rephrasing of the first sentence above:

"Cervical dislocation is an acceptable method for killing small numbers of broilers if carried out competently as described in Article 7.6.17."

Justification:

The Opinion of the Scientific Panel on Animal Health and Welfare on a request from the Commission related to welfare aspects of the main systems of stunning and killing the main commercial species of animals (The EFSA Journal (2004), 45, 1-29) concludes that cervical dislocation may not concuss poultry and it is therefore uncertain whether it causes immediate unconsciousness, and therefore recommends that cervical dislocation should be performed after the birds have been stunned by some other means (pp 24 and 25). This indicates that the method is not acceptable. However, it has been accepted that this method can be used to kill a small number of birds of less than 3 kg, when no other method is available.

Outcome based measurables: ~~normal and abnormal~~ behaviour; performance; injury rate; mortality; vocalisation; ~~and~~ morbidity.

n) Personnel training

All people responsible for the broilers should receive appropriate training so that they are competent to carry out their responsibilities and should have sufficient knowledge of broiler behaviour, handling techniques, emergency euthanasia procedures, biosecurity, general signs of disease, and indicators of poor *animal welfare* such as stress and pain, and their alleviation.

EU comment

The EU asks the OIE to consider replacing the word "euthanasia" with "killing" so that the sentence above reads:

"All people responsible for the broilers should receive appropriate training 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 their alleviation."

Justification:

The phrase "euthanasia" is not used in e.g. the recently adopted beef cattle chapter. The wording in this chapter should be consistent with chapters already adopted.

Outcome based measurables: all measurables could apply.

o) Emergency plans

EU comment

The EU asks the OIE to consider using the terminology "emergency preparedness" and "contingency plans".

Justification:

Consistency throughout the Code.

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, back up 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 emergency plan for animal health should be developed consistent with national programs established or recommended by *Veterinary Services* as appropriate.

EU comment

The EU asks the OIE to consider adding the following text after the above sentence:

"In listed disease outbreak situations further contingencies should be planned for including minimizing the welfare impact of movement restrictions, requirement for indoor housing (for birds that would usually have access to outdoor ranges or verandas) and emergency killing options."

Justification:

Specific welfare issues are associated with listed disease outbreaks and this aspect needs to be addressed.

- 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.

EU comment

The EU asks the OIE to consider the following rephrasing of the paragraph above:

"The location of broiler farms should be chosen to avoid or minimise the risk ~~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 ~~breaches~~ risks, exposure of broilers to chemical and physical contaminants, noise and adverse climatic conditions. Where such risks cannot be sensibly or practically avoided, there should be appropriate contingency plans (as described at (o)) in place to minimise the impact of such risks on broiler health and welfare"

Justification:

For better clarity.

~~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.

EU comment

The EU asks the OIE to consider the following rephrasing of the sentence above:

"Broiler houses construction ~~should be constructed and~~ including electrical and fuel installations should be designed and fitted to minimise the risk of fire and other hazards."

Justification:

For better clarity.

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*).

EU comment

The EU asks the OIE to consider the following addition to the sentence:

"Outcome based measurables: injury rate (wing and leg fractures, hip dislocation, bruises, back scratches); mortality rate at harvesting and on arrival at the slaughterhouse/abattoir."

Justification:

Wing and leg fractures, bruises etc. are all injuries that are present in cases of rough catching and bad transport conditions.

~~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.~~

~~Cransberg, P.H., P.H. Hemsworth, G.J. Coleman. 2000. Human factors affecting the behavior and productivity of commercial broiler chickens. *British Poultry Science*, 41:272-279~~

~~Dawkins, M.S., Donnelly, C.A., and T.A. Jones. 2004. Chicken welfare is influenced more by housing conditions than by stocking density. *Nature*, 427:342-344.~~

~~Garner, J.P., C. Falcone, P. Wakenell, M. Martin, and J.A. Mench 2002. Reliability and validity of a modified gait scoring system and its use in assessing tibial dyschondroplasia in broilers. *British Poultry Science*, 43, 355–363.~~

~~Glatz, P.C. and Miao, Z.H. 2005. Bird health and handling issues associated with beak-trimming. In: Glatz, P.C. (2005) *Poultry Welfare Issues: Beak Trimming*. Nottingham University Press, Nottingham, United Kingdom, pp. 87–92.~~

~~Hemsworth, P.H., Coleman, J.G., Barnett, J.L., Jones, R.B 1994. Behavioural responses of humans and the productivity of commercial broiler chickens. *Applied Animal Behaviour Science*, 41:101-114.~~

~~Hester, P.Y. and Shea-Moore, M. (2003) Beak trimming egg-laying strains of chickens *World's Poultry Science Journal*, 59, 458–474.~~

~~Jones, E.K.M., Wathes, C.M., and Webster, A.J.F. (2005) Avoidance of atmospheric ammonia by domestic fowl and the effect of early experience, *Applied Animal Behavioral Science*, 90:293-308.~~

~~Kestin, S.C., T.G. Knowles, A.E. Tinch, and N.G. Gregory. 1992. Prevalence of leg weakness in broiler chickens and its relationship with genotype. *Veterinary Record*, 131:190-194.~~

~~Kristensen, H.H., and Waathes, C.M. (2000) Ammonia and poultry, *World Poultry Science Journal*, 56:235-243.~~

~~Mench, J.A. 2004. Lameness. In: *Measuring and Auditing Broiler Welfare*, eds. C.A. Weeks and A. Butterworth. CABI, Wallingford, U.K., pp. 3-18.~~

~~Mench, J.A. and Keeling, L.J. .2001. The social behaviour of domestic birds. In *Social Behaviour in Farm Animals*, ed. L.J. Keeling and H. Gonyou. CAB International, Wallingford, Oxon, UK, p. 177-210.~~

Morrow, C 2008, 'Management as a cause of disease in poultry', in *Poultry Diseases*, 6th edn, eds. M Pattison, P McMullin, J Bradbury, D Alexander, Elsevier, pp 536-547.

Newberry, R.C. Cannibalism. 2004. In: *Welfare of the Laying Hen*, ed. G.C. Perry. Wallingford, UK, CABI Publishing, pp. 227-238.

Nicol, CJ & Scott, GB 1990, 'Pre-slaughter handling and transport of broiler chickens', *Applied Animal Behaviour Science*, vol. 28, pp. 57–73.

Olsson, A. and L.J. Keeling. 2005. Why in earth? Dustbathing behavior in junglefowl and domestic fowl reviewed from a Tinbergian and animal welfare perspective. *Applied Animal Behaviour Science*, 93:259-282.

Rodenburg, T.B. and Koene, P. 2004. Feather pecking and feather loss. In: *Welfare of the Laying Hen*, ed. G.C. Perry. Wallingford, UK, CABI Publishing, pp. 227-238.

RSPCA. 2008. Welfare standards for chickens. Royal Society for Prevention of Cruelty to Animals. <http://www.rspca.org.uk/servlet/Satellite?blobcol=urlblob&blobheader=application%2Fpdf&blobkey=id&blobtable=RSPCABlob&blobwhere=1158755026986&ssbinary=true>.

SCAHAW (Scientific Committee on Animal Health and Animal Welfare), European Commission 2000 *The Welfare of Chickens Kept for Meat production (Broilers)*

Webster, A.B., Fairchild, B.D., Cummings, T.S., Stayer, P.A. 2008. Validation of a three-point gait scoring system for field assessment of walking ability of commercial broilers. *Journal of Applied Poultry Research*, 17, 529–539.

Weeks, C.A., T.G. Knowles, R.G. Gordon, A.E. Kerr, S.T. Payton, and N.T. Tilbrook. 2002. New method for objectively assessing lameness in broiler chickens. *Veterinary Record*, 151, 762–764.

Welfare Quality® Assessment Protocol for Poultry, 2009, ISBN/EAN 978-90-78240-06-8.

— Text deleted.

CHAPTER 7.1.

INTRODUCTION TO THE
RECOMMENDATIONS FOR ANIMAL WELFARE**EU comments**

The EU supports most of the proposed changes in this chapter. The EU has only commented on text that has been revised since the 80th General Session in May 2012.

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 design criteria, be the basis for comparison of *animal welfare* standards and recommendations.

Annex XVI (contd)

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.

EU comment

The EU strongly supports the inclusion of this sentence in Article 7.1.4., but would ask the OIE to consider a slight rewording of the sentence as follows:

"Animals chosen for introduction into new environments should be suited to the local climate and able to adapt successfully to the local environment diseases, parasites and local nutrition as well as being protected against diseases and parasites."

Justification:

It is not only a question of animals being suited (to their indoor and/or outdoor environments) but also being appropriately protected against diseases and parasites.

- ~~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.

EU comment

The EU supports the rewording of "for housed animals". However, the EU would ask the OIE to consider an additional sentence as follows:

"Where animals are kept outdoors they should, wherever possible, be given opportunities to seek protection from adverse weather and predators."

Justification:

Also animals kept outdoors need adequate protection.

- 76) *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.
- 87) *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.
- 98) Where painful procedures cannot be avoided, the resulting pain should be managed to the extent that available methods allow.
- 109) The handling of *animals* should foster a positive relationship between humans and animals and should not cause injury, panic, lasting fear or avoidable stress.
- 1140) Owners and handlers should have sufficient skill and knowledge to ensure that *animals* are treated in accordance with these principles.

 — Text deleted.

CHAPTER 7.8.

USE OF ANIMALS IN RESEARCH AND
EDUCATION**EU comments****The EU thanks the OIE and supports the proposed changes to Article 7.8.10.**

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.

Annex XVII (contd)

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 the opposite of good *welfare*.

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.

Annex XVII (contd)

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.

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 primary 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;

Annex XVII (contd)

- 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.

Annex XVII (contd)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 *animal/veterinarian* 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.

Annex XVII (contd)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.

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 *animals* 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.

Annex XVII (contd)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 *animals* 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.

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*.

Annex XVII (contd)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 unforeseen 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 XVII (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.

— Text deleted.

CHAPTER 7.9.
**ANIMAL WELFARE
 AND BEEF CATTLE PRODUCTION SYSTEMS**

EU comments

The EU thanks the OIE and in the main supports the proposed changes in this chapter. The EU does however have some comments as indicated below.

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.

EU comment

In Article 7.9.4. number 4 the word "temporo-spatial pattern" should be defined.

Justification:

See relevant Article below.

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.

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.

EU comment

In the second sentence of the paragraph above the word "temporo-spatial pattern" should be defined.

The EU agrees that the mortality rate should be recorded regularly rather than reported. However, the OIE should consider the following rephrasing of the sentence:

"Mortality rates should be recorded regularly, i.e. daily, monthly, annually or with reference to key husbandry activities within the production cycle."

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.

Given the change made to the text it isn't equally appropriate to have lengthy periods between the recordings. Recordings would need to be performed on a more regular basis (daily, weekly) to be meaningful.

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.

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 excessive lifting.

EU comment

The EU strongly supports the proposed additional wording.

Justification:

This emphasises the need to carefully consider whether non-ambulatory animals need to be moved and to reduce likelihood of unnecessary suffering if treatment / management can be managed in situ.

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~~.

EU comments

The EU would ask the OIE to consider a slight rewriting of the text as proposed below:

"Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, behaviour, physical appearance, and changes in weight and body condition."

We also ask the OIE to review the use of the phrases "body condition" and "body condition score" throughout the chapter as the use varies in the different articles.

Justification:

Linguistic purposes and consistency throughout the text.

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 provision of shade, free access to drinking water, and cooling by the use of sprinkled water that penetrates the hair coat.

EU comment

The EU would ask the OIE to consider inserting an additional measure in the third sentence in the paragraph above:

"If the risk of heat stress reaches very high levels the animal handlers should institute an emergency 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."

Justification:

High stocking density increases the heat production and decreases the possibility for the animals to reduce excess body heat.

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 NH₃ 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.

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.

EU comment

The EU strongly supports the proposed second sentence.

Justification:

Scientific research shows that fully slatted floors are detrimental to the health and welfare of cattle. The proposed text has the potential to ameliorate the situation somewhat by providing 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 injury rate~~ injuries and have an adverse effect on growth rate, feed efficiency and behaviour, such as locomotion, resting, feeding and drinking.

EU comment

The EU does not support the proposed change made to the text. The EU would ask the OIE to consider a slight rewriting of the text as proposed below:

"High stocking densities may increase the occurrence of injuries ~~injury rate~~ and have an adverse effect on growth rate, feed efficiency and behaviour, such as locomotion, resting, feeding and drinking."

Justification:

All injuries in livestock systems are a concern, changing this from “injuries” to “injury rate” suggests that a certain level of injury (or injury rate) is acceptable in a housing system. This is not the case. Each injury should be evaluated in its own right and actions taken to reduce or remove the risk.

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.

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~~.

EU comment

The EU would ask the OIE to consider a slight rewriting of the final sentence in the paragraph above as follows:

"These procedures should be performed at as early an age as possible, ideally ~~or~~ using anaesthesia or analgesia under the recommendation or supervision of a veterinarian."

Justification:

The introductory Chapter 7.1.4.9. states: "Where painful procedures cannot be avoided, the resulting pain should be managed to the extent that available methods allow." If appropriate anaesthesia and analgesia are available for food producing animals then these should be used during painful procedures. Neonates feel pain and indeed exposure to pain at very early age will increase their sensitivity to pain in later life.

Future options for enhancing *animal welfare* in relation to these procedures include: 4) 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 tethered should, as a minimum, be able to lie down, turn around and walk.

EU comment

The EU strongly supports this new sentence. The EU would however ask the OIE to consider the following rephrasing of the sentence above:

"Cattle that are kept tethered should, as a minimum, be able to lie down, and if tethered outdoors should also be able to turn around and walk."

Justification:

The new text supports the Introductory Chapter 7.1.4.4. "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." However indoors a tether that enables the animal to turn around and walk might create problems for the animals.

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 conducted 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.

CHAPTER 8.3.

INFECTION WITH BLUETONGUE VIRUSES**EU comments**

The EU thanks the OIE and in general supports the proposed changes to this chapter.

However, the title should be amended to read "[...] virus" (singular), to be consistent with other chapters where several serotypes of the pathogen species exist (e.g. AHS, EHD). Indeed, the causative agent of bluetongue disease is bluetongue virus, i.e. a single virus species. This is also correctly stated in the case definition (cf. first sentence of Article 8.3.1) and should be used consistently throughout the text.

A further comment is inserted in the text below.

Article 8.3.1.

General provisions

A case refers to an *animal* infected with BT virus (BTV).

The following defines the occurrence of BTV infection:

- 1) BTV has been isolated and identified as such from an *animal* or a product derived from that *animal*, or
- 2) viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of BTV has been identified in samples from one or more *animals* showing clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected case, or giving cause for suspicion of previous association or contact with BTV, or
- 3) antibodies to structural or nonstructural proteins of BTV that are not a consequence of vaccination have been identified in one or more *animals* that either show clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected case, or give cause for suspicion of previous association or contact with BTV."

For the purposes of *international trade*, a distinction should be made between a case as defined above and an *animal* that is potentially infectious to vectors.

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

EU comments

As in the title (see general comment above), reference should be made to "bluetongue virus" (singular) throughout the text.

Historically, the global BTV distribution has been confined between the latitudes of approximately 53°N and north of 34°S with a recent extension in Northern Europe.

In the absence of clinical *disease* in a country or *zone*, its BTV status should be determined by an ongoing *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.). The programme may need to be adapted to target parts of the country or *zone* at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology, or proximity to enzootic or incursional zones as described in Articles 8.3.16. to 8.3.21.

All countries or *zones* adjacent to a country or *zone* not having free status should be subjected to similar *surveillance*. The *surveillance* should be carried out over a distance of at least 100 kilometres from the

border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of BTV or a bluetongue *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.) in the country or *zone* not having free status supports a lesser distance.

Standards for diagnostic tests and vaccines 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 8.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BTV status of the ruminant population of the *exporting country or zone*.

Article 8.3.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any BTV related conditions regardless of the BTV status of the ruminant population of the *exporting country or zone*:

- 1) *milk and milk products*;
- 2) *meat and meat products*;
- 3) hides and skins;
- 4) wool and fibre;
- 5) *in vivo* derived bovine embryos and oocytes collected, processed and stored in conformity with the provisions of Chapter 4.7. except for BTV8 (under study).

Article 8.3.3.

BTV free country or zone

- 1) A country or a *zone* may be considered free from BTV when bluetongue is notifiable in the whole country and either:
 - a) a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has demonstrated no evidence of BTV in the country or *zone* during the past two years; or
 - b) an ongoing *surveillance* programme has demonstrated no evidence of *Culicoides* in the country or *zone*.
- 2) A BTV free country or *zone* in which ongoing *vector surveillance*, performed according to point 5 of Article 8.3.19., has found no evidence of *Culicoides* will not lose its free status through the importation of vaccinated, seropositive or infective *animals*, or semen, ~~or~~ embryos ~~or~~ ova from infected countries or *infected zones*.
- 3) A BTV free country or *zone* in which *surveillance* has found evidence that *Culicoides* are present will not lose its free status through the importation of vaccinated or seropositive *animals* from infected countries or *infected zones*, provided:
 - a) the *animals* have been vaccinated, at least 60 days prior to dispatch, in accordance with the *Terrestrial Manual* with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and the *animals* are identified in the accompanying certification as having been vaccinated; or
 - b) the *animals* are not vaccinated and, at least 60 days prior to dispatch, are demonstrated to have specific antibodies against the bluetongue virus serotypes whose presence has been demonstrated in the *exporting country or zone*.

- 4) A BTV free country or *zone* adjacent to an infected country or *infected zone* should include a *zone* as described in Article 8.3.1. in which *surveillance* is conducted in accordance with Articles 8.3.16. to 8.3.21. *Animals* within this *zone* 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 BTV transmission.

Article 8.3.4.

BTV seasonally free zone

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

For the application of Articles 8.3.7., 8.3.10. and 8.3.13., the seasonally free period is taken to commence the day following the last evidence of BTV transmission (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides*.

For the application of Articles 8.3.7., 8.3.10. and 8.3.13., the seasonally free period is taken to conclude either:

- 1) at least 28 days before the earliest date that historical data show bluetongue virus activity has recommenced; or
- 2) immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of adult *Culicoides*.

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

Article 8.3.5.

BTV infected country or zone

For the purposes of this chapter, a BTV infected country or *infected zone* is a clearly defined area where evidence of BTV has been reported during the past two years. Such a country or *zone* may contain a BTV seasonally free *zone*.

Article 8.3.6.

Recommendations for importation from BTV free countries or zones

For ruminants and other BTV susceptible herbivores

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

- 1) the *animals* were kept in a BTV free country or *zone* since birth or for at least 60 days prior to shipment; or
- 2) the *animals* were kept in a BTV free country or *zone* for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual* and remained in the BTV free country or *zone* until shipment; or
- 3) the *animals* were kept in a BTV free country or *zone* for at least seven days, then were subjected, with negative results, to an agent identification test according to the *Terrestrial Manual*, and remained in the BTV free country or *zone* until shipment; or

Annex XIX (contd)

- 4) the *animals*:
- a) were kept in a BTV free country or *zone* for at least seven days;
 - b) were vaccinated, at least 60 days before the introduction into the free country or *zone*, in accordance with the *Terrestrial Manual* against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme as described in Articles 8.3.16. to 8.3.21.;
 - c) were identified as having been vaccinated; and
 - d) remained in the BTV free country or *zone* until shipment;

AND

- 5) if the *animals* were exported from a free *zone* within an infected country, either:
- a) did not transit through an *infected zone* during transportation to the *place of shipment*; or
 - b) were protected from attack from *Culicoides* at all times when transiting through an *infected zone*; or
 - c) had been vaccinated in accordance with point 4 above.

Article 8.3.7.

Recommendations for importation from BTV seasonally free zonesFor ruminants and other BTV susceptible herbivores

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

- 1) were kept during the seasonally free period in a BTV seasonally free *zone* since birth or for at least 60 days prior to shipment; or
- 2) were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual*, with negative results, carried out at least 28 days after the commencement of the residence period; or
- 3) were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after the commencement of the residence period; or
- 4) were kept during the seasonally free period in a BTV seasonally free *zone* and were vaccinated, at least 60 days before the introduction into the free country or *zone*, 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 8.3.16. to 8.3.21. and were identified as having been vaccinated and remained in the BTV free country or *zone* until shipment;

AND

- 5) either:
- a) did not transit through an *infected zone* during transportation to the *place of shipment*, or
 - b) were protected from attack from *Culicoides* at all times when transiting through an *infected zone*; or
 - c) were vaccinated in accordance with point 4 above.

Article 8.3.8.

Recommendations for importation from BTV infected countries or zones

For ruminants and other BTV susceptible herbivores

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

- 1) were protected from attack from *Culicoides* in a *vector-protected establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or
- 2) were protected from attack from *Culicoides* in a *vector-protected establishment* for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, carried out at least 28 days after introduction into the *vector-protected establishment*; or
- 3) were protected from attack from *Culicoides* in a *vector-protected establishment* for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after introduction into the *vector-protected establishment*; or
- 4) were vaccinated, at least 60 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 8.3.16. to 8.3.21., and were identified in the accompanying certification as having been vaccinated or, if demonstrated to have antibodies, have been protected from vectors for at least 60 days prior to shipment; or
- 5) demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21.

Article 8.3.9.

Recommendations for importation from BTV free countries or zones

For semen of ruminants and other BTV susceptible herbivores

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

Annex XIX (contd)

- 1) the donor *animals*:
 - a) were kept in a BTV free country or *zone* for at least 60 days before commencement of, and during, collection of the semen; or
 - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after the last collection for this consignment, with negative results; or
 - c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.3.10.

Recommendations for importation from BTV seasonally free zonesFor semen of ruminants and other BTV susceptible herbivores

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

- 1) the donor *animals*:
 - a) were kept during the BTV seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the semen; or
 - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or
 - c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.3.11.

Recommendations for importation from BTV infected countries or zonesFor semen of ruminants and other BTV susceptible herbivores

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

Annex XIX (contd)

- 1) the donor *animals*:
 - a) were kept in a *vector-protected establishment* for at least 60 days before commencement of, and during, collection of the semen; or
 - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or
 - c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.3.12.

Recommendations for importation from BTV free countries or zonesFor *in vivo* derived embryos of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

- 1) the donor females:
 - a) were kept in a BTV free country or *zone* for at least the 60 days prior to, and at the time of, collection of the embryos; or
 - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or
 - c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.3.13.

Recommendations for importation from BTV seasonally free zonesFor *in vivo* derived embryos ~~/ or~~ oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

- 1) the donor females:
 - a) were kept during the seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the embryos ~~/ or~~ oocytes; or

Annex XIX (contd)

- b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or
 - c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;
- 2) the embryos/ or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.3.14.

Recommendations for importation from BTV infected countries or zones

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

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

- 1) the donor females:
 - a) were kept in a *vector-protected establishment* for at least 60 days before commencement of, and during, collection of the embryos/ or oocytes; or
 - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or
 - c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;
- 2) the embryos/ or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.3.15.

Protecting animals from Culicoides attack1. Vector-protected establishment or facility

The *establishment* or *facility* should be approved by the *Veterinary Authority* and the means of protection of the ~~*establishment* or *facility*~~ should at least comprise the following:

- a) Appropriate physical barriers at entry and exit points, e.g. 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 the manufacturers' instructions;
- c) *vector surveillance* and control within and around the building;
- d) measures to limit or eliminate breeding sites for *vectors* in the vicinity of the *establishment* or facility;
- e) standard operating procedures, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of *animals* to the place of *loading*.

2. During transportation

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

Potential *risk management* strategies include:

- a) treating *animals* with insect repellents prior to and during transportation;
- b) *loading*, transporting and *unloading animals* at times of low *vector* activity (i.e. bright sunshine, low temperature);
- c) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the *animals* are held behind insect proof netting;
- d) darkening the interior of the *vehicle*, for example by covering the roof ~~and~~ or sides of *vehicles* with shadecloth;
- e) *surveillance* for *vectors* at common stopping and offloading points to gain information on seasonal variations;
- f) using historical information ~~and~~ or information from appropriately verified and validated BTV epidemiological models to identify low risk ports and transport routes.

Article 8.3.16.

Surveillance: introduction

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

Articles 8.3.16. to 8.3.21. define the principles and provide a guide on the *surveillance* for BT complementary to Chapter 1.4. and for *vectors* complementary to Chapter 1.5., applicable to Members seeking to determine their BT status. This may be for the entire country or *zone*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of BT status is also provided.

BT is a *vector-borne infection* transmitted by different species of *Culicoides* insects in a range of ecosystems.

An important component of BT epidemiology is vectorial capacity which provides a measure of *disease risk* that incorporates *vector* competence, abundance, biting rates, survival rates and extrinsic *incubation period*.

However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context. Therefore, *surveillance* for BT should focus on transmission in domestic ruminants.

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

Annex XIX (contd)

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

~~Article 8.3.17.~~~~Surveillance: case definition~~

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

~~For the purposes of international trade, a distinction should be made between a case as defined below and an animal that is potentially infectious to vectors. The conditions for trade are defined in Articles 8.3.1. to 8.3.15. of this chapter.~~

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

~~The following defines the occurrence of BTV infection:~~

- ~~1. BTV has been isolated and identified as such from an animal or a product derived from that animal, or~~
- ~~2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of BTV has been identified in samples from one or more animals showing clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected case, or giving cause for suspicion of previous association or contact with BTV, or~~
- ~~3. antibodies to structural or nonstructural proteins of BTV that are not a consequence of vaccination have been identified in one or more animals that either show clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected case, or give cause for suspicion of previous association or contact with BTV.~~

Article 8.3.17⁹.**Surveillance: general conditions and methods**

- 1) A surveillance system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:
 - a) a formal and ongoing system for detecting and investigating outbreaks of disease should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of BT to a laboratory for BT diagnosis as described in the *Terrestrial Manual*;
 - c) a system for recording, managing and analysing diagnostic and surveillance data should be in place.
- 2) The BT surveillance programme should:
 - a) in a country, **or** zone free or seasonally free, include an early warning system for reporting suspicious cases. Farmers and workers, who have regular contact with domestic ruminants, as well as diagnosticians, should report promptly any suspicion of BT to the *Veterinary Authority*.

They should be supported directly or indirectly (e.g. through private *veterinarians* or *Veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. An effective *surveillance* system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is BTV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected cases of BT should be investigated immediately and samples should be taken and submitted to 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*.

Generally, the conditions to prevent exposure of susceptible *animals* to BTV infected *vectors* will be difficult to apply. However, under specific situations, in establishments such as *artificial insemination centres* or *quarantine stations* exposure to *vectors* may be preventable. The testing requirements for *animals* kept in these facilities are described in Articles 8.3.11. and 8.3.14.

Article 8.3.189.

Surveillance strategies

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

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

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

A Member should justify the *surveillance* strategy chosen as being adequate to detect the presence of BTV *infection* in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. sheep).

Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. cattle).

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

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

Annex XIX (contd)

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect evidence of *infection* if it were to occur at a predetermined minimum rate. The sample size and expected prevalence determine the level of confidence in the results of the survey. The Member 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 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 those which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease* or *infection* are technically well defined. The design of *surveillance* programmes to prove the absence of BTV *infection* and circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

1. Clinical surveillance

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

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

2. Serological surveillance

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

Surveillance may include serological surveys, for example *abattoir* surveys, the use of cattle as sentinel *animals* (which should be individually identifiable), or a combination of methods. *Surveillance* may also be conducted by sampling and testing of bulk milk using an ELISA, as prescribed in the *Terrestrial Manual*.

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

- a) natural *infection* with BTV,
- b) *vaccination* against BTV,
- c) maternal antibodies,
- d) positive results due to the lack of specificity of the test.

It may be possible to use sera collected for other survey purposes for BTV *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of BTV *infection* should not be compromised.

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

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

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

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

3. Virological surveillance

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

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

- a) to identify virus circulation in at risk populations,
- b) to confirm clinically suspect cases,
- c) to follow up positive serological results,
- d) to better 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 are the preferred strategy for BTV *surveillance*. They comprise groups of unexposed *animals* managed at fixed locations and sampled regularly to detect new BTV *infections*.

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

Annex XIX (contd)

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

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

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

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

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

5. Vector surveillance

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

The main purpose of *vector surveillance* is to determine areas of different levels of risk and local details of seasonality by determining the various *vector* species present in an area, their respective seasonal occurrence, and abundance. *Vector surveillance* has particular relevance to potential areas of spread.

Long term *surveillance* can also be used to assess *vector* suppression measures.

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

Vector surveillance should be based on scientific sampling techniques. The choice of the number and type of traps to be used in *vector surveillance* and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

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

The use of a *vector surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low *vector infection* rates mean that such detections can be rare.

Other *surveillance* strategies, (e.g. such as the use of sentinel *animals* of domestic ruminants), are preferred to detect virus circulation.

Article 8.3. ~~1920~~.

Documentation of BTV infection free status

1. Members declaring freedom from BTV infection for the country or zone: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member declaring freedom from BTV *infection* for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter, to demonstrate absence of BTV *infection* during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a *laboratory* able to undertake identification of BTV *infection* through virus detection and antibody tests described in the *Terrestrial Manual*. This *surveillance* should be targeted to non-vaccinated *animals*. Clinical *surveillance* may be effective in sheep while serological *surveillance* is more appropriate in cattle.

2. Additional requirements for countries or zones that practise vaccination

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

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

Article 8.3. ~~2021~~.

The use and interpretation of serological and virus detection tests

1. Serological testing

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

Annex XIX (contd)2. Virus detection

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

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

- a) The nested PCR assay detects BTV nucleic acid in ruminants long after the clearance of infectious virus. Thus positive PCR results do not necessarily coincide with active *infection* of ruminants. Furthermore, the nested PCR assay is especially prone to template contamination, thus there is considerable risk of false positive results.
- b) PCR procedures other than real time PCR allow sequence analysis of viral amplicons from ruminant tissues, insect *vectors* or virus isolates. These sequence data are useful for creating data bases to facilitate important epidemiological studies, including the possible distinction of field and vaccine virus strains of BTV, genotype characterization of field strains of BTV, and potential genetic divergence of BTV relevant to vaccine and diagnostic testing strategies.

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

Fig. 1. Application of laboratory tests in serological surveillance

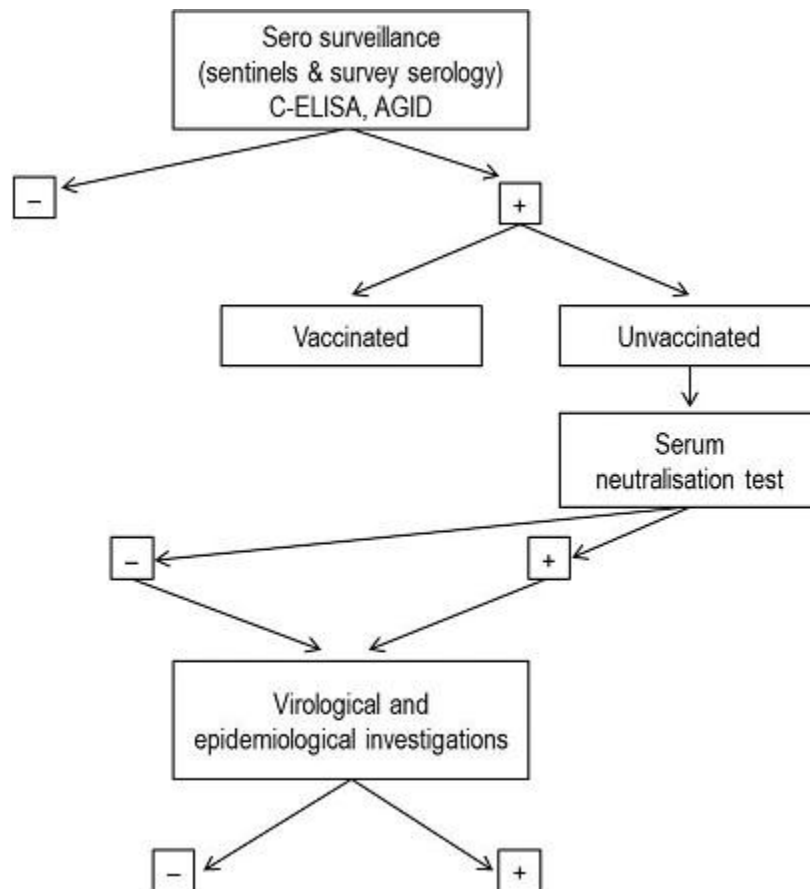
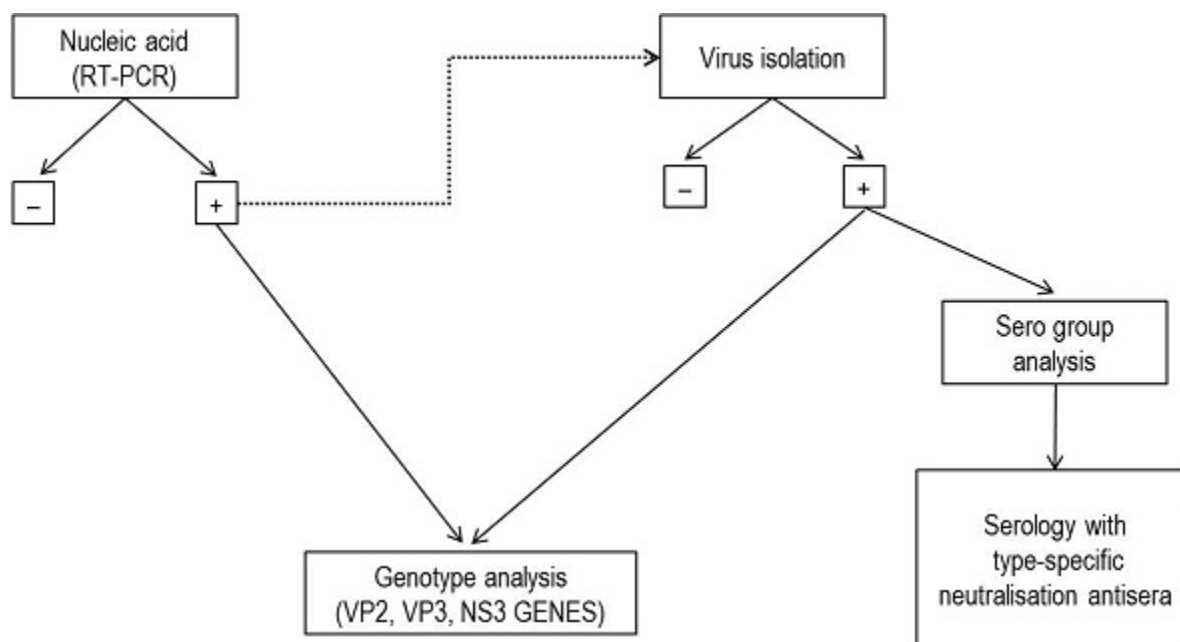


Fig 2. Application of laboratory tests in virological surveillance



— Text deleted.

CHAPTER 8.4.

INFECTION WITH *ECHINOCOCCUS GRANULOSUS***EU comments**

The EU thanks the OIE and in general supports the proposed changes to this chapter. However, the EU cannot support the proposed treatment time period for canids imported from infected countries. A specific comment to this effect as well as some further comments is inserted in the text below.

Article 8.4.1.

General provisions

Echinococcus granulosus is a widely distributed cestode (tapeworm) ~~found worldwide~~. The adult worms occur in the small intestines 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 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 canid 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 e~~ 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.

EU comment

In the first sentence of the paragraph above, the EU is of the opinion that it would be useful here to specify also how infection of dogs can be prevented, by adding the following after "infection of canids":

"[...] by elimination of hydatid-infected offal at slaughterhouses".

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*, *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 prevention and control of infection with *E. granulosus*, the *Veterinary Authority* or other *Competent Authority* should carry out community awareness programmes on 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, 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 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 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; where 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, and would prefer the interval to be 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, 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 hydatid~~s~~ eysts.
- b) When hydatid~~s~~ eysts are detected during post-mortem meat inspection:
 - i) offal containing hydatid~~s~~ eysts 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 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 canid faecal samples from the environment.
- b) Appropriate monitoring strategies should be designed according to local conditions, in particular, where large populations of stray dogs and wild canids exist. Under these circumstances surveillance of environmental samples (faeces, soil) may provide a useful indicator of infection pressure.
- e) ~~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 hydatid cysts in livestock in *slaughterhouses/abattoirs*.
- b) Data collected should be used for the design or adaptation of control programmes.

Veterinary Authorities should use any information 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

EU comment

As not only international commercial movements of dogs and wild canids are concerned, the EU suggests amending the title of this article as follows:

"Recommendations for the importation and international movement 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 48 and 72 hours prior to shipment with praziquantel (5 mg/kg), or another cestocidal product with comparable efficacy against intestinal forms of *E. granulosus*;

EU comments

The EU does not agree with the proposed treatment time period, and refers to its previous comment and the scientific opinion of EFSA (<http://www.efsa.europa.eu/en/efsajournal/pub/441.htm>) which states that "The treatment should be administered between 24 and 48h prior to departure so that the probability of re-infection in the country of origin, and the probability of viable egg elimination in the importing country are reduced".

Indeed, 24h is the well accepted minimum time necessary to eliminate viable eggs, whereas limiting the treatment to a maximum of 48h prior to departure would limit the risk of reinfection.

Since the OIE has proposed to add the point 2 below, requiring adequate precautions to be taken to avoid reinfection, the EU could support a maximum treatment time of 72h prior to departure.

However, the EU cannot support a minimum treatment time of 48h prior to departure and requests the OIE to provide the scientific rationale for that proposal.

Furthermore, to avoid confusion and to be in line with the wording of point 2 below, the word "shipment" should be replaced by "embarkation" in point 1 above.

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 in offal

For the inactivation of *E. granulosus* cysts 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.

— Text deleted.

CHAPTER X . X .

INFECTION WITH *ECHINOCOCCUS*
*MULTILOCULARIS***EU comments**

The EU thanks the OIE and in general supports the proposed changes to this chapter. However, the EU cannot support the proposed treatment time period for canids imported from infected countries. A specific comment to this effect as well as further comments is inserted in the text below.

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 intestines of canids (definitive hosts), particularly foxes, and larval stages (metacestode) in tissues of various liver and other organs of other mammals, in hosts (commonly rodents), (intermediate hosts), including humans are infected occasionally. ~~Infection with the larval stage of the parasite in the intermediate host, which causes severe disease, in humans (referred to as 'alveolar 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 hosts 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 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.

EU comment

In order to avoid confusion, the EU suggests replacing the words "canine faeces" by "faeces of canids" at the end of the paragraph above, as it is not clear whether "canine" would refer only to dogs or also other canids.

Indeed, also fox faeces or other wild canid faeces play a role and should be referred to here.

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 ~~can~~ be reduced by good food hygiene and personal

hygiene, community health education and preventing infection of dogs ~~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*.]

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* 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 makes a control programme 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 monitoring strategies should be designed according to local conditions, in particular, where large populations of definitive hosts exist. Under these circumstances environmental sampling (faeces) may provide a useful indicator of infection pressure.
2. Surveillance in slaughterhouses/abattoirs
 - a) The *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 information 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.

Article X.X.4.

Recommendations for the importation of dogs⁷ 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 48 and 72 hours prior to shipment with praziquantel (5 mg/kg), or another cestocidal product with a comparable efficacy against intestinal forms of *E. multilocularis*

EU comment

The EU does not agree with the proposed treatment time period, and refers to its previous comment and the scientific opinion of EFSA

(<http://www.efsa.europa.eu/en/efsajournal/pub/441.htm>) which states that "*The treatment should be administered between 24 and 48h prior to departure so that the probability of re-infection in the country of origin, and the probability of viable egg elimination in the importing country are reduced*".

Indeed, 24h is the well accepted minimum time necessary to eliminate viable eggs, whereas limiting the treatment to a maximum of 48h prior to departure would limit the risk of reinfection.

Since the OIE has proposed to add the point 2 below, requiring adequate precautions to be taken to avoid reinfection, the EU could support a maximum treatment time of 72h prior to departure.

However, the EU cannot support a minimum treatment time of 48h prior to departure and requests the OIE to provide the scientific rationale for that proposal.

Furthermore, to avoid confusion and to be in line with the wording of point 2 below, the word "shipment" should be replaced by "embarkation" in point 1 above.

2. adequate precautions have been taken to avoid reinfection of the *animal* between treatment and embarkation.

— Text deleted.

CHAPTER 8.13.

INFECTION WITH *TRICHINELLA* SPP.**EU comments**

The EU would like to thank the OIE for the progress made in the draft Chapter 8.13 of the OIE Terrestrial Animal Health Code and for inviting the European Commission to participate as observer to the OIE *ad hoc* group meeting of 23 to 25 July 2012.

The EU would like to remind the OIE that it is co-chairing the development of Codex Alimentarius guidelines on parasites in meat and fully supports consistency between both OIE and Codex Alimentarius draft proposals. In order to further develop the Codex guidelines, while taking into account the OIE guidance, and in view of the on-going revision of EU pig meat inspection rules, the EU would support the adoption of the OIE guidance at its earliest convenience.

The EU considers that significant progress has been made with this chapter. In line with the objective of ensuring consistency with the Codex guidelines, the EU would like to make the following comments:

1. The Codex Committee for Food Hygiene (CCFH) at its meeting in New Orleans from 12 to 16 November 2012 discussed several pathways to consider the public health concern including the one proposed in the OIE draft Chapter 8.13. The CCFH, however, also supported an alternative pathway to the one described in Chapter 8.13 and encouraged Members to collaborate with their national OIE Delegates to ensure alignment of Codex and OIE work on *Trichinella*. Based on the outcome of the CCFH meeting and considering pre-harvest control options and the development of a negligible risk compartment as an OIE competence, the EU requests the OIE to address the pre-harvest control options for an alternative pathway leading to a negligible risk compartment. In particular, more flexibility should be given as regards the verification of the on-farm conditions. Specific suggestions have been made in the text below to address this.

2. The EU accepts the current limitation to a negligible risk status for herds or compartments in order to reach adoption of the guidelines as soon as possible. However, it would like to know the reason for the deletion of the notion of negligible risk status for countries by the OIE. Several EU Member States have made huge efforts to successfully achieve this status in accordance with former guidance of the OIE.

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 of which have been designated as species. There is geographical variation amongst the genotypes.

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*;

EU comment

In point a) above, the EU suggests replacing the text by the following (text taken from the JOV/AO proposal):

"a) none of the animals has access to outdoor facilities unless the food business operator can show by a risk analysis to the satisfaction of the Veterinary Authority that the time period, facilities and circumstances of outdoor access do not pose a danger for introduction of *Trichinella* in the holding."

Rationale:

The prevention of exposure of pigs to rodents and wildlife is the only specific measure for the on-farm control of *Trichinella* and is of major importance. All other measures

and prerequisites are general measures described in such chapters of the OIE animal health Terrestrial Code. It should therefore be better defined/specified.

- b) raw food waste of animal origin should not be present at the farm level;
- 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 disposed of in accordance with provisions of Chapter 4.12.;

EU comment

In point e) above, the EU proposes to add the following additional sentence:

"In remote areas where this may not be possible, dead animals must be immediately removed from the pigsty and stored in such a way that rodents, wildlife or other animals have no access to the dead animals."

Rationale:

The immediate removal of dead animals may not always be possible in remote areas, therefore alternatives must be considered without increasing the risk.

- 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, a minimum of 6 months apart, have been made in the 12 months preceding recognition to verify compliance with good management practices described in point 1.;

EU comment

Point b) above seems overly prescriptive. The EU therefore suggests replacing the text by the following:

"b) visits of holdings recognised as applying controlled housing conditions are carried out periodically. The frequency of inspections shall be risk-based, taking account of disease history and prevalence, previous findings, the geographical area, local susceptible wildlife, animal husbandry practices, veterinary supervision and farmers' compliance, as well as slaughterhouse monitoring results if applied."

Rationale:

Some flexibility should be provided to avoid a disproportionate burden for the Veterinary Authority by extended on-farm visits, by allowing for a risk based approach that would make use of information available to the Veterinary Authority, including slaughterhouse monitoring results, in the risk analysis defining the frequency of visits. This would also be in line with discussions at CCFH (Codex Committee for Food Hygiene). See also rationale for the first specific comment (Article 8.13.3. point 1 a).

- c) a subsequent programme of audits is conducted.

EU comment

Point c) above also seems overly prescriptive. The EU therefore suggests adding the following after the word "conducted":

"[...] which takes into account the factors described under point b, especially slaughterhouse monitoring results if applied."

Rationale:

See justification of the comment under Article 8.13.3. point 1 a) above.

Alternatively, points 2 b) and c) above could be merged, as point 2 b) as proposed by the EU already covers periodic visits to herds subsequent to official recognition.

Article 8.13.4.

Prerequisite criteria for the establishment of a compartment with a negligible risk of *Trichinella* infection in domestic pigs kept under controlled management conditions

A *compartment* with a negligible risk of *Trichinella* infection in domestic pigs kept under controlled management conditions can only be established if the following criteria 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 is established between the *Veterinary Authority* and the Public Health 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;
- 6) *surveillance* appropriate to the assessed epidemiological situation and capable of detecting the presence of *Trichinella* infection (including genotype, if relevant) in domestic pigs and 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

A *compartment* 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 requirements in Article 8.13.3.;
- 2) the criteria described in Article 8.13.4. have 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 the prevailing, or historical, 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.;

EU comment

The EU proposes to slightly amend point 4) above as follows:

"[...] a subsequent programme of audits of all herds within the compartment, which takes into account slaughterhouse monitoring if applied, is in place [...]"

Rationale:

Slaughterhouse monitoring should be taken into account in the subsequent programme of audits to avoid a disproportionate burden for the Veterinary Authority (preferably a representative monitoring plan).

- 5) if the audit identified a lack of compliance with one or more of the criteria described in Article 8.13.3. and the *Veterinary Authority* determined 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

Point 5) above should begin as follows:

"if the audit or slaughterhouse monitoring identified [...]"

Rationale:

In case slaughterhouse monitoring results in the finding of positive pigs, the status of the herd should also be withdrawn.

Furthermore, the following sentence should be added at the end of point 5:

"The compartment may include all herds in a country or region which comply with the conditions in this Chapter."

Rationale:

It should be clarified that the application of negligible risk compartment to all herds in a country or zone that comply with the relevant criteria is possible.

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 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 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].

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 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 the digestion method for the detection of *Trichinella* larvae as described in the *Terrestrial Manual*.

— Text deleted.

CHAPTER 8.12.

RINDERPEST

EU comments

The EU is of the opinion that this proposed modified chapter still needs substantial revision and is not ready for adoption as it stands.

As a general comment, it would be desirable to have this draft chapter adopted at the same time as the international contingency plan. As the international contingency plan is currently being prepared by the JAC and its contents are thus not yet known to Member Countries, it will otherwise be difficult to support the adoption of the respective changes to the chapter.

The OIE should consider renaming the chapter into "Infection with Rinderpest virus", for consistency with other chapters.

Some further specific comments are inserted in the text below.

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.

EU comment

In the paragraph above, please delete the word "as" before "RPV-containing" (editorial).

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.

Article 8.12.3.

Ongoing surveillance post global freedom

All countries in the world, whether or not Members of the OIE, have completed all the procedures necessary to be recognised as free from RP *infection* and annual re-confirmation of RP absence is no longer required. However, countries are still required to carry out general *surveillance* in accordance with Chapter 1.4. to detect RP 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.

EU comment

In the paragraph above, please replace "RP" by "RPV" or "rinderpest", as appropriate, for reasons of consistency with the rest of the chapter.

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 related conditions.

EU comment

In the paragraph above, please replace "RP" by "rinderpest", for consistency with the rest of the chapter.

Article 8.12.5.

Response to recurrence of RP

EU comment

In the title above, please replace "RP" by "rinderpest", for consistency with the rest of the chapter.

Furthermore, this article appears to need substantial redrafting in clear language, to be in line with OIE standards.

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' 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; diarrhoea; dysentery; dehydration or *death*;
- b) necropsy findings of haemorrhages on serosal surfaces; haemorrhages and erosions on alimentary mucosal surfaces; 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 be differentiated, 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.

EU comment

From the wording of point 1 above, it is unclear what exactly is defined as a suspected case: only the detection of antibodies (as clearly stated in the last paragraph) or also the clinical or necropsy findings of "stomatitis-enteritis syndrome" as described above. This should be clarified.

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 must be 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.

EU comments

As the first sentence of the paragraph above relates to and modifies the notification obligations of OIE Member Countries as regards rinderpest, the EU suggests moving it to Article 8.12.2. "Definitions and general provisions" and to slightly reword it to be in line with similar provisions in other chapters, as follows:

"For the purpose of the Terrestrial Code: in the post-eradication era, any direct or indirect detection of RPV in an *animal* or animal product shall be notified immediately to OIE and FAO. Confirmation in an appointed OIE-FAO Reference Laboratory must be sought immediately."

Indeed, reporting of indirect detection (i.e. antibodies) considerably changes the notification obligations. Furthermore, a reporting obligation of OIE Members to the FAO should not be introduced in the OIE Code.

Consequently, the second sentence above, if to be retained at all, should be moved to the beginning of point 4 below ("Procedures to be followed...") and be reworded as follows:

"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".

Upon detection of a suspected case, the national contingency plan should be implemented immediately. If the contingency procedure cannot rule out the suspicion of rinderpest RP, 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 dispatched to one of the appointed OIE-FAO Reference Laboratories for rinderpest RP to enable molecular characterisation of the virus to facilitate identification of its source. A full epidemiological investigation should simultaneously be conducted to provide supporting information and to assist in identifying the possible source and spread of the virus.

EU comments

For clarity reasons, the EU suggests adding the following to the first sentence of the paragraph above:

"in order to rule out infection with rinderpest virus".

It is also unclear what is meant by "suspected case" in the first sentence (cf. EU comment above), i.e. should every clinical suspicion of BVD/MD immediately trigger the national rinderpest contingency plan.

In addition, it is unclear what is meant by an "international reference laboratory" in the second sentence, and if this is different from the "appointed OIE-FAO Reference Laboratories". This should be clarified.

Furthermore, as the reason for sending a sample to an appointed OIE-FAO Reference Laboratory is to confirm or rule out the suspicion of rinderpest, the last part of the second sentence should be amended as follows:

"[...] to one of the appointed OIE-FAO Reference Laboratories for rinderpest for confirmation and, if applicable, for molecular characterisation of the RPV isolate or nucleic acid amplification product in order to facilitate identification of its source".

3. Definition of a case of rinderpest RP

Rinderpest RP should be considered as confirmed when, based on a report from an 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

Immediately following the confirmation of the presence of RPV virus, viral RNA or antibody, the 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 Chapter 8.12. of the *Terrestrial Animal Health Code* 2010 Edition.

EU comment

For reasons of legal certainty, an explicit reference to the respective articles of the 2010 version of Chapter 8.12. should be added in the point above.

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.

EU comment

For reasons of clarity, the second sentence of the paragraph above should be moved to the end of this article (after "[...] evidence by the OIE").

The time needed to recover rinderpest RP free status of the entire country or of the *containment zone*, if one is established, depends on the methods employed to achieve the elimination of *infection*.

EU comment

In the paragraph above, reference is made to the "entire country" or to the "containment zone", whereas the first paragraph of this article refers to "country or zone". This seems to be inconsistent and should be clarified.

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.

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.

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 require reestablishment of an internationally coordinated rinderpest RP eradication programme and assessments of rinderpest RP free country status.

EU comment

In the opinion of the EU, global freedom can only be reinstated if the country or zone where an outbreak was confirmed has regained freedom, in accordance with Article 8.12.6. Therefore, a point 7 should be added as follows:

"7) the country or zone concerned by an outbreak of rinderpest has regained free status in accordance with Article 8.12.6."

Furthermore, in the light of the criteria of Article 8.12.6. (3 months waiting period, international expert mission), a period of 6 months for reinstating global freedom after an outbreak seems too short, especially when considering that all countries would otherwise need to demonstrate freedom again in accordance with the 2010 version of the Code chapter.

Article 8.12.8.

Surveillance for recovery of RP free status

EU comment

This article should be moved after Article 8.12.6. (to become 8.12.7.). Thus the current Article 8.12.7. would become 8.12.8.

A country applying for reinstatement of 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 RP susceptible species within the country. In certain areas some *wildlife* populations, such as African buffaloes, act as sentinels for RP *infection*.

EU comment

The EU would like to ask the OIE whether the notion of "all populations of RP susceptible species" in point 1 above would include all wildlife species.

- 2) Given that RP is an acute *infection* with no known carrier state, virological *surveillance* using tests described in the *Terrestrial Manual* should be conducted to confirm clinically 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*.

EU comment

In point 2 above, "an appointed OIE-FAO Reference Laboratory " should not be italicised as there is no definition for that term in the glossary.

- 3) An awareness programme should be established for all animal health professionals including *veterinarians*, both official and private, and livestock owners to ensure that 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 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.~~

EU comments

Article 8.12.6. refers to both infected country or infected zone, whereas this article only refers to the country. There should be consistency in both articles as to the zoning approach.

In addition, in the article above, please replace "RP" by "RPV" or "rinderpest", as appropriate, for consistency with the rest of the chapter.

Article 8.12.9.

Annual update on RPV-containing material

Annual reports should be submitted to the OIE by the end of November each year by the *Veterinary Authority* of the Member hosting an institution holding RPV-containing material. A separate report, drawn up in accordance with the model below should be produced by each institution. A final report should be submitted to the OIE when all material has been destroyed and no new activities are fore seen for the future.

EU comment

For clarity reasons, the EU suggests the following changes to the paragraph above:

"Annual reports on RPV containing material, drawn up in accordance with the model below, should be submitted to the OIE by the end of November each year by the Veterinary Authorities of the Members hosting an institution or institutions holding RPV-containing material. A separate report, drawn up in accordance with the model below should be produced for each institution. A final report should be submitted to the OIE separately for each institution when all material has been destroyed and no new activities are fore seen 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.

Model annual report on Rinderpest Virus (RPV)-containing Material as of 1 November [year]

Name of institution:

Biosecurity level**EU comment****Please add the words "of the facility holding RPV-containing material" after "Biosecurity level".****Indeed, institutions may have several separate laboratories or facilities with different biosafety / biosecurity levels.**

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 <u>Live viruses, including field isolates but excluding vaccine strains</u>	Vaccine <u>stocks including</u> seed strains virus	Other virus isolates <u>potentially infectious materials</u>	Other (serum, tissue etc)
Check [x] if yes	[]	[]	[]	[]
Strain/Genetic characterisation				
Quantity/doses (if applicable)				
Ownership (if other institution)				

Annex XXII (contd)

EU comment

The OIE should consider adding a footnote to the third column clarifying what is meant by "other potentially infectious materials (e.g. blood samples of susceptible species collected for surveillance of diseases other than rinderpest during at a time when rinderpest was present in the respective country or zone).

2. RPV-containing material destroyed during the past 12 months

Type	Vaccine stocks <u>Live viruses, including field isolates but excluding vaccine strains</u>	Vaccine <u>stocks including</u> seed strains virus	Other virus isolates <u>potentially infectious materials</u>	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 <u>Live viruses, including field isolates but excluding vaccine strains</u>	Vaccine <u>stocks including</u> seed strains virus	Other virus isolates <u>potentially infectious materials</u>	Other (serum, tissue etc)
Check [x] if yes	[]	[]	[]	[]

Transferred to				
Strain/Genetic characterisation				
Quantity/doses (if applicable)				

Annex XXII (contd)

4. RPV-containing material received from another institution during the past 12 months

Type	Vaccine stocks <u>Live viruses, including field isolates but excluding vaccine strains</u>	Vaccine <u>stocks including</u> seed strains virus	Other virus isolates <u>potentially infectious materials</u>	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]

CHAPTER 4.14.

OFFICIAL HEALTH CONTROL OF BEE DISEASES

EU comments

The EU thanks the OIE and supports the proposed changes to this 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* and 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*.

Annex XXIII (contd)

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*;

Annex XXIII (contd)

- 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 disinfection of apicultural equipment

Veterinary Authority or other Competent Authorities of countries are requested to regulate the use of products and means for sanitation and *disinfection* or *disinfection* 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 *disinfection* 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 *disinfection* 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*.

 — Text deleted.

CHAPTER 9.1.

INFESTATION OF HONEY BEES WITH ACARAPIS
WOODI ACARAPISOSIS OF HONEY BEES**EU comment****The EU thanks the OIE and supports the proposed changes to this 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;
- 2) honey bee semen;
- 3) and honey bee venom;
- 234) 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.

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*;

Annex XXIV (contd)

- 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/compartiment (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/compartiment (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/compartiment (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 apiary situated in a country or ~~zone/compartiment (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 the Article 4.14.5.2., 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/compartiment (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*.~~

 — Text deleted

CHAPTER 9.2.

**INFECTION AMERICAN FOULBROOD OF HONEY
BEES WITH PAENIBACILLUS LARVAE
(AMERICAN FOULBROOD)**

EU comments

The EU thanks the OIE and in general supports the proposed changes to this chapter. Some comments are 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*, 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 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.

EU comment

For clarity reasons, the EU suggests adding the words "infected pre-imago bees" after "Combs with American foulbrood". Indeed, combs could also contain contaminated honey or pollen in the absence of infected pre-imago bees, and those combs would not show clinical signs of American foulbrood.

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.

EU comment

The EU does not support the inclusion of honey bee eggs in the list of safe commodities, as there is a risk of contamination of eggs with bacteria or spores.

Indeed, only larvae after at least 53 hours after eclosion can be considered as safe commodities (as established in the OIE Manual), and most important, American foulbrood spores can contaminate the cells where the eggs are laid.

~~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.~~

Article 9.2.3.

~~Determination of the American foulbrood status of a country or zone/compartement~~

The American foulbrood status of a country or ~~zone/compartement (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/compartement (under study)~~ and all clinical signs suggestive of American foulbrood should be subjected to field **and**/or laboratory investigations;

EU comment

In the point above, the EU suggests keeping the "and" instead of the "or". Indeed, both field and laboratory investigations of clinical suspicions should be carried out to determine country or zone status. Furthermore, this would be consistent with the deletion of "or" in Article 9.2.4. point 2b).

- 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/compartement (under study) free from American foulbrood~~

1. Historically free status

A country or ~~zone/compartement (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/compartement (under study)~~ complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

A country or ~~zone/compartement (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/compartement (under study)~~;
- b) American foulbrood is notifiable in the whole country or ~~zone/compartement (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/compartement (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/compartement (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 mellifera* or other possible host species in the country or zone/compartement (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/compartement (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 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 apiary situated in a country or ~~zone/compartement (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 the honey bees:
 - a) come from an apiary meeting the conditions prescribed in Article 4.14.5.;
 - 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~~

EU comment

The EU is of the opinion that eggs should not be deleted from this article (for rationale see above EU comment on safe commodities article).

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

- 1) come from an apiary situated in ~~were sourced from a~~ free country or ~~zone/compartement (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 *apiary* 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 *apiary* 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 *apiary* 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 30 kGy or any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the importing and exporting countries; or

EU comment

The EU would like to ask the OIE for the rationale for having different requirements as to the irradiation treatment of honey for use in apiculture and for human consumption.

3) have been found free from spore forms of *P. larvae* by a test method described in the relevant chapter of the *Terrestrial Manual*.

— Text deleted

CHAPTER 9.3.

**INFECTION EUROPEAN FOULBROOD OF HONEY
BEES WITH *MELISSOCOCCUS PLUTONIUS*
(EUROPEAN FOULBROOD)**

EU comments

The EU thanks the OIE and in general supports the proposed changes to this chapter. Some comments are inserted in the text below.

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 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.

EU comment

The EU does not support the inclusion of honey bee eggs in the list of safe commodities, as there is a risk of contamination of eggs with bacteria. Since eggs could be laid in cells that can be contaminated.

~~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/compartiment* (~~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:

- 1) the honey bees come from an apiary situated in a country or *zone/compartiment* (~~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 the honey bees:
 - a) come from an apiary meeting the conditions prescribed in Article 4.14.5.:
 - 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~~, larvae and pupae of honey bees

EU comment

The EU is of the opinion that eggs should not be deleted from this article (for rationale see above EU comment on safe commodities article).

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

- 1) come from an apiary situated in ~~were sourced from~~ a free country or *zone/compartiment* (~~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 apiary 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 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 apiary situated where 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 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 apiary 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 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.

— Text deleted

CHAPTER 9.4.

INFESTATION WITH AETHINA TUMIDA
SMALL HIVE BEETLE INFESTATION
 (*Aethina tumida*)

EU comments

The EU thanks the OIE and in general supports the proposed changes to this chapter but has some comments.

For consistency with the other bee disease chapters and in order to avoid confusion, the EU suggests keeping the former name "Small Hive Beetle" in parenthesis in the title, as follows:

"INFESTATION WITH AETHINA TUMIDA (SMALL HIVE BEETLE)".

Indeed, the current list of diseases in Chapter 1.2. still refers to "Small hive beetle infestation (*Arthina tumida*)".

It is still unclear why different levels of irradiation treatment are proposed in Chapter 9.4. (400 Gy) and Chapters 9.5. and 9.6. (350 Gy). The EU would like to reiterate its request for the scientific rationale for these different levels.

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* refer 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, ~~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;
- 24) 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;
- 32) on-going awareness and training programmes should be in place to encourage reporting of all cases suggestive of *A. tumida* infestation;
- 34) 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.

Annex XXIV (contd)

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 reported 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;
- 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 apiary 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:~~

42) 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

23) 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

34) 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

45) 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 apiary 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 apiary 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

Annex XXIV (contd)

- 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 apiary situated in a country or zone free from *A. tumida* infestation; and
- b) contains no live honey bees or bee brood;

OR

- e) contains no live honey bees or bee brood; and
- eb) 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 and
 - 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 9.4.8bis.**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 apiary situated in a country or zone free from *A. tumida*.

OR

b) is strained:

EU comment

The EU suggests replacing the word "is strained" by "is fine strained to remove any life stages". Indeed, this wording would state more explicitly what is to be achieved by this procedure.

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 apiary situated in a country or zone free from *A. tumida* infestation; and

b) contains no live honey bees or bee brood;

OR

eb) contains no live honey bees or bee brood; and

ec) 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 apiary 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:

1) the royal jelly:EITHER

a) comes from an apiary 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~~

— Text deleted

CHAPTER 9.5.

TROPILAEELAPS INFESTATION OF HONEY BEES WITH TROPILAEELAPS SPP.**EU comments**

The EU thanks the OIE and supports the proposed changes to this chapter but has a comment.

It is still unclear why different levels of irradiation treatment are proposed in Chapter 9.4. (400 Gy) and Chapters 9.5. and 9.6. (350 Gy). The EU would like to reiterate its request for the scientific rationale for these different levels.

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*.

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 reported 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;

Annex XXIV (contd)

- 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 apiary 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 of in 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 apiary situated in a country or ~~zone/compartiment (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 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.

Article 9.5.87.

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 apiary situated in a country or ~~zone/compartiment (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) is strained honey; 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 2448 hours once the core reached -20°C, or

Annex XXIV (contd)

- e) 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
- dc) 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 apiary 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.

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 apiary 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.
-

— Text deleted

CHAPTER 9.6.

INFESTATION VARROOSIS OF HONEY BEES
WITH VARROA SPP.**EU comments**

The EU thanks the OIE and in general supports the proposed changes to this chapter. However, important comments are inserted in the text below for consideration by the Code Commission.

For consistency with the other bee disease chapters and in order to avoid confusion, the EU suggests keeping the former name "varroosis" in parenthesis in the title, as follows:

"INFESTATION OF HONEY BEES WITH VARROA SPP: (VARROOSIS)".

Indeed, the current list of diseases in Chapter 1.2. still refers to "varroosis of honey bees".

It is still unclear why different levels of irradiation treatment are proposed in Chapter 9.4. (400 Gy) and Chapters 9.5. and 9.6. (350 Gy). The EU would like to reiterate its request for the scientific rationale for these different levels.

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 corana* (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, it needs mites to be spread from one colony to the other.

EU comments

The EU cannot support the changes introduced in the case definition of varroosis in the paragraph above, i.e. by adding "viruses" as the cause of the disease without further specifying which viruses these are.

Indeed, the case definition should be clear, unambiguous and based on sound science, especially as it forms the basis for notification of outbreaks by Member countries to the OIE. Failing this, the identification of *Varroa* mites alone, without detection of simultaneous infection of the *Varroa* infested bees with "viruses", would not result in meeting the case definition of varroosis, thus preventing a Member from notifying the occurrence of the disease in accordance with the Terrestrial Code. This would also put into question the justification for keeping this disease on the OIE list, as the criteria for listing would hardly be met (i.e. "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'). Furthermore, this new case definition would impact the determination of the status of a country or zone, as freedom from varroosis could only be considered as freedom from *Varroa* spp. and freedom of the "viruses". As these "viruses" are not further specified, this would render the chapter utterly inapplicable.

Therefore, either the case definition is reverted to varroosis being caused "by mites in the genus *Varroa*, primarily *Varroa destructor*", or – should the combination of mites and "viruses" be retained as the cause of the disease – the species of viruses concerned are all explicitly mentioned (if at all known) or are restricted to Deformed Wing Virus, which is mentioned in the current proposal.

The EU would prefer the former option, as the detection of *Varroa* mites without the simultaneous detection of Deformed Wing Virus or other bee viruses should suffice, for the purpose of the Terrestrial Code, to declare an outbreak of varroosis. Moreover, throughout the rest of the chapter, including the title, reference is made solely to *Varroa* spp., e.g. when defining country status and making recommendations for safe trade, which seems inconsistent with the newly proposed case definition.

Furthermore, should the latter option be retained, the viruses concerned should be added to the OIE list of diseases, along with *Varroa* spp.

Finally, the last 4 sentences of the paragraph above are unclear and should be redrafted in accordance with the final case definition, and could indeed describe the multifactorial aspects contributing to clinical disease manifestation. More specifically, the meaning of the word "activator" is unclear. If it is to be understood that *Varroa* mites suppress the defence or resistance of bees against viruses that would cause mere asymptomatic infection in the absence of the mite, allowing clinical manifestation of virus infections, this should be clearly explained. Also the word "transferred" should be replaced by "conferred".

The number of 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. **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.**

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.

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).

EU comment

The EU does not support the inclusion of pollen and propolis in the list of safe commodities, as specific import conditions are laid down below for these commodities.

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/compartiment~~ (under study);

- b) the presence of *Varroa* spp. varroosis is notifiable in the whole country or ~~zone/compartiment~~ (under study), and any clinical cases suggestive of varroosis are subjected to field and laboratory investigations;
- c) for the 3 years following the last reported ~~case of 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/compartiment~~ (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/compartiment~~ (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/compartiment~~ (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/compartiment~~ (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 apiary situated in a country or zone/compartiment (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

EU comment

The EU suggests adding the words "or a suitable biocide product" after "effective veterinary medicinal product", in order to take into account possible resistance to certain VMP, and different legal categorisation of products as either VMP or biocide product in different OIE members.

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 bee 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 attendants 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/compartiment* (under study); or~~
- ~~2. have originated from queens in a *quarantine station* and were inspected and found free of *Varroa destructor*.~~

~~Article 9.6.76.~~

~~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 apiary situated in a country or *zone/compartiment* (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 9.6.87.~~

~~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 apiary situated in** a country or zone/~~compartment (under study)~~ free from ***Varroa* spp.** varroosis; or
- 2) **is strained honey; 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) **have** 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**
 - e) **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**
 - dc) **irradiation with 350 Gy;**
 - 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 apiary 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 apiary 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.*

— Text deleted.

CHAPTER 10.4.

INFECTION WITH VIRUSES OF
NOTIFIABLE AVIAN INFLUENZA**EU comments**

The EU in general supports the proposed changes to this chapter but has some comments inserted in the text below.

Article 10.4.1.

General provisions

- 1) ~~Infection with H~~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) 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 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 viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) viruses and low pathogenicity notifiable avian influenza (LPNAI) viruses:
 - a) HPNAI 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 isolates, the isolate being tested should be considered as HPNAI virus;
 - b) LPNAI viruses are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.
- 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 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.
- ~~5~~4) For the purposes of the *Terrestrial Code*, the *incubation period* for NAI shall be 21 days.
- ~~6~~5) This chapter deals not only with the occurrence of clinical signs caused by NAI virus, but also with the presence of *infection* with NAI virus in the absence of clinical signs.
- ~~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 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~~.

Annex XXV (contd)

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*.~~
- 8) For the purposes of the *Terrestrial Code*, 'NAI free establishment' means an *establishment* in which the *poultry* have shown no evidence of ~~NAI-infection~~ with NAI viruses, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.
- 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*.
10. A Member should not impose immediate bans on the trade in *poultry commodities* in response to a notification, 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 status of a country, zone or compartment

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

- 1) NAI is notifiable in the whole country, an on-going NAI awareness programme is in place, and all notified suspect occurrences of NAI are subjected to field and, where applicable, *laboratory* investigations;
- 2) appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in *poultry*, and the risk posed by birds other than *poultry*; this may be achieved through a NAI *surveillance* programme in accordance with Articles 10.4.27. to 10.4.33.;
- 3) consideration of all epidemiological factors for NAI occurrence and their historical perspective.

Article 10.4.3.

NAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from NAI when it has been shown that ~~neither HPNAI nor LPNAI infection in *poultry* with HPAI or LPNAI 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 free status can be regained:

- 1) In the case of ~~HPNAI infections~~ with HPAI 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.

Annex XXV (contd)

- 2) In the case of ~~LPNAI infections with LPNAI 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 viruses in poultry~~

A country, *zone* or *compartment* may be considered free from ~~HPNAI~~ infection with HPAI viruses in poultry when:

- 1) it has been shown that ~~HPNAI-infection in poultry with HPAI viruses~~ has not been present in the country, *zone* or *compartment* for the past 12 months, although its ~~LPNAI~~ status with respect to LPNAI 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 but any NAI virus detected has not been identified as HPNAI virus.

The *surveillance* may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If *infection* has occurred in *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 a NAI free country, zone or compartmentFor live poultry (other than day-old poultry)

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

- 1) the *poultry* showed no clinical sign of NAI on the day of shipment;
- 2) the *poultry* were kept in a NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*;
- 4) if the *poultry* have been vaccinated against NAI, 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*.

Annex XXV (contd)

Article 10.4.6.

Recommendations for the importation of live birds other than poultry

Regardless of the NAI 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 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 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 in *poultry*;
- 4) the birds are transported in new or appropriately sanitized *containers*;
- 5) if the birds have been vaccinated against NAI, 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 a NAI free country, zone or compartmentFor day-old live poultry

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

- 1) the *poultry* were kept in a NAI free country, *zone* or *compartment* since they were hatched;
- 2) the *poultry* were derived from parent *flocks* which had been kept in a NAI free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*;
- 4) if the *poultry* or the parent *flocks* have been vaccinated against NAI, 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 viruses in poultryFor 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 viruses in poultry since they were hatched;

Annex XXV (contd)

- 2) the *poultry* were derived from parent *flocks* which had been kept in a NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*;
- 4) if the *poultry* or the parent *flocks* have been vaccinated against NAI, 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 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 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;
- 4) the birds are transported in new or appropriately sanitized *containers*;
- 5) if the birds or parent *flocks* have been vaccinated against NAI, 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 a NAI free country, zone or compartmentFor hatching eggs of poultry

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

- 1) the eggs came from a NAI free country, *zone* or *compartment*;
- 2) the eggs were derived from parent *flocks* which had been kept in a NAI free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the eggs are transported in new or appropriately sanitized packaging materials;
- 4) if the parent *flocks* have been vaccinated against NAI, 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*.

Annex XXV (contd)

Article 10.4.11.

Recommendations for importation from a ~~HPNAI~~ free country, zone or compartment free from infection with HPAI viruses in poultryFor 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 viruses in poultry;
- 2) the eggs were derived from parent *flocks* which had been kept in a NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
- 4) the eggs are transported in new or appropriately sanitized packaging materials;
- 5) if the parent *flocks* have been vaccinated against NAI, 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 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 NAI~~ infection with NAI viruses;
- 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 the parent *flocks* have been vaccinated against NAI, 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 a NAI free country, zone or compartmentFor 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 NAI 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 viruses in poultryFor 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 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 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 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 virus.

Article 10.4.16.

Recommendations for importation from a NAI free country, zone or compartmentFor poultry semen

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

- 1) showed no clinical sign of NAI on the day of semen collection;
- 2) were kept in a NAI free country, zone or compartment for at least the 21 days prior to and at the time of semen collection.

Annex XXV (contd)

Article 10.4.17.

Recommendations for the importation from a ~~HPNAI-free~~ country, zone or compartment free from infection with HPAI 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 virus on the day of semen collection;
- 2) were kept in a ~~HPNAI-free~~ country, zone or compartment free from infection with HPAI 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 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 in *poultry* during the isolation period;
- 3) were tested within 14 days prior to semen collection and shown to be free of NAI *infection*.

Article 10.4.19.

Recommendations for importation from ~~either a NAI or HPNAI-free~~ country, zone or compartment free from NAI or free from infection with HPAI 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 HPAI 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 HPAI 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.

Article 10.4.20.

Recommendations for the importation of meat products of poultry

Regardless of the NAI 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 *fresh meat* which meet the requirements of Article 10.4.19.; or

Annex XXV (contd)

- 2) the *commodity* has been processed to ensure the destruction of NAI 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 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 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 free country, *zone* or *compartment* from *poultry* which were kept in a NAI free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*, or
- 2) these *commodities* have been processed to ensure the destruction of NAI virus (under study);

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.22.

Recommendations for the importation of feathers and down of poultry

Regardless of the NAI 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 a NAI free country, *zone* or *compartment*, or
- 2) these *commodities* have been processed to ensure the destruction of NAI virus (under study);

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.23.

Recommendations for the importation of feathers and down of birds other than poultry

Regardless of the NAI 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 virus (under study); and
- 2) the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Annex XXV (contd)

Article 10.4.24.

Recommendations for the importation of feather meal and poultry meal

Regardless of the NAI 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 free country, *zone* or *compartment* from *poultry* which were kept in a NAI free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
- 2) these *commodities* have been processed either:
 - a) with moist heat at a minimum temperature of 118°C for minimum of 40 minutes; or
 - b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122°C 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 74°C;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

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*.

	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 complementary to Chapter 1.4., applicable to Members seeking to determine their NAI status. This may be for the entire country, *zone* or *compartment*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of NAI status is also provided.

The presence of avian influenza viruses in wild birds creates a particular problem. In essence, no Member can declare itself free from avian influenza (AI) in wild birds. However, the definition of NAI in this chapter refers to the *infection* in *poultry* only, and Articles 10.4.27. to 10.4.33. were developed under this definition.

The impact and epidemiology of NAI differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from NAI at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of *poultry* with wild birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific *surveillance* strategies to address each specific situation. It is incumbent upon the Member to provide scientific data that explains the epidemiology of NAI in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Members to provide a well-reasoned argument to prove that absence of NAI virus (NAIV) *infection* is assured at an acceptable level of confidence.

Surveillance for NAI should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from ~~NAIV infection~~ with NAIV.

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:

Annex XXV (contd)

- a) a formal and ongoing system for detecting and investigating *outbreaks of disease* or ~~NAIV~~ infection with NAIV should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of NAI to a *laboratory* for NAI diagnosis as described in the *Terrestrial Manual*;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
- 2) The NAI *surveillance* programme should:
- a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of NAI to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of NAI should be investigated immediately. As suspicion cannot 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 diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;
 - b) implement, when relevant, regular and frequent clinical inspection, serological and virological testing of high-risk groups of *animals*, such as those adjacent to a NAI infected country, *zone* or *compartment*, places where birds and *poultry* of different origins are mixed, such as live bird markets, *poultry* in close proximity to waterfowl or other potential sources of NAIV.

An effective *surveillance* system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is NAIV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications Documentation for freedom from ~~NAIV~~ infection with NAIV should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 10.4.29.

Surveillance strategies

1. Introduction

The target population for *surveillance* aimed at identification of *disease* and *infection* should cover all the susceptible *poultry* species within the country, *zone* or *compartment*. Active and passive *surveillance* for NAI should be ongoing. The frequency of active *surveillance* should be at least every 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 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 status of high risk populations.

A Member should justify the *surveillance* strategy chosen as adequate to detect the presence of NAIV infection with NAIV in accordance with Chapter 1.4. and the prevailing epidemiological situation, including cases of HPAI 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 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 ~~for~~ circulation of NAIV needs to be carefully followed to avoid producing results that are either insufficiently reliable, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

2. Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of NAI at the *flock* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory *disease* or a drop in egg production, is important for the early detection of NAIV infection with NAIV. In some cases, the only indication of LPNAIV virus *infection* may be a drop in feed consumption or egg production.

Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of NAI suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should have restrictions imposed upon it until NAI *infection* is ruled out.

Annex XXV (contd)

Identification of suspect *flocks* is vital to the identification of sources of NAIV and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that NAIV isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterization.

3. Virological surveillance

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

- a) to monitor at risk populations;
- b) to confirm clinically suspect cases;
- c) to follow up positive serological results;
- d) to test 'normal' daily mortality, to ensure early detection of *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.

4. Serological surveillance

Serological *surveillance* aims at the detection of antibodies against NAIV. Positive NAIV antibody test results can have four possible causes:

- a) natural *infection* with NAIV;
- b) vaccination against NAI;
- c) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to 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 *surveillance*. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of NAIV should not be compromised.

The discovery of clusters of seropositive *flocks* may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or *infection*. As clustering may signal *infection*, the investigation of all instances 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 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 or freedom from infection with HPAI viruses in poultry

1. Additional surveillance procedures for Members declaring freedom of the country, zone or compartment from NAI or HPNAI from infection with HPAI 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 or from infection with HPAI 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 or HPNAIV ~~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 or HPNAIV ~~viruses~~ through virus detection and antibody tests described in the *Terrestrial Manual*. This *surveillance* may be targeted to *poultry* population at specific risks linked to the types of production, possible direct or indirect contact with wild birds, multi-age *flocks*, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding and poor biosecurity measures in place.

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

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

In all vaccinated *flocks* there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every 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.

Annex XXV (contd)

Article 10.4.31.

Additional surveillance procedures for countries, zones or compartments declaring that they have regained freedom from NAI or from infection with HPAI 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 or from infection with HPNAI 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 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 free establishments within HPNAI free compartments: additional surveillance procedures

The declaration of NAI free *establishments* requires the demonstration of absence of ~~NAI~~ infection with NAI. Birds in these *establishments* should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these recommendations. The frequency of testing should be based on the risk of *infection* and at a maximum interval of 21 days.

Article 10.4.33.

The use and interpretation of serological and virus detection tests

Poultry infected with NAI virus produce antibodies to haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will not be covered in this chapter. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct and blocking ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI), ELISA and neutralization (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies to the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype AI viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of AI viruses.

Poultry can be vaccinated with a variety of AI vaccines including inactivated whole AI virus vaccines, and haemagglutinin expression-based vaccines. Antibodies to the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

AI virus *infection* of unvaccinated birds including sentinels is detected by antibodies to the NP/M, subtype specific HA or NA proteins, or NSP. *Poultry* vaccinated with inactivated whole AI vaccines containing an influenza virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies to the NA of the field virus. For example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies to NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In *poultry* vaccinated with haemagglutinin expression-based vaccines, antibodies are detected to the specific HA, but not any of the other AI viral proteins. *Infection* is evident by antibodies to the NP/M or NSP, or the specific NA protein of the field virus. Vaccines used should comply with the standards of the *Terrestrial Manual*.

All *flocks* with seropositive results should be investigated. Epidemiological and supplementary *laboratory* investigation results should document the status of NAI ~~*infection/circulation*~~ for each positive *flock*.

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

1. The follow-up Procedure in case of positive test results if vaccination is used

In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on NAI-vaccinated *poultry*. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated *animals*.

- a) Inactivated whole AI virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If *poultry* in the population have antibodies to NP/M and were vaccinated with inactivated whole AI virus vaccine, the following strategies should be applied:
 - i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating AI virus *infection*, specific HI tests should be performed to identify H5 or H7 AI virus *infection*;
 - ii) if vaccinated with inactivated whole AI virus vaccine containing homologous NA to field virus, the presence of antibodies to NSP could be indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins;
 - iii) if vaccinated with inactivated whole AI virus vaccine containing heterologous NA to field virus, presence of antibodies to the field virus NA or NSP would be indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

Annex XXV (contd)

- b) Haemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect AI *infection*. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.
2. ~~The follow-up Procedure in case of positive test results indicative of infection for determination of infection due to with HPNAI or LPNAI viruses~~

The detection of antibodies indicative of an ~~NAI virus infection with a NAI virus in unvaccinated poultry as indicated in point a)) above~~ should will result in the initiation of epidemiological and virological investigations to determine if the *infections* are due to HPNAI or LPNAI viruses.

Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of AI virus, by virus isolation and identification, ~~and/or~~ detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting *infection* by AI virus and the method is described in the *Terrestrial Manual*. All AI virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens ~~and/or~~ sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as HPNAI, LPNAI or ~~LPAI (not notifiable) other AI~~ viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as HPNAI or LPNAI viruses. The 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 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 transmission.

The entire investigative process should be documented as standard operating procedure within the epidemiological *surveillance* programme.

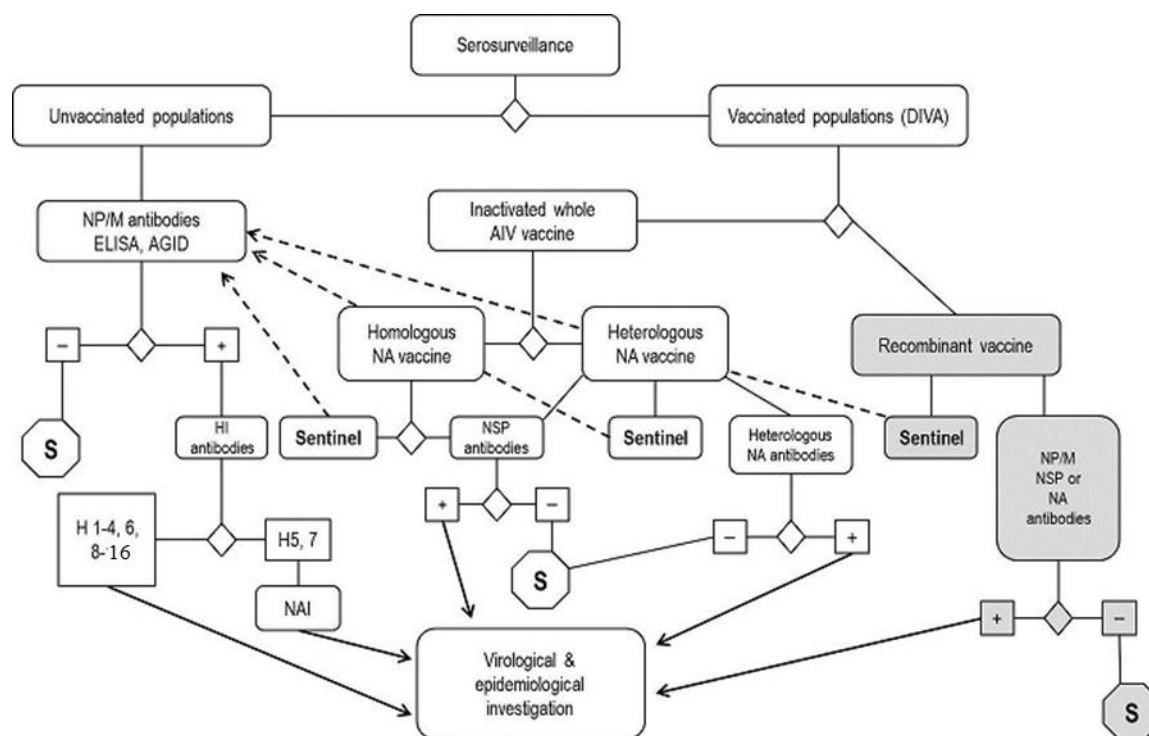
Figures 1 and 2 indicate the tests which are recommended for use in the investigation of *poultry flocks*.

Fig. 1. Schematic representation of laboratory tests for determining evidence of NAI infection through or following serological surveys

EU comments

The two flowcharts below, and specially for determining the evidence of NAI infection with serological methods (Fig. 1), need to be revised as they may be contradictory or at least confusing. Indeed, on the left hand side, a positive HI antibody test leads to H5 or H7, which leads to NAI. This may be wrongly interpreted as infection. It is therefore suggested to move this "NAI" box to a position under "virological and epidemiological investigation", if those conclude that infection is present. Thus the arrow would point from "H5, 7" directly to "virological & epidemiological investigation".

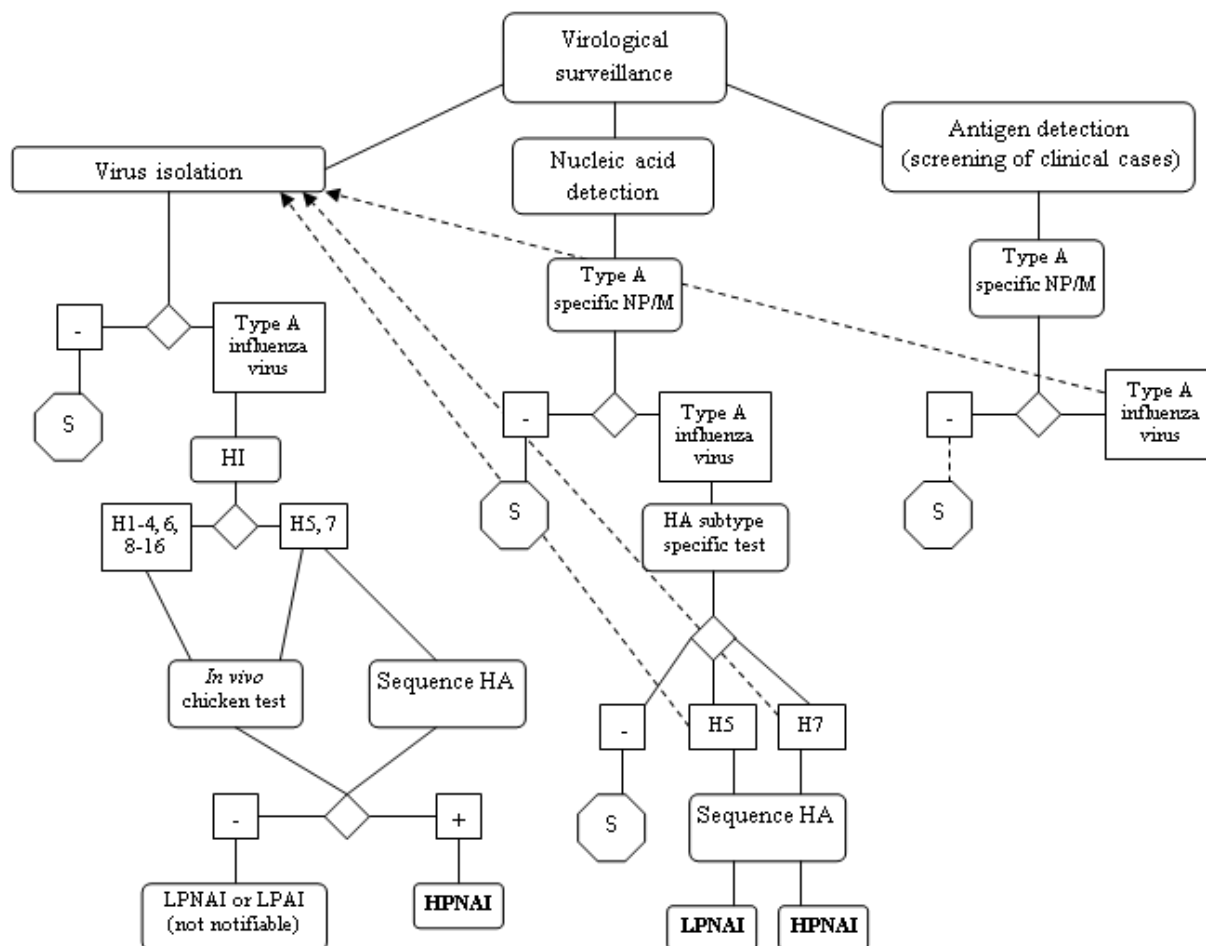
Furthermore, for reasons of consistency, please replace "HPNAI" by "HPAI" in 2 of the boxes at the bottom of figure 2.



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

Annex XXV (contd)

Fig. 2. Schematic representation of laboratory tests for determining evidence of NAI 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

— Text deleted.

CHAPTER 11.8.

CONTAGIOUS BOVINE PLEUROPNEUMONIA

EU comments

The EU supports the proposed changes to this chapter and has a comment.

For consistency with the new approach adopted for OIE Code chapters, the title should be amended by referring to the aetiological agent, and keeping for the time being the name of the disease on brackets to avoid confusion, as follows:

"INFECTION WITH *MYCOPLASMA MYCOIDES* SUBSP. *MYCOIDES* SC (CONTAGIOUS BOVINE PLEUROPNEUMONIA)"

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 (*MmmSC*), and freedom from CBPP means freedom from *MmmSC* 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 *MmmSC*, but also with the presence of *infection* with *MmmSC* in the absence of clinical signs.

The following defines the occurrence of *MmmSC* infection:

- 1) *MmmSC* has been isolated and identified as such from an *animal*, embryos, oocytes or semen; or
- 2) antibodies to *MmmSC* antigens which are not the consequence of vaccination, or *MmmSC* DNA, have been identified in one or more *animals* showing pathological lesions consistent with *infection* with *MmmSC* 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).

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 countries₇ or zones_± or from CBPP free compartmentsFor 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 zonesFor 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 countries₇ or zones_± or from CBPP free compartmentsFor 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.

Annex XXVI (contd)

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;
 - 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 compartmentsFor *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;

Annex XXVI (contd)

- 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. 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.

Annex XXVI (contd)

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 strategies1. Introduction

The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species (*Bos taurus*, *B. indicus* and *Bubalus bubalis*) within the country, zone or *compartment*.

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.

Annex XXVI (contd)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 *MmmSC*.

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.~~

~~Article 11.8.17.~~

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.

Annex XXVI (contd)

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.

— Text deleted.

CHAPTER 14.5.

INFECTION WITH CHLAMYDOPHILA ABORTUS
~~INFECTION~~
 (ENZOOTIC ABORTION OF EWES, OVINE
 CHLAMYDIOSIS)

EU comment

The EU supports the proposed changes to this 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 *Chlamydomphila 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;

Annex XXVII (contd)

- 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.

Article 14.5.4.

Recommendations for the importation of semen of sheep

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

- 4- the donor *animals* showed no clinical signs on the day of semen collection, and:
- 1a) have been kept in *establishments* or *artificial insemination centres* free from EAE according to Article 14.5.3. during the past two years, and have not been in contact with *animals* of a lower health status; or
 - 2b) have remained since birth, or for the previous two years, 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**

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 the past two years 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, 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.

 — Text deleted.

CHAPTER x . x .

INFECTION WITH EPIZOOTIC HEMORRHAGIC
DISEASE VIRUS**EU comments**

The EU thanks the OIE for its work and welcomes this new chapter on EHD. A number of comments are inserted in the text below.

Article x.x.1.

General provisions

For the purposes of the *Terrestrial Code*, epizootic hemorrhagic disease (EHD) is an *infection* of cervids, and cattle with one of several serotypes of epizootic hemorrhagic disease virus (EHDV). *Outbreaks* of *disease* due to EHDV are sporadic and geographically restricted. EHDV is not regarded as a significant pathogen of livestock in many countries in which it is present.

For the purposes of the *Terrestrial Code*, the *infective period* for EHDV shall be 60 days.

In the absence of clinical *disease* in a country or *zone*, its EHDV status should be determined by an ongoing *surveillance* programme (in accordance with Article x.x.16.). The programme may need to be adapted to target parts of the country or *zone* at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology.

EU comment

A "case definition" is missing. The EU suggests using the same as the one proposed in Article 8.3.1. for bluetongue.

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

EU comment

There are currently no vaccines available for EHD. The OIE Terrestrial Manual currently does not contain an EHD specific chapter, as EHD is covered by Chapter 2.1.3 on Bluetongue and EHD (in the section on diagnostic tests; the vaccine section merely states that vaccines are currently not readily available).

Article x.x.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any EHDV related conditions regardless of the EHDV status of the ruminant population of the *exporting country* or *zone*:

1. *milk* and *milk products*;
2. *meat* and *meat products*;
3. hides, skins, antlers and hooves;
4. wool and fibre.

Article x.x.3.

EHDV free country or zone

1. A country or a *zone* may be considered free from EHDV when epizootic haemorrhagic disease is notifiable in the whole country and either:
 - a) a *surveillance* programme in accordance with Article x.x.16. has demonstrated no evidence of EHDV transmission in the country or *zone* during the past 2 years; or
 - b) an ongoing *surveillance* programme has demonstrated no evidence of *Culicoides* in the country or *zone*.
2. An EHDV free country or *zone* in which ongoing *vector surveillance* has found no evidence of *Culicoides* will not lose its free status through the importation of seropositive or infective *animals*, or semen, embryos or ova from infected countries or *infected zones*.
3. An EHDV free country or *zone* in which *surveillance* has found evidence that *Culicoides* are present will not lose its free status through the importation of seropositive *animals*

EU comment

The EU suggests adding the following condition to point 3, in analogy to the respective provision of the bluetongue chapter (Article 8.3.3, point 3):

" , provided that the animals are demonstrated to have specific antibodies against the EHD virus serotypes whose presence has been demonstrated in the exporting country or zone."

Article x.x.4.

EHDV seasonally free zone

An EHDV seasonally free *zone* is a part of an infected country or an *infected zone* for which for part of a year *surveillance* demonstrates no evidence either of EHDV transmission or of adult *Culicoides*.

EU comment

The EU suggests adding the further points on the application of the seasonally free zone, in analogy to the respective provisions of the bluetongue chapter (Article 8.3.4.).

Article x.x.5.

EHDV infected country or zone

For the purpose of this chapter, an EHDV infected country or *infected zone* is a clearly defined area where evidence of EHDV transmission has been reported during the past 2 years. Such a country or *zone* may contain an EHDV seasonally free *zone*.

Article x.x.6.

Recommendations for importation from EHDV free countries or zonesfor cattle and cervids

Where EHDV is of concern, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the *animals* were kept in an EHDV free country or *zone* since birth or for at least 60 days prior to shipment; or
2. the *animals* were kept in an EHDV free country or *zone* for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the EHDV group and remained in the EHDV free country or *zone* until shipment; or
3. the *animals* were kept in an EHDV free country or *zone* for at least 7 days, then were subjected, with negative results, to an agent identification test and remained in the EHDV free country or *zone* until shipment;

AND

4. if the *animals* were exported from a free *zone* within an *infected country* either:
 - a) did not transit through an *infected zone* during transportation to the *place of shipment*; or
 - b) were protected from attack by *Culicoides* at all times when transiting through an *infected zone*

Article x.x.7.

Recommendations for importation from EHDV seasonally free zones

for cattle and cervids

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

1. were kept during the seasonally free period in an EHDV seasonally free *zone* since birth or for at least 60 days prior to shipment; or
2. were kept during the EHDV seasonally free period in an EHDV seasonally free *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibody to the EHDV group with negative results, carried out at least 28 days after the commencement of the residence period; or
3. were kept during the EHDV seasonally free period in an EHDV seasonally free *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test with negative results, carried out at least 14 days after the commencement of the residence period

AND

4. either:
 - a) did not transit through an *infected zone* during transportation to the *place of shipment*; or
 - b) were protected from attack by *Culicoides* at all times when transiting through an *infected zone*

Article x.x.8.

Recommendations for importation from EHDV infected countries or zones

for cattle and cervids

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

1. were protected from attack by *Culicoides* in a vector-protected *establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or

2. were protected from attack by *Culicoides* in a vector-protected establishment for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test to detect antibody to the EHDV group, with negative results, carried out at least 28 days after introduction into the vector-protected *establishment*; or
3. were protected from attack by *Culicoides* in an vector-protected *establishment* for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test with negative results, carried out at least 14 days after introduction into the vector-protected *establishment*; or
4. were demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme in accordance with Article x.x.16.

Article x.x.9.

Recommendations for importation from EHDV free countries or zones

for semen of cattle and cervids

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

1. the donor *animals*:
 - a) were kept in an EHDV free country or *zone* for at least 60 days before commencement of, and during, collection of the semen; or
 - b) were subjected to a serological test to detect antibody to the EHDV group, between 21 and 60 days after the last collection for this consignment, with negative results; or
 - c) were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article x.x.10.

Recommendations for importation from EHDV seasonally free zones

for semen of cattle and cervids

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

1. the donor *animals*:
 - a) were kept during the EHDV seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the semen; or
 - b) were subjected to a serological test to detect antibody to the EHDV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or
 - c) were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article x.x.11.

Recommendations for importation from EHDV infected countries or zones

for semen of cattle and cervids

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

1. the donor *animals*:
 - a) were kept in a vector-protected *establishment* for at least 60 days before commencement of, and during, collection of the semen; or
 - b) were subjected to a serological test to detect antibody to the EHDV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or
 - c) were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article x.x.12.

Recommendations for importation from EHDV free countries or zones

for embryos or oocytes of cattle and cervids

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

1. the donor females:
 - a) were kept in an EHDV free country or *zone* for at least the 60 days prior to, and at the time of, collection of the embryos; or
 - b) were subjected to a serological test to detect antibody to the EHDV group, between 21 and 60 days after collection, with negative results; or
 - c) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article x.x.13.

Recommendations for importation from EHDV seasonally free zones

for embryos or oocytes of cattle and cervids

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

1. the donor females:
 - a) were kept during the seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the embryos or oocytes; or
 - b) were subjected to a serological test to detect antibody to the EHDV group, between 21 and 60 days after collection, with negative results; or

Annex XXVIII (contd)

- c) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;
2. 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 x.x.14.

Recommendations for importation from EHDV infected countries or zones

for embryos or oocytes of cattle and cervids

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

- 1. the donor females:
 - a) were kept in a vector-protected *establishment* for at least 60 days before commencement of, and during, collection of the embryos or oocytes; or
 - b) were subjected to a serological test to detect antibody to the EHDV group, between 21 and 60 days after collection, with negative results; or
 - c) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;
- 2. 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 X.X.15.

Protecting animals from Culicoides attack

EU comments

For this Article, the EU suggests using the same wording as in the bluetongue chapter (Article 8.3.15), including the requirement that the vector-protected establishment or facility be approval by the Veterinary authority. Indeed, the vectors for EHD are the same as for bluetongue.

1. Vector-protected establishment or facility

Where movement of animals or collection of genetic material requires a vector-protected facility, the following criteria apply:

- 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 or eliminate breeding sites for *vectors* in the vicinity of the *establishment* or facility;
- e) standard operating procedures, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of animals to the place of *loading*.

2. During transportation

When transporting *animals* through EHDV infected countries or *infected zones*, *Veterinary Authorities* should require strategies to protect *animals* from attack by *Culicoides* during transport.

Risk management strategies may include:

- a) *loading*, transporting and *unloading animals* at times of low vector activity (i.e. bright sunshine, low temperature);
- b) ensuring *vehicles* do not stop en route during times of high vector activity (i.e. dawn or dusk, or overnight).

Article x.x.16.

Surveillance

This article is complementary to Chapters 1.4. and 1.5. and outlines the principles for EHDV *surveillance* applicable to Members seeking to determine the EHDV status of a country or a *zone*.

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

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

General provisions on surveillance for arthropod *vectors* are in Chapter 1.5.

More specific approaches to surveillance for *Culicoides* transmitted *Orbivirus infections* are described in Chapters 8.3 and 12.1. Passive surveillance for clinical cases of EHD in susceptible wild ruminants can be a useful tool for detecting *disease*, based on lesions of haemorrhagic disease combined with viral detection techniques.

**FUTURE WORK PROGRAMME FOR THE
TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

EU comments

The EU thanks the OIE for having considered its request for the inclusion of an introductory text explaining and clarifying the various purposes of the *Terrestrial Code*, strongly supports the proposal to adapt the User's Guide in this respect and encourages the Code Commission to embark on this important work.

As regards the current review of the chapter on CSF, the EU would suggest the following to be taken into account:

Article 15.2.21 paragraph 3 "Dry cured pork meat" describes conditions for inactivation of CSFV by dry salting for Italian and Spanish style meats. It is suggested that these provisions be enlarged to other types of meats e.g. French style hams, by way of process analogy, or that the conditions for inactivation of CSFV be described by type of process and characteristics of the meat (i.e. size of the product etc.), instead of referring to a specific country style product.

Topic		
Action	How to be managed	Status (Sep. 2012)
Restructuring of the <i>Terrestrial Code</i> Harmonisation of the <i>Terrestrial and Aquatic Codes</i>		
1. Work with AAHSC towards harmonisation, as appropriate, of the Codes	TAHSC & ITD	1. Ongoing, revised CH 1.1. for MC
2. CH rename by disease agents		2. Ongoing
3. Revision and formatting of Section 7	3.TAHSC &	
4. Revision of the Users' guide	AWWG	
Listed diseases		
1. Criteria for listing	TAHSC & SCAD & AHG	1. Adopted
2. List of diseases		2. MC sought for proposed changes
CWD		
Decision on listing (new CH)	TAHSC & SCAD	AHG said NO, MC sought
PRRS		
New CH	SCAD	Pending new info on diagnostics
Evaluation of VS and OIE PVS pathway		
1. Inclusion of legislation aspect	TAHSC & AHG & ITD	1. Adopted
2. Veterinary education aspect		2. Ongoing
CSF		
Official recognition CSF	SCAD/AHG	AHG to be convened
AHS		
Official recognition	SCAD & TAHSC	Adopted
FMD		
Revise chapter including wildlife	SCAD & TAHSC	Pending production of draft CH

RP		
Global freedom era	SCAD & TAHSC & AHG	Pending development of the Joint FAO/OIE Advisory Committee on Rinderpest Revised chapter for MC
Other Terrestrial Code texts in need of revision		
Pet food certificate CH	TAHSC	On hold
Update CH on Brucellosis	AHG/SCAD & TAHSC	AHG to be convened
Update CH on Rabies	SCAD & TAHSC	Adopted
Update CH on Bee diseases	AHG/SCAD & TAHSC	Revised CH 4.14. adopted Others for MC
Update CH on PPR	SCAD & TAHSC	AHG to be convened
CH on EHD	SCAD & TAHSC	New chapter for MC
Update CH on SVD	SCAD & TAHSC	Pending delisting
Update CH on ASF (SURV)	SCAD	Pending SCAD revision
CH on Paratuberculosis	BSC (diagnostic test) & STD (guidance document)	Pending delisting
Update CH on Avian Mycoplasmosis	SCAD and TAHSC	Pending SCAD revision

Animal production food safety		
1. Salmonellosis Update biosecurity procedures CH	APFSWG & AHG	1. Adopted
2. Zoonotic parasitic diseases a. <i>Trichinella</i> spp. b. Echinococcosis c. <i>Taenia solium</i> (Porcine cysticercosis)	AHG & TAHSC	a. Revised text for MC b. Revised text for MC c. On hold pending delisting
Animal welfare		
New texts: 1. Laboratory animals 2. Livestock production systems a. Broiler b. General principles c. Beef cattle	AWWG & AHGs TAHSC supervision	1. Adopted 2. a. New chapter for MC b. Adopted c. Adopted
Horse diseases		
Review for competition horses	SCAD & TAHSC	Ongoing
Collection and processing of equine semen		
Convene an <i>ad hoc</i> group		Pending
OIE policy on wildlife		
Draft policy	TAHSC with WG on	MC sent to Headquarters

	Wildlife & SCAD	
Invasive alien species		
Guidance on RA	TAHSC & SCAD	Guidelines on the OIE website
Compartmentalisation		
Generic Checklist	TAHSC & SCAD	Sent to SCAD
Veterinary products (AMR)		
1. Updating CH 6.7. & 6.8. 2. Updating CH 6.9. 3. Updating CH 6.10.	TAHSC & SCAD & AHG	1. Adopted 2. Revised CH for MC 3. MC to AHG

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			Horizontal issue		
3	V		Glossary	Sep. 12	
4	VI	1.1.	Notification of diseases and epidemiological information	Sep. 12	
5		1.2.	Criteria for listing diseases		
	VII		Report of <i>ad hoc</i> Group on Notification of animal diseases and pathogenic agents		
6	VIII	3.2.	Evaluation of veterinary services	Sep. 12	
		3.4.	Veterinary legislation		
	XXXII		Report of <i>ad hoc</i> Group on Evaluation of VS		
7	IX	4.6.	Collection and processing of bovine, small ruminant and porcine semen	Sep. 12	
		4.7.	Collection and processing of <i>in vivo</i> derived embryos from livestock and horses		
8	X	6.4.	Biosecurity procedures in poultry production	Sep. 12	
9	XI	6.6.	Introduction to the recommendations for controlling antimicrobial resistance	Sep. 12	
	XII	6.7.	Harmonisation of national antimicrobial resistance surveillance and monitoring programmes	Sep. 12	
	XIII	6.9.	Responsible and prudent use of antimicrobial	Sep. 11	
10	XIV	6.11.	Zoonoses transmissible from non-human primates	Sep. 12	
11	XVI	7.1.	Introduction to the recommendation for AW (General principle for production system)	Sep. 11	
	XVII	7.8.	Use of animals in research and education	Sep. 12	
	XVIII	7.9.	Beef cattle production systems	Sep. 12	
	XV	NEW	Broiler chicken production systems	Sep. 10	
	XXXIII		AWWG work programme		
12		8.2.	Aujeszky's disease		
13	XIX	8.3.	Bluetongue	Sep. 11	
14	XX	8.4.	Echinococcosis (<i>E. granulosus</i>)	Feb. 11	
		NEW	Echinococcosis (<i>E. multilocularis</i>)	Feb. 11	
	XXI	8.13.	<i>Trichinella</i> infection	Feb. 11	
	XXXIV		Report of <i>ad hoc</i> Group on Zoonotic Parasites		

Annex XXX (contd)

Item	Annex	Chapter	Title	Provided for comments	GS81
15		8.5.	Foot and mouth disease		
		1.6.	Questionnaire on foot and mouth disease (Article 1.6.7.)		
16		8.10. 5.11.	Rabies Rabies model international veterinary certificate for domestic dogs (<i>Canis familiaris</i>), cats (<i>Felis catus</i>) and ferrets (<i>Mustela putorius furo</i>)		
17	XXII	8.12.	Rinderpest	Sep. 11	
18	XXIII	4.14.	Official health control of bee diseases	Sep. 12	
	XXIV	9.1.	Acarapisosis of honey bees	Sep. 09	
		9.2.	American foulbrood of honey bees		
		9.3.	European foulbrood of honey bees		
		9.4.	Small hive beetle infestation (<i>Aethina tumida</i>)		
	9.5.	<i>Tropilaelaps</i> infestation of honey bees			
	9.6.	Varroosis of honey bees			
19		10.3.	Avian infectious laryngotracheitis		
20	XXV	10.4.	Infection with viruses of notifiable avian influenza	Sep. 12	
21		11.3.	Brucellosis		
22	XXVI	11.8.	CBPP	Sep. 12	
23		12.1.	Infection with African horse sickness virus		
		12.6.	Infection with equine influenza virus		
		12.9.	Infection with equine viral arteritis virus		
24	XXVII	14.5.	Infection with <i>Chlamydophila abortus</i>	Sep. 12	
25		14.8.	Peste des petits ruminants	Sep. 11	
26		14.9.	Scrapie		
27		15.2.	Classical swine fever	Sep. 10	
28	XXVIII	New	Epizootic haemorrhagic disease		
29	XXIX		Report of the <i>ad hoc</i> Group on VE		
30	XXX		Work programme		
31			IAS		
32			Review of application for recognition as an OIE collaboration centre		
33			Generic checklist on the practical application of compartmentalisation		
34	XXXI	1.6.	Procedure for self declaration and for official recognition by the OIE	Sep. 12	
		11.5.	BSE		
35			Publication on the history of development of the OIE standards on avian influenza		

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.

Annex XXX (contd)

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

CHAPTER 1.6.

PROCEDURES FOR SELF DECLARATION AND FOR
OFFICIAL RECOGNITION BY THE OIE**EU comment****The EU supports the proposed changes to this chapter.**

Article 1.6.1.

[No change]

Article 1.6.2.

[No change]

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, *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, *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, *zone* or *compartment* (Articles 11.5.3. and 11.5.4.).

Annex XXXI (contd)

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, *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.

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, *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, *zone* or *compartment* of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
- feeding and management of the imported cattle in the country, *zone* or *compartment* of origin;
- use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported cattle represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- dairy versus meat breeds, where there are differences in exposure in the country, *zone* or *compartment* of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

Evidence required:

- a) Documentation including tables on the country, *zone* or *compartment* of origin of imports. This should identify the country, *zone* or *compartment* of origin of the cattle, the length of time they lived in that country, *zone* or *compartment* and of any other country in which they have resided during their lifetime.
- 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, *zone* or *compartment* of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
- feeding and management of the cattle in the country, *zone* or *compartment* of origin;
- use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported cattle represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- dairy versus meat breeds, where there are differences in exposure in the country, *zone* or *compartment* of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

Evidence required:

- a) Documentation on the country, *zone* or *compartment* of origin of imports. This should identify the country, *zone* or *compartment* of origin of cattle from which the products were derived, the length of time they lived in that country, *zone* or *compartment* and of any other country in which they have resided during their lifetime.
- 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, *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, *zone* or *compartment* is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the *risk assessment* to conclude that the cattle population of a country, *zone* or *compartment* is of negligible or controlled BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified. If potentially infected cattle or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity. Where *meat-and-bone meal* is utilized in the production of any cattle feed, the risk of cross-contamination exists.

Evidence required:

- 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 effectiveness is claimed)	Type of plant (renderer or feed mill)	Number of plants processing ruminant material	Number of plants in (A) inspected	Total number of visual inspections in (B)	Total number of plants in (B) with infractions	Total number of inspected plants in (B) with sampling	Total number of plants in (C) with positive test results
		(A)	(B)			(C)	
Year 1	Renderer						

	Feed mill						
Year 2, etc.	Renderer						
	Feed mill						

- 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 effectiveness is claimed)	Type of plant (renderer or feed mill)	Number of plants processing non-ruminant material	Number of plants in (A) inspected	Total number of visual inspections in (B)	Total number of plants in (B) with infractions	Total number of inspected plants in (B) with sampling	Total number of plants in (C) with positive test results
		(A)	(B)			(C)	
Year 1	Renderer						
	Feed mill						
Year 2, etc.	Renderer						
	Feed mill						

- 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				

Annex XXXI (contd)

- 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.

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, *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.

Annex XXXI (contd)*Evidence required:*

1. Documentation that the samples collected are representative of the distribution of cattle population in the country, *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, *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, *zone* or *compartment*.

SECTION 4: BSE HISTORY OF THE COUNTRY, ZONE OR COMPARTMENT (see Articles 11.5.3. and 11.5.4.)

Questions to be answered:

- Has BSE occurred in the country, *zone* or *compartment*?
- How has it been dealt with?

Rationale:

The categorization of a country, *zone* or *compartment* in either negligible or controlled risk is dependent upon, the outcome of the *risk assessment* described in Section 1, compliance with the provisions described in Section 2, the results of *surveillance* described in Section 3, and the history of BSE in the country, *zone* or *compartment*. This section provides the opportunity to describe the BSE history in the country, *zone* or *compartment*.

Evidence required:

1. Documentation of whether a case of BSE has ever been diagnosed in the country, *zone* or *compartment*.

In the case of positive BSE findings:

2. Documentation on the origin of each BSE case in respect to the country, *zone* or *compartment*. Indicate the birth date and place of birth.

Annex XXXI (contd)

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, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Article 1.6.4.

[No change]

Article 1.6.5.

[No change]

Article 1.6.6.

[No change]

Article 1.6.7.

[No change]

Article 1.6.8.

[No change]

CHAPTER 11.5.

BOVINE SPONGIFORM ENCEPHALOPATHY

EU comment

The EU supports the proposed changes to this 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*.

Annex XXXI (contd)

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:

- 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;

Annex XXXI (contd)

- 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;

Annex XXXI (contd)

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.

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.

Annex XXXI (contd)

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.

Article 11.5.9.

Recommendations for the importation of cattle from a country, zone or compartment posing an undetermined BSE riskFor 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 riskFor 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.

Annex XXXI (contd)

Article 11.5.11.

Recommendations for the importation of meat and meat products from a country, zone or compartment posing a controlled BSE riskFor 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 riskFor 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;

Annex XXXI (contd)

- 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.
- 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.

Annex XXXI (contd)

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 $\geq 138^{\circ}\text{C}$ 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.

Annex XXXI (contd)

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);

Annex XXXI (contd)

- 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.

Annex XXXI (contd)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*.

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;

- 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.

Annex XXXI (contd)**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

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.

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 \geq 1 year and <2 years			
0.01	0.2	0.4	N/A
Age \geq 2 year and <4 years (young adult)			
0.1	0.2	0.4	260
Age \geq 4 year and <7 years (middle adult)			
0.2	0.9	1.6	750
Age \geq 7 year and <9 years (older adult)			
0.1	0.4	0.7	220
Age \geq 9 year and <2 years (aged)			
0.0	0.1	0.2	45

If a country, *zone* or *compartment* determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'casualty or emergency slaughter, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the *surveillance* point values accorded to the combined subpopulation would be that of 'fallen stock'.

The total points for samples collected may be accumulated over a period of a maximum of seven consecutive years to achieve the target number of points determined in Table 1.

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:

Annex XXXI (contd)

- a) *meat-and-bone meal* or *greaves*;
- b) live *animals*;
- c) animal feed and feed ingredients;
- d) products of animal origin for human consumption.

2. Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

- a) epidemiological situation concerning BSE agents in the country or *zone*;
- b) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;
- c) the origin and use of ruminant carcasses (including fallen stock), by-products and *slaughterhouse* waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- d) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed; 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.

Annex XXXI (contd)

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.

Annex XXXI (contd)

- *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*.

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*.

Annex XXXI (contd)*Evidence required:*

- Documentation on the country of origin of imports. This should identify the country of breeding of *animals*, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the end use of imported animal products, and the disposal of 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.

Annex XXXI (contd)

- 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).

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.

— 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.