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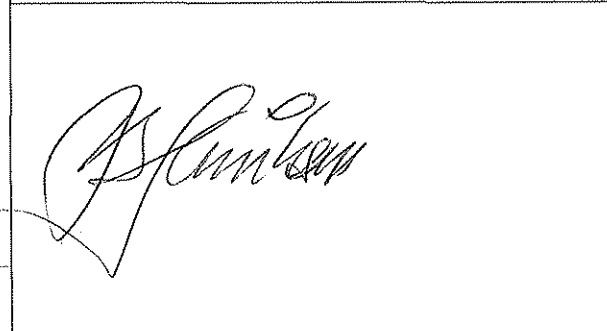
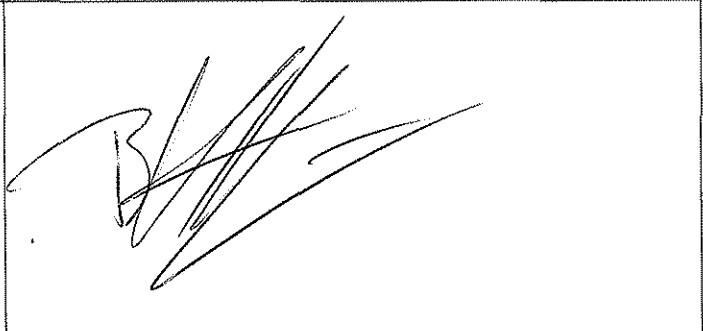
Dear Director General,

Please find attached, for your informal information, annexes indicating the intended positions of the European Union (EU) on the reports of the Terrestrial and Aquatic Animal Health Standards Commissions to be raised and drafts proposed for adoption at the 80th General Session in May 2012 in Paris.

We take this opportunity to inform you that the EU supports the adoption of the 25 draft revised chapters of the OIE *Terrestrial Manual* to be proposed for adoption in May 2012 and supports the proposed new Reference Laboratories and Collaborating Centres as proposed by the Biological Standards Commission.

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

Yours sincerely,

Dr Per Henriksen Chief Veterinary Officer Denmark	Dr Bernard Van Goethem Director for Veterinary and International affairs European Commission, DG Health and Consumers
	

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Annexes: 3

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



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ANNEX 1

Original: English
February 2012

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

Paris, 14–23 February 2012

The OIE Terrestrial Animal Health Standards Commission (the Code Commission) met at the OIE Headquarters in Paris from 14 to 23 February 2012.

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

The Code Commission thanked the following Members for providing written comments: Argentina, Australia, Canada, Chile, the People's Republic of China, Chinese Taipei, Colombia, Cuba, the European Union (EU), Japan, Mexico, New Zealand, Norway, Peru, South Africa, Switzerland, the United States of America (USA) and Uruguay. Comments were also received from the Secretariat of the Codex Alimentarius Commission (CAC), the Food and Agriculture Organization of the United Nations (FAO), the Secretariat of the Committee on Sanitary and Phytosanitary Measures of the World Trade Organization (WTO SPS Committee), two regional organisations – African Union – InterAfrican Bureau for Animal Resources (AU-IBAR); the Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA); the International Embryo Transfer Society (IETS), and a non-governmental organisation, the International Coalition for Farm Animal Welfare (ICFAW).

The Code Commission reviewed the documents identified in the agenda, addressing comments that Member Countries had submitted by 13 January 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. The amendments made at the February 2012 meeting are highlighted with a coloured background in order to distinguish them from those made at the September 2011 meeting.

All Member comments were considered by the Code Commission. However, because of the very large volume of work, the Commission was not able to prepare a detailed explanation of the reasons for accepting or not accepting every proposal received. Member Countries are reminded that if comments are resubmitted without modification or new justification, the Commission will not, as a rule, repeat previous explanations for decisions. The Commission encourages Member Countries to refer to previous reports when preparing comments on longstanding issues.

Member Countries should note that texts in Part A of this report are proposed for adoption at the 80th OIE General Session in May 2012. Texts in Part B are submitted for comment by Member Countries and all comments received will be addressed during the Commission's meeting in September 2012. The reports of meetings (Working Groups and *ad hoc* Groups) are also attached in Part B of this report.

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

Comments on this report must reach OIE Headquarters by 2 August 2012 to be considered at the September 2012 meeting of the Commission.

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

A. MEETING BETWEEN THE CODE COMMISSION AND THE SCIENTIFIC COMMISSION

A joint meeting of the Code Commission and Scientific Commission for Animal Diseases (the Scientific Commission) took place on Tuesday 14 February 2012. Dr Bernard Vallat, Director General of the OIE, and Dr Karim Ben Jebara, Head of the OIE Sanitary Information Department, attended part of the joint meeting.

The key points discussed are as follows:

Restructuring Volume 2 of the *Terrestrial Code*

Dr Kahn explained that the Code Commission proposes to continue progressively renaming the chapters in Volume 2 of the *Terrestrial Code* to make reference to the pathogen name, that is 'Infection with (disease agent)'. However, in response to comments from Member Countries, the proposal to completely restructure Volume 1 of the *Terrestrial Code* has been reconsidered based on the need to keep the *Terrestrial Code* as 'user friendly' as possible to the Member Countries. It is now proposed to maintain the current structure (that is, diseases of multiple species, diseases of bovidae, etc.). As each disease chapter is updated, provisions on relevant wildlife species will be added as appropriate. If a disease occurs in wild animals, this will not necessarily mean it will be considered as a disease of 'multiple species'. Rather, the inclusion of the chapter under a specific section (for example, bovidae) will reflect the presence of the disease in the species of greatest economic importance.

The meeting discussed the application of this approach in the recent merging of existing chapters on brucellosis into a proposed new Chapter 11.3. Infection with *Brucella abortus*, *B. melitensis* and *B. suis*. Dr Brückner, President of the Scientific Commission, outlined potential problems that had been identified in comments received from Member Countries on the proposed new chapter in which the three *Brucella* species had been addressed in a single chapter. Some Member Countries commented that they had difficulty harmonising this approach with existing disease control programmes and legislation, as well as declarations of disease freedom. It was foreseen that similar problems might be encountered with the planned revision of the chapters on tuberculosis. All agreed on the need to adopt an approach that would maximise Member Countries' ease in using the *Terrestrial Code*. The two Commissions decided to send the revised text, with Member Countries' comments, to a new *ad hoc* group, which could consider drafting three separate revised chapters.

It was agreed that the new approach of making provisions for wildlife in the disease chapters and requiring the reporting of findings in species of epidemiological significance raises complex issues, not least relating to requirements for risk management and disease surveillance, and for making decisions on disease status of countries. The two Commissions will proceed with this approach on a case by case basis.

It had previously been agreed that, following this approach, the two chapters dealing with *M. bovis* infection should be revised and combined into a single chapter. Noting that these texts had recently been updated, the Code Commission considered that there was no urgency to undertake this work. However, Dr Gideon Brückner indicated that a revision of the tuberculosis chapters had been listed as a priority on the Scientific Commission's work programme, once the revision of the chapters on brucellosis had been adopted.

The meeting agreed that the comments of Member Countries on the revised chapter on brucellosis had provided valuable feedback as to the concerns about the new approach.

Proposed OIE policy on addressing wildlife in the *Terrestrial Code* – discussion paper

Dr Kahn indicated that the Code Commission had received comments from many Member Countries on the proposed policy and that these were broadly supportive of the proposed direction, although there were some questions about how the policy would be applied. Dr De Clercq asked the Code Commission to explain how ‘epidemiologically significant’ would be defined, given the multiplicity of issues relevant to each disease.

The two Commissions are aware that a group of wildlife experts is currently drafting a book titled ‘*IUCN Guide to Wildlife Disease Risk Analysis*’. The methodology and terminology used are consistent with those of the OIE and the Scientific Commission indicated the need to make the *Guide* readily available to Members to help with the identification of epidemiological important species and to prioritise relevant wildlife diseases.

Dr Thiermann confirmed that the considerations and provisions for each disease would be set out in each individual disease chapter and regularly reviewed based on developments in scientific knowledge. These would then be submitted for comments by Member Countries and eventual adoption in the *Terrestrial Code*. Given the increasing recognition of the importance of wildlife and healthy ecosystems to human wellbeing, the Commissions recommended that, at the 80th General Session (2012), the Director General propose a final OIE policy on wildlife in the standards.

Disease listing criteria – proposed modification of Chapter 1.2.

Dr Thiermann indicated that the Code Commission had received comments from many Member Countries on the revised text circulated after the Code Commission’s meeting of September 2011. These, together with comments of the Scientific Commission, would be addressed and a revised text will be proposed for adoption at the 80th General Session. Dr Vallat endorsed the importance of finalising the revised chapter, which had been under review for some time, as it has broad implications for OIE standards. Revision of chapters on certain diseases, such as swine vesicular disease and vesicular stomatitis, was ‘on hold’ pending adoption of the new disease listing criteria, which would be followed by reassessment to determine whether these diseases continue to be listed.

Dr Ben Jebara informed the meeting that, once the draft chapter had been adopted, the *ad hoc* Group on Notification of Animal Diseases and Pathogenic Agents would be convened prior to the September 2012 Commission meetings to review the list of diseases in the *Terrestrial Code*.

Chapter 8.5. – Foot and mouth disease

Dr Brückner informed the Code Commission that a fundamental review of the chapter had commenced with the meeting of an *ad hoc* Group in February 2012 and was ongoing. It is hoped that the revised text would be provided to the Code Commission for consideration at its September 2012 meeting. The revision of the chapter will attempt to make it more user-friendly, especially in relation to the application of concepts such as compartmentalisation and recovery of free status. Dr Brückner requested the Code Commission to propose important modifications to the FMD questionnaire (Article 1.6.) for adoption at the 80th General Session. These modifications provide for the endorsement of official national disease control programmes for FMD and their adoption could avoid problems identified in the evaluation of the dossiers received from Member Countries. The Code Commission agreed to address the proposed amendments to the questionnaire as a matter of priority.

The Scientific Commission also proposed to provide latest scientific evidence on virus inactivation in casings. This evidence will comprise recent scientific publications and the outcome of an EFSA meeting in February 2012, in addition to a risk assessment from the International Scientific Working Group of the International Natural Sausage Casings Association provided by the Code Commission.

Chapter 8.10. – Rabies

Dr Vallat highlighted the importance of the revision of Chapter 8.10. in view of the OIE's ongoing collaboration with the WHO and FAO on the global control and prevention of rabies, which is one of the most important zoonotic pathogens in the world. Dr Vallat encouraged the Commissions to finalise their review of Chapter 8.10. and to propose a final text for adoption by Members in May 2012. Dr Thiermann advised that, in the second round of Member Country comment, the Code Commission had again received many, sometimes contradictory, comments on the revised text. Dr Brückner indicated that the Scientific Commission would review the Member Countries' comments and forward its advice to the Code Commission. Both Commissions agreed that a revised chapter would be proposed for adoption in May 2012.

African horse sickness (AHS)

Dr Vallat noted the importance of expediting the proposal for official recognition of AHS freedom. Dr Thiermann agreed that the Code Commission would review Member Countries' comments on the revised chapter, and Scientific Commission comments, with a view to proposing revised provisions in Chapters 12.1. (African horse sickness) and 1.6. on Procedures for official recognition for adoption at the 80th General Session.

Chapter 15.2. – Classical swine fever (CSF)

Dr Brückner informed the meeting that the *ad hoc* Group on classical swine fever had completed its review of Chapter 15.2. and that the Scientific Commission would send a revised text with proposed requirements for official recognition for CSF free status, including a questionnaire and surveillance guidelines, to the Code Commission for review. Dr Vallat asked the Code Commission to prioritise its review and to provide a draft for consideration by Member Countries, with a view to potential adoption of the revised text and provisions for official recognition at the 81st General Session (2013). Dr Thiermann confirmed that the Code Commission would examine the draft text as a high priority item when received.

Chapter 14.8. – Peste des petits ruminants (PPR)

Dr Vallat noted the interest of OIE Member Countries in considering the establishment of conditions for recognition of official PPR free status and urged the two Commissions to progress this work as a matter of priority. The Code Commission expressed its concern regarding the current draft text, as it found it to be excessively restrictive in terms of recommendations for trading of commodities and inclusion of host species of low epidemiological significance, such as cattle and camels. Both Commissions agreed to prioritise the review of Member Countries' comments. Dr Brückner advised that the process would be to aim for adoption of the amended Chapter 14.8. followed by approval of the OIE Council for the policy of providing official OIE recognition for PPR status and, finally, the declaration of a global control programme for PPR.

Chapter 8.12. – Rinderpest

Dr Vallat highlighted the priority of progressing work identified in the Resolution on Global Freedom from Rinderpest adopted at the 79th General Session. The Code Commission undertook to review Member comments on the revised text of Chapter 8.12., with a view to adoption at the 80th General Session. Both Commissions expressed concern at the delay in further action, which is dependent on progress and information to both Commissions, especially on the procedures and guidelines for the sequestration of rinderpest virus from the Joint OIE/FAO Advisory Committee on Rinderpest.

Requirements for notification – avian influenza

Dr Vallat asked the Commissions to consider the need to clarify the reporting provisions for notifiable avian influenza, based on some concerns that had been raised with him. Dr Thiermann advised that the Code Commission had already considered this matter and would propose a simple amendment to Chapter 10.4., which would not change the current provisions but rather would state them more clearly.

Schmallenberg virus

Dr Vallat noted that the OIE has received requests for advice on the risk of spreading this new virus as a consequence of international trade. An expert meeting had been convened and had provided advice on scientific issues, trade related concerns and risk management and a statement would be published this week. Key points to note are that there is no evidence suggesting that this new virus has any zoonotic implication. It is an arboviral disease and animal products such as meat and milk pose no animal or public health risk. Dr Vallat noted that there are still many gaps in the existing scientific knowledge of the disease. This matter would thus be kept under review. Dr Vallat recommended that the *ad hoc* Group meet again before the 80th General Session in May 2012 and agreed that the Scientific Commission would be given time during its presentation to update Member Countries on the disease.

After Dr Vallat left the meeting, due to commitments to other meetings, the two Commissions continued to discuss issues of mutual interest, as follows:

Invasive alien species

Professor MacDiarmid provided a short update on the results of a meeting at the OIE Headquarters on invasive alien animal species held at the end of 2011. Prof. Stuart MacDiarmid noted that he and Dr Brückner attended the meeting, as did the Chair of the OIE Working Group on Wildlife Diseases, representatives of the Secretariats of the Convention on Biological Diversity (CBD) and the World Trade Organization SPS Committee. The meeting produced a document on draft report 'Guidelines for assessing the risk of non-native animals becoming invasive'. Both Commissions commended this initiative of the OIE in undertaking this work and asked the Director General to take appropriate steps to publish the Guidelines on the OIE website, for guidance of Members.

Brainstorming on equine diseases

Dr Kahn informed the two Commissions about a brainstorming meeting to be held in Paris on 12-14 March on facilitating safe international movement of horses to equine events. The meeting will be attended by several OIE reference experts on equine diseases, as well as representatives of the Federation Equestre Internationale (FEI), with which the OIE has an official agreement. The objective of the meeting is to identify constraints and areas in which the OIE and the FEI might collaborate to review standards or provide advice to Members on this topic in view of the growing international movement of horses to participate in events. The meeting will report to both the Scientific Commission and the Code Commission.

OIE policy on official recognition of collaborating centres

Dr Kahn informed the meeting that an OIE collaborating centre (CC) on multiple topics had applied for recognition as four separate CCs on the topics of animal welfare, food safety, epidemiology and veterinary training. She noted that the Code Commission would consider the proposal relating to animal welfare and food safety (including seeking advice from the relevant OIE Working Groups). Dr Elisabeth Erlacher-Vindel advised that the Scientific Commission would review the proposal relating to epidemiology. The OIE Council's review of policy on CCs would need to be considered in relation to the proposal regarding veterinary training.

It was agreed that the OIE International Trade Department and the OIE Technical and Scientific Department would ensure coordination in the handling of this request.

Chapter 8.13. – Infection with *Trichinella* spp.

Dr Thiermann informed the meeting that the Code Commission had received many Member comments on the revised Chapter 8.13. Dr Bonbon, who was an observer at the most recent meeting of the *ad hoc* Group on this topic, explained the approach taken to the revision of Chapter 8.13., which now specifically addresses infection with *Trichinella* species in addition to *T. spiralis*. The Scientific Commission noted this information. Dr Thiermann advised that this topic continues to be of high priority for the Code Commission and that it would review Member comments and provide guidance to a review by a new *ad hoc* group.

Generic checklist on the practical application of compartmentalisation

Dr Brückner advised that the Scientific Commission had considered the comments provided by the Code Commission and would provide a revised text in due course. Dr Brückner discussed the evaluation of sanitary status when the compartment approved for a specific disease experienced an outbreak of another disease. Both Commissions agreed that notification should be carried out in the same way had the outbreak happened anywhere else in the country. However, the Scientific Commission proposed that the sequence of interventions be managed differently in a compartment. The Scientific Commission proposed to decide on disease status after an evaluation of the biosecurity measures in the compartment had been taken. Both Commissions agreed. The Code Commission will check the proposed text so that it aligns with *Terrestrial Code* provisions and refer it back to the OIE Scientific and Technical Department for publishing on the OIE website for information of Member Countries.

Dr Thiermann stated that more specific guidelines on contingency planning are needed in this checklist, as the application of these are critical in the recognition of the status of a compartment by importing countries.

B. ADOPTION OF THE AGENDA

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

The Code Commission acknowledged the record number of Member Country comments received on texts circulated after its September 2011 meeting, with a high proportion coming from the Latin American countries and OIRSA. The OIE is committed to continuing to improve the Spanish language edition of the *Terrestrial Code* and so the participation of the Latin American countries in the standard setting process is particularly appreciated. The large number of comments from the African Union-InterAfrican Bureau for Animal Resources (AU-IBAR) was also appreciated.

With reference to the many linguistic revisions to the Spanish edition of the *Terrestrial Code* proposed by the Code Commission in response to the comments of Hispanophone Members, it was decided to present these text modifications only in the Spanish version of this report. The Commission noted that it had received a significant number of Member Countries' comments and concerns on certain chapters revised by the *ad hoc* Groups and had to spend considerable time to address these comments. The Commission considered that *ad hoc* Groups should be given clearer guidance when undertaking their reviews. With this in mind, Dr Vallat was asked to invite participation by a member of the Code Commission in the *ad hoc* Groups on classical swine fever, peste des petits ruminants, brucellosis and antimicrobial resistance.

Item 1 General comments of OIE Member countries

- a) General comments from Member Countries
- b) OIE standard setting procedures

Lacking time, these two items were carried over to the September 2012 meeting.

EU comment

The EU regrets that its general comments were not addressed by the Code Commission in its February 2012 meeting. With regards to its September 2012 meeting, the EU strongly suggests the Code Commission consider adding on its work programme the drafting of an introductory chapter to the Code, which would include relevant elements detailed in the Foreword.

Item 2 Horizontal issues

- a) Restructuring of the *Terrestrial Code* Volume 2

EU comment**The EU supports the proposed approach on the restructuring of Volume 2 of the Terrestrial Code.**

The approach proposed by the Commission on this issue is detailed in the section ‘A meeting between the Code Commission and the Scientific Commission’ (above).

b) Development of the *Terrestrial Code* to address wildlife

The Code Commission received comments from many Member Countries on the proposed policy for addressing wildlife in the *Terrestrial Code*. Most comments were broadly supportive, although some asked questions about how the policy would be applied and how ‘epidemiologically significant’ would be determined.

The Commission considered that this could only be done on a disease by disease basis, as discussed at the joint meeting of the Code Commission and the Scientific Commission with Dr Vallat.

The Code Commission considered that the proposed policy represents a practical compromise. The objective is to encourage reporting and the collection of relevant information on animal diseases, including in wild animals, by establishing a framework with which Member Countries can comply under real-life conditions. The Commission recognised the need to maintain balance between the various national priorities of Veterinary Services, for which disease surveillance is just one priority, and disease reporting in wildlife a sub-set of this. To encourage transparency, it is important to avoid generating trade bans or other practical problems as side effects of reporting findings in wildlife species which may have little significance for national programmes for animal health and food safety.

In response to Member Countries’ requests for explanations of how the policy would be applied in practice, the Code Commission considered that this matter would need to be studied in light of experience. Noting that many *Terrestrial Code* chapters are currently under review, the Commission decided to defer detailed consideration of Members’ comments on the proposed wildlife policy until after the 80th General Session. This would allow for consideration of several relevant amendments to the *Terrestrial Code*, and outcomes of the proposed new listing criteria (should they be adopted) to be factored into the discussion.

In the meantime, the Commission encouraged Member Countries to accept the proposed policy as a practical basis on which to proceed.

EU comment**The EU supports the proposed policy of the Code Commission on the development of the Terrestrial Code to address wildlife.****Item 3 Glossary**

Comments were provided by Chile.

On the basis of discussion within the OIE regarding the lack of a definition for the term ‘infestation’ in the Glossary, even though the term ‘disinfestation’ is defined, the Code Commission drafted a new definition of ‘infestation’ and amended the definition of ‘disinfestation’ as appropriate.

The amended Glossary, proposed for adoption, is attached as Annex III.

EU position**The EU supports the adoption of the modified Glossary.**

Item 4 Chapter 1.2. Criteria for the inclusion of diseases and infections on the OIE List

The Code Commission reviewed comments from Argentina, Australia, Canada, Chile, the EU, Japan, New Zealand, Norway, South Africa, Switzerland, the USA and regional organisations (AU-IBAR and OIRSA).

The Commission strengthened the reference to WAHIS by including a reference to this in the revised Article 1.2.1. The phrase ‘taking into account the animal health information notified in WAHIS’ was removed from Article 1.2.1., subpoint 2, because the information in WAHIS should generally be consulted, not only in seeking to specifically demonstrate disease freedom.

Based on the comments of two Member Countries, supported by the Scientific Commission, the Code Commission deleted the phrase ‘excepting the situation where effective prevention and control measures are commonly used’. However, the Commission recommended that when examining the current significance of morbidity or mortality of disease, the availability and common use of effective prevention and control measures be taken into account.

A comment of a Member Country on the criterion for the effect of diseases in wildlife was not supported.

A Member Country’s comment on the criterion for emerging diseases was not supported because emerging diseases typically present potentially significant (but initially unclear) risks. This criterion recognises uncertainty. The Commission did not agree that the human illness should be addressed in the manner proposed by the Member Country, as the phrase ‘with evidence of zoonotic properties’ was considered to cover this point adequately.

A Member Country proposed to include a new point 6; ‘The disease has been eradicated globally but is under surveillance for eventual reoccurrence’. The rationale for this modification related to the need to keep rinderpest as a listed disease post-global freedom. However, the Code Commission was confident that under criteria, 1 to 5, rinderpest would continue to be listed and that there was no need to add new text to address this.

In Article 1.2.2., the Code Commission did not accept the recommendations of a Member Country, supported by the Scientific Commission, to add the phrase ‘infectious pustular balanopostitis’ to the name of the disease ‘infectious bovine rhinotracheitis/infectious pustular vulvovaginitis’ (IBR/IPV). The Commission acknowledged that while balanopostitis is one of the clinical manifestations of infection with bovine herpesvirus, the common name of the diseases is ‘infectious bovine rhinotracheitis/infectious pustular vulvovaginitis’ and, therefore, the name is correctly stated in the *Terrestrial Code*.

A Member Country proposed to list respiratory coronavirus. The Code Commission recommended that the Member Country send appropriate information relevant to the disease listing criteria to the *ad hoc* Group on Notification of Animal Diseases and Pathogenic Agents once the revised listing criteria had been adopted.

The Commission agreed with Member Countries’ proposals on Article 1.2.2. and added the word ‘infestation’ where needed to cover diseases caused by screwworm and certain bee parasites.

The revised Chapter 1.2., proposed for adoption, is at Annex V.

EU position

The EU thanks the OIE and supports in general the adoption of this modified chapter and has some comments inserted in the text of the Annex V.

The Commission was informed by the OIE Animal Health Information Department that telegram has not been in use as a means of disease notification to the OIE and decided to revise Chapter 1.1., as appropriately.

The revised Chapter 1.1., proposed for adoption, is at Annex IV.

EU position

The EU supports in general the adoption of this modified chapter and has one comment, inserted in the text of Annex IV.

Item 5 Animal health surveillance (Chapter 1.4.)

The Code Commission thanked Prof. MacDiarmid, who had made an editorial revision of the chapter with the intention of correcting and clarifying the English text. After review, the Commission confirmed that the scientific provisions had not been changed. The Commission removed the reference to ‘compartment’ from point 1 (a) of Article 1.4.6. ‘historically free’ as the concept of ‘historically free compartment’ was not considered to be meaningful, given the disease-specific biosecurity management procedures which must be implemented and documented when designating a compartment.

The revised Chapter 1.4., proposed for adoption, is at Annex VI.

EU position

The EU supports the adoption of this modified chapter but has two comments inserted in the text of Annex VI.

Item 6 Import risk analysis (Chapter 2.1.)

Comments were received from Argentina, Australia, Canada, Chile, the EU, New Zealand, South Africa and OIRSA. The Code Commission also reviewed the comments provided by the USA on Chapter 2.2. of OIE the *Aquatic Animal Health Code (Aquatic Code)*, which were considered to be relevant to the *Terrestrial Code* Chapter 2.1.

The Code Commission noted that Member Countries had supported the amendment proposed in September 2011. Consistent with the approach agreed in September 2011, the Commission will make the same amendment in other relevant parts of the *Terrestrial Code* as appropriate upon the adoption of this chapter.

The Code Commission also noted several more extensive amendments suggested by a Member Country. However, because the Commission considered that these would not significantly improve the current text and were already well covered by the OIE *Handbook on Import Risk Analysis for Animals and Animal Products*, the Commission did not accept these comments. A proposal to include a new diagram was not accepted because it illustrated a process different from that of the OIE and used some terms not used by the OIE.

The amended chapter, proposed for adoption, is at Annex VII.

EU position

The EU supports the adoption of this modified chapter.

Item 7 Support for Veterinary Services

a) Evaluation of Veterinary Services (Chapter 3.2.)

Comments were received from the EU and Switzerland supporting the modification of the text.

The amended chapter, proposed for adoption, is at Annex VIII.

EU position

The EU supports the adoption of this modified chapter and has three comments to be taken into consideration by the Code Commission at its next meeting.

b) Communication (Chapter 3.3.)

Comments were received from the EU, Norway and OIRSA. The Commission also reviewed the comments of Australia, Canada, the EU and New Zealand on the new draft Chapter XX of the *Aquatic Code*, which were considered to be relevant to *Terrestrial Code* Chapter 3.3.

The comments of Member Countries on point 2 of Article 3.3.2. were not accepted, because the Commission considered that the current text provides for the integration of veterinary expertise and communication expertise in the veterinary services while giving sufficient flexibility.

Following a Member's comment on point 4 (b) of Article 3.3.4., the Commission deleted 'long-term plan' and clarified the text.

The amended chapter, proposed for adoption, is at Annex IX.

EU position

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

c) Veterinary legislation (proposed new Chapter 3.4.)

Comments were received from the EU, Japan, New Zealand, Norway, Switzerland, the OIE Animal Production Food Safety Working Group (APFSWG), the Secretariat of the Codex Alimentarius Commission (CAC), the Secretariat of the WTO SPS Committee, and OIRSA.

The Commission reviewed the report of the *ad hoc* Group on Veterinary Legislation, which met in January 2012. The Commission endorsed the work of the *ad hoc* Group and made some comments and modifications to the draft Chapter 3.4., in response to Member Countries' comments, as described below.

In response to a Member Country which opposed the inclusion of this new chapter in the *Terrestrial Code*, the Code Commission stated that the OIE fully appreciates the diverse conditions that exist in OIE Member Countries. However, Member Countries have asked the OIE to provide standards on the fundamental elements to be covered in veterinary legislation. At the request of Member Countries, the OIE is already undertaking missions on veterinary legislation as a follow-up to an initial evaluation mission under the PVS Pathway. Standards on veterinary legislation will be used as the reference point in these missions. These standards can also be used to help Veterinary Services (VS) in developing countries convince governments and donors of the need to modernise legislation and harmonise it with the international standards as a fundamental aspect of VS competency and governance.

In response to a Member Country's comments that it was not the OIE's role to define legal terms, the Code Commission considered that some terms used in the chapter needed to be defined to aid understanding and noted that the phrase in Article 3.4.2. 'for the purpose of this chapter' makes this clear.

On Article 3.4.11. (Veterinary medicines and biologicals), the Code Commission agreed with the *ad hoc* Group's recommendation that the *Terrestrial Code* terminology on veterinary medicines and biological products (variously referred to as veterinary products, pharmaceutical products, etc.) should be reviewed for consistency and consideration given to defining key terms. The OIE International Trade Department undertook to report to the Commission's September 2012 meeting on this topic.

Dr Kahn informed the Commission that the OIE had received rather detailed comments from the FAO legal offices (LEGN-AGN) on the draft text after the meeting of the *ad hoc* Group. The Commission asked the *ad hoc* Group to review these comments at its next meeting.

The revised text of the new Chapter 3.4., proposed for adoption, is at Annex X.

EU position

The EU thanks the OIE and supports in general the adoption of this new chapter but has comments, some of which should be taken into account before adoption.

Indeed, the EU supports the adoption of this new chapter 3.4. on veterinary legislation and its inclusion in the OIE Terrestrial Code, as long as this represents a real help for Members and will not be used to create unjustified barriers to trade.

The report of the *ad hoc* Group is at Annex XXX for information.

Item 8 Semen and embryos

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

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

The recommendation of a Member Country to make new provisions on equine semen was noted and tentatively added to the Commission's work programme. The Commission noted that if this proposal for new work is supported by Member Countries, the Scientific Commission would be asked to convene an *ad hoc* Group on the topic. The Commission also noted that it would be preferable to develop a new chapter on equine semen, in order to avoid introducing further complexity to Chapter 4.6., and in light of the fact that the equine artificial insemination industry may be quite different from that covered in Chapter 4.6.

A Member Country's recommendation to add 'producing semen for international distribution' to Article 4.6.1. was not accepted, because the term 'artificial insemination centres' is defined in the Glossary and the usage in this article is based on the definition.

The entire chapter was modified by deleting 'mucosal disease', as bovine viral diarrhoea is the name of the listed disease given in Chapter 1.2.

Based on the rationale given by Member Countries, the Commission modified the text of Article 4.6.3. to require that animals, but not semen, be tested for maedi-visna and caprine arthritis encephalitis.

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

The Commission reviewed comments from Chile, the EU, the USA and the IETS.

In response to a comment from a Member Country and the IETS, the Commission added equine viral arteritis to the Category 4 diseases in Article 4.7.14., as recommended by the IETS Regulatory Sub-Committee (report dated January 2012).

In response to a request from the IETS Regulatory Sub-Committee to retain the IETS categorisation of diseases and pathogenic agents without modification, the Code Commission modified Article 4.7.14. indicating that the categorisation is based on IETS recommendations and clearly identifying unlisted diseases, as 'not an OIE listed disease'.

The amended Chapters 4.6. and 4.7., proposed for adoption, are at Annex XII.

EU position

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

Item 9 OIE procedures relevant to the WTO SPS Agreement (Chapter 5.3.)

The Commission reviewed the revision of Article 5.3.1. (Obligations of WTO Members) proposed by the *ad hoc* Group on veterinary legislation in response to concerns raised by the Secretariat of the WTO SPS Committee. The Commission noted that the obligation of notification was for WTO Members only, and that not all OIE Member Countries are WTO Members. The Commission revised the proposed text for better alignment with the obligation in the WTO SPS Agreement.

The revised Chapter 5.3., proposed for adoption, is at Annex XIII.

EU position

The EU supports the adoption of this modified chapter.

Item 10 Salmonellosis

- a) Biosecurity procedures in poultry production (Chapter 6.4.)

The Code Commission reviewed this chapter, taking into account comments from the EU and Peru and made some amendments, as appropriate.

The Code Commission agreed with a Member Country's comment to add a reference to the Codex 'Guidelines for the Control of *Campylobacter* and *Salmonella* in chicken meat (CAC/GL 78-2011)' in Article 6.4.2.

Following a Member Country's comment, a new sub-point (c) was added to Article 6.4.5., point 2, reading 'All equipment should be cleaned and sanitized before being taken into a poultry house'.

The amended Chapter 6.4., proposed for adoption, is attached at Annex XIV.

EU position

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

The EU reiterates its former comment that the Code should have an introductory chapter including some part of the Foreword, so that this Chapter 6.4. (and others) would not be used as unjustified barriers to trade.

- b) Cross reference to Chapter 6.4. in Article 13.2. (Rabbit haemorrhagic disease)

Comments were received from the EU, supporting the proposed amendment.

The amended Chapter 13.2., proposed for adoption, is attached at Annex XV.

EU position

The EU supports the adoption of this modified chapter.

Item 11 Antimicrobial resistance

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

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

The Code Commission noted that the *ad hoc* Group on Antimicrobial Resistance had reviewed most but not all Member Country comments and provided relevant technical advice on them. The Commission reviewed the report of the *ad hoc* Group and those Member Countries' comments that had not been addressed by the *ad hoc* Group.

Based on the *ad hoc* Group report and following Member Countries' comments, the Commission modified the text as appropriate.

In response to a Member Country's request for clarification on the inclusion of a table and a reference to a journal article in Article 6.7.3., the Commission deleted the reference, as this was considered to be background information and inappropriate in a *Terrestrial Code* chapter.

The Commission referred to the *ad hoc* Group a Member's request to modify Article 6.7.3., subpoint 6 (a ii).

The revised Chapter 6.7., proposed for adoption, is at Annex XVI.

EU position

The EU thanks the OIE and supports the adoption of this modified chapter and has some comments inserted in the text of Annex XVI.

b) Monitoring of the quantities of antimicrobials used in animal husbandry (Chapter 6.8.)

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

The Commission reviewed the report of the *ad hoc* Group on antimicrobial resistance and amended the texts taking the recommendations of *ad hoc* Group into consideration.

The revised Chapter 6.8., proposed for adoption, is at Annex XVII.

EU position

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

In order to better harmonise the Terrestrial and Aquatic Codes and to make economies of scale, the EU encourages the OIE to have a single *ad hoc* Group dealing with both the Terrestrial and Aquatic Codes on this matter.

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

Comments were received from Argentina, Australia, Canada, Chile, the People's Republic of China, Cuba, the EU, Mexico, New Zealand, Switzerland, the USA and AU-IBAR.

The Commission noted the extensive comments received after the *ad hoc* Group meeting in December 2011 and referred these back to the *ad hoc* Group for advice.

EU comment

The EU thanks the OIE and hopes that its comments will be taken into account by the *ad hoc* group.

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

The Commission noted the report of the *ad hoc* Group on Antimicrobial Resistance had revised Chapter 6.10., which had been approved by the Scientific Commission.

The revised Chapter 6.10., for Member Country comment, is attached at Annex XXXI.

EU comment

The EU thanks the OIE and will send comments on this chapter by 2 August 2012.

Item 12 Zoonoses transmissible from non-human primates (Chapter 6.11.)

The Code Commission reviewed the revised chapter provided by the Scientific Commission in September 2011, taking into account comments from the *ad hoc* Group on the Welfare of Animals used in research and education, and made some amendments to the text as appropriate.

The revised Chapter 6.11. for adoption is at Annex XVIII.

EU position

The EU can support the adoption of this modified chapter on the condition that its comment as to CITES inserted in the text of Annex XVIII is taken into account.

Further comments are inserted in the text of Annex XVIII as to a reference to Article 7.8.7 on use of purpose bred non-human primates and the entries for "Tuberculosis" in the tables.

Item 13 Animal welfare

- a) Draft new Article 7.1.4. Animal welfare and livestock production systems – guiding principles

Comments were received from Australia, Canada, Chile, Chinese Taipei, Colombia, the EU, Japan, New Zealand, Peru, Switzerland, Uruguay and the USA as well as two regional organisations (AU-IBAR and OIRSA) and a NGO (ICFAW).

In addition to commenting on the new draft Article 7.1.4, the Code Commission noted that several Member Countries had recommended modifications to the established Articles 7.1.1. to 7.1.3.

On Article 7.1.1., the Commission did not agree to change ‘care’ to ‘management’ as this last word is included in ‘husbandry’. Regarding a Member Country’s comment on the addition of the words ‘appropriate and timely’ it was decided to add ‘appropriate’ which includes the concept of timeliness.

On Article 7.1.2, the Commission did not agree with a Member Country’s suggestion to include a reference to the Farm Animal Welfare Committee (FAWC) in point 2 because the concept of the ‘internationally accepted 5 freedoms’ has been in the *Terrestrial Code* for several years and the Commission did not consider it appropriate to now introduce a reference to FAWC.

Following a Member Country’s comment, the Commission replaced the word ‘science’ with ‘research’ in point 5 of Article 7.1.2.

Regarding a Member Country’s comment on the inclusion of the word ‘health’ in point 8 of Article 7.1.2., the Commission did not accept the inclusion and explained that there are two broad sets of performance criteria; namely, those that are based on outcomes for the animal, and those based on the design of the production system, also known as design-based criteria.

Following several Member Countries’ comments, the Commission added ‘should always take into account’ before ‘health and welfare of animals’ in point 1 and deleted the word ‘genetically’.

Following several Member Countries’ comments, the Commission modified point 2 to read ‘so as to minimise the risk of injury and transmission of diseases...’.

Following Member Countries’ comments, point 4 was modified by adding ‘be managed to allow positive social behaviour and minimise injury, distress and chronic fear’ and point 5 was modified to read ‘Air quality, including temperature and humidity, in confined spaces....’.

Following Member Countries' comments, in point 6, the words 'serious or' were removed and 'productivity' introduced in place of 'vigour'.

The Commission noted a recommendation from a NGO but did not accept the proposed inclusion of a new point 6A. While it agreed on the need for production systems to avoid ill-health, pain and injury, it considered that this point was well addressed through the ten points in the draft Article 7.1.4.

Following Member Countries' comments, in point 7, the words 'and controlled' were added after 'prevented' and 'economic constraints' was deleted from point 8.

In point 9, the only modification made was to clarify the 'human-animal relationship'.

Most of the comments submitted by Member Countries were addressed and some were partially addressed in those situations in which opposing recommendations from Members Countries could not be totally reconciled.

The revised Chapter 7.1., proposed for adoption, is at Annex XIX.

EU position

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

b) Animal welfare and beef cattle production systems (draft new Chapter 7.X.)

Comments were received from Australia, Canada, Chile, the EU, Japan, New Zealand, Norway, South Africa, Switzerland, Uruguay, the USA, a regional organisation (OIRSA) and a NGO (ICFAW).

The Commission greatly appreciated the disciplined work of the *ad hoc* Group, which had addressed the multiple and diverse comments of Member Countries and produced a much simpler and clearer text. The Commission considered all Member Countries' comments carefully and made some amendments to the text. In its review, the Commission noted that many Member Countries' comments, if accepted, would have introduced excessive detail into the text. Modifications were made only where the Commission considered that they would improve the text significantly. As most of the comments were minor, in terms of the substance of the draft, the Commission was of the opinion that the draft should be submitted for adoption at the 80th General Session

Following several Member Countries' comments on Article 7.X.2., the Code Commission clarified the scope by replacing the words 'on-farm' by 'welfare' and by deleting the second sentence.

The Commission did not agree with a Member Country's recommendation to include the word 'housing' and a new definition for 'Intensive grazing' as it considered that these modifications were unnecessary.

In response to the comment of a NGO on the need to take resource-based criteria into account, the Commission added a sentence to address this concern.

In order to address several Member Countries' comments with which the Commission agreed, some modifications were made to point 1 of Article 7.X.4., taking care to maintain a clear and simple text.

The Commission did not agree with a Member Country's recommendation to move the paragraph on post-mortem examination to the point on 'Mortality', as it considered that the point was correctly placed.

The Commission did not agree to add 'the presence of endoparasites' to point 6, bullet 1, as suggested by two Member Countries, as the concept of physical observance of endoparasites was not considered to be meaningful.

Several Member Countries recommended deleting 'depression' from the list in point 6 'Physical appearance' as this trait is more accurately described as an attribute of behaviour. The Commission agreed and moved 'depression' to point 1 'Behaviour'.

The Commission modified the terminology used for restraining boxes in Article 7.X.4., point 7, ('Handling responses') and, in accordance with a Member Country's comment, included the word 'slipping' under point 7, bullet 3.

Notwithstanding several Member Countries' comments, the Commission did not agree to remove the word 'percentage' as this was considered to be correct.

Following the comments of several Member Countries on Article 7.X.4., point 8, the Commission amended the text but did not add any new bullets to this point.

Following the recommendations of several Member Countries to modify Article 7.X.5. to improve the language in both Spanish and English, the Commission made appropriate amendments.

The Commission modified and simplified the text in Article 7.X.5., point 1 (b), 'Animal health management' to make it less prescriptive.

Following comments from several Member Countries on Article 7.X.5., point 2, 'Environment', the Commission made appropriate amendments to the text. The Commission did not accept a Member's recommendation to include 'shelter' in this point as it did not consider 'shelter' to be pertinent in extensive farming systems.

In relation to a comment on ammonia, the Commission referred the Member Country to the explanation provided in the *ad hoc* Group's report which was included as Annex XII to the report of the Code Commission's September 2011 meeting.

The Commission did not accept a Member Country's proposal to make reference to the level of haemoglobin under Article 7.X.5., point (e), 'Nutrition', as it considered that such level of detail is too prescriptive.

A Member and a NGO recommended against the use of fully slatted floors and one Member commented that rubber-coated slats were preferable to wood or concrete. The Commission considered this to be an excessive level of detail and referred concerns on this point to the report of the *ad hoc* Group.

In response to Member Countries' comments the Commission modified the text on the mixing of horned and non-horned cattle in Article 7.X.5., point 2 subpoint (g), 'Social environment'.

The Commission did not agree with the comment of a Member Country on the need to include 'outdoor areas' in Article 7.X.5., point 2 sub-point (h), 'Stocking density', as it considered that this was effectively covered in point (f) 'Flooring, bedding, resting surfaces and outdoor areas'.

Following Member Countries' comments on point 3 of Article 7.X.5. 'Management', the Commission agreed to replace the word 'ability' by 'instincts' under point (a) 'Genetic selection', and to replace 'operator' by 'handler' under point (b) 'Reproductive management'.

Regarding a NGO's comment on the use of double muscled animals in point (b) 'Reproductive management', the Commission considered that this issue was already addressed in the text and in the list of identified outcome-based measurables.

Concerning a Member Country's comments on point (c) of Article 7.X.5.3. 'Colostrum', the Commission did not agree to reduce the hours from 24 to 6, as it was not considered achievable by all OIE Members. The Commission also noted that the authority cited for such a change was a document on intensive veal calf production and veal production is specifically excluded from this Chapter. Regarding the modification suggested by a Member Country on the outcome-based measurable for the same point, the Commission decided that a reduction in the weight is indeed a

change in weight and therefore decided not to change the text and keep it as already defined in point 4) of Article 7.X.4.

In order to address Member Countries' comments on point (d) 'Weaning' of Article 7.X.5.3., the Commission agreed with the provided rationale, and made minor changes in the text.

Regarding Members' comments suggesting to modify the text of the first paragraph in point e) 'Painful husbandry procedures' of Article 7.X.5.3., the Commission, after a thorough discussion, and taking into account the comments of the *ad hoc* Group on this point, deleted 'Where possible' because it considered that this phrase did not make a useful contribution to the paragraph. The Commission did not accept the recommendation to remove the word 'or' from the last sentence of paragraph one.

In response to several Member Countries' comments on point (e) 'Painful husbandry procedures' of Article 7.X.5.3., the Commission states that this point merely lists examples of painful procedures and that there is no intention to suggest a hierarchy of preferable methods.

The Commission agreed to delete specific names of the method of castration given in the brackets, i.e. 'knife', 'banding or ringing' and 'Burdizzo operation' as suggested by a Member Country leaving the text making only reference to 'and disruption of the spermatic cord'.

The Commission did not agree with a Member Country's recommendation to advance the deadline for castration to six months.

Following a Member Country's comment on point (v) 'Identification', the Commission agreed with the provided rationale but considered that the text should not go into details and should be kept as simple as possible.

Several conflicting comments from Member Countries were received on point (f) 'Handling and inspection', but the Commission decided to leave the text of the first paragraph unchanged. The Commission accepted a recommendation to add a sentence referring to the number of animal handlers to ensure animal health and welfare. On the same point and regarding a Member Country's comment on the inclusion of 'a veterinarian' in paragraph 4, the Commission considered that the last sentence of the paragraph already covers that issue.

The Commission did not agree with Member Countries' comments recommending the addition of text in paragraph 5, as it was considered that even if an animal is experiencing severe and lasting pain, treatment could be an alternative to killing.

The Commission decided not to accept the inclusion of the word 'vocalisation' under the list of outcome-based measurables, as suggested by a Member Country, because it was considered to be already covered in 'behaviour'.

Regarding Member Countries' comments on point (h) 'Emergency plans', the Commission considered that the proposed text did not improve the content; however a few amendments were made to address other Member Countries' concerns.

Following Member Countries' comments on point (i) 'Location, construction and equipment', the Commission made some changes in the title and in the text to better describe certain structures in the three official languages.

Under point (j) 'Humane killing', the Commission decided not to include a new point, as suggested by a Member Country, as it considered that all significant points were already covered.

Conclusions

Based on the support expressed by most Member Countries, the Commission decided to submit the draft chapter for adoption. However, the Commission did not have time to make a detailed review of the many comments submitted by Members on the tables in Article 7.X.5.

The Commission decided to review comments on the tables in September 2012. The Commission decided that the tables would not be included in the chapter because this represents too much detail. Once Members' comments had been reviewed, the tables will be placed on the OIE website for guidance to Member Countries. Noting that this approach breaks with the approach in other chapters in Section 7, the Commission invited Members to advise if they wish to see a similar approach taken to other animal welfare texts.

The Commission agreed with a Member Country's recommendation to improve the structure of the chapter and asked the OIE International Trade Department to propose a new structure presenting the text in short articles and paragraphs once the chapter has been adopted. The OIE International Trade Department will undertake to provide a report to the Commission in September 2012.

The draft new Chapter 7.X., proposed for adoption, is at Annex XX.

EU position

The EU thanks the OIE for taking a majority of its comments into account and can support the adoption of this new chapter. However, the EU asks the OIE to consider a few amendments to the text as indicated in Annex XX.

- c) Model veterinary certificate for international trade in laboratory animals (Proposed as Chapter 5.13.)

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

The Commission accepted a Member Country's suggestion to include 'ferrets' in the list of animals included in the scope of this chapter.

The Commission noted a Member Country's comment pointing out the URL given in Boxes 5 and 7 was not functional. The Commission decided to modify the text in these boxes to align with Chapter 5.10.

Regarding the inclusion of 'the name and contact details of the person responsible for each stage of the journey' in Box I.12, the Commission did not agree to include the sentence as suggested, but rather made reference to the 'name and contact detail of an emergency contact person'.

The Commission did not agree to add 'when appropriate' in Box I.20 as suggested by a Member Country as the box makes reference to 'Identification system' not 'individual identification' as mentioned in the rationale provided.

Regarding a Member Country's comment on Box I.17 and point 3 'Part II. Classification of Pathogen Free Status', the Commission did not agree to amend the existing text as it was considered that the current wording was correct.

The draft new Chapter 5.13., proposed for adoption, is at Annex XXI.

EU position

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

- d) Use of animals in research and education (Chapter 7.8)

Comments were provided by Canada, the EU, New Zealand, Switzerland, the USA and a NGO (ICFAW).

Comments were received on the entire chapter but, due to time constraints, the Commission limited its review to the draft new Article 7.8.10. 'Transportation'. The comments received on other articles will be addressed at the Code Commission's meeting in September 2012.

Following Member Countries' comments on the need to make cross references to other chapters in Section 7, the Commission added an appropriate sentence.

In order to address a Member Country's comments on contingency planning, the Commission included a text referring to the nomination of an emergency contact person in Article 7.8.10. and in the related text of Chapter 5.13. (Box 1.12 of the model veterinary certificate).

The Commission did not agree with a statement of a Member Country discouraging the international transport of laboratory animals and instead referred Member Countries to the OIE/IATA discussion paper on the transport of animals used in research and education (http://www.oie.int/fileadmin/Home/eng/Animal_Welfare/docs/pdf/Others/IATA/ENG_IATA_paper_2009.pdf).

The Commission agreed with a Member Country's proposal to include 'or other competent person' under point 3 (c).

In response to a Member Country's comment on point 4, the Commission added the heading 'Delivery' and moved this paragraph to a new point 6. Also under point 4, sub-point (c), the new sub-point 6 (c) was amended according to a NGO's comment.

The Commission disagreed with a Member Country's request to add a reference to disinfection on arrival as it considered that it was out of the scope of Chapter 7.8., which addresses animal welfare and not disease prevention, consistent with the approach taken in other chapters on animal welfare.

The Commission, as in previous years, received many comments on existing text (Chapters 7.2 to 7.7). The Commission did not have time to consider all comments in detail and considered that the priority was to address the extensive comments on new texts that would be proposed for adoption in May 2012. In addition, at its September 2012 meeting the Commission will consider modifications to the structure of the chapters in Section 7 and the implications of removing tables containing detailed information from the Code - see comments on Chapter 7.X in this report. The Commission decided to hold the comments on Chapters 7.2 to 7.7 for future consideration.

The revised Chapter 7.8., proposed for adoption, is at Annex XXII.

EU position

The EU wishes to thank the OIE for its efforts to introduce a new Article 7.8.10 on transportation of animals used for research and education under Chapter 7.8 and recognises that some of the EU comments were incorporated in the proposed text for adoption. However, the EU regrets that three comments of importance were not taken into account.

The EU would like to support the adoption of this modified chapter provided that the EU comment on the introductory paragraph of Article 7.8.10 is taken into account. If a specific reference is made to the requirements under Chapters 7.3. and 7.4., it is equally necessary to highlight the genuine need for an exemption to these. In exceptional cases, there may be justifiable reasons to transport animals whose fitness for transport is compromised due to the scientific procedures that they are intended for. This has to be acknowledged and specific attention paid to the needs of these animals.

- e) Work programme of AWWG

The Commission provided advice on the work programme, as requested by the AWWG. The amended work programme, for information and comment of Member Countries, is at annex XXXII.

EU comment

The EU commends the AWWG for its work done in the course of the past year and supports its proposed amended work programme.

Item 14 Aujeszky's disease (Chapter 8.2.)

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

Following a Member Country's comment, the Commission modified the title of the chapter to 'Infection with Aujeszky's disease virus'.

The Commission did not agree with a Member Country's recommendation to delete references to captive wild pigs from this chapter, as this text had been adopted at the 79th General Session. The Commission did, however, consider the Member Country's comment and amended the text by adding 'which are under direct human supervision or control', in order to clarify the definition of captive wild pigs for the purpose of the *Terrestrial Code*.

Following a Member Countries' comments on the Note attached to Article 8.2.11., the Commission added an introductory text.

The revised Chapter 8.2., proposed for adoption, is at Annex XXIII.

EU position

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

Item 15 Bluetongue (Chapter 8.3.)

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

Following a Member Country's comment, the Commission changed the title of the chapter to 'Infection with bluetongue viruses'.

The Commission referred to the Scientific Commission a Member Country's request for a clear case definition, including the definition of epidemiologically significant susceptible species, with reference to the various serotypes and their specific epidemiology.

The Commission did not recognise a need to clarify Article 8.3.1, paragraph 4, as requested by a Member Country, specifically with reference to the word 'adjacent', by adding the phrase 'relevance of ecological or geographical features likely to interrupt the transmission of BTV'. The Commission noted that the *Oxford English Dictionary* states that 'adjacent' means: 'next to or very near to something else; neighbouring; bordering, contiguous; adjoining' and the word is used in this sense in the text.

In reply to a Member Country's comment, the Commission advised that the proposed text under Article 8.3.15., point 1, does not imply a need for facilities that are not involved in international trade to meet these conditions.

The Commission referred a Member Country's comment on Article 8.3.19. to the Scientific Commission for advice.

The Commission referred a Member Country's request for reference to serological surveillance methods and a Member Country's comment on serogroup analysis to the OIE Biological Standards Commission (Laboratories Commission) for advice.

The Commission considered that this chapter should not be further revised until such time as new scientific evidence or trade problems warrant.

Item 16 Zoonotic parasites

a) Trichinellosis (Chapter 8.13.)

Comments were received from Argentina, Australia, Canada, the EU, Japan, New Zealand, Norway, Switzerland and the USA, as well as OIRSA.

The Commission agreed with Member Countries which commented on the importance of the OIE working in close collaboration with the Codex Alimentarius Commission. The OIE has participated in meetings of the Codex Working Group on the Proposed Draft Guidelines for Control of Specific Zoonotic Parasites in Meat: *Trichinella spiralis* and *Cysticercus bovis*, which is developing guidelines on the control of these parasites in meat.

Dr Kahn informed the Commission that the OIE continues to work with the CAC Secretariat to encourage the development of complementary standards. At the coming meeting of the Codex Committee on General Principles (CCGP) (2–6 April 2012), the OIE would make a proposal for the OIE and CAC to aim also for ‘mutual recognition’ of standards. The current work of the OIE on zoonotic parasites and previous work on salmonellosis is entirely consistent with these approaches. In addition to the CAC Secretariat, the joint chairs of the Codex Working Group would be invited to the next meeting of the OIE *ad hoc* Group on Zoonotic Parasites. The Commission endorsed this approach.

In light of several Member Countries’ comments and concerns, the Commission advised that the objective of this chapter is to recommend measures to mitigate human health risks arising from *Trichinella* spp., as appropriate to the country and production sector.

The Commission agreed on the need to consider the review of the text very carefully, as the revised Chapter 8.13 will be used as a model for other chapters on zoonotic diseases.

The Commission noted that the disease listed as notifiable is ‘trichinellosis’. Therefore, all *Trichinella* species should be considered, as well as the associated risk management measures. The Commission noted that trichinellosis is not contagious and does not cause disease in animals. The management of the human health risk posed by trichinellosis can be largely based on biosecurity and feeding practices on-farm, rather than measures to inactivate the specific agent in meat. Therefore, the inclusion of other species of *Trichinella* in the chapter need not lead to major difficulties in formulating recommendations; the biosecurity management that protects pigs from acquiring infection with *Trichinella spiralis* should also protect them from infection by other *Trichinella* species such as *T. britovi*, etc.

Because of the low sensitivity of available tests, individual testing is not a good tool in low prevalence conditions as has been shown by ample historical data and categorising herds as ‘trichinella free’ on the sole basis of testing is probably not feasible. However, good biosecurity and management practices could be recommended which would allow herds to be classified as ‘negligible risk’ and this, taken together with historical data, could ensure negligible risk at herd or zone level. For herds in production systems in which appropriate biosecurity measures could not be applied (for example, backyard and so-called ‘free range’ production), the risks could be managed after slaughter, using testing or treatment.

The Commission considered that the principal aim of this chapter should be to provide recommendations on the determination and management of risk in domestic pigs and horses.

The Commission sent Member Countries’ comments to the *ad hoc* Group for consideration, taking into account the guidance provided above.

EU comment

The EU thanks the OIE and hopes that its comments will be taken into account by the *ad hoc* group.

b) Echinococcosis/hydatidosis (revised Chapter 8.4.)

The Code Commission reviewed the report of the *ad hoc* Group on Zoonotic Parasites, noting the extensive comments provided by Member Countries and the significant difference in the lifecycles of these two pathogenic agents. The Commission endorsed the separation of the original text into two separate chapters, i.e.: Chapter 8.4. – Infection with *E. granulosus* and Chapter X.X. – Infection with *E. multilocularis*. The Commission made some text modifications for editorial purposes.

The revised Chapter 8.4. and the proposed draft Chapter X.X. are at Annex XXXIII for Member Country comment.

EU comment

The EU thanks the OIE and will send comments on this chapter by 2 August 2012.

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

Item 17 Foot and mouth disease (FMD)

- a) Revision of Chapter 8.5.

Comments were submitted by the EU and AU-IBAR.

The Code Commission noted that further advice would be provided by the Scientific Commission.

- b) FMD Questionnaire (Chapter 1.6.)

Following the advice of the Scientific Commission, the Commission made minor amendments to Chapter 1.6.

The revised chapter, for adoption, is at Annex XXIV.

EU position

The EU supports the adoption of this modified chapter and has a comment inserted in the text of Annex XXIV.

Item 18 Rabies

- a) Rabies (Chapter 8.10.)

Comments were received from Australia, Chile, the People's Republic of China, Chinese Taipei, the EU, Japan, New Zealand, Norway, the USA and two regional organisations (AU-IBAR and OIRSA).

The Code Commission reviewed all comments, taking into account the Scientific Commission's comments on scientific issues raised by Members.

The Commission and the Scientific Commission agreed that a Member who requested access to supporting documents should make reference to comments in the *ad hoc* Group report of April 2011.

A Member Country's recommendation to make reference to birds in Article 8.10.1. was not accepted. While birds may very rarely be infected, this article is prefaced: 'For the purpose of the *Terrestrial Code*'. This means that the key points relevant to the *Terrestrial Code* are covered in this article and inclusion of the reference to birds is not warranted.

The Code Commission and the Scientific Commission did not accept a Member Country's recommendation for the word 'species' to be removed from '*Rabies virus* species'. The correct nomenclature is *Rabies virus* according to the International Committee on the Taxonomy of Viruses; see <http://ictvonline.org/virusTaxonomy.asp?version=2009>

Point 3 of Article 8.10.1. was not modified because the Commission considered the text to be clear and did not recognise any conflict with the definition of infective period in the Glossary.

On Article 8.10.2., the Commission carefully reviewed Member Countries' comments. The Commission reiterated its view that in determining the rabies status of a country, the key issue is findings of rabies virus infection in species in the Orders of Carnivora and Chiroptera. Thus, the finding of *Rabies virus* infection in a species other than a one that is a member of these two Orders should not result in the loss of rabies free status of a country.

Following a Member Country's recommendations, the word 'reservoir' was removed from point 5 in this article.

The comment of a regional organisation was accepted and a new point added to Article 1, which states that 'For the purposes of the *Terrestrial Code*... a country that does not fulfil the requirements in Article 2 is considered to be infected with *Rabies virus*'.

Member Countries' comments on the need for permanent identification were not accepted because this is already covered in Article 5.11. (International veterinary certificate for dogs and cats originating from rabies infected countries).

The Commission did not follow a recommendation of the Scientific Commission to delete point 2 ('were permanently identified and their identification number stated in the certificate') because this point was considered to be important and the text to be clear.

Following Member Countries' comments, supported by the Scientific Commission, Article 8.10.5., point 3, was modified to reflect the need for both the use and the production of the vaccine to accord with provisions in the *Terrestrial Manual*.

In response to a Member Country's comment, the Commission advised that all significant changes in Chapter 8.10. are based on the recommendations of the *ad hoc* Group, which are available on the OIE website (http://www.oie.int/fileadmin/Home/eng/International_Standard_Setting/docs/pdf/SCAD/A_SCAD_Aug-Sept2011.pdf).

Following a Member Country's recommendation, point 3 (a) of Article 8.10.6. was modified to improve clarity.

The same change made in Article 8.10.5. was introduced in point 3 (b) of Article 8.10.6.

On Article 8.10.8., the Commission reviewed Member Countries' comments and the Scientific Commission advice regarding clarification of the use of the word 'wildlife' but finally recommended that no changes be made.

The Commission did not accept a Member Country's proposal to add a new clause on vaccination in the certification provisions of Article 8.10.8. as the rabies status of wildlife is unknown; the proposed requirement (separation for six months prior to shipment) was considered by both Commissions to be appropriate.

b) Chapter 5.11. (Revised model certificate)

Comments were received from the People's Republic of China, the EU, New Zealand, the USA and OIRSA.

The Code Commission reviewed all comments, taking into account the Scientific Commission comments on scientific issues raised by Members.

Following a Member Country's comment, the title of this chapter was amended by adding 'for international movement of' after Model veterinary certificate, to be consistent with Article 5.12.

Several Member Country comments were not accepted as they were inconsistent with recommendations in Chapter 8.10.

In response to a Member Country which commented that the certifying veterinarian is not always the person who vaccinates or takes blood samples from the animal, the text in points (iv) and (v) were amended to clarify that the certifying veterinarian should have 'seen evidence' relating to the conduct of these procedures. The Commission noted that all amendments made to Chapter 5.11. were consistent with the recommendations in Chapters 5.1. and 5.2.

The revised Chapters 8.10. and 5.11., proposed for adoption, are at Annex XXV.

EU position

The EU thanks the OIE and supports the adoption of these modified chapters but has some important comments inserted in the text of Annex XXV.

Item 19 Rinderpest (Chapter 8.12.)

Comments were received from Australia, the EU, Japan, New Zealand, Switzerland and two regional organisations (AU-IBAR and OIRSA).

The Commission noted that Member Countries' comments on the revised Chapter 8.12. would be addressed once the two Commissions receive the information awaited from Joint FAO/OIE Advisory Committee on Rinderpest in case of a re-occurrence of rinderpest and on rinderpest virus sequestration.

Item 20 Vesicular stomatitis (Chapter 8.15.)

Comments were received from Canada, Chile and the EU.

The Code Commission modified the title of the chapter to 'Infection with vesicular stomatitis virus'.

Following a Member Country's recommendation, the Commission deleted 'free zone' from Articles 8.15.8. and 8.15.9.

The Commission referred to the Scientific Commission a Member Country's request for the definition of susceptible species and the proposal to include the concept of zoning in Articles 8.15. 4. to 8.15.7.

The Commission will review the text in its next meeting in September 2012.

Item 21 Review of chapters on bee diseases

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

Comments were received from Australia, Canada, Chile, the People's Republic of China, the EU, Japan, Norway and Switzerland.

Dr Francois Diaz, member of the OIE Scientific and Technical Department, joined the Code Commission for the discussion on bee diseases.

Dr Diaz informed the Commission that, following Member Countries' comments and consistent with the revised title of Chapter 4.14. (Official health control of bee diseases), the *ad hoc* Group had revised and clarified the text. The Commission endorsed the work done by the *ad hoc* Group and made some additional amendments, mainly of an editorial nature.

The revised Chapter 4.14., proposed for adoption, is at Annex XXVI.

EU position

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

b) Chapters 9.1. to 9.6. inclusive – Members' comments.

The following Member Countries submitted comments:

Chapter 9.1. – Chile, the EU, Japan, New Zealand and OIRSA.

Chapter 9.2. – the EU, Jamaica, New Zealand and Switzerland.

Chapter 9.4. – Australia, Chile, the EU, Japan, Switzerland and OIRSA.

Chapter 9.5. – Chile, the People's Republic of China, the EU, Japan, New Zealand, Switzerland and OIRSA.

Chapter 9.6. – Chile, the People's Republic of China, the EU, Norway and Switzerland.

Dr Diaz indicated that there were two key issues that still need to be addressed by the *ad hoc* Group, (1) text modifications that need to be made to reflect the eventual updating of the chapter names (e.g. 'Infestation of honey bees with *Acarapis woodi*') and (2) the definition of the commodity 'honey'. The *ad hoc* Group referred several Member Country comments to the Commission for its review.

Dr Diaz noted that several Member Countries had pointed out the difficulty in achieving disease freedom in the situation where there are wild or feral bee populations. The *ad hoc* Group considered that it would only be possible to address this issue if surveillance could be conducted on the wild and feral populations, and this approach would have to be incorporated into the relevant chapters.

The Commission noted Member Countries' concerns about the provision in Article 9.5.4. opposing the importation of bees from countries that have established disease freedom as a result of an eradication programme. The Commission emphasised that the *Terrestrial Code* provides criteria by which a Member can assess the disease risks posed by importation; it does not, however, provide predetermined assessments of risk.

Dr Diaz noted that the *ad hoc* Group had reviewed Chapter 5.10. ('Model veterinary certificates') and had concluded that no amendment was required as a consequence of the revision of the bee disease chapters.

The Commission noted that the *ad hoc* Group would meet again in June or July 2012 and would address scientific aspects of the comments provided by Member Countries. For the purpose of guidance to the *ad hoc* Group, the Commission proposed the following modifications to the chapter names.

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

Chapter 9.2. Infection of honey bees with *Paenibacillus larvae*

Chapter 9.3. Infection of honey bees with *Melissococcus plutonius*

Chapter 9.4. Infestation with *Aethina tumida*

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

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

Item 22 Avian influenza (Chapter 10.4.)

The Code Commission modified the title of Chapter 10.4. to 'Infection with viruses of notifiable avian influenza' and clarified the reporting provisions for notifiable avian influenza by repeating text from point 6 of Article 1.2.3. to Chapter 10.4. The Commission emphasised that this does not change the current notification obligations; rather, it states them more clearly.

The amended chapter proposed for adoption is at Annex XXVII.

EU position

The EU would support the adoption of this modified chapter, but only on the condition that the word "notifiable" is added between "low pathogenicity" and "avian influenza"

in the proposed new point 1 of Article 10.4.1. Indeed, the proposed sentence is contradictory to the current Code Chapter 1.2.3. and cannot be accepted as such.

Item 23 Newcastle disease (Chapter 10.9.)

The Code Commission reviewed a Member Country's comment but made no changes to the text.

Item 24 Proposed new chapter on Infection with *B. abortus*, *B. melitensis* and *B. suis*

Comments were received from Argentina, Australia, Canada, Chile, the EU, New Zealand, Japan, South Africa and the USA and from the IETS and OIRSA.

The Code Commission was informed by the Scientific Commission about concerns with the amended chapter, based on the difficulty of Members to understand how the proposed approach could be harmonised with disease control measures and existing legislation and provisions for the declaration of free status.

The proposal to develop a single chapter covering the three *Brucella* species had come from the *ad hoc* group, supported by the Scientific Commission. However, in light of Members' comments and the current advice of the Scientific Commission, the Code Commission referred the revised text and Members' comments to a new *ad hoc* group with a request to re-establish three separate chapters.

EU comment

The EU thanks the OIE and hopes that its comments will be taken into account by the *ad hoc* group.

Item 25 Lumpy skin disease (Chapter 11.12.)

Comments were received from Chile, the EU and Switzerland.

The Commission noted Member Countries' comments on the need for more stringent risk reduction measures and import requirements, based on the lack of diagnostic testing methods. The Commission requested that the Laboratories Commission advise on the possibility of improving the recommendations on prescribed tests in the *Terrestrial Manual*.

Following Member Countries' comments, the Commission deleted 'or' between sub-point 2 (b) and point 3 of Article 11.12.5.

The Commission made some modifications of an editorial nature.

In light of the fact that the modifications to the chapter were minimal, the Commission asked the OIE International Trade Department to keep these in a working document. Once the additional information on diagnostic tests is available, the Commission will address the Member Countries' comments on the need for more stringent risk reduction options.

Item 26 Diseases of horses

a) African horse sickness (Chapter 12.1.)

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

The Code Commission reviewed Member Countries' comments, including the Scientific Commission advice on the scientific points raised by Member Countries.

In response to a Member Country's comment on the need to define the word 'adjacent' in Article 12.1.1., the Commission agreed with the Scientific Commission that the text is compatible with Chapter 8.3. (Bluetongue). In addition, the Commission noted a definition from the *Oxford*

English Dictionary, where adjacent means: ‘next to or very near to something else; neighbouring; bordering, contiguous; adjoining.’

Following a Member Country’s comment on point 4 (b ii) of Article 12.1.2. and the Scientific Commission’s advice, the Commission replaced ‘systematic’ with ‘routine’.

Following a Member Country’s comment, the Commission deleted ‘should’ in point 5 of Article 12.1.2.

The Commission did not agree with a Member Country which called for a definition of ‘vector protected establishment’, as the relevant definition is in Article 12.1.10.

The Commission did not agree with a Member Country which questioned the efficacy of vaccination in Article 12.1.7., paragraph 3 (d), on the grounds that paragraph 3 (d) does not recommend the use of vaccination alone. Rather it recommends the use of vaccination in conjunction with prolonged isolation in a vector protected establishment.

The revised Chapter 12.1., for adoption, is at Annex XXVIII.

EU position

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

The EU will carefully scrutinize how the notion of "adjacent" will be handled in practice by the *ad hoc* group on Official Disease Status Recognition. The EU is willing to propose expertise for this group. Point 2 of Article 12.1.2, linked with Article 12.1.4 virtually imply that at the time of adoption of the chapter, all OIE Member Countries will be considered infected and will have to perform surveillance, except if they are "not adjacent", which is not defined either. Thus the role of the *ad hoc* Group and the guidance of the SCAD in interpreting the term "adjacent" will be crucial.

b) Questionnaire (Article 1.6.6.bis.)

The Code Commission amended the questionnaire for consistency with the modifications made to Chapter 12.1. and made several amendments for editorial purposes.

The revised texts of Chapter 1.6., proposed for adoption, is attached in Annex XXIV.

EU position

The EU supports the adoption of this modified chapter.

c) Chapter 12.6. Equine influenza

Comments were received from Canada, the EU, South Africa and Switzerland.

Following a Member Country’s comment, the Commission changed the title of the chapter to ‘Infection with equine influenza virus’.

It is anticipated that a Member Country’s comment on the use of vaccination for competition horses will be addressed by an OIE brainstorming meeting on safe international movement of horses, which will meet on 12–14 March.

d) Chapter 12.9. Equine viral arteritis

Comments were received from Chile, the EU, Peru and the USA.

The Code Commission noted that some comments would be addressed by the OIE brainstorming meeting on safe international movement of horses, which will meet on 12–14 March.

Following a Member Country's comment, the Commission changed the title of the chapter to 'Infection with equine arteritis virus' and modified the General provisions, to align with the new title.

Following a Member Country's comment on Article 12.9.4, the Commission deleted the word 'animal'.

The revised Chapters 12.6. and 12.9., proposed for adoption, are at Annex XXIX.

EU position

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

Item 27 Peste des petits ruminants (Chapter 14.8.)

The Code Commission reviewed the comments submitted by Australia, Canada, the EU, Japan, New Zealand and two regional organisations (AU-IBAR and OIRSA), and received advice from the Scientific Commission on the key concerns raised by Member Countries.

The Commission noted the support of some Member Countries and a regional organisation for the proposed development of an official pathway to global freedom from peste des petits ruminants (PPR).

The Commission noted that the Scientific Commission would seek further advice from the *ad hoc* Group on PPR on the two major concerns raised by Member Countries, namely the definition of epidemiologically significant susceptible species and on the inclusion of meat as a safe commodity for the purpose of trade based on the nature of the virus.

The Commission agreed with a Member Country which raised concerns that the revised chapter, as presented by the *ad hoc* Group, took an overly conservative approach to risk. Risk management had been recommended for a much broader range of species, including cattle, camels, buffalo and wild ruminants, than previously covered. The Commission supported the recommendation of a Member Country which called for the inclusion of 'deboned skeletal muscle meat from animals that passed ante- and post- mortem inspections' as a second point in Article 14.8.2. ('safe commodities'). The Commission urged the Scientific Commission to consider the conclusions of a paper published in the OIE *Scientific and Technical Review* which concluded that 'there is no evidence to suggest that PPR could be introduced through the importation of sheep and goat meat'¹. The Commission also agreed with a Member Country which recalled the WTO-SPS principle that 'sanitary measures ... should be based on appropriate assessment of risk, not hypothetical possibilities'.

The Commission did not accept the proposal of a regional organisation to delete the reference to claws in Article 14.8.1., because the term 'claw' is routinely used to describe the bovine digit in some countries.

The revised chapter was sent back to the Scientific Commission for further advice on these points.

Item 28 Classical swine fever (Chapter 15.2.)

Comments were received from Argentina, Canada, Chile, the People's Republic of China, the EU, New Zealand, South Africa, Switzerland, the USA, AU-IBAR and OIRSA.

The Code Commission reviewed the major revision of Chapter 15.2. and the new questionnaire and surveillance guidelines that had been drafted by the *ad hoc* Group on the official disease status recognition for Classical swine Fever (CSF) and modified by the Scientific Commission.

¹ MacDiarmid S.C., Thompson E.J. (1997). The potential risk to animal health from imported sheep and goat meat. *Rev. sci. tech.*, Off. Int. Epiz., 16 (1), 45–56.

The aim of this revision had been to meet Member Countries' requests for the OIE to provide for official recognition of CSF free status based on the principles in the current *Terrestrial Code* chapter, i.e.:

- The recommendations in a single article on CSF free country or zone
- The CSF status of domestic and captive wild pig populations is not affected by infection in wild and feral pig populations.

The Code Commission noted that the *ad hoc* Group had reported to the Scientific Commission with a proposal for a new approach to the definition of host species and the addition of several articles on free country or zone, which is fundamentally different from the current Chapter 15.2. The Scientific Commission reviewed the report and considered that more discussion and consultation was required. In light of this, rather than reviewing the draft text, the Code Commission encouraged Member Countries to comment on the *ad hoc* Group's report, which would be provided to them as an annex to the Scientific Commission's report, with particular attention to the proposed definition of CSF and the multiple categories of 'free status'.

EU comment

The EU supports the Code Commission and strongly requests to retain the principles foreseen in the current chapter, i.e. that the recommendations on CSF free country or zone be drawn up in a single Article and that the CSF status of domestic and captive wild pigs not be affected by infection in wild and feral pigs if appropriate biosecurity measures are in place. Indeed, the version of the draft chapter circulated with the report of the September 2011 meeting of the Code Commission which was based on the version adopted by Members should be retained as the basis for future work on the CSF chapter.

Item 29 Epizootic haemorrhagic disease (EHD) – new chapter

The Code Commission began the review of the report of the *ad hoc* Group, including the new draft chapter. However, due to insufficient time at this meeting, the Commission decided to postpone the review of the draft chapter in September 2012.

Item 30 Report of the *ad hoc* Group on veterinary education

Dr Kahn outlined the productive work of the *ad hoc* Group on veterinary education, which had finalised a document 'Minimum Competencies expected of Day 1 Veterinary Graduates to assure delivery of high quality National Veterinary Services.'

Dr Kahn explained that OIE Headquarters was in the process of preparing a publication of the Day 1 Competencies, for distribution to Delegates at the 80th General Session.

OIE Headquarters is also producing Guidelines on Twinning for Veterinary Education Establishments, based on the successful Laboratory Twinning Programme.

The Commission noted and endorsed the report of the *ad hoc* Group, including the proposed future work on the core veterinary curriculum.

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

EU comment

The EU thanks the OIE and would like to know when the OIE would post the document on "Minimum Competencies expected of Day 1 Veterinary Graduates to assure delivery of high quality National Veterinary Services" on its website.

Item 31 Animal Production Food Safety Working Group

The Commission noted and endorsed the report of the Working Group's November 2011 meeting.

The report of the Working Group is attached as Annex XXXVI for information.

D. OTHER ISSUES**Item 32 Update of the Code Commission work programme**

The Code Commission updated its work programme, which is attached for Member Countries' information or comment at Annex XXXVII.

EU comments

In addition to taking up work on an introductory chapter to the Code (see also general comments), the EU would like the OIE TAHSC to include in its work programme a partial revision of the Chapter 14.9 of the Terrestrial Code regarding Scrapie. Details of this request are provided in Annex XXXVII.

Item 33 Invasive alien species

- a) Guidelines for assessment of the risk of non-native animal species becoming invasive.

The Code Commission noted and endorsed the Guidelines document, which had been produced at a brainstorming meeting convened by the OIE, with participation of representatives of the Convention on Biological Diversity (CBD) Secretariat and the WTO SPS Committee Secretariat.

The Commission thanked Prof. MacDiarmid for his contribution to the development of the Guidelines and supported publication of the document on the OIE website for guidance to Members.

The *Guidelines for assessment of the risk of non-native animal species becoming invasive* are attached as Annex XXXVIII, together with the report of the brainstorming meeting for information.

- b) WTO/STDF seminar on 'Invasive alien species and international trade'

Dr Kahn advised the Commission that the OIE was collaborating with the WTO Standards and Trade Development Facility in the planning of a seminar to be held on 12–13 July 2012, in Geneva, on 'Invasive alien species and international trade'. More information can be obtained at the WTO/STDF website: <http://www.standardsfacility.org/en/TAIAS.htm>

Item 34 Application from an OIE Collaborating Centre

The Code Commission reviewed the request from an OIE Collaborating Centre (CC) to divide into four separate CCs on animal welfare, food safety, epidemiology and training.

The Commission did not consider it appropriate for OIE CCs to be designated for the sole specialty of 'training', as this should be a function of all OIE CCs. The Commission noted that the Scientific Commission would address the request on epidemiology.

The Commission asked the OIE permanent Working Groups on Animal Welfare and on Animal Production Food Safety to provide advice by the time of the September 2012 meeting on the proposed CCs on animal welfare and food safety respectively.

Item 35 Generic checklist on the practical application of compartmentalisation

The Commission noted that the Scientific Commission had reviewed and approved the Generic checklist. Due to lack of time, the Commission carried over the review of the Generic checklist to the September meeting. The Commission noted a need to revise Chapter 4.4. in order to further clarify the purpose of a contingency plan and the intent of establishing a baseline animal health report.

The revised Chapter 4.4., proposed for adoption, is at Annex XI.

EU position**The EU supports the adoption of this modified chapter.****Item 36 Dates of next meetings**

The next meeting will take place on 3–13 September 2012.

The spring meeting is proposed to take place on 18–28 February 2013.

.../Annexes

UNOFFICIAL VERSION

GLOSSARY

EU position

The EU supports the adoption of the modified Glossary.

For the purposes of the *Terrestrial Code*:

Disinfestation

means the application of procedures intended to eliminate infestation arthropods which may cause diseases or are potential vectors of infectious agents of animal diseases, including zoonoses.

Infestation

means the external invasion or colonisation of animals or their immediate surroundings by arthropods, which may cause disease or are potential vectors of infectious agents.

— Text deleted

CHAPTER 1.1.

NOTIFICATION OF DISEASES AND
EPIDEMIOLOGICAL INFORMATION**EU position**

The EU supports in general the adoption of this modified chapter and has one comment.

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 to assist in achieving better worldwide control of these *diseases*.
2. To achieve this, Members shall comply with the *notification* requirements specified in Article 1.1.3.
3. To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the official OIE *disease* reporting format.
4. Recognising that scientific knowledge concerning the relationship between disease agents and *diseases* 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.
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, *notification* through the World Animal Health Information System (WAHIS) or by **telegram**, fax or e-mail, within 24 hours, of any of the following events:
 - 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*;

Annex IV (contd)

- 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;
 - 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 **telegram**, fax or e-mail subsequent to a *notification* under point 1 above, to provide further information on the evolution of an incident which justified urgent *notification*; these reports should continue until the situation has been resolved through either the *disease* being eradicated or 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 incident should be submitted;
 3. a six-monthly report on the absence or presence, and evolution of *listed disease* and information of epidemiological significance to other Members;
 4. an annual report concerning any other information of significance to other Members.

Article 1.1.4.

1. The *Veterinary Authority* of a territory in which an *infected zone* was located shall inform the *Headquarters* when this zone is free from the *disease*.
2. An *infected zone* 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* shall inform 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* on a map of the territory of the Member.

Article 1.1.5.

1. The *Headquarters* shall send by **telegram**, 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*.

Annex IV (contd)

Article 1.1.6.

~~Telegrams or 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, telegram 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

For reasons of consistency, the EU suggests also deleting the word "telegram" in sentence 2 of the above Article.

— Text deleted

CHAPTER 1.2.

CRITERIA FOR THE INCLUSION OF LISTING DISEASES AND INFECTIONS ON THE OIE LIST**EU position**

The EU thanks the OIE and supports in general the adoption of this modified chapter and has some comments.

The EU understands that, as the reference to "excepting the situation where effective prevention and control measures are commonly used" in Article 1.2.1bis No 3b has been removed, the *ad hoc* group on Notification of Animal Diseases and Pathogenic Agents will be asked to take the availability and common use of effective prevention and control measures into account, especially in cases where this would be decisive as to listing or not listing a given disease. The EU will carefully look at the reports of the *ad hoc* group on listing diseases in order to verify that it has been taken into account.

The EU invites the OIE to consider adding the word "infestation" also in the title of the Chapter, for it to read "CRITERIA FOR THE INCLUSION OF DISEASES, AND INFECTIONS AND INFESTATIONS ON THE OIE LIST", as well as in the first sentence of Article 1.2.1. Introduction, and in the first sentence and the different points of Article 1.2.1bis where the words "*diseases* or *infections*" appears.

One further comment is included in the text below.

Article 1.2.1.Introduction

The aim of the *Terrestrial Code* is the improvement of animal health and *welfare* and veterinary public health worldwide, including by describing health measures to be used by *Veterinary Authorities* to detect, report and control pathogenic agents, and to prevent their transfer via *international trade*.

The aim of this chapter is to describe the criteria for the inclusion of *diseases* and *infections* on the OIE List. The objective of listing *diseases* is to support Members' efforts to prevent the transboundary spread of important animal *diseases*, including *zoonoses*, through transparent and consistent reporting. Each listed *disease*, normally wherever practicable, has a corresponding chapter, to which assists *Member Countries* in the harmonisation of *disease* detection, prevention and control. Requirements for notification are detailed in Chapter 1.1. and notifications are to be made through WAHIS as described in Article 1.1.3.

EU comment

The EU supports the above reference to Article 1.1.3., however the entire range of possible means of notification as stated in that Article should be mentioned here. Thus, the sentence should read as follows:

"Requirements for notification are detailed in Chapter 1.1. and notifications are to be made through WAHIS or by fax or e-mail as described in Article 1.1.3."

Article 1.2.1bis.

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

1. International spread of the agent (via live animals, their products or fomites) has been proven ~~on~~ three or more occasions.

AND

AND

- 2.) ~~At least one number of countries with populations of susceptible animals are~~ has demonstrated freedom of the disease/ infection or face impending freedom from the disease or infection in populations of susceptible animals, (based on the animal health surveillance provisions of the Terrestrial Code, in particular those contained in Chapter 1.4., taking into account the animal health information notified in WAHIS)

OR

- ii) ~~OIE annual reports indicate that a number of countries with susceptible populations have reported absence of the disease for several consecutive years (based on the animal health surveillance information notified in WAHIS)~~

AND

AND

3. at) Natural ~~(Transmission to humans has been proven, and human infection is associated with severe consequences (death or serious illness).~~

OR

- bi) ~~The disease/ or infection has been shown to cause significant morbidity or mortality production losses in domestic animals at the level of a country or a zone,~~ excepting the situation where

~~effective prevention and control measures are commonly used~~ there is an efficient and affordable vaccine and vaccination is carried out by most Members.

~~OR~~or

~~ciii)~~ The ~~disease/~~infection has been shown to, or scientific evidence indicates that it would, ~~have a~~ cause significant morbidity or mortality ~~negative effect on~~ in wild animal populations.

~~AND~~

AND

~~4.)~~ A ~~repeatable and~~ 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 ~~pathologies~~diseases and infections.

OR

~~52.~~ The disease or infection is an emerging disease with ~~apparent evidence of~~ zoonotic properties, rapid spread, or ~~possible~~ significant ~~production losses~~ morbidity or mortality and a case definition is available to clearly identify cases and allow them to be distinguished from other ~~pathologies~~diseases or infections.

Article 1.2.2.

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

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

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

- Anthrax
- Aujeszky's disease
- Bluetongue
- Brucellosis (*Brucella abortus*)
- Brucellosis (*Brucella melitensis*)
- Brucellosis (*Brucella suis*)
- Crimean Congo haemorrhagic fever
- Echinococcosis/hydatidosis
- Epizootic haemorrhagic disease
- Equine encephalomyelitis (Eastern)
- Foot and mouth disease

- Heartwater
 - Japanese encephalitis
 - New world screwworm (*Cochliomyia hominivorax*)
 - Old world screwworm (*Chrysomya bezziana*)
 - Paratuberculosis
 - Q fever
 - Rabies
 - Rift Valley fever
 - Rinderpest
 - Surra (*Trypanosoma evansi*)
 - Trichinellosis
 - Tularemia
 - Vesicular stomatitis
 - West Nile fever.
2. The following diseases and infections are included within the category of cattle diseases and infections:
- Bovine anaplasmosis
 - Bovine babesiosis
 - Bovine genital campylobacteriosis
 - Bovine spongiform encephalopathy
 - Bovine tuberculosis
 - Bovine viral diarrhoea
 - Contagious bovine pleuropneumonia
 - Enzootic bovine leukosis
 - Haemorrhagic septicaemia
 - Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
 - Lumpy skin disease
 - Theileriosis
 - Trichomonosis
 - Trypanosomosis (tsetse-transmitted).
3. The following diseases and infections are included within the category of sheep and goat diseases and infections:
- Caprine arthritis/encephalitis
 - Contagious agalactia
 - Contagious caprine pleuropneumonia
 - Enzootic abortion of ewes (ovine chlamydiosis)

- Maedi–visna
 - Nairobi sheep disease
 - Ovine epididymitis (*Brucella ovis*)
 - Peste des petits ruminants
 - Salmonellosis (*S. abortusovis*)
 - Scrapie
 - Sheep pox and goat pox.
4. The following diseases and infections are included within the category of equine diseases and infections:
- African horse sickness
 - Contagious equine metritis
 - Dourine
 - Equine encephalomyelitis (Western)
 - Equine infectious anaemia
 - Equine influenza
 - Equine piroplasmosis
 - Equine rhinopneumonitis
 - Equine viral arteritis
 - Glanders
 - Venezuelan equine encephalomyelitis.
5. The following diseases and infections are included within the category of swine diseases and infections:
- African swine fever
 - Classical swine fever
 - Nipah virus encephalitis
 - Porcine cysticercosis
 - Porcine reproductive and respiratory syndrome
 - Swine vesicular disease
 - Transmissible gastroenteritis.
6. The following diseases and infections are included within the category of avian diseases and infections:
- Avian chlamydiosis
 - Avian infectious bronchitis
 - Avian infectious laryngotracheitis
 - Avian mycoplasmosis (*Mycoplasma gallisepticum*)
 - Avian mycoplasmosis (*Mycoplasma synoviae*)
 - Duck virus hepatitis
 - Fowl typhoid

- Highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in poultry as defined in Chapter 10.4.
 - Infectious bursal disease (Gumboro disease)
 - Newcastle disease
 - Pullorum disease
 - Turkey rhinotracheitis.
7. The following diseases and infections are included within the category of lagomorph diseases and infections:
- Myxomatosis
 - Rabbit haemorrhagic disease.
8. The following diseases and infections are included within the category of bee diseases, and infections and infestations:
- Acarapisosis of honey bees
 - American foulbrood of honey bees
 - European foulbrood of honey bees
 - Small hive beetle infestation (*Aethina tumida*)
 - *Tropilaelaps* infestation of honey bees
 - Varroosis of honey bees.
9. The following diseases and infections are included within the category of other diseases and infections:
- Camel pox
 - Leishmaniosis.

— Text deleted

CHAPTER 1.4.

ANIMAL HEALTH SURVEILLANCE

EU position

The EU supports the adoption of this modified chapter but has two comments.

Article 1.4.1.

Introduction and objectives

1. In general, *surveillance* is aimed at demonstrating the absence of *disease* or *infection*, determining the ~~occurrence~~ presence or distribution of *disease* or *infection*, ~~while also or~~ detecting as early as possible exotic or *emerging diseases*. The type of *surveillance* applied depends on the desired outputs needed to support decision-making. The following recommendations may be applied to all *diseases*, or infections ~~their agents~~ and all susceptible species (including *wildlife*) as listed in the *Terrestrial Code*, and are designed to assist with the development of *surveillance* methodologies. Except where a specific *surveillance* method for a certain *disease* or *infection* is already described in the *Terrestrial Code*, ~~The~~ general recommendations in this chapter may be ~~used to further refined~~ by the general specific approaches described ~~for a specific in the~~ disease or infection chapters. Where detailed *disease* ~~or/~~ *infection*-specific information is not available, suitable approaches should be based on the recommendations in this chapter.
2. Animal health *surveillance* is also a an essential tool to ~~detect disease or infection, to~~ monitor disease trends, to facilitate the control of *disease* or *infection*, ~~to support claims for freedom from disease or infection,~~ to provide data for use in *risk analysis*, for animal and/or public health purposes, and to substantiate the rationale for sanitary measures. Both domestic *animals* and wild animals *wildlife* are susceptible to certain *diseases* ~~or infections~~. However, the presence of a disease or infection in wild animals *wildlife* does not mean it that the same disease/infection is necessarily present in domestic *animals* in the same country or *zone* or vice versa. *Surveillance* data underpin the quality of disease status reports and should satisfy information requirements of *risk analysis* for *international trade* and for *national decision making*. *Wildlife* may be included in a surveillance system because they can serve as reservoirs of infection and as indicators of disease risk to humans and domestic animals and wildlife *disease*. *Wildlife disease/infection Surveillance in wildlife* presents specific challenges that may differ significantly from those in *surveillance* in domestic *animals*.
3. Prerequisites to enable an OIE Member to provide information for the evaluation of its animal health status are:
 - a) that the Member complies with the provisions of Chapter 3.1. of the Terrestrial Code;
 - b) that, where possible, *surveillance* data be complemented by other sources of information, such as ~~(e.g.~~ scientific publications, research data, documented field observations and other non-survey data);
 - c) that transparency in the planning and execution of *surveillance* activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.1. of the Terrestrial Code.
4. The objectives of this chapter are to:

- a) provide guidance to the type of outputs that a *surveillance* system should generate;
- b) provide recommendations to assess the quality of *disease/infection surveillance* systems.

Article 1.4.2.

Definitions

The following definitions apply for the purposes of this chapter:

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

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

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

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

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

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

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

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

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

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

Target population: means the population about which conclusions are to be inferred.

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

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

Article 1.4.3.

Principles of surveillance

1. Types of surveillance

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

Annex VI (contd)

- i) the means by which data are collected (active versus passive *surveillance*);
 - ii) the disease focus (pathogen-specific versus general *surveillance*); and
 - iii) the way in which units for observation are selected (structured surveys versus non-random data sources).
- b) In this chapter, *surveillance* activities are classified as being based on:

EITHER

- i) structured population-based surveys, such as:
 - systematic sampling at *slaughter*;
 - random surveys;
 - surveys for *infection* in clinically normal *animals*, including *wildlife*;

OR

- ii) structured non-random *surveillance* activities, such as:
 - *disease* reporting or notifications;
 - control programmes ~~/ or~~ health schemes;
 - targeted testing ~~/ or~~ screening;
 - ante-mortem and post-mortem inspections;
 - laboratory investigation records;
 - biological specimen banks;
 - sentinel units;
 - field observations;
 - farm production records;
 - *wildlife* disease data.
- c) In addition, *surveillance* data should be supported by related information, such as:
- i) data on the epidemiology of the *disease* ~~/ or~~ *infection*, including environmental, host population distribution, and climatic information;
 - ii) data on animal movements, including transhumance, ~~– as well as~~ and natural *wildlife* migrations;
 - iii) trading patterns for *animals* and animal products;

- iv) national animal health regulations, including information on compliance with them and their effectiveness;
 - v) history of imports of potentially infected material; and
 - vi) biosecurity measures in place;
 - vii) the likelihood and consequence of *disease* ~~or~~ *infection* introduction.
- d) The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

2. Critical elements

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

a) Populations

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

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

b) Time frame (or temporal values of surveillance data)

Surveillance should be carried out at a frequency that reflects the biology of the *infection* and the *risks* of its introduction.

c) Epidemiological unit

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

d) Clustering

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

Annex VI (contd)

e) Case definition

A case should be defined for each *disease/ infection* under *surveillance* using clear criteria, Where they one exists, the standards case definition in the specific chapter of Terrestrial Code should be used. If the Terrestrial Code does not give a case definition, a case should be defined using clear criteria for each disease or infection under surveillance. For *wildlife disease/ or infection surveillance*, it is essential to correctly identify and report host animal taxonomy (including genus and species).

f) Analytical methodologies

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

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

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

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

g) Testing

Surveillance involves the detection of *disease or infection* by the use of according to appropriate case definitions and based on the results of one or more tests for evidence of *infection* or immune status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity, and specificity and predictive values.

Imperfect sensitivity and/ or specificity will have an impact on the conclusions from *surveillance* and.

Therefore, these parameters should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.

The values of sensitivity and specificity values of for the tests used should be specified for each species in which they may be used, and the method used to determine or estimate these values should be documented. Alternatively, where values for sensitivity and/ or specificity for values of a particular test are specified in the *Terrestrial Manual*, these values may be used as a guide.

Samples from a number of *animals* or units may be pooled and subjected to a testing protocol.

The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.

h) Quality assurance

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

i) Validation

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

j) Data collection and management

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

- the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location; this requires effective collaboration among all stakeholders, such as governmental ministries, or non-governmental organisations, and others, particularly for data involving *wildlife*;
- the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;
- maintenance of disaggregated data rather than the compilation of summary data;
- minimisation of transcription errors during data processing and communication.

Article 1.4.4.

Structured population-based surveys

In addition to the principles for *surveillance* discussed in Article 1.4.3. above, the following recommendations should be used considered when planning, implementing and analysing surveys.

1. Types of surveys

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

- a) non-probability based sampling methods, such as:
 - i) convenience;
 - ii) expert choice;
 - iii) quota;

- b) probability based sampling methods, such as:
- i) simple random selection;
 - ii) cluster sampling;
 - iii) stratified sampling;
 - iv) systematic sampling.

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

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

2. Survey design

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

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

Data on wild animal wildlife population size often do not exist. and, to the extent possible, However, they should be determined to the extent possible before the survey is designed. The expertise of *wildlife* biologists may be sought in the gathering and interpretation of such population data. Historical population data should be updated since these may not reflect current populations.

3. Sampling

The objective of sampling from a population is to select a subset of units that is representative of the population of interest with respect to the objective of the study. Sampling should provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems.

Specimens of from *wildlife* for surveillance may be available from sources such as hunters and trappers, road-kills, *wild animal meat* markets, sanitary inspection of hunted *animals*, morbidity-mortality observations by the general public, *wildlife* rehabilitation centres, *wildlife* biologists and *wildlife* agency field personnel, farmers, and other landholders, naturalists and conservationists. *Wildlife* data such as census data, trends over time, and reproductive success can be used in a manner similar to farm production records for epidemiological purposes.

4. Sampling methods

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

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

Annex VI (contd)5. Sample size

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

Article 1.4.5.

Structured non-random surveillance

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

1. Common non-random surveillance sources

A wide variety of non-random *surveillance* sources may be available. These vary in their primary purpose and the type of *surveillance* information they are able to provide. Some *surveillance* systems are primarily established as early detection systems, but may also provide valuable information to demonstrate freedom from *infection*. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data, such as (e.g. disease reporting systems, sentinel sites, and testing schemes).

a) Disease reporting or notification systems

Data derived from *disease* reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for *risk analysis*, or for early detection. Effective laboratory support is an important component of any reporting system.

Reporting systems relying on laboratory confirmation of suspect clinical cases should use tests that have a high specificity. Reports should be released by the laboratory in a timely manner, with the amount of time from *disease* detection to report generation minimised (to hours in the case of introduction of a foreign animal disease).

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

b) Control programmes and health schemes

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

c) Targeted testing and screening

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

Annex VI (contd)

d) Ante-mortem and post-mortem inspections

Inspections of *animals* at *slaughterhouses* may provide valuable *surveillance* data. The sensitivity and specificity of *slaughterhouse* inspection for detecting the presence of specified *diseases* under should be pre-determined for the inspection system in place should be pre-determined. The accuracy of the inspection system will be influenced by:

- i) the training, experience and number of the inspection staff;
- ii) the involvement of the *Competent Authorities* in the supervision of ante-mortem and post-mortem inspections;
- iii) the quality of construction of the *slaughterhouse*, speed of the slaughter chain, lighting quality, etc.; and
- iv) staff morale and motivation for efficient performance.

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

For trace back and analysis of spatial and *herd*-level coverage, there should be, if possible, an effective identification system that relates *animals* in the *slaughterhouse* to their locality of origin.

e) Laboratory investigation records

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

f) Biological specimen banks

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

g) Sentinel units

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

Sentinel units may provide evidence of freedom from *infection*, or provide data on prevalence and incidence as well as the distribution of *disease* ~~/or~~ *infection*.

h) Field observations

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

i) Farm production records

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

j) Wildlife data

Specimens from ~~wild animals~~ *wildlife* for *disease* ~~/or~~ *infection surveillance* may be available from sources such as hunters and trappers, road-kills, *wild animal meat* markets, sanitary inspection of hunted *animals*, morbidity and mortality observations by the general public, *wildlife* rehabilitation centres, *wildlife* biologists and *wildlife* agency field personnel, farmers and other landholders, naturalists and conservationists. *Wildlife* data such as census data, trends over time, and reproductive success can be used in a manner similar to farm production records for epidemiological purposes.

2. Critical elements for structured non-random surveillance

There are a number of critical factors which should be taken into account when using structured non-random *surveillance* data. ~~These include such as~~ coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. *Surveillance* data from non-random sources can, however, be a cost-efficient method of early detection, and may increase the level of confidence or detect a lower level of prevalence compared to random sampling surveys.

3. Analytical methodologies

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

4. Combination of multiple sources of data

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

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

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

Article 1.4.6.

Surveillance to demonstrate freedom from disease~~/or~~ infection

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

EU comment

The title of point 1 and the first sentence below should not refer to compartments, since it's been deleted from the points a) and b). The word "compartment" should thus be deleted.

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

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

- in the absence of *disease* and vaccination, the animal population would become susceptible over a period of time;
- the disease agents to which these provisions apply are likely to produce identifiable clinical signs in susceptible *animals*;
- competent and effective *Veterinary Services* will be able to investigate, diagnose and report disease, if present;
- disease~~/or~~ infection can affect both ~~wild animals and~~ domestic *animals* ~~and wildlife~~;
- the absence of disease~~/or~~ infection over a long period of time in a susceptible population can be substantiated by effective disease investigation and reporting by a Member.

a) Historically free

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

- i) there has never been occurrence of *disease*, or
- ii) eradication has been achieved or the disease~~/or~~ infection has ceased to occur for at least 25 years, provided that for at least the past 10 years:
- iii) ~~it~~ ~~the disease~~ has been a *notifiable disease*;
- iv) an early detection system has been in place for all relevant species;
- v) measures to prevent disease~~/or~~ infection introduction have been in place; no vaccination against the *disease* has been carried out unless otherwise provided ~~for~~ in the *Terrestrial Code*;

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

b) Last occurrence within the previous 25 years

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

- i) ~~it~~ the *disease* has been a *notifiable disease*;
- ii) an early detection system has been in place;
- iii) measures to prevent the introduction of the *disease* or *infection* introduction have been in place;
- iv) no vaccination against the *disease* has been carried out unless otherwise provided for in the *Terrestrial Code*;
- v) *infection* is not known to be established in *wildlife* within the country or *zone* intended to be declared free. A country or *zone* cannot apply for recognition of freedom if there is any evidence of *infection* in *wildlife*.

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

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

EU comment

The fact that surveillance may be discontinued in a compartment is not coherent with Chapter 4.4. on compartmentalisation that indicates that surveillance should be on-going.

- a) ~~it~~ the *disease* is a *notifiable disease*;
- b) an early detection system is in place;
- c) measures to prevent the introduction of the *disease* or *infection* introduction are in place;
- d) vaccination against the *disease* is not applied;
- e) *infection* is known not to be established in *wildlife*. It can be difficult to collect sufficient epidemiological data to prove absence of *disease* or *infection* in *wild animal* populations. In such circumstances, a range of supporting evidence should be used to make this assessment.

3. Self declaration of freedom from *disease* or *infection*

A Member may make a self declaration according to Chapter 1.6. that its entire territory a country, a *zone* or a *compartment* is free from a *listed disease*, based on the implementation of the provisions of the

Terrestrial Code and the *Terrestrial Manual*—see relevant provisions in Chapter 1.6. The *Veterinary Authority* may wish to transmit this information to the OIE *Headquarters*, which may publish the information.

4. International recognition of disease~~/or~~ infection free status

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

5. Demonstration of freedom from infection

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

Freedom from *infection* implies the absence of the pathogenic agent in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of *infection*. Therefore, demonstrating freedom from infection involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Members) that infection with a specified pathogen if present, is present in less than a specified proportion of the population. is not present in a population. In practice, it is not possible to prove (i.e., be 100% confident) that a population is free from infection (unless every member of the population is examined simultaneously with a perfect test with both sensitivity and specificity equal to 100%). Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that infection, if present, is present in less than a specified proportion of the population.

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

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

Article 1.4.7.

Surveillance for distribution and occurrence of infection

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

Annex VI (contd)

In contrast to *surveillance* to demonstrate freedom from *infection*, *surveillance* used to assess progress in control or eradication of selected *diseases* or *infections* and *pathogens* is usually designed to collect data about a number of variables of animal health relevance, for example such as:

1. prevalence or incidence of *infection*;
2. morbidity and mortality rates;
3. frequency of *disease* or *infection risk* factors and their quantification;
4. frequency distribution of *herd* sizes or the sizes of other *epidemiological units*;
5. frequency distribution of antibody titres;
6. proportion of immunised *animals* after a vaccination campaign;
7. frequency distribution of the number of days elapsing between suspicion of *infection* and *laboratory* confirmation of the diagnosis and or to the adoption of control measures;
8. farm production records;
9. role of *wildlife* in maintenance or transmission of the *infection*.

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CHAPTER 2.1.

IMPORT RISK ANALYSIS

EU position**The EU supports the adoption of this modified chapter.**

Article 2.1.1.

Introduction

The importation of *animals* and animal products involves a degree of *disease risk* to the *importing country*. This *risk* may be represented by one or several *diseases* or *infections*.

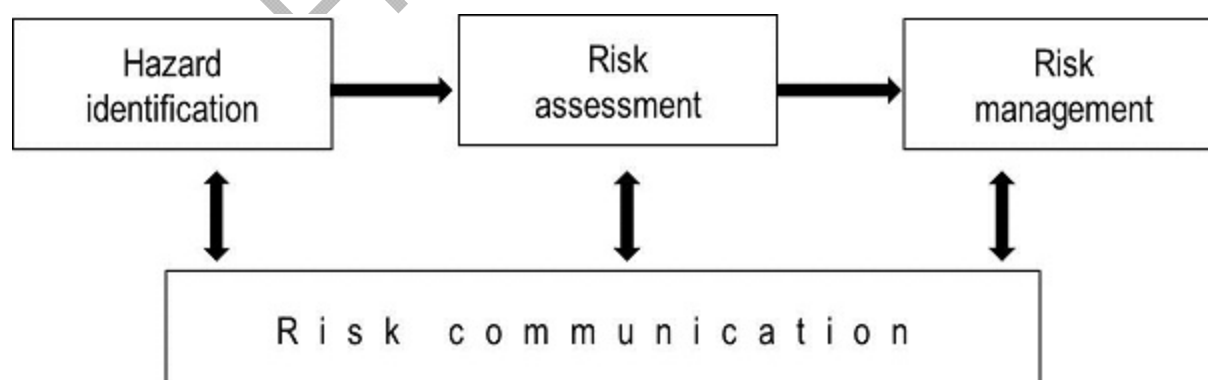
The principal aim of import *risk analysis* is to provide *importing countries* with an objective and defensible method of assessing the *disease risks* associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, biological products and *pathological material*. The analysis should be transparent. This is necessary so that the *exporting country* is provided with clear reasons for the imposition of import conditions or refusal to import.

Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

This chapter alludes to the role of the OIE with respect to the Agreement on the Application of Sanitary and Phytosanitary Measures (the so-called SPS Agreement) of the World Trade Organization (WTO), provides definitions and describes the OIE informal procedure for dispute mediation.

This chapter provides recommendations and principles for conducting transparent, objective and defensible *risk analyses* for *international trade*. The components of *risk analysis* described in this chapter are *hazard identification*, *risk assessment*, *risk management* and *risk communication* (Figure 1).

Fig. 1. The four components of risk analysis



The *risk assessment* is the component of the analysis which estimates the *risks* associated with a *hazard*. *Risk assessments* may be qualitative or quantitative. For many *diseases*, particularly for those *diseases* listed in this *Terrestrial Code* where there are well developed internationally agreed standards, there is broad agreement concerning the likely *risks*. In such cases it is more likely that a qualitative assessment is all that is required. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making. No single method of import *risk assessment* has proven applicable in all situations, and different methods may be appropriate in different circumstances.

Annex VII (contd)

The process of import *risk analysis* usually needs to take into consideration the results of an evaluation of *Veterinary Services*, zoning, compartmentalisation and *surveillance* systems in place for monitoring of animal health in the *exporting country*. These are described in separate chapters in the *Terrestrial Code*.

Article 2.1.2.

Hazard identification

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

The potential *hazards* identified would be those appropriate to the species being imported, or from which the *commodity* is derived, and which may be present in the *exporting country*. It is then necessary to identify whether each potential *hazard* is already present in the *importing country*, and whether it is a *notifiable disease* or is subject to control or eradication in that country and to ensure that import measures are not more trade restrictive than those applied within the country.

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

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

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

Article 2.1.3.

Principles of risk assessment

1. *Risk assessment* should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. *Risk assessment* should be able to accommodate the variety of animal *commodities*, the multiple *hazards* that may be identified with an importation and the specificity of each *disease*, detection and *surveillance* systems, exposure scenarios and types and amounts of data and information.
2. Both *qualitative risk assessment* and *quantitative risk assessment* methods are valid.
3. The *risk assessment* should be based on the best available information that is in accord with current scientific thinking. The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion.
4. Consistency in *risk assessment* methods should be encouraged and *transparency* is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.
5. *Risk assessments* should document the uncertainties, the assumptions made, and the effect of these on the final risk estimate.
6. *Risk* increases with increasing volume of *commodity* imported.
7. The *risk assessment* should be amenable to updating when additional information becomes available.

Article 2.1.4.

Risk assessment steps1. Entry Release assessment

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

- a) Biological factors
 - species, age and breed of *animals*
 - agent predilection sites
 - vaccination, testing, treatment and quarantine.
- b) Country factors
 - incidence or prevalence
 - evaluation of *Veterinary Services, surveillance* and control programmes and zoning and compartmentalisation systems of the *exporting country*.
- c) Commodity factors
 - quantity of *commodity* to be imported
 - ease of contamination
 - effect of processing
 - effect of storage and transport.

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

2. Exposure assessment

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

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

Annex VII (contd)

- a) Biological factors
 - properties of the agent.
- b) Country factors
 - presence of potential vectors
 - human and animal demographics
 - customs and cultural practices
 - geographical and environmental characteristics.
- c) Commodity factors
 - quantity of *commodity* to be imported
 - intended use of the imported *animals* or products
 - disposal practices.

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

3. Consequence assessment

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

- a) Direct consequences
 - animal *infection, disease* and production losses
 - public health consequences.
- b) Indirect consequences
 - *surveillance* and control costs
 - compensation costs
 - potential trade losses
 - adverse consequences to the environment.

4. Risk estimation

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

Annex VII (contd)

For a quantitative assessment, the final outputs may include:

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

Article 2.1.5.

Principles of risk management

1. *Risk management* is the process of deciding upon and implementing measures to achieve the Member's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimized. The objective is to manage *risk* appropriately to ensure that a balance is achieved between a country's desire to minimize the likelihood or frequency of *disease* incursions and their consequences and its desire to import *commodities* and fulfil its obligations under *international trade* agreements.
2. The international standards of the OIE are the preferred choice of *sanitary measures* for *risk management*. The application of these *sanitary measures* should be in accordance with the intentions in the standards.

Article 2.1.6.

Risk management components

1. Risk evaluation – the process of comparing the *risk* estimated in the *risk assessment* with the Member's appropriate level of protection.
2. Option evaluation – the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the *risk* associated with an importation in order to bring it into line with the Member's appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood **and**/or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the *risk assessment* and then comparing the resulting level of *risk* with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the *risk management* options.
3. Implementation – the process of following through with the *risk management* decision and ensuring that the *risk management* measures are in place.
4. Monitoring and review – the ongoing process by which the *risk management* measures are continuously audited to ensure that they are achieving the results intended.

Annex VII (contd)

Article 2.1.7.

Principles of risk communication

1. *Risk communication* is the process by which information and opinions regarding *hazards* and *risks* are gathered from potentially affected and interested parties during a *risk analysis*, and by which the results of the *risk assessment* and proposed *risk management* measures are communicated to the decision-makers and interested parties in the *importing* and *exporting countries*. It is a multidimensional and iterative process and should ideally begin at the start of the *risk analysis* process and continue throughout.
2. A *risk communication* strategy should be put in place at the start of each *risk analysis*.
3. The *communication of the risk* should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.
4. The principal participants in *risk communication* include the authorities in the *exporting country* and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups.
5. The assumptions and uncertainty in the model, model inputs and the risk estimates of the *risk assessment* should be communicated.
6. Peer review is a component of *risk communication* in order to obtain scientific critique and to ensure that the data, information, methods and assumptions are the best available.

— Text deleted

CHAPTER 3.2.

EVALUATION OF VETERINARY SERVICES

EU position

The EU supports the adoption of this modified chapter and has three comments to be taken into consideration by the Code Commission at its next meeting.

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~~ and zoosanitary conditions for the importation of a *commodity*, an *importing country* is justified in regarding its evaluation of the *Veterinary Services* of the *exporting country* as critical.

3. The purpose of evaluation may be either to assist a national authority in the decision-making process regarding priorities to be given to its own *Veterinary Services* (self-evaluation) or to assist the process of *risk analysis* in *international trade* in *animals* and animal-derived products to which official sanitary ~~and~~ and/or zoosanitary controls apply.
4. In both situations, the evaluation should demonstrate that the *Veterinary Services* have the capability for effective control of the sanitary and zoosanitary status of *animals* and animal products. Key elements to be covered in this process include adequacy of resources, management capability, legislative and administrative infrastructures, independence in the exercise of official functions and history of performance, including *disease* reporting.
5. Good governance is the key to competence, integrity and confidence in organisations. Mutual confidence between relevant official *Veterinary Services* of trading partner countries contributes fundamentally to stability in *international trade* in *animals* and animal-related products. In this situation, scrutiny is directed more at the *exporting country* than at the *importing country*.
6. Although quantitative data can be provided on *Veterinary Services*, the ultimate evaluation will be essentially qualitative. While it is appropriate to evaluate resources and infrastructure (organisational,

administrative and legislative), it is also appropriate to place emphasis on the evaluation of the quality of outputs and performance of *Veterinary Services*. Evaluation should take into consideration any quality systems used by *Veterinary Services*.

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

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

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.

Annex VIII (contd)

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 resources

1. Financial

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

Annex VIII (contd)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.g. e-mail and Internet services) are examples of useful communication services which, if available, can supplement or replace the others. A means for rapid international communication should be available to the *Veterinary Authority*, to permit reporting of changes in national disease status consistent with OIE recommendations and to allow bilateral contact on urgent matters with counterpart *Veterinary Authorities* in trading-partner countries.

c) Transport systems

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

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

3. Technical

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

a) Cold chain for laboratory samples and veterinary medicines

Adequate refrigeration and freezing systems should be available and should be used throughout the country to provide suitable low temperature protection for laboratory samples in transit or awaiting analysis, as well as veterinary medical products, such as (e.g. vaccines) when these are required for use in animal disease control programmes. If these assurances cannot be given, it

may be valid to discount many types of test results, as well as the effectiveness of certain disease control programmes and the export inspection system in the country undergoing evaluation.

b) Diagnostic laboratories

Analysis of the laboratory service component of *Veterinary Services*, which would include official governmental laboratories and other laboratories accredited by the *Veterinary Services* for specified purposes, is an essential element of the evaluation process. The quality of the veterinary diagnostic laboratories of a country underpins the whole control and certification processes of the zoosanitary⁷or 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.

EU comment

In the first sentence of the paragraph above, the word "accredited" might lead to confusion as this is a term widely used for quality assurance accreditation, while this sentence concerns the specific approval of a laboratory by the Veterinary Services. Thus it should be replaced by "approved" or "authorised".

Moreover, there should be an additional sentence added: "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".

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

c) Research

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

Article 3.2.7.

Legislation and functional capabilities

1. Animal health, animal welfare and veterinary public health

The *Veterinary Authority* should be able to demonstrate that it has the capacity, supported by appropriate legislation, to exercise control over all animal health matters. These controls should include, where appropriate, compulsory notification of prescribed animal diseases, inspection, movement controls through systems which provide adequate traceability, registration of facilities, quarantine of infected premises⁷or 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 ~~and~~ or withdraw official certification. Penalty provisions applying to malpractice on the part of certifying officials should be included.

The *Veterinary Services* should demonstrate that they are capable of providing accurate and valid certification for exports of *animals* and animal products, based on 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.

Annex VIII (contd)

Article 3.2.8.

Animal health controls1. 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 controls1. Food hygiene

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

2. Zoonoses

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

3. Chemical residue testing programmes

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

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

4. Veterinary medicines

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

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

It is valid, for evaluation purposes, to seek assurances of effective government controls over veterinary medicines in so far as these relate to the public health risks associated with residues of these chemicals in *animals* and animal-derived foodstuffs. This process should be consistent with the

standards set by the Codex Alimentarius Commission or with alternative requirements set by the *importing country* where the latter are scientifically justified.

Annex VIII (contd)

5. Integration between animal health controls and veterinary public health

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

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

Article 3.2.10.

Performance assessment and audit programmes

1. Strategic plans

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

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

2. Performance assessment

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

3. Compliance

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

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

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

A supplementary or an alternative process for setting performance standards and application of monitoring and audit is the implementation of formal quality systems to some or all activities for

which the *Veterinary Services* are responsible. Formal accreditation to international quality system standards should be utilised if recognition in the evaluation process is to be sought.

4. Veterinary Services administration

a) Annual reports

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

b) Reports of government review bodies

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

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

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

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

d) In-service training and development programme for staff

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

e) Publications

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

f) Formal linkages with sources of independent scientific expertise

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

g) Trade performance history

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

Annex VIII (contd)

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

2. Evaluation of objectives and functions

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

- a) to regulate *veterinarians* and *veterinary para-professionals* through licensing ~~and/or~~ registration of such persons;
- b) to determine the minimum standards of education (initial and continuing) required for degrees, diplomas and certificates entitling the holders thereof to be registered as *veterinarians* and *veterinary para-professionals*;
- c) to determine the standards of professional conduct of *veterinarians* and *veterinary para-professionals* and to ensure these standards are met.

3. Evaluation of legislative basis, autonomy and functional capacity

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

Annex VIII (contd)

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

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

4. Evaluation of membership representation

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

- a) *veterinarians* designated by the *Veterinary Authority*, such as the Chief Veterinary Officer;
- b) *veterinarians* elected by members registered by the *veterinary statutory body*;
- c) *veterinarians* designated or nominated by the veterinary association(s);
- d) representative(s) of veterinary para-professions;
- e) representative(s) of veterinary academia;
- f) representative(s) of other stakeholders from the private sector;
- g) election procedures and duration of appointment;
- h) qualification requirements for members.

5. Evaluation of accountability and transparency of decision-making

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

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

6. Evaluation of financial sources and financial management

Information regarding income and expenditure, including fee structure(s) for the licensing ~~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.

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

Article 3.2.14.

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

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;

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- private *veterinarians* authorised by the *Veterinary Services* to perform official veterinary functions [*Describe accreditation standards, responsibilities and/or limitations applying to these private veterinarians.*];
 - other *veterinarians*.
- iii) Animal health:
- Numbers associated with farm livestock sector on a majority time basis in a veterinary capacity, by geographical area [*Show categories and numbers to differentiate staff involved in field service, laboratory, administration, import~~and~~ export and other functions, as applicable.*]:
- full time government *veterinarians*: national and sub-national;
 - part time government *veterinarians*: national and sub-national;
 - other *veterinarians*.
- iv) Veterinary public health:
- Numbers employed in food inspection on a majority time basis, by commodity [*Show categories and numbers to differentiate staff involved in inspection, laboratory and other functions, as applicable.*]:
- full time government *veterinarians*: national and sub-national;
 - part time government *veterinarians*: national and sub-national;
 - other *veterinarians*.
- v) Numbers of veterinarians relative to certain national indices:
- per total human population;
 - per farm livestock population, by geographical area;
 - per livestock farming unit, by geographical area.
- vi) Veterinary education:
- number of veterinary schools;
 - length of veterinary course (years);
 - curriculum addressing the minimum competencies of day 1 veterinary graduates 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 ~~and~~ 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 ~~and~~ training details.

d) Support personnel

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

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

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

g) Additional information ~~and~~ or comments.

3. Financial management information

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

- i) for the national Veterinary Authority;
- ii) for each of any sub-national components of the Veterinary Authority;
- iii) for other relevant government-funded institutions.

b) Sources of the budgetary allocations and amount:

- i) government budget;
- ii) sub-national authorities;
- iii) taxes and fines;
- iv) grants;

- v) private services.
 - c) Proportional allocations of the amounts in a) above for operational activities and for the programme components of *Veterinary Services*.
 - d) Total allocation proportionate of national public sector budget. *[This data may be necessary for comparative assessment with other countries which should take into account the contexts of the importance of the livestock sector to the national economy and of the animal health status of the country.]*
 - e) Actual and proportional contribution of animal production to gross domestic product.
4. Administration details
- a) Accommodation

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

Summary of the forms of communication systems available to the *Veterinary Services* on a nation-wide and local area bases.
 - c) Transport
 - i) Itemised numbers of types of functional transport available on a full-time basis for the *Veterinary Services*. In addition provide details of transport means available part-time.
 - ii) Details of annual funds available for maintenance and replacement of motor vehicles.
5. Laboratory services
- a) Diagnostic laboratories (laboratories engaged primarily in diagnosis)
 - i) Descriptive summary of the organisational structure and role of the government veterinary laboratory service in particular its relevance to the field *Veterinary Services*.
 - ii) Numbers of veterinary diagnostic laboratories operating in the country:
 - government operated laboratories;
 - private laboratories accredited by government for the purposes of supporting official or officially-endorsed animal health control or public health testing and monitoring programmes and import ~~and~~ export testing.

EU comment

The word "accredited" above and "accreditation" below might lead to confusion as these are terms widely used for quality assurance accreditation, while this point concerns the specific approval of laboratories by the government. Thus they should be replaced by "approved" or "authorized" and "approval" or "authorisation".

Moreover, for reasons of consistency, the term "government" above should be replaced by "Veterinary Services".

- 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*).

EU comment

In point v) above, the following should be added: "List of related National Reference Laboratories, if any."

- vi) Details of collaboration with external *laboratories* including international reference laboratories and details on numbers of samples submitted.
 - vii) Details of quality control and assessment (or validation) programmes operating within the veterinary laboratory service.
 - viii) Recent published reports of the official veterinary laboratory service which should include details of specimens received and foreign animal disease investigations made.
 - ix) Details of procedures for storage and retrieval of information on specimen submission and results.
 - x) Reports of independent reviews of the laboratory service conducted by government or private organisations (if available).
 - xi) Strategic and operational plans for the official veterinary laboratory service (if available).
- b) Research laboratories (laboratories engaged primarily in research)
- i) Numbers of veterinary research *laboratories* operating in the country:
 - government operated *laboratories*;
 - private *laboratories* involved in full time research directly related to animal health and veterinary public health matters involving production animal species.
 - ii) Summary of human and financial resources allocated by government to veterinary research.
 - iii) Published programmes of future government sponsored veterinary research.
 - iv) Annual reports of the government research *laboratories*.
6. 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;
 - 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 and/or exports of the *commodities* concerned.

- ii) Zoonoses
 - Descriptive summary of the numbers and functions of staff of the *Veterinary Authority* involved primarily with monitoring and control of zoonotic diseases.
 - Descriptive summary of the role and relationships of other official organisations involved in monitoring and control of *zoonoses* to be provided if the *Veterinary Authority* does not have these responsibilities.
- iii) Chemical residue testing programmes
 - Descriptive summary of national surveillance and monitoring programmes for environmental and chemical residues and contaminants applied to animal-derived foodstuffs, *animals* and animal feedstuffs.
 - Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.
 - Descriptive summary of the analytical methodologies used and their consistency with internationally recognised standards.
- iv) Veterinary medicines
 - Descriptive summary of the administrative and technical controls involving registration, supply and use of veterinary pharmaceutical products especially including biological products. This summary should include a focus on veterinary public health considerations relating to the use of these products in food-producing *animals*.
 - Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.

8. Quality systems

a) Accreditation

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

b) Quality manuals

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

c) Audit

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

9. Performance assessment and audit programmes

a) Strategic plans and review

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

b) Compliance

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

c) Annual reports of the Veterinary Authority

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

d) Other reports

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

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

e) Training

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

ii) Summary descriptions of training courses and duration.

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

f) Publications

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

g) Sources of independent scientific expertise

List of local and international universities, scientific institutions and recognised veterinary 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 3.3.

COMMUNICATION

EU position

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

Article 3.3.1.

General considerations

In general, communication entails the exchange of information between various individual, institutional and public groups for purposes of informing, guiding and motivating action. The application of the science and technique of communication involves modulating messages according to situations, objectives and target groups.

The recognition of communication as a discipline of the *Veterinary Services* and its incorporation within it is critical for their operations. The integration of veterinary and communication expertise is essential for effective communication.

Communication should be an integral part of all the activities of the *Veterinary Services* including animal health (*surveillance*, early detection and rapid response, prevention and control), *animal welfare* and veterinary public health (food safety, *zoonoses*) and veterinary medicine.

Objectives of this chapter on communication for the *Veterinary Services* are to provide guidance for the development of a communication system, strategic and operational communication plans and elements to assess their quality.

Article 3.3.2.

Principles of communication

1. *Veterinary Services* should have the authority and capability to communicate on matters within their mandate.
2. Veterinary and communication expertise should be combined.
3. Communication should be targeted and follow the fundamental criteria of transparency, consistency, timeliness, balance, accuracy, honesty and empathy and respect the fundamental principles of quality of *Veterinary Services* (Article 3.1.2.).
4. Communication should be a continuous process.
5. *Veterinary Services* should ~~be responsible for~~ **have oversight of** planning, implementing, monitoring, evaluating and revising their strategic and operational communication plans.

Article 3.3.3.

Definitions

Communication: means the discipline of informing, guiding and motivating individual, institutional and public groups, ideally on the basis of interactive exchanges, about any issue under the competence of the *Veterinary Services*.

Crisis: means a situation of great threat, difficulty or uncertainty when issues under the competence of the *Veterinary Services* require immediate action.

Crisis communication: means the process of communicating information as accurately as possible, albeit of potentially incomplete nature within time constraints in the event of a crisis.

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

Article 3.3.4.

Communication system

In addition to the Principles ~~for~~ of Communication the following elements should be used in conjunction with Chapter 3.1., when planning, implementing and assessing a communication system:

1. Organisational chart indicating a direct link between the communication personnel and the Veterinary Authority, through the chain of command, such as (e.g. dedicated communication unit, communication officer)
2. Human resources
 - a) Identified and accessible official communication focal point
 - b) Job descriptions of communication personnel identifying roles and responsibilities
 - c) Sufficient number of qualified personnel with knowledge, skills, attitude and abilities relevant to communication
 - d) Continuous training and education on communication provided to communication personnel.
3. Financial and physical resources
 - a) Clearly identified budget for communication that provides adequate funding
 - b) Provision and/or access to appropriate material resources in order to carry out roles and responsibilities: suitable premises or accommodation that is adequately equipped with sufficient office and technical equipment, including information technology and access to the Internet.
4. Management of the communication system
 - a) Roles and responsibilities of the communication personnel
 - i) Report to the *Veterinary Authority*
 - ii) Engage in decision-making process by providing guidance and expertise on communication issues to the *Veterinary Services*
 - iii) Be responsible for the planning, implementation and evaluation of the strategic and operational plans for communication and relevant standard operating procedures
 - iv) Function as contact point on communication issues for the *Veterinary Services*
 - v) ~~Provide guidance and expertise on communication issues to the *Veterinary Services*~~
 - vi) Provide and coordinate continuous education on communication for the *Veterinary Services*.

Annex IX (contd)

b) Strategic plan for communication

A well-designed strategic plan for communication should support the *Veterinary Services* strategic plan and have management support and commitment. The strategic plan for communication should address all high level organisation-wide long-term communication objectives. The plan should be a long term plan.

A strategic plan for communication should be monitored, periodically reviewed and should identify measurable performance objectives and techniques to assess the effectiveness of communication.

The strategic plan for communication should consider the different types of communication: routine communication, *risk communication*, outbreak communication and crisis communication, to allow individuals, affected and/or interested parties, an entire community or the general public to make best possible decisions and be informed of and/or accept policy decisions and their rationale.

The key outcomes in effectively implementing a strategic plan for communication are increased knowledge and awareness of issues by the public and stakeholders, higher understanding of the role of the *Veterinary Services*, higher visibility of and improved trust and credibility in the *Veterinary Services*. These will enhance understanding and/or acceptance of policy decisions and subsequent change of perception, attitude and/or behaviour.

c) Operational plans for communication

Operational plans for communication should be based on the assessment of specific issues and should identify specific objectives and target audiences such as staff, partners, stakeholders, media and the general public.

Each operational plan for communication should consist of a well-planned series of activities using different techniques, tools, messages and channels to achieve intended objectives and utilising available resources within a specific timeframe.

— Text deleted

CHAPTER 3.4.

VETERINARY LEGISLATION

EU position

The EU thanks the OIE and supports in general the adoption of this new chapter but has comments, some of which should be taken into account before adoption.

Indeed, the EU supports the adoption of this new chapter 3.4. on veterinary legislation and its inclusion in the OIE Terrestrial Code, as long as this represents a real help for Members and will not be used to create unjustified barriers to trade.

Article 3.4.1.

Introduction and objective

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

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

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

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

Article 3.4.2.

Definitions

For the purposes of this chapter the following definitions apply:

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

Legal certainty: means the situation in which the legislation is clear, coherent, stable and transparent, and protects citizens are protected against any adverse side effects of legal instruments. The situation of legal uncertainty could arise when legislative instruments are not coherent, are overly complex or change frequently.

EU comment

The definitions of "legal certainty" and "quality of legislation" should be deleted and moved to Article 3.4.3 point 5 where they belong. Indeed, these terms are used only once in this chapter and these two elements are principles and should not require specific definitions. See below for wording of Article 3.4.3.

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

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

Primary legislation: legal instruments issued by the legislature legislative branch of government.

EU comment

This amendment is not supported by the EU as in many countries it is not the government but the parliament that issues primary legislation. This diversity is well reflected in the initially used term "legislature". An alternative would be to use the dictionary definition of "legislature": "the legislative body of a country or state".

Secondary legislation: means the legal instruments issued by the executive branch of government under the authority of primary legislation, and relating to the regulated domain. The equivalent term, subsidiary legislation, is used in some countries.

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

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

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

Article 3.4.3.

General principles1. Respect for the hierarchy of legislation

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

2. Legal basis

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

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

3. Transparency

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

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

4. Consultation

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

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

5. Legislative quality Quality of legislation and legal certainty

Veterinary legislation should achieve a high level of legislative quality so as to ensure legal certainty. A high quality of legislation is essential for achieving legal certainty.

EU comment

The definitions of "legal certainty" and "quality of legislation" should be deleted and moved to Article 3.4.3 point 5 where they belong. Indeed, these terms are used only once in this chapter.

Point 5 above should thus read: "Legislation should be clear, coherent, stable and transparent, in order to protect citizens against unintended adverse side effects of legal instruments and thereby provide citizens with legal certainty. Quality of legislation is defined by the technical relevance, acceptability to society, sustainability in technical, financial and administrative terms and increase possibilities for effective implementation of laws. A high quality of legislation is essential for achieving legal certainty."

Article 3.4.4.

The drafting of veterinary legislation

Veterinary legislation should:

- a) be drafted in a manner that establishes clear rights, responsibilities and obligations (i.e. 'normative');
- b) be unambiguous, with clear and consistent syntax and vocabulary;
- c) be precise and accurate even if this results in repetition and a cumbersome style;

- d) contain no definitions that create any conflict or ambiguity;
- e) include a clear statement of scope and objectives;
- f) provide for the application of penalties and sanctions, either criminal or administrative, as appropriate to the situation; and
- g) make provision for the financing needed for the execution of all activities of *Competent Authorities*.

EU comment

The point g) above might lead to confusion. The EU has already commented on that and would not support the text if its comment is not taken into account.

It should be clear that the veterinary legislation is separated from the national budgetary legal act and possible funding systems that include more sources than the national budget. Thus the point g) should be reworded as follows: "g) make provision for the financing needed for the execution of all activities of *Competent Authorities* and should be ensured in accordance with the national funding system."

Article 3.4.5.

Matters relating to the *Competent Authorities*

Competent Authorities should be organised to ensure that all necessary actions are taken quickly and coherently to address animal health and public health emergencies effectively.

EU comment

Animal welfare should be included in the sentence above: "animal health, public health and animal welfare emergencies".

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

Competent Authorities should be organised to ensure that all necessary actions are taken quickly and coherently to effectively address animal health and public health emergencies.

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

1. Necessary powers of the Competent Authority

The veterinary legislation should also ensure that:

- a) officials have the legal authority to intervene in accordance with the legislation and the penal procedures in force;
- b) while conducting their duties, officials are protected against legal action and physical harm;

EU comment

It should be clear that disciplinary sanction can be conducted, thus the following words should be added at the beginning of point b): "without prejudice to rules on disciplinary sanctions".

- c) the powers and functions of officials are explicitly and thoroughly listed to protect the rights of stakeholders and the general public against any abuse of authority. This includes respecting confidentiality, as appropriate; and
- d) at least the following powers are available through the primary legislation:
 - i) access to premises and vehicles for carrying out inspections;
 - ii) access to documents;
 - iii) taking samples;
 - iv) retention (setting aside) of *animals* and goods, pending a decision on final disposition;
 - v) seizure of *animals*, products and food of animal origin;
 - vi) suspension of one or more activities of an inspected establishment;
 - vii) temporary, partial or complete closure of inspected establishments; and
 - viii) suspension or withdrawal of authorisations or approvals.

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

2. Delegation of powers by the Competent Authority

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

For this purpose, the veterinary legislation should:

- a) define the field of activities and the specific tasks covered by the delegation;
- b) provide for the control, supervision and, when appropriate, financing of the delegation;
- c) define the procedures for making delegation;
- d) define the competencies to be held by persons receiving delegation; and
- e) define the conditions of withdrawals of delegations.

Article 3.4.6.

Veterinarians y professionals and veterinary para-professionals

1. Veterinary medicine/science

EU comment

The sentence below should be clearer: "In order to ensure quality in the ~~conduct~~ application of veterinary medicine/science by veterinarians, [...]".

The EU suggests that the OIE follows the same process to define "veterinary medicine/science" as proposed in the introduction part of the report for Article 3.4.11 on "veterinary medicines and biological".

Moreover, the second part of the first sentence should be deleted, since it's not necessary to give a definition of veterinary medicine.

In order to ensure quality in the conduct of veterinary medicine/science, the veterinary legislation should:

- a) provide ~~a~~ an official definition of veterinary medicine/science sufficient to address the following;
 - ab) define the prerogatives of the veterinarians professionals involved in the conduct of veterinary medicine and of the various categories of veterinary para-professionals that are recognised by each the Member Country;
 - be) define the minimum initial and continuous educational requirements and competencies for *veterinarians* and *veterinary para-professionals*;
 - ce) prescribe the conditions for recognition of the professional qualifications for *veterinarians* and *veterinary para-professionals*;
 - de) define the conditions to perform the activities of veterinary medicine/science; and
 - ef) identify the exceptional situations, such as epizootics, under which persons other than qualified veterinarians can undertake activities that are normally carried out by *veterinarians*.
2. The control of veterinarians ~~professionals~~ and veterinary para-professionals

Veterinary legislation should provide a basis for regulation of *veterinarians ~~professionals~~* and *veterinary para-professionals* in the public interest. To that end, the legislation should:

- a) describe the general system of control in terms of the political, administrative and geographic configuration of the country;
- b) describe the various categories of veterinary para-professionals recognised by the each Member Country according to its needs, notably in animal health and food safety, and for each category, prescribe its training, qualifications, tasks and extent of supervision;
- c) prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to veterinarians and veterinary para-professionals;
- db) provide for the possibility of the delegation of powers to a professional organisation such as a *veterinary statutory body*; and
- ce) where powers have been so delegated, describe the prerogatives, the functioning and responsibilities of the mandated professional organisation; and
- d) prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to veterinary professionals and veterinary para professionals.

Article 3.4.7.

Laboratories in the veterinary domain1. Facilities

Veterinary legislation should define the role, responsibilities, obligations and quality requirements for:

- a) reference *laboratories*, which are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods;
- b) *laboratories* designated by the *Competent Authority* for carrying out the analysis of official samples; and
- c) *laboratories* recognised by the *Competent Authority* to conduct analyses required under the legislation e.g. for the purposes of quality control.

The veterinary legislation should define the conditions for the classification, approval, operations and supervision of *laboratories* at each level.

2. Laboratory reagents

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) procedures for authorising **the** reagents that are used to perform official analyses;
- b) quality assurance by manufacturers of **the** reagents used in official analyses; and
- c) surveillance of marketing of reagents, where these can affect the quality of analyses required by the veterinary legislation.

Article 3.4.8.

Health provisions relating to animal production1. Identification and traceability

Veterinary legislation should provide a basis for actions to address all the elements in Article 4.2.3., point 6.

2. Animal markets and other gatherings

Veterinary legislation should address, for animal markets and other commercially or epidemiologically significant animal gatherings, the following elements:

- a) registration of animal markets and other animal gatherings;
- b) health measures to prevent *disease* transmission, including procedures for cleaning and *disinfection*, and *animal welfare* measures; and
- c) provision for veterinary checks.

3. Animal reproduction

Veterinary legislation should provide a basis for actions to address the health regulation of animal reproduction as appropriate. Health regulations may be implemented at the level of *animals*, genetic material, establishments or operators.

4. Animal feed

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) standards for the production, composition and quality control of animal feed;
- b) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and
- c) recall from the market of any product likely to present a *hazard* to human health or animal health.

5. Animal by-products

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) definition of the animal by-products subject to the legislation;
- b) rules for collection, processing, **methods and authorised uses and disposal** of animal by-products;
- c) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and
- d) rules to be followed by animal owners; **as appropriate, concerning owners' use and disposition of animal by-products.**

6. Disinfection

Veterinary legislation should provide a basis for actions to address the regulation and use of products and methods of *disinfection* relating to the prevention and control of *animal diseases*.

Article 3.4.9.

Animal diseases

Veterinary legislation should provide a basis for the *Competent Authority* to manage *diseases* of importance to the country and to list those *diseases*, guided by the recommendations in Chapters 1.1. and 1.2.

1. Surveillance

Veterinary legislation should provide a basis for the collection, transmission and utilisation of epidemiological data relevant to *diseases* listed by the *Competent Authority*.

2. Disease prevention and control

- a) Veterinary legislation should include general animal health measures applicable to all *diseases* and, if necessary, additional or specific measures such as *surveillance*, establishment of a regulatory programme or emergency response for particular *diseases* listed in the country.

- b) The legislation should also provide a basis for contingency plans to include the following for use in disease responses:
 - i) administrative and logistic organisation;
 - ii) exceptional powers of the *Competent Authority*; and
 - iii) special and temporary measures to address all identified *risks* to human or animal health.
- c) Veterinary legislation should provide for the financing of animal disease control measures, such as operational expenses and, as appropriate, owners' compensation in the event of killing or slaughtering of *animals* and seizure or destruction of carcasses, meat, animal feed or other things.

3. Emerging diseases

Veterinary legislation should provide for measures to investigate and respond to *emerging diseases*.

Article 3.4.10.

Animal welfare

1. General provisions

Veterinary legislation should provide a basis for actions to address the *animal welfare* related requirements in the *Terrestrial Code*.

To this end, the legislation should contain as a minimum, a legal definition of cruelty as an offence **subject to penal action**, and provisions for direct intervention of the *Competent Authority* in the case of neglect by animal keepers.

2. Stray dogs and other free-roaming animals

Veterinary legislation should provide a basis for actions to address the requirements in Chapter 7.7. and, as appropriate, prohibition of the abandonment of *animals*, and management of abandoned *animals*, including transfer of ownership, veterinary interventions and *euthanasia*.

Article 3.4.11.

Veterinary medicines and biologicals

Veterinary legislation should provide a basis for assuring the quality of veterinary medicines and biologicals and minimising the *risk* to human, animal and environmental health associated with their use.

1. General measures

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) definition of veterinary medicines and biologicals, including any specific exclusions; and
- b) regulation of the importation, manufacture, distribution and usage of, and commerce in, veterinary medicines and biologicals.

2. Raw materials for use in veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) quality standards for raw materials used in the manufacture or composition of veterinary medicines and biologicals and arrangements for checking quality;
- b) establishment of the withdrawal periods and maximum residue limits for veterinary medicines and biologicals, as appropriate; and
- c) requirements for substances in veterinary medicines and biologicals that may, through their effects, interfere with the conduct of veterinary checks.

3. Authorisation of veterinary medicines and biologicals

- a) Veterinary legislation should ensure that only authorised veterinary medicines and biologicals may be placed on the market.
- b) Special provisions should be made for:
 - i) medicated feed;
 - ii) products prepared by authorised *veterinarians* or authorised pharmacists; and
 - iii) emergencies and temporary situations.
- c) Veterinary legislation should address the technical, administrative and financial conditions associated with the granting, renewal, refusal and withdrawal of authorisations.
- d) In defining the procedures for seeking and granting authorisations, the legislation should:
 - i) describe the role of the relevant *Competent Authority*; and
 - ii) establish rules providing for the transparency in decision making.
- e) Veterinary legislation may provide for the possibility of recognition of the equivalence of authorisations made by other countries.

Annex X (contd)4. Quality of veterinary medicines and biologicals

Veterinary legislation should address the following elements:

- a) the conduct of clinical and non clinical trials to verify all claims made by the manufacturer;
- b) conditions for the conduct of trials;
- c) qualifications of experts involved in trials; and
- d) surveillance for adverse effects arising from the use of veterinary medicines and biologicals.

5. Establishments producing, storing and wholesaling veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the following elements:

- a) registration or authorisation of all operators manufacturing, importing, storing, processing, wholesaling or otherwise distributing veterinary medicines and biologicals or raw materials for use in making veterinary medicines and biologicals;
- b) definition of the responsibilities of operators;
- c) good manufacturing practices as appropriate;
- d) reporting on adverse effects to the *Competent Authority*; and
- e) mechanisms for traceability and recall.

6. Retailing, use and traceability of veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the following elements:

- a) control over the distribution of veterinary medicines and biologicals and arrangements for traceability, recall and conditions of use;
- b) establishment of rules for the prescription and provision of veterinary medicines and biologicals to end users;
- c) restriction to authorised professionals and, as appropriate, authorized veterinary paraprofessionals of commerce in veterinary medicines and biologicals that are subject to prescription;
- d) the supervision by an authorised professional of organisations approved for holding and use of veterinary medicines and biologicals;
- e) the regulation of advertising claims and other marketing and promotional activities; and
- f) reporting on adverse effects to the *Competent Authority*.

Article 3.4.12.

Human food production chain

Veterinary legislation should provide a basis for actions to safeguard the human food production chain through controls at all critical steps, consistent with national food safety standards. The role of the Veterinary Services in food safety is described in Chapter 6.1.

1. General

Veterinary legislation should provide a basis for actions to address the following elements:

- a) controls over all stages of the production, processing and distribution of food of animal origin;
- ~~b~~a) recording all significant animal and public health events that occur during primary production;
- c) giving operators of food production premises the primary responsibility for compliance with food safety requirements, including traceability established by the *Competent Authority*;
- b) prohibition of the marketing of products not fit for human consumption;
- ~~d~~e) inspection for compliance with food standards safety and food composition, where this is relevant to health or safety;
- ~~e~~d) inspection of premises;
- f) prohibition of the marketing of products not fit for human consumption; and
- e) controls over the implementation of the legislation at all stages of the production, processing and distribution of food of animal origin;
- f) giving operators of food production premises the primary responsibility for compliance with food safety requirements for established by the *Competent Authority*; and
- g) provisions for recall from the marketplace of all products likely to be hazardous for human or animal health.

2. Products of animal origin intended for human consumption

Veterinary legislation should provide a basis for actions to address the following elements:

- a) arrangements for inspection and audit;
- b) the conduct of inspection and audit on the basis of veterinary expertise;
- c) health standards; and
- d) the application of health identification marks that are visible to the intermediary or final user.

The *Competent Authority* should have the necessary powers and means to rapidly withdraw any products deemed to be hazardous from the food chain or to prescribe uses or treatments that ensure the safety of such products for human or animal health.

Annex X (contd)3. Operators responsible for premises and establishments pertaining to the food chain

Veterinary legislation should provide a basis for actions to address the following elements as appropriate:

- a) registration of premises and establishments by the *Competent Authority*;
- b) the use of risk-based management procedures based on HACCP principles; and
- c) prior authorisation of operations that are likely to constitute a significant *risk* to human or animal health.

Article 3.4.13.

Import ~~and~~ export procedures and veterinary certification

Veterinary legislation should provide a basis for actions to address the elements relating to import ~~and~~ export procedures and veterinary certification referred to in Section 5 of the *Terrestrial Code*.

— Text deleted

CHAPTER 4.4.

APPLICATION OF COMPARTMENTALISATION

EU position**The EU supports the adoption of this modified chapter.**

Article 4.4.1.

Introduction and objectives

The recommendations in this chapter provide a structured framework for the application and recognition of *compartments* within countries or *zones*, based on the provisions of Chapter 4.3. with the objective to facilitate trade in *animals* and products of animal origin and as a tool for *disease* management.

Establishing and maintaining a *disease* free status throughout the country should be the final goal for OIE Members. However, establishing and maintaining a *disease* free status for an entire country may be difficult, especially in the case of *diseases* that can easily cross international boundaries. For many *diseases*, OIE Members have traditionally applied the concept of zoning to establish and maintain an animal *subpopulation* with a different animal health status within national boundaries.

The essential difference between zoning and compartmentalisation is that the recognition of *zones* is based on geographical boundaries whereas the recognition of *compartments* is based on management practices and biosecurity. However, spatial considerations and good management practices play a role in the application of both concepts.

Compartmentalisation is not a new concept for *Veterinary Services*; in fact, it has been applied for a long time in many *disease* control programmes that are based on the concept of *disease-free herds/flocks*.

The fundamental requirement for compartmentalisation is the implementation and documentation of management and biosecurity measures to create a functional separation of *subpopulations*.

For example, an animal production operation in an infected country or *zone* might have biosecurity measures and management practices that result in negligible *risk* from *diseases* or agents. The concept of a *compartment* extends the application of a 'risk boundary' beyond that of a geographical interface and considers all epidemiological factors that can help to create an effective *disease*-specific separation between *subpopulations*.

In *disease*-free countries or *zones*, *compartments* preferably should be defined prior to the occurrence of a *disease outbreak*. In the event of an *outbreak* or in infected countries or *zones*, compartmentalisation may be used to facilitate trade.

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

Annex XI (contd)

Article 4.4.2.

Principles for defining a compartment

A *compartment* may be established with respect of a specific *disease* or *diseases*. A *compartment* should be clearly defined, indicating the location of all its components including *establishments*, as well as related functional units (such as feed mills, *slaughterhouses*, rendering plants, etc.), their interrelationships and their contribution to an epidemiological separation between the *animals* in a *compartment* and *subpopulations* with a different health status. The definition of *compartment* may revolve around *disease* specific epidemiological factors, animal production systems, biosecurity practices infrastructural factors and *surveillance*.

Article 4.4.3.

Separation of a compartment from potential sources of infection

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

1. Physical or spatial factors that affect the status of biosecurity in a compartment

While a *compartment* is primarily based on management and biosecurity measures, a review of geographical factors is needed to ensure that the functional boundary provides adequate separation of a *compartment* from adjacent animal populations with a different health status. The following factors should be taken into consideration in conjunction with biosecurity measures and, in some instances, may alter the degree of confidence achieved by general biosecurity and *surveillance* measures:

- a) disease status in adjacent areas and in areas epidemiologically linked to the *compartment*;
- b) location, disease status and biosecurity of the nearest *epidemiological units* or other epidemiologically relevant premises. Consideration should be given to the distance and physical separation from:
 - i) *flocks* or *herds* with a different health status in close proximity to the *compartment*, including *wildlife* and their migratory routes;
 - ii) *slaughterhouses*, rendering plants or feed mills;
 - iii) *markets*, fairs, agricultural shows, sporting events, zoos, circuses and other points of animal concentration.

2. Infrastructural factors

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

- a) fencing or other effective means of physical separation;
- b) facilities for people entry including access control, changing area and showers;
- c) *vehicle* access including washing and *disinfection* procedures;

Annex XI (contd)

- d) *unloading* and *loading* facilities;
- e) isolation facilities for introduced *animals*;
- f) facilities for the introduction of material and equipment;
- g) infrastructure to store feed and veterinary products;
- h) disposal of carcasses, manure and waste;
- i) water supply;
- j) measures to prevent exposure to living mechanical or biological vectors such as insects, rodents and wild birds;
- k) air supply;
- l) feed supply/source.

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

3. Biosecurity plan

The integrity of the *compartment* relies on effective biosecurity. The management of the *compartment* should develop, implement and monitor a comprehensive *biosecurity plan*.

The *biosecurity plan* should describe in detail:

- a) potential pathways for introduction and spread into the *compartment* of the agents for which the *compartment* was defined, including animal movements, rodents, fauna, aerosols, arthropods, *vehicles*, people, biological products, equipment, fomites, feed, waterways, drainage or other means. Consideration should also be given to the survivability of the agent in the environment;
- b) the critical control points for each pathway;
- c) measures to mitigate exposure for each critical control point;
- d) standard operating procedures including:
 - i) implementation, maintenance, monitoring of the measures,
 - ii) application of corrective actions,
 - iii) verification of the process,
 - iv) record keeping;
- e) contingency plan in the event of a change in the level of exposure addressing any potential future changes in the risk factors;

Annex XI (contd)

- f) reporting procedures to the *Veterinary Authority*;
- g) the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on biosecurity principles and practices;
- h) the *surveillance* programme in place.

In any case, sufficient evidence should be submitted to assess the efficacy of the *biosecurity plan* in accordance with the level of *risk* for each identified pathway. This evidence should be structured in line with the principles of Hazard Analysis and Critical Control Point (HACCP). The biosecurity risk of all operations of the *compartment* should be regularly re-assessed and documented at least on a yearly basis. Based on the outcome of the assessment, concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the disease agent into the *compartment*.

4. Traceability system

A prerequisite for assessing the integrity of a *compartment* is the existence of a valid *traceability* system. All *animals* within a *compartment* should be individually identified and registered in such a way that their history and movements can be documented and audited. In cases where individual identification may not be feasible, such as broilers and day-old chicks, the *Veterinary Authority* should provide sufficient assurance of *traceability*.

All animal movements into and out of the *compartment* should be recorded at the *compartment* level, and when needed, based on a *risk assessment*, certified by the *Veterinary Authority*. Movements within the *compartment* need not be certified but should be recorded at the *compartment* level.

Article 4.4.4.

Documentation

Documentation should provide clear evidence that the biosecurity, *surveillance*, *traceability* and management practices defined for a *compartment* are effectively and consistently applied. In addition to animal movement information, the necessary documentation should include *herd* or *flock* production records, feed sources, *laboratory* tests, birth and *death* records, the visitor logbook, morbidity history, medication and vaccination records, *biosecurity plans*, training documentation and any other criteria necessary for the evaluation of *disease* exclusion.

The historical status of a *compartment* for the *disease(s)* for which it was defined should be documented and demonstrate compliance with the requirements for freedom in the relevant *Terrestrial Code* chapter.

In addition, a *compartment* seeking recognition should submit to the *Veterinary Authority* a baseline animal health report indicating the presence or absence of *listed diseases* for the animal species of interest to the compartment according to Article 1.2.3. This report should be regularly updated to reflect the current animal health situation of the *compartment*.

Vaccination records including the type of vaccine and frequency of administration should be available to enable interpretation of *surveillance* data.

The time period for which all records should be kept may vary according to the species and *disease(s)* for which the *compartment* was defined.

All relevant information should be recorded in a transparent manner and be easily accessible so as to be auditable by the *Veterinary Authority*.

Article 4.4.5.

Surveillance for the agent or disease

The *surveillance* system should comply with Chapter 1.4. on Surveillance and the specific recommendations for *surveillance* for the *disease(s)* for which the *compartment* was defined, if available.

If there is an increased *risk* of exposure to the agent for which the *compartment* has been defined, the sensitivity of the internal and external *surveillance* system should be reviewed and, where necessary, increased. At the same time, biosecurity measures in place should be reassessed and increased if necessary.

1. Internal surveillance

Surveillance should involve the collection and analysis of *disease/infection* data so that the *Veterinary Authority* can certify that the animal *subpopulation* contained in all the *establishments* comply with the defined status of that *compartment*. A *surveillance* system that is able to ensure early detection in the event that the agent enters a *subpopulation* is essential. Depending on the *disease(s)* for which the *compartment* was defined, different *surveillance* strategies may be applied to achieve the desired confidence in *disease* freedom.

2. External surveillance

The biosecurity measures applied in a *compartment* should be appropriate to the level of exposure of the *compartment*. External *surveillance* will help identify a significant change in the level of exposure for the identified pathways for *disease* introduction into the *compartment*.

An appropriate combination of active and passive *surveillance* is necessary to achieve the goals described above. Based on the recommendations of Chapter 1.4., targeted *surveillance* based on an assessment of *risk* factors may be the most efficient *surveillance* approach. Targeted *surveillance* should in particular include *epidemiological units* in close proximity to the *compartment* or those that have a potential epidemiological link with it.

Article 4.4.6.

Diagnostic capabilities and procedures

Officially-designated *laboratory* facilities complying with the OIE standards for quality assurance, as defined in Chapter 1.1.3. of the *Terrestrial Manual*, should be available for sample testing. All *laboratory* tests and procedures should comply with the recommendations of the *laboratory* for the specific *disease*. Each *laboratory* that conducts testing should have systematic procedures in place for rapid reporting of *disease* results to the *Veterinary Authority*. Where appropriate, results should be confirmed by an OIE Reference Laboratory.

Article 4.4.7.

Emergency response and notification

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

In the event of suspicion of occurrence of the *disease* for which the *compartment* was defined, the free status of the *compartment* should be immediately suspended. If confirmed, the status of the *compartment* should be immediately revoked and *importing countries* should be notified following the provisions of Article 5.3.7.

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

In the event of a *compartment* being at risk from a change, in the surrounding area, in the disease situation for which the *compartment* was defined, the *Veterinary Authority* should re-evaluate without delay the status of the *compartment* and consider whether any additional biosecurity measures are needed to ensure that the integrity of the *compartment* is maintained.

Article 4.4.8.

Supervision and control of a compartment

The authority, organisation, and infrastructure of the *Veterinary Services*, including *laboratories*, should be clearly documented in accordance with Chapter 3.2. on the Evaluation of *Veterinary Services* of the *Terrestrial Code*, to provide confidence in the integrity of the *compartment*.

The *Veterinary Authority* has the final authority in granting, suspending and revoking the status of a *compartment*. The *Veterinary Authority* should continuously supervise compliance with all the requirements critical to the maintenance of the *compartment* status described in this chapter and ensure that all the information is readily accessible to the *importing countries*. Any significant change should be notified to the *importing country*.

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CHAPTER 4.6.

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

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

Article 4.6.1.

General considerations

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

1. maintain the health of *animals* on an *artificial insemination centre* at a level which permits the international distribution of semen with a negligible risk of infecting other *animals* or humans with pathogens transmissible by semen;
2. ensure that semen is hygienically collected, processed and stored.

Artificial insemination centres should comply with recommendations in Chapter 4.5.

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

Article 4.6.2.

Conditions applicable to testing of bulls and teaser animals

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

1. Prior to entering pre-entry isolation facility

The *animals* should comply with the following requirements prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the *diseases* in question.

- a) Bovine brucellosis – Point 3 or 4 of Article 11.3.5.
- b) Bovine tuberculosis – Point 3 or 4 of Article 11.6.5.
- c) Bovine viral diarrhoea-mucosal disease (BVD-MD)

The *animals* should be subjected to:

- i) a virus isolation test or a test for virus antigen, with negative results; and
 - ii) a serological test to determine the serological status of every *animal*.
- d) Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

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

- i) come from an IBR/IPV free *herd* as defined in Article 11.11.3.; or
- ii) be subjected, with negative results, to a serological test for IBR/IPV on a blood sample.

e) Bluetongue

The *animals* should comply with Articles 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* of origin of the *animals*.

2. Testing in the pre-entry isolation facility prior to entering the semen collection facilities

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

a) Bovine brucellosis

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

b) BVD-MD

i) The *animals* should be subjected to a virus isolation test or a test for virus antigen, with negative results ~~All *animals* should be tested for viraemia as described in point 1e) above. Only when all the *animals* in pre-entry isolation have had test negative results for viraemia, may the *animals* enter the semen collection facilities upon completion of the 28-day pre-entry isolation period.~~

ii) ~~After 21 days in pre-entry isolation,~~ All *animals* should be subjected to a serological test to determine the presence or absence of BVD-MD antibodies.

iii) Only if no sero-conversion 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 sero-conversion seroconversion occurs, all the *animals* that remain seronegative should be kept in pre-entry isolation until there is no more seroconversion in the group for a period of three weeks. Serologically positive *animals* may be allowed entry into the semen collection facilities.

c) *Campylobacter fetus* subsp. *venerealis*

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

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

d) *Tritrichomonas foetus*

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

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

e) IBR-~~IPV~~

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

f) Bluetongue

The *animals* should comply with the provisions referred to in Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* where the pre-entry isolation facility is located.

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

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

- a) Bovine brucellosis
- b) Bovine tuberculosis
- c) BVD-~~MD~~

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

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

d) *Campylobacter fetus* subsp. *veneralis*

- 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) *Trichostrongylus axei*

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

g) IBR/IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the *animals* should comply with the provisions in point 2)c) of Article 11.11.3.

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

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

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.

Annex XII (contd)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* and semen.
- d) Bluetongue

The *animals* should comply with the provisions referred to in Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* where the pre-entry isolation facility is located.

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

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

- a) caprine and ovine brucellosis;
- b) ovine epididymitis;
- c) maedi-visna and caprine arthritis/encephalitis;
- d) tuberculosis (for goats only);
- e) bluetongue – The *animals* should comply with the provisions referred to in Article 8.3.10. or Article 8.3.11.

Article 4.6.4.

Conditions applicable to testing of boars

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

1. Prior to entering pre-entry isolation facility

The *animals* should be clinically healthy, physiologically normal and comply with the following requirements within 30 days prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the *diseases* in question.

- a) Porcine brucellosis – Article 15.3.3.
- b) Foot and mouth disease – Articles 8.5.12., 8.5.13. or 8.5.14.

- c) Aujeszky's disease – Article 8.2.9. or Article 8.2.10.
- d) Transmissible gastroenteritis – Article 15.5.2.
- e) Swine vesicular disease – Article 15.4.5. or Article 15.4.7.
- f) African swine fever – Article 15.1.5. or Article 15.1.6.
- g) Classical swine fever – Article 15.2.5. or Article 15.2.6.
- h) Porcine reproductive and respiratory syndrome – Test complying with the standards in the *Terrestrial Manual*.

2. Testing in the pre-entry isolation facility prior to entering the semen collection facilities

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

- a) Porcine brucellosis – Article 15.3.5.
- b) Foot and mouth disease – Articles 8.5.15., 8.5.16., 8.5.17. or 8.5.18.
- c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.
- d) Transmissible gastroenteritis – Article 15.5.4.
- e) Swine vesicular disease – Article 15.4.9. or Article 15.4.10.
- f) African swine fever – Article 15.1.8. or Article 15.1.9.
- g) Classical swine fever – Article 15.2.8. or Article 15.2.9.
- h) Porcine reproductive and respiratory syndrome – The test complying with the standards in the *Terrestrial Manual*.

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

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

- a) Porcine brucellosis – Article 15.3.5.
- b) Foot and mouth disease – Articles 8.5.15., 8.5.16., 8.5.17. or 8.5.18.
- c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.
- d) Transmissible gastroenteritis – Article 15.5.4.
- e) Swine vesicular disease – Article 15.4.9. or Article 15.4.10.
- f) African swine fever – Article 15.1.8. or Article 15.1.9.
- g) Classical swine fever – Article 15.2.8. or Article 15.2.9.

- h) Porcine reproductive and respiratory syndrome – The test complying with the standards in the *Terrestrial Manual*.

Article 4.6.5.

General considerations for hygienic collection and handling of semen

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

Article 4.6.6.

Conditions applicable to the collection of semen

1. The floor of the mounting area should be clean and provide safe footing. A dusty floor should be avoided.
2. The hindquarters of the teaser, whether a dummy or a live teaser animal, should be kept clean. A dummy should be cleaned completely after each period of collection. A teaser animal should have its hindquarters cleaned carefully before each collecting session. The dummy or hindquarters of the teaser animals should be sanitised after the collection of each ejaculate. Disposable plastic covers may be used.
3. The hand of the person collecting the semen should not come into contact with the *animal's* penis. Disposable gloves should be worn by the collector and changed for each collection.
4. The artificial vagina should be cleaned completely after each collection where relevant. It should be dismantled, its various parts washed, rinsed and dried, and kept protected from dust. The inside of the body of the device and the cone should be disinfected before re-assembly using approved *disinfection* techniques such as those involving the use of alcohol, ethylene oxide or steam. Once re-assembled, it should be kept in a cupboard which is regularly cleaned and disinfected.
5. The lubricant used should be clean. The rod used to spread the lubricant should be clean and should not be exposed to dust between successive collections.
6. The artificial vagina should not be shaken after ejaculation, otherwise lubricant and debris may pass down the cone to join the contents of the collecting tube.
7. When successive ejaculates are being collected, a new artificial vagina should be used for each mounting. The vagina should also be changed when the *animal* has inserted its penis without ejaculating.
8. The collecting tubes should be sterile, and either disposable or sterilised by autoclaving or heating in an oven at 180°C for at least 30 minutes. They should be kept sealed to prevent exposure to the environment while awaiting use.
9. After semen collection, the tube should be left attached to the cone and within its sleeve until it has been removed from the collection room for transfer to the laboratory.

Annex XII (contd)

Article 4.6.7.

Conditions applicable to the handling of semen and preparation of semen samples in the laboratory1. Diluents

- a) All receptacles used should have been sterilised.
- b) Buffer solutions employed in diluents prepared on the premises should be sterilised by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additive and antibiotics.
- c) If the constituents of a diluent are supplied in commercially available powder form, the water used should have been distilled or demineralised, sterilised (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.
- d) Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product should be free of pathogens or sterilised; milk heat-treated at 92°C for 3–5 minutes, eggs from SPF flocks when available. When egg yolk is used, it should be separated from eggs using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination, may be used. Other additives should also be sterilised before use.
- e) Diluent should not be stored for more than 72 hours at +5°C before use. A longer storage period is permissible for storage at -20°C. Storage vessels should be stoppered.
- f) A mixture of antibiotics should be included with a bactericidal activity at least equivalent to that of the following mixtures in each ml of frozen semen: gentamicin (250 µg), tylosin (50 µg), lincomycin–spectinomycin (150/300 µg); penicillin (500 IU), streptomycin (500 µg), lincomycin–spectinomycin (150/300 µg); or amikacin (75 µg), divekacin (25 µg).

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

2. Procedure for dilution and packing

- a) The tube containing freshly collected semen should be sealed as soon as possible after collection, and kept sealed until processed.
- b) After dilution and during refrigeration, the semen should also be kept in a stoppered container.
- c) During the course of filling receptacles for dispatch (such as insemination straws), the receptacles and other disposable items should be used immediately after being unpacked. Materials for repeated use should be disinfected with alcohol, ethylene oxide, steam or other approved *disinfection* techniques.
- d) If sealing powder is used, care should be taken to avoid its being contaminated.

3. Conditions applicable to the storage of semen

Semen for export should be stored 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)⁴.

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.

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- ~~4- The ICAR international standards on straws are contained in Recording Guidelines – Appendices to the international agreement of recording practices. The text of this document is available at the following web site: www.icar.org~~

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CHAPTER 4.7.

**COLLECTION AND PROCESSING OF *IN VIVO*
DERIVED EMBRYOS FROM LIVESTOCK AND ~~HORSES~~
EQUIDS**

EU position

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

Article 4.7.1.

Aims of control

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

Article 4.7.2.

Conditions applicable to the embryo collection team

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

1. The team should be approved by the *Competent Authority*.
2. The team should be supervised by a team *veterinarian*.
3. The team *veterinarian* is responsible for all team operations which include verification of donor health status, sanitary handling and surgery of donors and *disinfection* and hygienic procedures.
4. Team personnel should be adequately trained in the techniques and principles of disease control. High standards of hygiene should be practiced to preclude the introduction of *infection*.
5. The collection team should have adequate facilities and equipment for:
 - a) collecting embryos;
 - b) processing and treatment of embryos at a permanent site or mobile laboratory;
 - c) storing embryos.

These facilities need not necessarily be at the same location.

6. The embryo collection team should keep a record of its activities, which should be maintained for inspection by the *Veterinary Authority* for a period of at least two years after the embryos have been exported.
7. The embryo collection team should be subjected to regular inspection at least once a year by an *Official Veterinarian* to ensure compliance with procedures for the sanitary collection, processing and storage of embryos.

Annex XII (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. ~~and footnote~~).
- 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* and/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. 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* (e.g. bovine herpesvirus-1, and Aujeszky's disease virus) is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual.
 - 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.

Article 4.7.6.

Conditions applicable to the collection and storage of embryos

1. Media

Any biological product of animal origin used in the media and solutions for collection, processing, washing or storage of embryos should be free of pathogenic micro-organisms. Media and solutions used in the collection and storage of embryos should be sterilised by approved methods according to the IETS 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 Manual³.

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 Manual³.
- 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 Manual²).

Annex XII (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.

- When treatment of the viable embryos is modified to include additional washings with the enzyme trypsin (see paragraph 2c) in Article 4.7.5.), the procedure should be carried out according to the IETS Manual^a. 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

- 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.
- Only embryos from the same individual donor should be stored together in the same ampoule, vial or straw.
- 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.
- Ampoules, vials or straws should be sealed at the time of freezing (or prior to export where cryopreservation is not possible), and they should be clearly identified by labels according to the standardised system recommended in the IETS Manual^a.
- Liquid nitrogen containers should be sealed under the supervision of the *Official Veterinarian* prior to shipment from the *exporting country*.
- 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 XII (contd)

Article 4.7.11.

Specific conditions/~~comments~~ 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 equines routinely involved in events or competitions at the international level. For instance, in appropriate circumstances horses travelling with an *international veterinary certificate* (~~e.g. competition horses~~) may be exempt where mutually agreed upon on a bilateral basis between the respective *Veterinary Authorities*.

Article 4.7.12.

Specific conditions/~~comments~~ 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*. ~~It should be noted however that in 2008 the The~~ development of cryopreservation methods for storage of camelid embryos is still at a an very early stage, and also that pathogen interaction studies with camelid embryos have not yet been carried out.

Article 4.7.13.

Specific conditions/~~comments~~ 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 Research Subcommittee of the Health and Safety Advisory Committee (HASAC)~~ of the IETS, the following listed diseases and pathogenic agents are categorised into four categories, which applies only to *in vivo* derived embryos.

1. Category 1

- a) Category 1 *diseases* or pathogenic agents are those for which sufficient evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual.
- b) The following *diseases* or pathogenic agents are in Category 1:
 - Aujeszky's disease (~~pseudorabies~~) (swine 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 (~~hog cholera~~).

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
 - ≡ Bovine immunodeficiency virus (not a listed disease)
 - Bovine spongiform encephalopathy (goats)
 - ≡ Bovine spongiform encephalopathy (goats) (not a listed disease of goats)
 - Bovine viral diarrhoea virus (cattle)
 - ~~Campylobacter fetus (sheep)~~
 - ≡ Campylobacter fetus (sheep) (not a listed disease of sheep)
 - Foot and mouth disease (swine pigs, sheep and goats)
 - ~~Haemophilus somnus (cattle)~~
 - ≡ Haemophilus somnus (cattle) (not a listed disease)
 - Maedi-visna (sheep)
 - ~~Mycobacterium paratuberculosis (cattle)~~
 - ~~Neospora caninum (cattle)~~
 - ≡ Neospora caninum (cattle) (not a listed disease)
 - ~~Ovine pulmonary adenomatosis~~
 - ≡ 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.
- b) The following *diseases* or pathogenic agents are in Category 4:

- African swine fever
- ~~Akabane (cattle)~~
- == Akabane (cattle) (not a listed disease)
- Bovine anaplasmosis
- Bluetongue (goats)
- ~~Border disease (sheep)~~
- == Border disease (sheep) (not a listed disease)
- ~~Bovine herpesvirus 4~~
- == Bovine herpesvirus-4 (not a listed disease)
- *Chlamydia psittaci* (cattle, sheep)
- Contagious equine metritis
- Enterovirus (cattle, swine)
- == Enterovirus (cattle, swine pigs) (not a listed disease)
- Equine rhinopneumonitis
- == Equine viral arteritis
- ~~*Escherichia coli* O9:K99 (cattle)~~
- == *Escherichia coli* O9:K99 (cattle) (not a listed disease)
- ~~*Leptospira borgpetersenii* serovar *hardjobovis* (cattle)~~
- == *Leptospira borgpetersenii* serovar *hardjobovis* (cattle) (not a listed disease)
- ~~*Leptospira* sp. (swine)~~
- == *Leptospira* sp. (swine pigs) (not a listed disease)
- Lumpy skin disease
- *Mycobacterium bovis* (cattle)
- *Mycoplasma* spp. (swine pigs)
- Ovine epididymitis (*Brucella ovis*)
- ~~Parainfluenza 3 virus (cattle)~~
- == Parainfluenza-3 virus (cattle) (not a listed disease)
- ~~Parvovirus (swine)~~
- == Parvovirus (swine pigs) (not a listed disease)
- ~~Porcine circovirus (type 2) (pigs)~~
- == Porcine circovirus (type 2) (pigs) (not a listed disease)
- Scrapie (goats)
- *Trichostrongylus axei* (cattle)
- ~~*Ureaplasma/Mycoplasma* spp. (cattle, goats)~~
- == *Ureaplasma and Mycoplasma* spp. (cattle, goats) (not a listed disease)
- Vesicular stomatitis (cattle, swine pigs).

1— ~~Based on available research and field information, the Research Subcommittee of the Health and Safety Advisory Committee (HASAC) of the International Embryo Transfer Society (IETS) has categorised some diseases based on their relative risk of dissemination by properly processed and handled *in vivo* derived embryos. This chapter that contains the complete list of IETS categorised diseases is shown in Article 4.7.14.~~

2— ~~Manual of the International Embryo Transfer Society.~~

— Text deleted

CHAPTER 5.3.

**OIE PROCEDURES RELEVANT TO THE AGREEMENT
ON THE APPLICATION OF SANITARY AND
PHYTOSANITARY MEASURES OF THE WORLD
TRADE ORGANIZATION**

EU position

The EU supports the adoption of this modified chapter.

Article 5.3.1.

The Agreement on the Application of Sanitary and Phytosanitary Measures and role and responsibility of the OIE

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) encourages the Members of the World Trade Organization to base their *sanitary measures* on international standards, guidelines and recommendations, where they exist. Members may choose to adopt a higher level of protection than that provided by international texts if there is a scientific justification or if the level of protection provided by the relevant international texts is considered to be inappropriate. In such circumstances, Members are subject to obligations relating to *risk assessment* and to a consistent approach of *risk management*.

The SPS Agreement encourages Governments to make a wider use of *risk analysis*: WTO Members shall undertake an assessment as appropriate to the circumstances of the actual *risk* involved.

The SPS Agreement, in Article 7, obliges WTO Members to notify changes in, and provide relevant information on, sanitary measures which may, directly or indirectly, affect international trade.

The SPS Agreement recognises the OIE as the relevant international organisation responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in live *animals* and animal products.

Article 5.3.2.

Introduction on the judgement of the equivalence of sanitary measures

The importation of *animals* and animal products involves a degree of *risk* to the animal health status of an *importing country*. The estimation of that *risk* and the choice of the appropriate *risk management* option(s) are made more difficult by differences among the animal health and production systems in OIE Members. It is now recognised that significantly different animal health and production systems can provide equivalent animal and human health protection for the purpose of *international trade*, with benefits to both the *importing country* and the *exporting country*.

These recommendations are to assist OIE Members to determine whether *sanitary measures* arising from different animal health and production systems may provide the same level of animal and human health protection. They discuss principles which might be utilised in a judgement of equivalence, and outline a step-wise process for trading partners to follow in facilitating a judgement of equivalence. These provisions are applicable whether equivalence applies at the level of specific measures or on a systems-wide basis, and whether equivalence applies to specific areas of trade or *commodities*, or generally.

Annex XIII (contd)

Article 5.3.3.

General considerations on the judgement of the equivalence of sanitary measures

Before trade in *animals* or their products may occur, an *importing country* must be satisfied that its *animal health status* will be appropriately protected. In most cases, the *risk management* measures drawn up will rely in part on judgements made about the animal health and production system(s) in the *exporting country* and the effectiveness of sanitary procedures undertaken there. Systems operating in the *exporting country* may differ from those in the *importing country* and from those in other countries with which the *importing country* has traded. Differences may be with respect to infrastructure, policies or operating procedures, *laboratory* systems, approaches to the pests and *diseases* present, border security and internal movement controls.

International recognition of the legitimacy of different approaches to achieving the *importing country's appropriate level of protection (ALOP)* has led to the principle of equivalence being included in trade agreements, including the SPS Agreement of the WTO.

Benefits of applying equivalence may include:

1. minimising costs associated with *international trade* by tailoring animal health measures to local circumstances;
2. maximising animal health outcomes for a given level of resource input;
3. facilitating trade by achieving the required health protection through less trade restrictive *sanitary measures*; and
4. decreased reliance on relatively costly *commodity* testing and isolation procedures in bilateral or multilateral agreements.

The *Terrestrial Code* recognises equivalence by recommending alternative *sanitary measures* for many *diseases* and pathogenic agents. Equivalence may be gained, for example, by enhanced *surveillance* and monitoring, by the use of alternative test, treatment or isolation procedures, or by combinations of the above. To facilitate the judgement of equivalence, Members should base their *sanitary measures* on OIE standards, guidelines and recommendations.

It is essential to apply a scientific *risk analysis* to the extent practicable in establishing the basis for a judgement of equivalence.

Article 5.3.4.

Prerequisite considerations in a judgement of equivalence1. Application of risk assessment

Application of the discipline of *risk assessment* provides a structured basis for judging equivalence among different *sanitary measures* as it allows a close examination to be made of the effect of a measure(s) on a particular step(s) in the importation pathway, and the relative effects of proposed alternative measure(s) on the same or related steps.

A judgement of equivalence needs to assess the *sanitary measure* in terms of its effectiveness regarding the particular *risk* or group of *risks* against which the measure is designed to protect. Such an assessment may include the following elements: the purpose of the measure, the level of protection

achieved by the measure and the contribution the measure makes to achieving the ALOP of the *importing country*.

2. Categorisation of sanitary measures

Proposals for equivalence may be in terms of a measure comprising a single component of a measure (e.g. an isolation procedure, a test or treatment requirement, a certification procedure) or multiple components (e.g. a production system for *commodity*), or a combination of measures. Multiple components or combinations of measures may be applied consecutively or concurrently.

Sanitary measures are those described in each chapter of the *Terrestrial Code* which are used for *risk* reduction and are appropriate for particular *diseases*. *Sanitary measures* may be applied either alone or in combination and include test requirements, processing requirements, inspection or certification procedures, quarantine confinements, and sampling procedures.

For the purposes of judging equivalence, *sanitary measures* can be broadly categorised as:

- a) infrastructure: including the legislative base (e.g. animal health law) and administrative systems (e.g. organisation of national and regional animal health authorities, emergency response organisations);
- b) programme design or implementation: including documentation of systems, performance and decision criteria, *laboratory* capability, and provisions for certification, audit and enforcement;
- c) specific technical requirement: including requirements applicable to the use of secure facilities, treatment (e.g. retorting of cans), specific test (e.g. ELISA) and procedures (e.g. pre-export inspection).

A *sanitary measure(s)* proposed for a judgement of equivalence may fall into one or more of these categories, which are not mutually exclusive.

In some cases, a comparison of specific technical requirements may suffice. In many instances, however, a judgement as to whether the same level of protection is likely to be achieved may only be able to be determined through an evaluation of all relevant components of an *exporting country's* animal health and production system. For example, a judgement of equivalence for a specific *sanitary measure* at the programme design or implementation level may require a prior examination of infrastructure while a judgement of equivalence for a specific measure at the specific technical requirement level may require that the specific measure be judged in its context through examination of infrastructure and programmes.

Article 5.3.5.

Principles for judgement of equivalence

In conjunction with the above considerations, judgement of the equivalence of *sanitary measures* should be based on application of the following principles:

1. an *importing country* has the right to set the level of protection it deems appropriate (its ALOP) in relation to human and animal life and health in its territory; this ALOP may be expressed in qualitative or quantitative terms;
2. the *importing country* should be able to describe the reason for each *sanitary measure* i.e. the level of protection intended to be achieved by application of the identified measure against a *hazard*;
3. an *importing country* should recognise that *sanitary measures* different from the ones it has proposed may be capable of providing the same level of protection;

Annex XIII (contd)

4. the *importing country* should, upon request, enter into consultations with the *exporting country* with the aim of facilitating a judgement of equivalence;
5. any *sanitary measure* or combination of *sanitary measures* can be proposed for judgement of equivalence;
6. an interactive process should be followed that applies a defined sequence of steps, and utilises an agreed process for exchange of information, so as to limit data collection to that which is necessary, minimise administrative burden, and facilitate resolution of claims;
7. the *exporting country* should be able to demonstrate objectively how the alternative *sanitary measure(s)* proposed as equivalent will provide the same level of protection;
8. the *exporting country* should present a submission for equivalence in a form that facilitates judgement by the *importing country*;
9. the *importing country* should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner, and according to appropriate *risk assessment* principles;
10. the *importing country* should take into account any knowledge of and prior experience with the *Veterinary Authority* or other *Competent Authority* of the *exporting country*;
11. the *exporting country* should provide access to enable the procedures or systems which are the subject of the equivalence judgement to be examined and evaluated upon request of the *importing country*;
12. the *importing country* should be the sole determinant of equivalence, but should provide to the *exporting country* a full explanation for its judgement;
13. to facilitate a judgement of equivalence, OIE Members should base their *sanitary measures* on relevant OIE standards;
14. to allow the judgement of equivalence to be reassessed if necessary, the *importing country* and the *exporting country* should keep each other informed of significant changes to infrastructure, health status or programmes which may bear on the judgement of equivalence; and
15. an *importing country* should give positive consideration to a request by an exporting developing country for appropriate technical assistance that would facilitate the successful completion of a judgement of equivalence.

Article 5.3.6.

Sequence of steps to be taken in judgement of equivalence

There is no single sequence of steps which must be followed in all judgements of equivalence. The steps that trading partners choose will generally depend on the circumstances and their trading experience. The interactive sequence of steps described below may be useful for all *sanitary measures* irrespective of their categorisation as infrastructure, programme design or implementation or specific technical requirement components of an animal health and production system.

This sequence assumes that the *importing country* is meeting its obligations under the WTO SPS Agreement and has in place a transparent measure based either on an international standard or a *risk analysis*.

Annex XIII (contd)

Recommended steps are:

1. the *exporting country* identifies the measure(s) for which it wishes to propose an alternative measure(s), and requests from the *importing country* a reason for its *sanitary measure* in terms of the level of protection intended to be achieved against a *hazard(s)*;
2. the *importing country* explains the reason for the measure(s), in terms which would facilitate comparison with an alternative *sanitary measure(s)* and consistent with the principles set out in these provisions;
3. the *exporting country* demonstrates the case for equivalence of an alternative *sanitary measure(s)* in a form which facilitates analysis by an *importing country*;
4. the *exporting country* responds to any technical concerns raised by the *importing country* by providing relevant further information;
5. judgement of equivalence by the *importing country* takes into account as appropriate:
 - a) the impact of biological variability and uncertainty;
 - b) the expected effect of the alternative *sanitary measure(s)* on all relevant *hazards*;
 - c) OIE standards;
 - d) application of solely qualitative frameworks where it is not possible or reasonable to conduct *quantitative risk assessment*;
6. the *importing country* notifies the *exporting country* of its judgement and the underlying reasons within a reasonable period of time:
 - a) recognition of the equivalence of the *exporting country's* alternative *sanitary measure(s)*;
 - b) request for further information; or
 - c) rejection of the case for equivalence of the alternative *sanitary measure(s)*;
7. an attempt should be made to resolve any differences of opinion over judgement of a case, either interim or final, by using an agreed mechanism to reach consensus (e.g. the OIE informal procedure for dispute mediation), or by referral to an agreed expert;
8. depending on the category of measures involved, the *importing country* and the *exporting country* may enter into a formal equivalence agreement giving effect to the judgement or a less formal acknowledgement of the equivalence of a specific measure(s) may suffice.

An *importing country* recognising the equivalence of an *exporting country's* alternative *sanitary measure(s)* needs to ensure that it acts consistently with regard to applications from third countries for recognition of equivalence applying to the same or very similar measure(s). Consistent action does not mean however that a specific measure(s) proposed by several *exporting countries* should always be judged as equivalent as a measure(s) should not be considered in isolation but as part of a system of infrastructure, policies and procedures.

Annex XIII (contd)

Article 5.3.7.

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

There is no single sequence of steps which should be followed in establishing a *zone* or a *compartment*. The steps that the *Veterinary Services* of the *importing country* and the *exporting country* choose and implement will generally depend on the circumstances existing within the countries and at their borders, and their trading history. The recommended steps are:

1. For zoning

- a) The *exporting country* identifies a geographical area within its territory, which it considers to contain an animal *subpopulation* with a distinct health status with respect to specific *disease(s)*, based on *surveillance*.
- b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures which are being, or will be, applied to distinguish such an area epidemiologically from other parts of its territory, in accordance with the recommendations in the *Terrestrial Code*.
- c) The *exporting country* provides:
 - i) the above information to the *importing country*, with an explanation of why the area can be treated as an epidemiologically separate *zone* for *international trade* purposes;
 - ii) access to enable the procedures or systems that establish the *zone* to be examined and evaluated upon request by the *importing country*.
- d) The *importing country* determines whether it accepts such an area as a *zone* for the importation of *animals* and animal products, taking into account:
 - i) an evaluation of the *exporting country's Veterinary Services*;
 - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
 - iii) its own animal health situation with respect to the *disease(s)* concerned; and
 - iv) other relevant OIE standards.
- e) The *importing country* notifies the *exporting country* of its determination and the underlying reasons, within a reasonable period of time, being:
 - i) recognition of the *zone*; or
 - ii) request for further information; or
 - iii) rejection of the area as a *zone* for *international trade* purposes.
- f) An attempt should be made to resolve any differences over recognition of the *zone*, either in the interim or finally, by using an agreed mechanism to reach consensus such as the OIE informal procedure for dispute mediation (Article 5.3.8.).

Annex XIII (contd)

- g) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognizing the *zone*.

2. For compartmentalisation

- a) Based on discussions with the relevant industry, the *exporting country* identifies within its territory a *compartment* comprising an animal *subpopulation* contained in one or more *establishments* or other premises operating under common management practices related to biosecurity. The *compartment* contains an identifiable animal *subpopulation* with a distinct health status with respect to specific *disease(s)*. The *exporting country* describes how this status is maintained through a partnership between the relevant industry and the *Veterinary Authority* of the *exporting country*.
- b) The *exporting country* examines the *compartment's biosecurity plan* and confirms through an audit that:
- i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and
 - ii) the *surveillance* and monitoring programme in place is appropriate to verify the status of such a *subpopulation* with respect to such *disease(s)*.
- c) The *exporting country* describes the *compartment*, in accordance with the recommendations in the *Terrestrial Code*.
- d) The *exporting country* provides:
- i) the above information to the *importing country*, with an explanation of why such a *subpopulation* can be treated as an epidemiologically separate *compartment* for *international trade* purposes; and
 - ii) access to enable the procedures or systems that establish the *compartment* to be examined and evaluated upon request by the *importing country*.
- e) The *importing country* determines whether it accepts such a *subpopulation* as a *compartment* for the importation of *animals* and animal products, taking into account:
- i) an evaluation of the *exporting country's Veterinary Services*;
 - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
 - iii) its own animal health situation with respect to the *disease(s)* concerned; and
 - iv) other relevant OIE standards.
- f) The *importing country* notifies the *exporting country* of its determination and the underlying reasons, within a reasonable period of time, being:
- i) recognition of the *compartment*; or
 - ii) request for further information; or

- iii) rejection of such a *subpopulation* as a *compartment* for *international trade* purposes.
- g) An attempt should be made to resolve any differences over recognition of the *compartment*, either in the interim or finally, by using an agreed mechanism to reach consensus such as the OIE informal procedure for dispute mediation (Article 5.3.8.).
- h) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognizing the *compartment*.
- i) The *Veterinary Authority* of the *exporting country* should promptly inform *importing countries* of any occurrence of a *disease* in respect of which the *compartment* was defined.

Article 5.3.8.

The OIE informal procedure for dispute mediation

OIE shall maintain its existing voluntary in-house mechanisms for assisting OIE Members to resolve differences. In-house procedures which will apply are that:

1. Both parties agree to give the OIE a mandate to assist them in resolving their differences.
 2. If considered appropriate, the Director General of the OIE recommends an expert, or experts, and a chairman, as requested, agreed by both parties.
 3. Both parties agree on the terms of reference and working programme, and to meet all expenses incurred by the OIE.
 4. The expert or experts are entitled to seek clarification of any of the information and data provided by either country in the assessment or consultation processes, or to request additional information or data from either country.
 5. The expert or experts shall submit a confidential report to the Director General of the OIE, who will transmit it to both parties.
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CHAPTER 6.4.

BIOSECURITY PROCEDURES IN POULTRY PRODUCTION

EU position

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

The EU reiterates its former comment that the Code should have an introductory chapter including some part of the Foreword, so that this Chapter 6.4. (and others) would not be used as unjustified barriers to trade.

Article 6.4.1.

Introduction

~~This chapter provides recommended biosecurity procedures in *poultry* production and is not specifically related to trade (under study).~~

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 *poultry* production. It should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005) and 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) *Establishments* should be free from unwanted vegetation and debris that could attract or harbour pests.
- g) Procedures for the prevention of entry of wild birds into *poultry* houses and buildings, and the control of vermin such as rodents and arthropods should be implemented.
- h) Access to the *establishment* should be controlled to ensure only authorised persons and *vehicles* enter the site.
- i) All personnel and visitors entering an *establishment* should follow a biosecurity procedure. The preferred procedure is for visitors and personnel entering the *establishment* to shower and change into clean clothes and footwear provided by the *establishment*. Where this is not practical, clean outer garments (coveralls or overalls, head covering and footwear) should be provided. Entry of visitors and vehicles should be registered by the establishment.

Annex XIV (contd)

- j) Personnel and visitors should not have had recent contact with other *poultry*, *poultry* waste, or *poultry* processing plant(s). This time period should be based on the level of risk of transmission of infectious agents. This will depend on the *poultry* production purpose, biosecurity procedures and *infection* status (e.g. the time between visiting a breeder *flock* and then a broiler *flock* would be less than the time between visiting a broiler *flock* and then a breeder *flock*).
- k) Any *vehicle* entering an *establishment* should be cleaned and disinfected according to a *biosecurity plan*. Delivery *vehicles* should be cleaned, and disinfected before *loading* each consignment of eggs or *poultry*.
2. Additional measures for all poultry farms
- a) Whenever possible, the 'all-in all-out' single age group principle should be used. If this is not feasible and several *flocks* are maintained on one *establishment*, each *flock* should be managed as a separate *epidemiological unit*.
- b) All personnel and visitors entering a *poultry* house should wash their hands with soap and water or sanitize them using a disinfectant. Personnel and visitors should also change footwear, use a boot spray or use a properly maintained disinfectant footbath. The disinfectant solution in the footbath should be changed on a regular basis to ensure its efficacy, according to the manufacturer's instructions.
- c) Any equipment should be cleaned and sanitized before being taken into a poultry house.
- d) Animals, other than *poultry* of the appropriate (resident) species and age, should not be permitted access to *poultry* houses. No animals should have access to other buildings, such as (e.g. 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 (e.g. 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.

Annex XIV (contd)

lk) To minimise stress *poultry* should be transported in well ventilated *containers* and should not be over crowded. Exposure to extreme temperatures should be avoided.

ll) *Containers* should be cleaned and disinfected between each use, or disposed of in a safe manner.

lm) 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.

ln) 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 (e.g.) household waste, litter storage areas, other animals, stagnant water and water of unknown quality). The nesting area should be inside the *poultry* house.

lo) 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 *Terrestrial Code* 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.

Annex XIV (contd)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*.

EU comment

In order to avoid antimicrobial resistance at the level of the hatchery, a new point g) should be added, which could be drafted in a similar way as point o) of paragraph 2.

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. A veterinarian should be consulted immediately.~~
- ~~3.~~ When *infection* has been confirmed, epidemiological investigations should be carried out to determine the origin and route of transmission of the infectious agent.
- ~~4.~~ *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.
- ~~5.~~ 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*.

56. 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 (e.g. 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 13.2.

RABBIT HAEMORRHAGIC DISEASE

EU position**The EU supports the adoption of this modified chapter.**

Article 13.2.1.

General provisions

For the purposes of the *Terrestrial Code*, the *infective period* for rabbit haemorrhagic disease (RHD) shall be 60 days.

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

Article 13.2.2.

RHD free country

A country may be considered free from RHD when it has been shown that the *disease* has not been present for at least one year, that no vaccination has been carried out in the previous 12 months, and that virological or serological surveys in both domestic and wild rabbits have confirmed the absence of the *disease*.

This period may be reduced to six months after the last *case* has been eliminated and *disinfection* procedures completed in countries adopting a *stamping-out policy*, and where the serological survey confirmed that the *disease* had not occurred in the wild rabbits.

Article 13.2.3.

RHD free establishment

An *establishment* may be considered free from RHD when it has been shown, by serological testing, that the *disease* has not been present for at least one year, and that no vaccination has been carried out in the previous 12 months. Such *establishments* should be regularly inspected by the *Veterinary Authority*.

A previously infected *establishment* may be considered free when six months have elapsed after the last *case* has been eliminated, and after:

1. a *stamping-out policy* has been adopted and carcasses have been disposed of by burning;
2. the rabbitry has been thoroughly disinfected and kept empty for at least six weeks;
3. the rabbitry is properly fenced to prevent the straying of wild lagomorphs into the rabbitry.

Annex XV (contd)

Article 13.2.4.

Trade in commodities

Veterinary Authorities of RHD free countries may prohibit importation or transit through their territory, from countries considered infected with RHD, of live rabbits, semen, *meat* and non-treated pelts.

Article 13.2.5.

Recommendations for importation from RHD free countriesFor domestic rabbits destined for breeding

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

1. showed no clinical sign of RHD on the day of shipment;
2. were kept in a RHD free country since birth or for at least the past 60 days.

Article 13.2.6.

Recommendations for importation from RHD free countriesFor day-old rabbits destined for breeding

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

1. showed no clinical sign of RHD on the day of shipment;
2. were born from female rabbits which had been kept in a country free from RHD for at least the past 60 days.

Article 13.2.7.

Recommendations for importation from countries considered infected with RHDFor domestic rabbits destined for breeding or pharmaceutical or surgical or agricultural or industrial use

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

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

AND

2. were kept in a RHD free *establishment* where no clinical *case* of RHD was found when inspected by an *Official Veterinarian* immediately prior to shipment;

OR

3. were kept in an *establishment* where no *case* of RHD was reported during the 60 days prior to shipment and no clinical *case* of RHD was found when inspected by an *Official Veterinarian* immediately prior to shipment; and

Annex XV (contd)

4. were kept in an *establishment* where no *animal* has been vaccinated against RHD; and
5. were kept in an *establishment* where breeding rabbits (at least 10 percent of the *animals*) were subjected to the serological test for RHD with negative results during the 60 days prior to shipment; and
6. have not been vaccinated against RHD; or
7. were vaccinated against RHD immediately before shipment (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate).

Article 13.2.8.

Recommendations for importation from countries considered infected with RHDFor day-old rabbits destined for breeding

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

1. were kept in a RHD free *establishment* where no clinical *case* of RHD was found when inspected by an *Official Veterinarian* immediately prior to shipment;

OR

2. were kept in an *establishment* where no *case* of RHD was reported during the 30 days prior to shipment and no clinical *case* of RHD was found when inspected by an *Official Veterinarian* immediately before shipment; and
3. have not been vaccinated against RHD; and
4. were born from female rabbits which were subjected to the serological test for RHD with negative results during the 60 days prior to shipment.

Article 13.2.9.

Recommendations for importation from countries considered infected with RHDFor domestic rabbits destined for immediate slaughter

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

1. showed no clinical sign of RHD on the day of shipment;
2. were kept in an *establishment* where no *case* of RHD was reported during the 60 days prior to shipment.

Article 13.2.10.

Recommendations for importation from countries considered infected with RHDFor semen

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

Annex XV (contd)

1. showed no clinical sign of RHD on the day of collection of the semen;
2. were subjected to the serological test for RHD with negative results during the 30 days prior to collection.

Article 13.2.11.

Recommendations for importation from countries considered infected with RHDFor domestic rabbit meat

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

1. were kept in an *establishment* where no *case* of RHD was reported during the 60 days prior to transport to the approved *abattoir*;
2. were subjected to ante-mortem inspections for RHD with favourable results;
3. showed no lesions of RHD at post-mortem inspections.

Article 13.2.12.

Recommendations for importation from RHD free countriesFor non-treated pelts

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the pelts come from rabbits which had been kept in a country free from RHD for at least 60 days before *slaughter*.

Article 13.2.13.

Recommendations for importation from countries considered infected with RHDFor pelts

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the pelts were subjected to a drying treatment for at least one month and a formalin-based treatment by spraying at a three percent concentration, or by fumigation carried out ~~in conformity with one of the methods described in Chapter 6.4.~~, not more than seven days prior to shipment.

 — Text deleted

CHAPTER 6.7.

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

EU position

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

Moreover, the EU reiterates its former comment: there is not enough emphasis on animal pathogens in some of the sections. The guidance seems to be focussed entirely on monitoring of resistance of potential food borne pathogens. No guidance with relevance for pathogens of animal health concern is given on sample sources, and in particular not for the type of samples. It is important that the animal health aspect (and thus animal pathogens, including non-enteric ones) is also included in this OIE guidance.

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 (e.g. avian, bovine, caprine, equine, ovine, porcine) 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.

4. Surveillance and monitoring of antimicrobial resistance is necessary to:

- 1.a) follow trends in assess and determine the trends and sources of antimicrobial resistance trends in bacteria;
- 2.b) detect the emergence of new antimicrobial resistance mechanisms;
- 3.e) provide the data necessary for conducting risk analyses ~~with as~~ relevant ~~to for~~ animal ~~human~~ and human ~~animal~~ health;
- 4.d) provide a basis for policy recommendations for animal and human ~~public~~ health;

- 5.e) provide information on for for evaluating antimicrobial prescribing practices and, useful for development of prudent use recommendations.

EU comment

There should be a new point 6: "assess and determine effects of actions to combat antimicrobial resistance". Indeed, this point is important and is not covered in the points above.

2. National antimicrobial resistance monitoring and surveillance programmes may include the following components:
 - a) ~~scientifically based surveys (including statistically based programmes);~~
 - b) ~~routine sampling and testing of animals on the farm, at market or at slaughter;~~
 - c) ~~an organised sentinel programme, sampling animals, herds, flocks, and vectors;~~
 - d) ~~analysis of veterinary practice and diagnostic laboratory records.~~
3. ~~Countries should conduct active surveillance and monitoring. Passive surveillance and monitoring may offer additional information.~~
4. ~~Targeted surveillance is conducted through an active sampling scheme designed to meet programme objectives. Passive surveillance is conducted when samples are submitted to a laboratory for testing from sources outside the programme.~~

Article 6.7.3.

The development of antimicrobial resistance surveillance and monitoring programmes

1. General aspects

Surveillance of antimicrobial resistance at ~~regular or targeted~~ intervals or ongoing monitoring of the prevalence of resistance in prevalence changes of resistant bacteria from of animals, food, environmental and humans origin, constitutes a critical part of a animal health and food safety strategies aimed at limiting the spread of antimicrobial resistance and optimising the choice of antimicrobial agents used in therapy.

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 scientifically based surveys (including statistically based programmes);
- b) routine 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.

EU comment

In order to be consistent with the second paragraph above and other parts of this chapter, as well as with the Codex Alimentarius recommendations, there should be a new point e): "sampling and testing of food products of animal origin."

2. Sampling strategies

a) General

i) Sampling should be conducted on a statistical basis. The sampling strategy should ~~ensure~~ assure:

- the sample ~~is~~ representativeness of the population of interest;
- the robustness of the sampling method.

ii) The following criteria are to be considered:

sample size;

- sample source (~~e.g. such as~~ food producing animal, food, animal feed);
- animal species;
- category of *animal* within species (~~e.g. such as~~ age group, production type);
- stratification within category;
- health status of the *animals* (~~e.g. such as~~ healthy, diseased);
- ~~random~~ sample selection (~~e.g. such as~~ targeted, systematic random);
- type of sample specimens (e.g. faecal, carcass, ~~processed~~ food product).

sample size;

b)3) Sample size

The sample size should be: i) large enough to allow detection of existing and emerging antimicrobial resistance resistance phenotypes;

ii) not excessively large to avoid waste of resources.

Samples size estimates for prevalence of antimicrobial resistance in a large population is provided
Details are provided in Table 1 below. Sampling ~~fall~~ follow standard operating procedures.

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

Expected prevalence	90% Level of confidence			95% Level of confidence		
	90% Desired precision			95% 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
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Calculations based on v6.04b to c Upgrade, October 1997, Centers for Disease Control (public domain software available at <http://www.cdc.gov/epo/epi/epiinfo.htm>) Epi-Info version 3.5.1, November 2010, Centers for Disease Control and Prevention (public domain software available at <http://www.cdc.gov/>). Further information on sample size calculation can also be found in Annex 1 of the EFSA Journal (2007), 96, 1-46, "Report including a proposal for a harmonized monitoring scheme of antimicrobial resistance in *Salmonella* in fowl (*Gallus gallus*), turkeys, and pigs and *Campylobacter jejuni* and *C. coli* in broilers."

34. 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 and decide, after risk analysis, the relative importance of antimicrobial resistance and its impact on animal and human health.

a) Animal feed

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

ba) Food producing animals

Each OIE Member should examine its livestock production systems and decide, after risk analysis, the relative importance of antimicrobial resistance and its impact on animal and human health.

Categories of food producing animals livestock that should be considered for sampling include cattle and calves, slaughter pigs, broiler chickens, layer hens and/or other poultry and farmed fish considered for sampling should be relevant to the country's production system livestock and include.

bc) Food and animal feed

Members should consider including relevant food products originating from food producing animals in surveillance and monitoring programmes as foodborne transmission Contaminated food is commonly considered to be an important the principal route for the transfer of antimicrobial resistance from animals to humans. Plants and vegetables of different types may be exposed to manure or sewage from livestock and may thereby become contaminated with resistant bacteria of animal origin. Animal feed, including imported feed, may also be considered in surveillance and monitoring programmes.

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

Expected prevalence	Level of confidence					
	90% Desired precision			95% 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

Calculations based on Epi-Info v6.04b to c Upgrade, October 1997, Centers for Disease Control (public domain software available at <http://www.cdc.gov/epo/epi/epiinfo.htm>)

45. Type of Sample specimens 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.

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) all from livestock, and whole caeca should be collected from poultry. In cattle and pigs, a faecal sample size at least of 5 g provides a sufficient sample for isolation of the bacteria of concern.

Sampling of the carcasses at the *abattoir* provides information on *slaughter* practices, *slaughter* hygiene and the level of microbiological faecal contamination and cross-contamination of meat during the slaughter process. Further sampling of the product at retail sales level from the retail chain may provides additional information on the overall microbiological contamination from slaughter to the consumer. prevalence changes before the food reaches the consumer.

Existing food processing microbiological monitoring, and 'hazard analysis and critical control points' (HACCP) 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 of monitoring

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

		originating from animal feed, exposure data for animals	
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56. 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 human and human animal health;
- ii) guide *veterinarians* in their prescribing decisions.

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, cattle, pigs, broilers and other poultry, and animal derived food products. For the purpose of consistency and harmonisation, samples should be preferably taken at the abattoir. facilitating sampling and reducing the concurrent costs, samples should preferably be taken at the abattoir.

Surveillance and monitoring programmes may also ~~use~~ 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 ~~accepted~~ procedures.

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

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.

Validated antimicrobial susceptibility testing methods should be used.

- ii) *Campylobacter*

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

Validated antimicrobial susceptibility testing methods should be used.

Agar or broth micro-dilution methods are recommended for *Campylobacter* susceptibility testing. Internal and external quality control programmes should be strictly adhered to.

Validated methods with appropriate reference strains are expected to become available in the near future.

iii) Other emerging bacterial pathogens Enterohaemorrhagic *Escherichia coli*

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.

Enterohaemorrhagic *Escherichia coli* (EHEC), such as the serotype O157, which is pathogenic to humans but not to animals, may be included in resistance surveillance and monitoring programmes.

Validated antimicrobial susceptibility testing methods should be used.

c) Commensal bacteria

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

These bacteria are commonly used in surveillance and monitoring programmes as indicators, providing information on the potential reservoir considered to constitute a reservoir of antimicrobial resistance genes, which may be transferred to pathogenic bacteria, causing disease in animals or humans. It is considered that these bacteria should be isolated from healthy animals, preferably at the abattoir, and be monitored for antimicrobial resistance.

Validated antimicrobial susceptibility testing methods should be used.

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

Source	Sample type	Outcome	Additional information required/additional stratification
Herd of origin		Prevalence of resistance in bacteria originating from animal populations (of different production types) Relationship resistance – antibiotic use	Per age categories, production types, etc. Antibiotic use over time
Abattoir	Faecal	Prevalence of resistance in bacterial populations originating from animals at slaughter age	
	Intestine	As above	
	Carcass	Hygiene, contamination during slaughter	
Processing, packing	Meat products	Hygiene, contamination during processing and handling	
Retail	Meat products	Prevalence of resistance in bacteria originating from food, exposure data for consumers	
	Vegetables	Prevalence of resistance in bacteria	

		originating from vegetables, exposure data for consumers	
Various origin	Animal feed	Prevalence of resistance in bacteria originating from animal feed, exposure data for animals	

67. 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.

78. Antimicrobials to be used in susceptibility testing

Clinically important antimicrobial agents ~~or~~ classes used in human and veterinary medicine should be included in antimicrobial resistance surveillance programmes monitored. Member Countries should refer to Chapter 1.1.6. of the Terrestrial Manual and 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.

89. Type of data to be recorded and stored

Data on antimicrobial susceptibility data should be reported quantitatively (minimum inhibitory concentrations [MICs] or inhibition zone diameters), rather than qualitatively.

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.

949. Recording, storage and interpretation of data results

- 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 of the data 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~~ shall be recorded quantitatively:
 - i) as distributions of minimum inhibitory concentrations (MICs) in milligrams per litre;
 - ii) or inhibition zone diameters in millimetres.
- d) The information to be recorded should include, where possible, at least the following aspects:
 - i) sampling programme;
 - ii) sampling date;
 - iii) animal species ~~or~~ livestock category 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) age of ~~A~~ 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) serovar type ~~/~~ or serovar,
 - vi) phage-type,
 - vii) antimicrobial susceptibility result ~~/~~ or resistance phenotype,
 - viii) molecular genotype.
- f) The proportion of isolates regarded as resistant should be reported, including the defined interpretive criteria breakpoints used.
- g) In the clinical setting, breakpoints are used to categorise bacterial strains as susceptible, intermediate susceptible or resistant. These clinical breakpoints, often referred to as clinical or pharmacological breakpoints, may be ~~are~~ elaborated on a national basis and may vary between Members.
- h) The system of reference used should be recorded. 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 if available, data should be collected at the individual isolate level, allowing antimicrobial resistance patterns to be recorded ~~the phenotype of the isolates (resistance pattern) should be recorded.~~

110. 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 at a central location ~~location~~ within the country;
 - iii) produce an annual report on the antimicrobial resistance situation ~~of~~ in the country.

Annex XVI (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.

Table 3. Examples of animal bacterial pathogens that may be included in resistance surveillance and monitoring

Target animals	Respiratory pathogens	Enteric pathogens	Udder pathogens	Other pathogens
Cattle	<i>Pasteurella</i> spp.	<i>Escherichia coli</i>	<i>Staphylococcus aureus</i>	
	<i>Haemophilus somnus</i>	<i>Salmonella</i> spp.	<i>Streptococcus</i> spp.	
Pigs	<i>Actinobacillus pleuropneumoniae</i>	<i>Escherichia coli</i>		<i>Streptococcus suis</i>
		<i>Brachyspira</i> spp.		
		<i>Salmonella</i> spp.		
Poultry				<i>Escherichia coli</i>
Fish				<i>Vibrio</i> spp.
				<i>Aeromonas</i> spp.

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CHAPTER 6.8.

**MONITORING OF THE
QUANTITIES AND USAGE PATTERNS OF
ANTIMICROBIALS AGENTS USED IN
FOOD PRODUCING ANIMALS ANIMAL HUSBANDRY**

EU position

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

In order to better harmonise the Terrestrial and Aquatic Codes and to make economies of scale, the EU encourages the OIE to have a single *ad hoc* Group dealing with both the Terrestrial and Aquatic Codes on this matter.

Article 6.8.1.

Purpose

The purpose of these recommendations is to describe an approach to the monitoring of the quantities of antimicrobials agents used in food producing animals animal husbandry.

~~These recommendations are intended for use by OIE Members to collect objective and quantitative information to evaluate usage patterns by animal species, antimicrobial class, potency and type of use~~

In order to evaluate antimicrobial exposure in food producing animals, quantitative information should be collected to monitor usage patterns by animal species, antimicrobial agents ~~or~~ class, type of use (therapeutic or non-therapeutic) and route of administration.

Article 6.8.2.

Objectives

The information provided in these recommendations is essential for antimicrobial resistance risk analyses and planning purposes and should be read in conjunction with Terrestrial Code Chapters 6.7. and 6.10. This information, is necessary can be helpful in for interpreting antimicrobial resistance surveillance data and can assist in the ability to responding to problems of antimicrobial resistance in a precise and targeted way. The continued collection of this basic information will also help to give an indication of trends in the use of antimicrobial agents in animals over time and potential associations with antimicrobial resistance in animals. This information may also assist in risk management to ~~in~~ evaluating the effectiveness of efforts to ensure responsible and prudent use and mitigation strategies (for example, by identifying changes in veterinary prescribing practices for veterinarians) and to indicate where change alteration of antimicrobial usage prescribing practices might be appropriate. The publication of some or all of these data may be helpful is important to ensure transparency and to allow all interested parties to assess trends, to perform risk assessments and for risk communication purposes. ~~; or if changes in prescription practice have altered the pattern of antimicrobial use.~~

~~The continued collection of this basic information will also help give an indication of trends in the use of animal antimicrobials over time and the role of these trends in the development of antimicrobial resistance in animals.~~

~~For all OIE Members, the minimum basic information collected should be the annual weight in kilograms of the active ingredient of the antimicrobial(s) used in food animal production. In addition, the type of use~~

(therapeutic or growth promotion) and route of administration (parenteral or oral administration) should be recorded.

Members may wish to consider, for reasons of cost and administrative efficiency, collecting medical, food *animal*, agricultural and other antimicrobial use data in a single programme. A consolidated programme would also facilitate comparisons of animal use with human use data for relative *risk analysis* and help to promote optimal usage of antimicrobials.

Article 6.8.3.

Development and standardisation of antimicrobial monitoring systems

Systems to monitor antimicrobial usage consist of the following elements:

1. Sources of antimicrobial data

a) Basic sources

Sources of data will vary from country to country. Such sources may include customs, import and export data, manufacturing and ~~manufacturing~~ sales data.

b) Direct sources

Data from ~~animal~~ veterinary medicinal product drug registration authorities, wholesalers, retailers, pharmacists, veterinarians, feed stores, feed mills and ~~organised pharmaceutical~~ industry associations ~~in these countries can~~ might be efficient and practical sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by pharmaceutical manufacturers to the regulatory authority one of the requirements of antimicrobial registration.

c) End-use sources (veterinarians and food animal producers)

This may be appropriate when basic or direct sources cannot be used for the routine collection of ~~this~~ the information ~~and or~~ when more accurate and locally specific information is required (such as off label use).

Periodic collection of this type of information may be sufficient.

It may be important when developing ~~writing~~ recommendations on antimicrobial resistance usage to take into account factors such as seasonality and disease conditions, species and age affected, agricultural systems and animal movements (e.g. extensive range conditions and feedlots), dose rate, duration and length of treatment with antimicrobials.

Collection, storage and processing of data from end-use sources should be carefully designed, well managed and are likely to be inefficient and expensive processes unless carefully designed and well managed, but should have the capability to produce advantage of producing accurate and targeted information.

d) Other sources

Non-conventional sources including internet sales data related to antimicrobial agents could be collected where available.

Members may wish to consider, for reasons of cost and administrative efficiency, collecting medical, food producing animal, agricultural and other antimicrobial use data in a single programme. A consolidated programme would also facilitate comparisons of animal use with human use data for risk analysis purposes and help to promote optimal usage of antimicrobial agents.

2. Types and reporting formats of antimicrobial usage data Categories of data

a) Type of Requirements for antimicrobial use data on antimicrobial use

The ~~minimal~~ data collected at minimum should be the ~~annual~~ weight in kilograms of the active ingredient of the antimicrobial(s) used in food producing animals production per year. This should be related to the scale of production (see point 3 below). It is possible to estimate total usage by collecting sales data, prescribing data, manufacturing data, export/import import and export data or any combination of these.

The total number of food producing animals by species, type of production and their weight in kilograms for food production per year (as relevant to the country of production) is essential basic information.

Information on ~~dose regimes~~ dosage regimens (dose, dosing interval and duration of the treatment) and route duration of administration are elements to include when estimating antimicrobial usage in food producing animals.

b) Reporting formats of antimicrobial use data

The antimicrobial agents~~;~~ classes~~;~~ or sub-classes to be included in data reporting should be based on current known mechanisms of antimicrobial activity and antimicrobial resistance data.

Nomenclature of antimicrobial agents should comply with international standards where available.

For active ingredients present in the form of compounds or derivatives, the mass of active entity of the molecule should be recorded. For ~~antibiotics~~ antimicrobial agents expressed in International Units, the calculation required factor used to convert these units to mass of active entity should be stated.

The reporting of antimicrobial use data may be further organised by species, by route of administration (specifically in-feed, in-water, injectable, oral, intramammary, intra-uterine and topical) and by type of use (therapeutic~~;~~ or non-therapeutic).

Regarding data coming from end-use sources, further breakdown of data for analysis of antimicrobial use at the regional, local, *herd* and individual veterinarian~~;~~ or veterinary practice levels may be possible.

If a Member has the infrastructure for capturing basic animal antimicrobial use data for a specific antimicrobial, then additional information can be considered to cascade from this in a series of subdivisions or levels of detail. Such a cascade of levels should include the following:

- i) ~~The absolute amount in kilograms of active antimicrobial used per antimicrobial family per year, or for a specific antimicrobial chemical entity when this information is required.~~
- ii) ~~Therapeutic and growth promotion use in kilograms of the specific active antimicrobial.~~
- iii) ~~Subdivision of antimicrobial use into therapeutic and growth promotion use by animal species.~~
- iv) ~~Subdivision of the data into the route of administration, specifically in-feed, in-water, injectable, oral, intramammary, intra-uterine and topical.~~

- v) Further subdivision of these figures by season and region by a Member may be useful. *(Note: This may be especially management conditions, or where animals are moved from one locality to another during production.)*
- vi) Further breakdown of data for analysis of antimicrobial use at the regional, local, ~~herd~~ and individual veterinarian levels may be possible, using veterinary practice computer management software as part of specific targeted surveys or audits. Analysis of this information with the local or regional context could be useful for individual practitioners and practices where specific antimicrobial resistance has been identified and feedback is required.

b) ~~Classes of antimicrobials~~

~~Nomenclature of antimicrobials should comply with international standards where available.~~

~~Decisions need to be made on what classes of antimicrobials should be considered and what members of various antimicrobial classes should be included in the data collection programme. These decisions should be based on currently known mechanisms of antimicrobial activity and resistance of the particular antimicrobial and its relative potency.~~

e) ~~Species and production systems~~

~~Countries should keep a register of all animal use of antimicrobials for individual food animal species (cattle, sheep, goats, pigs, poultry, horses and fish) and for specific diseases. This will help to identify possible nonauthorised usage.~~

3. ~~Other important information~~

~~Breakdown of farm livestock into species and production categories, including total live weights, would be most useful in any *risk analysis* or for comparison of animal antimicrobial use with human medical use within and between countries. For example, the total number of food *animals* by category and their weight in kilograms for food production per year (meat, dairy and draught cattle, and meat, fibre, poultry and dairy sheep) in the country would be essential basic information.~~

Article 6.8.4.

Interpretation

According to the OIE risk assessment guidelines (refer to Chapter 6.10.), factors such as the number ~~or~~ percentage of animals treated, treatment regimes, type of use and route of administration are key elements to consider.

When comparing antimicrobial use data over time, changes in the size and composition of animal populations should also be taken into account.

The interpretation and communication of results should take into account factors such as seasonality and disease conditions, animal species and age affected, agricultural systems (e.g. extensive range conditions and feedlots), animal movements, ~~dose regimes and dosage regimens and duration of treatment with antimicrobial agents.~~

— Text deleted

CHAPTER 6.11.

ZOOSES TRANSMISSIBLE
FROM NON-HUMAN PRIMATES

Article 6.11.1.

EU comments

The EU can support the adoption of this modified chapter on the condition that its comment as to CITES inserted in the text below is taken into account.

Further comments are inserted in the text below as to a reference to Article 7.8.7 on use of purpose bred non-human primates and the entries for "Tuberculosis" in the tables.

Introduction

There are about 180-376 different species of non-human primates belonging to 32 suborders which are split into 12-15 families. The tree shrew family (previously considered as belonging to the primates) has not been included in these recommendations.

All wild 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.

EU comment

The EU suggests amending the paragraph above as follows:

"All wild 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."

Justification

Technical correction to be in line with the text of CITES which covers all non-human primates (wild and those bred in captivity) and concerns trade, not transportation.

Most imported non-human primates are destined for research, educational or breeding purposes. Before non-human primates are used for any purpose, all alternatives to their use should be explored.

EU comment

In the paragraph above, the EU would like to add the following sentence:

"With regard to non-human primates used in research and education, Article 7.8.7. is applicable."

Justification

As already stated a number of these animals are used in research and education and it is important to note that additional guidelines in Chapter 7.8 of the Code apply. This is in particular relevant for non-human primates, which should not be wild caught.

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 risk 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 risk 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 diseases 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* (under study).

Article 6.11.2.

General recommendations

Veterinary Authorities of *exporting countries* should issue *international veterinary certificates* only upon presentation of valid CITES documentation.

Veterinary Authorities should make sure that the animals are individually identified by approved methods that assure traceability and to avoid transmission of *disease* (see Chapter 4.15.).

For reasons of public health, animal welfare and pathogen introduction to wild populations, *Veterinary Authorities* of *importing countries* should not authorise the import of non-human primates for the purpose of being kept as pets.

In the case of a non-human primate being imported directly from a country within the natural range of the animals species concerned, and where only limited diagnostic testing is available, health guarantees can be given, *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> <u>complex</u> <u>hominis</u> and <i>M. bovis</i>)	Marmosets and tamarins	Two tests at an interval of 2 to 4 weeks	Skin test or serology. <u>Of the skin tests, the Mantoux test is the most reliable of all and has the advantage over others in that the size of the reaction to the test is related to the severity of infection.</u> 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 and ELISA may eliminate confusion. <u>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 such as Primagam®, and PCR of gastric or bronchial lavage, faeces or tissues may eliminate confusion.</u>
	Prosimians, New World monkeys, Old World monkeys, gibbons and great apes	At least three tests at intervals of 2 to 4 weeks	
Other bacterial pathogens (<i>Salmonella</i> , <i>Shigella</i> , <i>Yersinia</i> and others as appropriate)	All species	Daily test for 3 days <u>within the first 5 days</u> 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

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

"Tuberculosis (*Mycobacterium tuberculosis* complex hominis and *M. bovis*)"

Justification

The whole *Mycobacterium 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) as they all are possible causative agents of tuberculosis and may be harbored by non-human primates.

In addition, Veterinary Authorities of importing countries should recognise the public health importance of

other zoonoses listed in the table below as well such 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 if this is correctly implemented during a 12-week period. For some viral zoonoses, e.g. Herpes B, current diagnostic testing is not reliable, and for others, e.g. herpes viruses or retroviruses, which can be latent and relatively ubiquitous, producing life-long infections in some species, the diagnosis and exclusion of such infected animals may not be possible for the purposes of importation. Therefore, 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.

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;
- Annex XVIII (contd)
- c) have been kept in buildings and enclosures in which no case of tuberculosis has occurred during the last 2 years prior to shipment;
 2. a description of the health monitoring programme implemented by the establishment of origin;
 3. the placement of the animals in a *quarantine station* meeting the standards set in Chapter 5.9. for at least 30 days; and during this period:
 - a) all animals should be monitored daily for signs of illness and, if necessary, be subjected to a clinical examination;
 - b) all animals dying for any reason should be subjected to complete post-mortem examination at a laboratory approved for this purpose;
 - c) animals should be subjected to the following diagnostic tests and treatments in accordance with Chapter 4.15.:

Disease/agent	Animal groups	Schedule	Methods

Bacterial pathogens (<i>Salmonella</i> , <i>Shigella</i> , <i>Yersinia</i> and others as appropriate)	All species	Daily test for 3 days within the first 5 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 diseases** 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*;

Annex XVIII (contd)

- 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. <u>In-vitro gamma interferon assay or polymerase chain reaction (PCR) assay.</u> (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 <u>within the first 5 days</u> 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)"

Justification

The whole *Mycobacterium 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) as they all are possible causative agents of tuberculosis and may be harbored by non-human primates.

Veterinary Authorities of importing countries may should 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:

Annex XVIII (contd)

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 **lifetime** 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

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

EU position

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

Article 7.1.1.

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, appropriate 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 science 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.

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 promote always take into account the health and welfare of animals. Breeds of animals should be introduced only into environments to which they are genetically suited.
2. The physical environment, including the substrate (walking surface, resting surface, etc.), should be suited to the species so as not to cause minimise risk of injury or and transmit transmission of diseases or parasites to animals.
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.
4. Social grouping of animals should be managed to allow positive social behaviour and not cause minimise injury, distress or and chronic fear.
5. Air quality, temperature and humidity in confined spaces should support good animal health and not be aversive to animals. The temperature and humidity of the environment should be within the animals' ability to adapt. Where extreme conditions occur, animals should not be prevented from using their natural methods of thermo-regulation.
6. Animals should have access to sufficient food feed and water, suited to the animals' age and needs, to maintain normal health and vigour productivity and to prevent serious or prolonged hunger, thirst, malnutrition or dehydration.
7. Diseases and parasites should be prevented and controlled as much as possible through good management practices. Animals with serious health problems should be isolated and treated promptly or killed humanely if treatment is not feasible or recovery is unlikely.

Annex XIX (contd)

8. Where painful procedures cannot be avoided, the resulting pain should be managed ~~as much as~~ available to the extent that available methods and economic constraints allow.
9. The handling of *animals* should foster a positive ~~human-animal~~ relationship between humans and ~~animals~~ and should not cause injury, panic, lasting fear or avoidable stress.
10. Owners and handlers should have sufficient skill and knowledge to ensure that *animals* are treated in accordance with these principles.

— Text deleted

DRAFT CHAPTER 7.X.

ANIMAL WELFARE AND BEEF CATTLE PRODUCTION SYSTEMS

EU position

The EU thanks the OIE for taking a majority of its comments into account and can support the adoption of this new chapter. However, the EU asks the OIE to consider a few amendments to the text as indicated below.

Article 7.X.1.

Definitions

~~The *ad hoc* Group discussed the application of the OIE recommendations and decided that these should be designed with application to commercial beef production. Beef cattle production systems are defined as all commercial cattle production systems where the purpose of the operation includes some or all of the breeding, rearing and finishing of cattle intended for beef consumption.~~

Article 7.X.2.

Scope

~~The first priority is to~~ This chapter addresses the **welfare on farm** aspects of the beef cattle production systems, from birth through to finishing. **The areas of emphasis are cows with calves cow-calf, rearing, stockers or store cattle and finishing beef production.** This scope does not include veal production.

Article 7.X.3.

Commercial beef cattle production systems

Commercial beef cattle production systems include:

1. Intensive (stocker and finishing)

~~These are systems where~~ Would include cattle are in that are place on confinement and are fully dependent on humans to provide for basic animal needs such as food, ~~Animals are depending on the daily animal husbandry for provision of feed, shelter and water on a daily basis.~~

2. Extensive (all areas)

~~Would include from a wide range grazing habitat.~~ These are systems where **animals cattle** have the freedom to roam outdoors, and where the **animals cattle** have some autonomy over diet selection (through grazing), water consumption and access to shelter.

3. Semi Intensive (mixed)

~~Would include a combination of intensive and extensive systems.~~ These are systems where **animals 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 animals cattle.

Article 7.X.4.

Criteria or measurables for the welfare of beef cattle

The following outcome (~~animal~~) 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 anorexia, 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, such as including disease, lameness, post-procedural complication and injury rates, above recognised thresholds can 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, could may be direct or indirect indicators of the animal welfare situation 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 can be reported daily, monthly, annually or with reference to key husbandry activities within the production cycle.

EU comment

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

"Mortality rates should be recorded on a regular basis and may can be reported daily, monthly, annually or with reference to key husbandry activities within the production cycle. "

Justification

It is important to record mortality rates regularly to be able to identify possible developments with regard to the health and welfare of the animals. Without records, reporting will not be possible. Reporting is an additional step that may follow due to circumstances arising or be required by the competent authority.

4. Changes in weight gain and body condition score

In growing ~~animals~~ animals, weight gain ~~could~~ ~~may~~ be an indicator of animal health and *animal welfare*. Poor body condition score and significant weight loss ~~could~~ ~~may~~ be an indicator of compromised welfare ~~in mature cattle~~.

5. ~~reproductive rates~~ Reproductive efficiency

Reproductive efficiency can be an indicator of animal health and *animal welfare* ~~situation 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 ~~can~~ ~~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 coat that is rough or excessively soiled soiling with faeces, mud or dirt,
- ≡ dehydration,
- ≡ emaciation.
- ≡ depression.

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~~ ~~animals~~ slipping or falling,
- ≡ percentage of ~~animals~~ ~~animals~~ moved with an electric goad,
- ≡ percentage of ~~animals~~ ~~animals~~ striking fences or gates,
- ≡ percentage of ~~animals~~ ~~animals~~ injured during handling, such as broken horns, broken legs, and lacerations,
- ≡ percentage of ~~animals~~ ~~animals~~ vocalizing during restraint

8. Complications due to ~~R~~ routine procedure management ~~and rate of~~ ~~post-procedures~~ ~~complications~~

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 where complications occur at levels above expected thresholds. Indicators of such problems could include:

- ≡ post procedure infection and swelling,
 - ≡ myiasis,
 - ≡ mortality,
9. post-mortem pathology
10. survivability.

Article 7.X.5.

Recommendations

Each recommendation includes a list of relevant outcome-based measurables derived from section Article 7.X.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 ~~protect a herd from~~ maintain a herd at a particular health status and to prevent the entry or spread (or exit) of infectious agents.

~~Biosecurity programmes should be implemented, commensurate with the risk of disease~~ Biosecurity programmes 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 chapters on OIE listed diseases.

These ~~biosecurity programmes plans~~ should address the control of the major sources and pathways routes for agents for spread of disease and pathogens transmission, as follows:

- 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 is a~~ 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, prevent diseases occurring in cattle herds and also providing treatments for animals when disease occurs.~~

There should be an effective programme for the prevention and treatment of diseases and conditions consistent with the programmes established by a qualified veterinarian and/or the Veterinary Services as appropriate.

Those responsible for the care of cattle should be aware of the signs of ill-health or distress, such as reduced food feed and water intake, changes in weight gain and body condition, changes in behaviour or abnormal physical appearance.

Cattle ~~with at~~ higher risk ~~for from of disease~~ or distress will require more frequent inspection by ~~animal~~ animal handlers. If animal handlers are not able to correct the causes 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 bovine veterinarians or other qualified advisers. ~~Veterinary treatments should be prescribed by a qualified veterinarian.~~

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 ~~caring for downer non-ambulatory~~ cattle. They should also have experience in managing chronically ill or injured animals cattle. Euthanasia on ~~a~~ Non-responding cattle should be killed humanely done as soon as recovery is deemed not possible according to Chapter 7.5 of the Terrestrial Animal Health Code.

Non-ambulatory animals cattle should have access to water at all times and be provided with feed at least once daily. ~~They Non-ambulatory animals should not be transported or moved except for treatment or diagnosis. Such Non-ambulatory animals should be moved-movement should be done very carefully using acceptable methods avoiding excessive lifting such as a sled, low boy trailer or in the bucket of a loader. Animals should be gently rolled on to the conveyance or lifted with a full body support.~~

When treatment is attempted, cattle that are unable to stand up unaided and refuse to eat or drink should be humanely killed humanely according to Chapter 7.5. as soon as recovery is deemed unlikely.

Non-ambulatory animals should not be transported according to Article 7.3.7 of the Terrestrial Code.

Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, behaviour, physical appearance and changes in weight and body condition score.

2. Environment

a) Thermal environment

Although cattle can adapt to a wide range of thermal environments particularly if appropriate breeds are used for the anticipated conditions, sudden fluctuations in weather can cause heat or cold stress.

i) Heat stress

The risk of heat stress for cattle Thermal Heat Index (THI) is influenced by environmental factors including air temperature, relative humidity and wind speed, and animal factors including breed, age, fatness body condition, metabolic rate and coat colour and density. As

the THI increases the risk of hyperthermia increases. Also as cattle are fed longer and become fatter are more susceptible to heat stress.

Animal handlers should be aware of the **risk that** critical THI **heat stress** threshold for their **animals poses to cattle**. ~~When~~ **If** conditions are the THI is expected to reach this threshold, routine daily ~~processes~~ **activities that require moving cattle that include cattle movement** should cease. ~~If~~ **As** the **risk of heat stress** THI ~~moves into emergency~~ **reaches very high** levels the *animal handlers* should institute an emergency action plan that could include **provision of** shade, **improved** access to drinking water, **and cooling by the use of** sprinkling water ~~to that~~ **penetrates** the hair coat.

EU comment

The EU does not agree with the deletion of the word "improved" in connection with access to drinking water.

Justification:

This requirement relates to an extraordinary situation and it is difficult to understand why the word "improved" was deleted as regards access to drinking water. The EU asked previously that "improved" be replaced by "free", as this was considered important in a situation where there is a risk of animals suffering from heat stress. Even in ordinary situations animals are supposed to have access to water. The proposed text does not provide any extra benefit or preventive measure to avoid or minimise the risk for heat stress. Reinserting "improved" or "free" is necessary.

Outcome-based measurables: behaviour, (including panting score and respiratory rate), morbidity rate, mortality rate,

ii) Cold stress

Protection from ~~wind and rain~~ extreme weather conditions should be provided when these conditions are likely to create a serious risk to where possible, particularly for young stock outdoors for the first time the welfare of cattle animals, particularly in neonates and young cattle animals 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 **time of extreme cold weather conditions** **heavy snowfall or blizzard,** *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 **sufficient** supplementary lighting **which follow natural periodicity sufficient** for their health and welfare, to facilitate natural behaviour patterns and to allow adequate inspection of the **animals** **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 in intensive and confined production systems. It is a composite variable of affected by air constituents such as gases, dust and micro-organisms, that and is strongly influenced by how facilities are managed management, particularly in intensive systems the management of the beef producer. 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 CO₂, 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 gain.

d) ~~Acoustic environment~~ Noise

Cattle are adaptable to different levels and types of noise acoustics environments. 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. Other irritating noises should also be taken into consideration, such as dogs barking and other outdoor sounds.

Outcome-based measurables: Behaviour.

e) Nutrition

The nutrient requirements of beef cattle have been well defined. Energy, protein, amino acid, mineral and vitamin contents of the diet are major factors determining the growth, feed efficiency, reproductive efficiency, and body composition.

Animal handlers should provide cattle a level of nutrition that meets or exceeds their maintenance requirements from the previously reference materials. Cattle should be provided with access to an appropriate quantity and quality of balanced nutrition that meets their physiological needs. It should be noted that cattle in certain climates and production systems may experience short term periods of below maintenance nutrition without compromise their welfare. 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 score to drop below fall outside these an acceptable range critical thresholds. As a guide, assessing body condition score on a scale of 1 to 5, the target range for acceptable animal health and welfare should be between 2 and 4. If supplementary feed is not available, In times of severe drought, steps should be taken to avoid starvation of animals wherever possible, including supplementary feeding, slaughter, sale or relocation of the animals cattle, or humane killing.

~~In intensive production systems cattle should have access to adequate feed and water supply to meet their physiological needs.~~

~~Feedstuffs and feed ingredients should be of satisfactory quality to meet nutritional needs, and under certain circumstances (e.g., drought, frost, and flood), should be tested for the presence of substances (e.g. mycotoxins and nitrates) that can be detrimental to cattle health and welfare.~~

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 ~~sequelae~~ (acidosis, bloat, liver abscess, laminitis). Where appropriate beef producers should consult a cattle nutritionist (~~private consultant, university or feed company employee~~) 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.

The water quality and the method of supply can affect welfare. All cattle need an adequate supply and access to palatable water that ~~also~~ meets their physiological requirements and is free from contaminants ~~potentially~~ hazardous to cattle health.

Outcome-based measurables: Mortality rates, morbidity rates, behaviour, changes in weight gain and body condition scoring, reproductive efficiency rates.

- f) Flooring, bedding, resting surfaces and outdoor areas (~~litter quality~~)

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 (e.g. excessive water, / 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.

Mud depth should not consistently be deeper than the ankles of cattle in pens.

Slopes of pens should be maintained to allow water to ~~run off~~ drain away from the feed troughs bunks and not pool excessively in the pens.

If slope is not sufficient to allow for proper drainage, a mound should be constructed in each pen to allow cattle to have a dry place to lie down.

Pens should be ~~thoroughly cleaned after each production cycle as conditions warrant.~~ cleaned as conditions warrant and, at a minimum, after each production cycle.

If cattle animals are housed in on a slatted floor shed, the slat and gap widths should be appropriate to the hoof size of the cattle animals to prevent injuries.

In straw or other bedding systems, the bedding should be maintained to provide allow cattle animals 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 gain, and body condition score, and physical appearance.

g) Social environment

Management of cattle ~~in outdoor and indoor intensive production systems methods~~ should take into account the social environment of cattle as it relates to *animal welfare*, particularly in intensive systems. Problem areas include: ~~buller~~ 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.

In the case of buller animals, they should be identified and removed from the pen immediately. Beef producers should utilize management practices to reintroduce these animals. If reintroduction fails these animals will have to housed separately from the pen mates. *Animal handlers* should work to feed cattle of the same size and age in the same pens. Depending on feeding systems, health status of the animals and size of the animals beef producer will need to allow adequate feeder space and water access for the cattle.

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 (e.g. 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. Animals Cattle that are suffering from excessive agonistic activity or mounting behaviour should be removed from the group.

Where the mixing of Horned horned and non horned cattle is likely to increase the risk of injury, these classes of animals 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 gain and body condition score, morbidity and mortality rate.

h) Stocking density

High stocking densities may increase injuries and have an adverse effect on growth rate, feed efficiency, survivability, carcass quality and behaviour, such as (e.g. locomotion, resting, feeding and drinking).

EU comment

The EU asks the OIE to consider a slight rephrasing of the text so that the sentence above reads:

"High stocking densities may increase the occurrence of injuries and have an adverse effect on growth rate, feed efficiency, [...]"

Justification:**Linguistic reasons.**

~~In extensive outdoors systems stocking density should be managed to ensure an adequate feed supply for the cattle.~~

Stocking density should be managed such that crowding does not adversely impact key components of affect normal behaviour of cattle. This ~~ese~~ 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. Excessive if tongue rolling abnormal behaviour can be associated with overcrowding of confined cattle. is seen, measures should be taken such as reducing stocking density.

In extensive systems, stocking density should be matched to the available managed to ensure an adequate feed supply for the cattle or the cattle should be moved regularly or provided with supplementary feed.

Outcome-based measurables: Behaviour, morbidity rate, mortality rate, changes in weight gain and body condition score, physical appearance.

ii) Outdoor areas

Not applicable.

ij) Protection from predators

Where practical, 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 the following traits beneficial to animal health and welfare. These include Maternal ability 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 Animals observed to be having difficulty in calving should be assisted by a competent operator 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

Calves are born without any immunity. Ensuring that each calf receives sufficient colostrum (first milk) immediately after calving is one of the most important factors in ensuring their survival and health. Colostrum contains both antibodies (immunoglobulins, which protect against specific diseases and anti-infective protective agents, such as lactoferrins, which prevent bacterial growth. Receiving adequate immunity from colostrum generally depends on the volume and quality of colostrum ingested, and how soon after birth the calf receives it.

As the ability of the calf to absorb immunoglobulins starts to decline progressively after 4 to 6 hours, and ceases around 24 hours after birth, the earlier a calf is fed/suckles, the greater the level of immunoglobulin absorption.

Where possible, animal handlers should ensure that calves receive sufficient colostrum within 24 hours of birth.

EU comment

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

"Where possible, animal handlers should ensure that calves receive sufficient colostrum as soon as possible after within 24 hours of birth."

Justification

The calves need to receive colostrum shortly after birth. If one waits till 23-24 hours it is too late to benefit their welfare.

Outcome-based measurables: mortality rate, morbidity rate, changes in weight.

b)d) Weaning

For the purposes of this Chapter, ~~W~~weaning means is the term used to describe the transfer of the calf from a milk based diet (from nursing the dam or being fed with milk or milk replacer) to a fibrous diet ~~from nursing the dam or being fed with milk or milk replacer~~. 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 systems ~~has~~ developed sufficiently to enable them to maintain growth and welfare.

The practice of creep feeding is sometimes utilised prior to weaning to help the calf more easily adapt to a solid diet.

There are different weaning strategies utilised in the beef cattle production systems. These **could** 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, ~~off farm~~ as ~~research has shown that~~ calves are at risk of increased morbidity under these circumstances.

If necessary, bP 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 gain and body condition score.

e)-e) Painful husbandry procedures

~~Surgical~~ 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. Where possible, these procedures should be performed in such a way as to minimise any pain and stress to on the animal. Options to consider including the performing the procedure at as early an age as possible or where appropriate use of analgesia. Performing these procedures at as early an age as possible or using anaesthesia and/or analgesia should be considered under the recommendation or supervision of a veterinarian should be considered.

Future options for enhancing *animal welfare* in relation to these procedures include: 1) ceasing the procedure and addressing the current need for the operation through management strategies; 2) breeding animals 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*; or 4) performing the procedure in a way that minimises pain.

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, ~~remove~~ avoid the risk of unwanted pregnancies in the *herd*, and enhance production efficiency ~~by producing beef that better meets market requirements.~~

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 (knife) removal of the testes, ischaemic methods (banding or ringing), and crushing and disruption of the spermatic cord (Burdizzo operation).

Where practical, cattle should be castrated before the age of 3 months, or at the first available handling opportunity beyond this age.

EU comment

The EU asks the OIE to consider rephrasing the text to include elements concerning the choice of castration method so that the sentence above reads:

"Where practical, cattle should be castrated before the age of 3 months, or at the first available handling opportunity beyond this age, using the method available that causes least pain or suffering to the animal."

Justification

Not all of the methods listed are equally acceptable and may, in varying degrees, cause unnecessary or prolonged pain or distress. This needs to be emphasised. Additionally, such a change would be in line with the requirements in Article 7.1.4. and with the table that the OIE proposes to place on their website for guidance.

Producers should seek guidance from *veterinarians* on the availability and advisability of analgesia or anaesthesia for castration of beef cattle, particularly in older animals 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.

<u>Gastration</u>			
<u>Procedure</u>	<u>Specific method</u>	<u>Key animal welfare requirements</u> <u>Applicable</u>	<u>Comment</u>
<u>Burdizzo method</u>	<u>This procedure requires the male calf to be restrained as the Burdizzo device is placed on the scrotum above the testicles and is closed to crush and disrupt the spermatic cord. Each spermatic cord is crushed separately. This action severs the blood supply to the testicles causing them to degenerate.</u>	<u>High level of operator competency, competent operation and maintenance of equipment; restraint; accuracy.</u>	<u>This method shuts off the blood supply to the testicle and causes the testicle to be reabsorbed if properly done (bloodless and no open wound).</u> <u>The Burdizzo procedure requires certain skill to use properly and may result in only partial castration depending on competency of the operator.</u> <u>Post castration discomfort or pain from the use of the Burdizzo is comparable with other castration methods.</u> <u>Cannot visually confirm if procedure has been successful.</u> <u>A veterinarian should be consulted on how to control pain during such procedures.</u>
<u>Rubber ring method</u>	<u>Small rubber rings are used for calves less than one month of age (rubber ring castration), and for older calves heavy wall latex bands are used along with a grommet to securely fasten the mechanically tightened bands at the appropriate tension. After several weeks, the testicles and scrotum degenerate and slough from the body.</u>	<u>High level of operator competency, competent operation and maintenance of equipment; restraint; accuracy.</u>	<u>Post castration discomfort may be prolonged by this method compared with other castration methods.</u> <u>High tetanus risk</u> <u>A veterinarian should be consulted on how to control pain during such procedures.</u>

<u>Castration (contd)</u>			
<u>Procedure</u>	<u>Specific method</u>	<u>Key animal welfare requirements</u> <u>Applicable</u>	<u>Comment</u>
<u>Banding method</u>	<u>A fast, easy and effective non-surgical method of castrating large animals.</u>	<u>High level of operator competency, competent operation and maintenance of equipment; restraint; accuracy.</u>	<u>Post castration discomfort may be prolonged by this method compared with other castration methods.</u> <u>High tetanus risk.</u> <u>A veterinarian should be consulted on how to control pain during such procedures.</u>
<u>Surgical method.</u>	<u>Removal of the testicles using sharp cutting instruments and emasculators involves opening the scrotum and removing the testicles by severing them from the spermatic cords.</u>	<u>High level of operator competency, competent operation and maintenance of equipment; restraint; accuracy.</u>	<u>Risk of haemorrhage is greater after surgical castration.</u> <u>Post castration discomfort is normally not as long as it is when castrators are used.</u> <u>Potential complications associated with castration include haemorrhage, excessive swelling or oedema, infection, poor wound healing, and failure</u> <u>A veterinarian should be consulted on how to control pain during such procedures.</u>
<u>Chemical castration</u>	<u>Chemical castration includes injection of sclerosing or toxic agents (e.g. 88% lactic acid) into the testicular parenchyma to cause irreparable damage and loss of function.</u>	<u>High level of operator competency, competent operation and maintenance of equipment; restraint; accuracy.</u> <u>The procedures are bloodless but require extreme skill because chemical substances must be injected directly into the testicles.</u> <u>Chemical castration requires additional procedural time and technical skill, and almost twice the healing time compared with surgical castration.</u>	<u>Studies have reported that 25% of the chemically castrated calves had scrotal necrosis caused by the high pressure of injection and drug leakage from the testes.</u> <u>A veterinarian should be consulted on how to control pain during such procedures.</u>

ii) Dehorning (including disbudding)

Beef cattle ~~which~~ 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 ~~can remove the need for~~ dehorning.

Annex XX (contd)

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 ~~through~~ of the horn by cutting or sawing ~~at~~ 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~~ 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.

Dehorning/disbudding			
Procedure	Specific method	Key animal welfare requirements Applicable	Comment
Disbudding (thermo-cautery)	<u>Hot iron disbudding is performed by applying the hot iron device, electric or butane gas heated to over 600°C, over the horn bud destroying the growing tissue at its base. This method is performed when horn buds are evident by palpation which usually occurs at an age of 2–8 weeks.</u>	<u>High level of operator competency, competent operation and maintenance of equipment; restraint; accuracy.</u>	<u>The different methods of horn removal can be ranked on the basis of the acute stress (cortisol) and behavioural responses and the production effects.</u> <u>Methods that elicit less struggling during the procedure and lower overall distress responses are preferred.</u> <u>A veterinarian should be consulted on how to control pain during such procedures.</u>
Caustic paste	<u>Paste disbudding is caused by the chemical burn of underlying tissue. The active ingredient used for disbudding is usually sodium hydroxide or calcium hydroxide.</u> <u>These strong alkalis cause liquefactive necrosis, resulting in saponification of fats and denaturation of proteins, which allows deeper penetration of the chemical. With caustic burns, tissue damage continues to increase as long as the active chemical is in contact with the tissue.</u>	<u>High level of operator competency, competent operation, restraint; Accuracy.</u> <u>The evidence indicates that caustic paste disbudding causes distress for at least 3 h and that local anaesthesia is efficient in controlling pain for the first hour but discomfort returns after the nerve blocking subsides.</u>	<u>A veterinarian should be consulted on how to control pain during such procedures.</u> <u>Inert lying is a sign of distress in young calves after caustic paste disbudding.</u> <u>Caustic dehorning chemicals should only be used with care. They can spread into the eyes if the skin gets wet.</u>

Dehorning/disbudding			
Procedure	Specific method	Key animal welfare requirements	Comment
Dehorning methods 1. Scoop dehorning 2. Guillotine shears 3. Saw 4. Foototomy 5. Cryosurgery	Dehorning of older cattle is carried out by various methods and includes: 1. Scoop dehorning consists of two interlocking semicircular blades attached to handles that amputate the horn close to the underlying bone. Scoop dehorning which may cause either shallow or deep impact on the underlying bone and surrounding skin 2. Guillotine shears / crange device. 3. Saw – where the horn is cut close to the skull bone using a tenon saw. 4. Foototomy wire – where the horn is cut close to the skull bones by repeated sawing with a foototomy wire. 5. Cryosurgery	Applicable High level of operator competency, competent operation and maintenance of equipment; restraint; accuracy. The cortisol responses of male Friesian calves (5 to 6 mo of age) to amputation dehorning by each of the first 4 methods listed were similar, suggesting that the degree of distress and pain caused by the different methods of dehorning are similar.	There is a complete absence of literature available on other methods of amputation dehorning (foototomy wire, saw, guillotine crange) and alleviation of the associated pain. A veterinarian should be consulted on how to control pain during such procedures.
Tipping of the horn	Removal of the non sensitive tip of the horn	High level of operator competency, competent operation, restraint; accuracy.	A veterinarian should be consulted on how to control pain during such procedures.

iii) Ovariectomy (spaying) (ovariectomy)

Ovariectomy Spaying of heifers is sometimes required for international trade or 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.

Spaying			
Procedure	Specific method	Key animal welfare requirements	Comment
Spaying	Ovarian removal by flank incision	High level of operator competency, hygienic operation and maintenance of equipment; restraint; accuracy.	Produces a longer lasting inflammatory response than per vagina method Mortality rates in studies shown as comparable or slightly higher than per vagina method Administration of local anaesthetic where applied may produce less complications than epidural block for per vagina method. Applicable to different stages of pregnancy, but results in abortion if gestation is less than 4.5 months

Annex XX (contd)

<u>Spaying (contd)</u>			
<u>Procedure</u>	<u>Specific method</u>	<u>Key animal welfare requirements</u> <u>Applicable</u>	<u>Comment</u>
	<u>'Willis' dropped ovary technique (per vagina approach)</u>	<u>High level of operator competency, hygienic operation and maintenance of equipment; restraint; accuracy.</u>	<u>Produces a shorter-lasting inflammatory response than flank incision, but a comparable stress and behavioural response</u> <u>Mortality rates in studies shown as comparable or slightly lower than flank method</u> <u>Epidural administration of local anaesthetic where applied may produce a greater risk of complications than local or regional block for flank method.</u> <u>Applicable only for non-pregnant, or early pregnancy (< 4 months). Results in abortion if pregnant animal is thus spayed.</u> <u>Greater risk of leaving ovarian tissue intact if operator not fully experienced.</u>
	<u>Ovarian removal by vaginal incision</u>	<u>High level of operator competency, hygienic operation and maintenance of equipment; restraint; Accuracy.</u>	<u>Similar method to Willis technique, but requires larger vaginal incision and manual manipulation removal of the ovaries. Tissue trauma is likely to be greater.</u>

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 means 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 the Chapter 4.1. of the Terrestrial Code on General principles on identification and traceability of live animals.

Identification			
Procedure	Specific method	Key animal welfare requirements Applicable	Comment
Ear tagging	Insertion of ear tag with visible identification marks	Hygienic operation and maintenance of equipment; restraint; Moderate level of operator competency	<p>Ear tagging when performed well causes little distress additional to any effects of handling and restraint.</p> <p>Poor equipment or low operator competency can increase the risk of retention failure, requiring animals to undergo additional procedures.</p> <p>Visible ear tags make identification easier from a distance, potentially reducing the need for handling, but the increased tag size can increase the risk of it being caught on fences and other objects, leading to tearing of the ear pinna and tag loss.</p>
	Insertion of radio frequency identification device	Hygienic operation and maintenance of equipment; restraint; Moderate level of operator competency	<p>Insertion of RFID when performed well causes little distress additional to any effects of handling and restraint.</p> <p>Poor equipment or low operator competency can increase the risk of retention failure, requiring animals to undergo additional procedures.</p> <p>The risk of retention failure is lower in RFID only tags because they are smaller, but tag reading requires specialized equipment at a short distance (< 1m).</p>
Tattooing	Ear tattooing	Hygienic operation and maintenance of equipment; restraint; Moderate level of operator competency	<p>Ear tattooing when performed well is permanent and causes little distress additional to any effects of handling and restraint.</p> <p>Because the tattoo can only be read at close quarters, animals may need to be restrained for subsequent identification checks, or the tattoo may be need to be supplemented by an additional form of identification, requiring an additional procedure.</p>
Ear notching		Hygienic operation and maintenance of equipment; restraint; Moderate to high level of operator competency	<p>Ear notching results in a slightly larger area of tissue damage than tagging or tattooing and therefore can cause more discomfort or pain.</p> <p>Has the advantage of being permanent if applied correctly.</p> <p>Ear notching may be more suitable for herd identification, as the number of variations available is less than for other identification methods.</p> <p>Subsequent hair growth or ear trauma can obscure the identification notch.</p> <p>Risk of infection or parasite infestations (miasis)</p>

Annex XX (contd)

<u>Identification</u>			
<u>Specific method</u>	<u>Specific method</u>	<u>Specific method</u>	<u>Specific method</u>
<u>Branding</u>	<u>Freeze branding</u>	<u>High level of operator competency, hygienic operation and maintenance of equipment; restraint; accuracy.</u>	<u>Thermal injury and subsequent inflammatory response has the potential to cause a moderate degree of discomfort and pain, and a good result is highly dependent on operator competence.</u> <u>Freeze branding may be less effective on white or light coat coloured cattle.</u> <u>Results in a permanent brand when applied appropriately.</u> <u>Requires specialized equipment and can be expensive and more time-consuming than other methods.</u>
	<u>Hot iron branding</u>	<u>High level of operator competency, hygienic operation and maintenance of equipment; restraint; Accuracy.</u>	<u>Thermal injury and subsequent inflammatory response caused by heated iron contact has the potential to cause a significant degree of discomfort and pain.</u> <u>A good identification marking is highly dependent on operator competence.</u> <u>Leaving the brand in contact with the skin for longer than the minimum time necessary can cause thermal injury to subcutaneous structures and severe tissue trauma.</u> <u>Hot iron branding is permanent, and in some environments may currently be the only practical means of individual animal identification.</u> <u>Risk of infection or parasite infestations (miasis).</u>

Outcome-based measurables: ~~Rate of postprocedural~~ complications rate, ~~mortality~~ morbidity rate, behaviour, physical appearance, changes in weight gain and body condition score.

d) 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 animals cattle. In intensive farming systems, animals cattle should be inspected at least once a day.

Some animals animals may benefit from more frequent inspection for example: neonatal calves, cows in late gestation, newly weaned calves, and cattle experiencing environmental stress and after 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, then the services of a veterinarian should be enlisted sought.

If ~~prognosis~~ of the animal's condition suggests the prognosis is poor with little chance of recovery, humane euthanasia of the animal should be considered 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. ~~of the OIE Terrestrial Code~~.

EU comment

The EU asks the OIE to consider a reference to Article 7.1.4., as this article contains requirements pertinent to the situation.

Recommendations on the handling of cattle are also found in Chapter 7.5. ~~and Articles 7.5.1. and 7.5.2. of the OIE Terrestrial Code~~.

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 distresscollapse. 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 ~~tools~~ 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.

Electro immobilisation should not be used.

Outcome-based measurables: Handling response, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight gain and body condition score.

e)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 and/or practical experience.

Outcome-based measurables: Handling response, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight gain and body condition score.

f) h) Emergency plans

Where the failure of power, water and feed supply systems could compromise animal welfare, Bbeef producers should have contingency plans to cover the failure of these systems power,

~~water and feed supply.~~ These plans may include the provision of fail-safe alarms ~~devices~~ 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 e.g., heat stress, drought, blizzard and flooding. Humane killing procedures for sick or injured animals 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.

g) Location, construction and equipment of farms

Farms for beef cattle should be situated in an appropriate geographical location for the health, *welfare* and productivity of the animals cattle ~~while considering environmental sustainability.~~

All facilities for beef cattle should be constructed, maintained and operated to minimise the risk to the *welfare* of the animals cattle and human safety.

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~~ must be offered adequate space for comfort, ~~and socialisation and environmental management.~~ Whenever possible, beef cattle housed in intensive production systems should have access to pasture.

In intensive production systems the feeder should be sufficiently large so that animals 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 ~~clean and clear~~ water at all times.

Floors in housing facilities should be properly drained, and barns and races and chutes handling alleys should provide traction to prevent injuries to cattle animals and handlers.

Races, chutes Handling alleys and housing pens should ~~must~~ be free of from sharp edges and protrusions to prevent injury to cattle animals and handlers.

~~Design and operate~~ Alleys and gates should be designed and operated to avoid impeding cattle movement. Avoid Slippery surfaces should be avoided, especially where cattle enter a single file alley leading to a chute or where they exit the chute. 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 operating gates and catches are operated, ~~reduce~~ excessive noise should be minimised, which because it may cause distress to the cattle animals.

Adjust h Hydraulic, pneumatic or and manual restraining chutes equipment should be adjusted, as appropriate, to the appropriate size of cattle to be handled. Hydraulic or 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 and handlers.

Mechanical and electrical devices used in housing facilities ~~should~~ must be safe for cattle animals and humans.

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 ~~or~~ and drowning.

The loading of the cattle animals at the farms should be conducted accordingly to Chapters 7.2., 7.3. and 7.4. (~~Transport of animals by sea, land and air respectively~~).

Outcome-based measurables: Handling response, morbidity rate, mortality rate, behaviour, changes in weight gain and body condition score, physical appearance, lameness.

h) ~~On farm harvesting~~

~~Refer to point 3e) of Article 7.X.5.~~

h) Humane killing

For sick and injured cattle animals a prompt diagnosis should be made to determine whether the animal should be humanely killed or receive additional care.

~~Animal handlers should provide feed and water to non-ambulatory cattle at least once daily~~

~~Non-ambulatory animals should be moved very carefully and dragging non-ambulatory animals is unacceptable.~~

~~Likewise, animals should not be lifted with chains onto transportation conveyances. Acceptable methods of transporting non-ambulatory animals include a sled, low-boy trailer or in the bucket of a loader.~~

~~When treatment is attempted, cattle that are unable to sit up unaided and refuse to eat or drink should be humanely euthanized as soon as recovery is deemed not possible.~~

~~Cattle that are non-ambulatory must not be sent to a livestock market or to a processing facility.~~

~~Humane killing should occur without pain or suffering.~~

The decision to humanely kill an animal and the procedure itself should be undertaken by a competent person.

Reasons for ~~euthanasia~~ 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 ~~sit~~ 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;

Annex XX (contd)

- 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 ~~other~~ methods for the humane *killing* of beef cattle see Article 7.6.5. ~~of the~~
Terrestrial Code.

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CHAPTER 5.13.

**MODEL VETERINARY CERTIFICATE
FOR INTERNATIONAL TRADE IN
LABORATORY ANIMALS**

Article 5.13.1.

EU position

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

Introduction and scope

Transportation of laboratory animals between institutes is a specialised and important activity supporting scientific research. The use, and transportation, of laboratory animals is essential to some types of medical and veterinary research.

The majority of laboratory animals used and transported are rats, mice, and fish. Other species, including guinea pigs, **ferrets**, gerbils, hamsters, rabbits, cats, dogs, pigs, amphibians, and a few species of non-human primates are used in relatively small numbers.

This chapter applies to all *animals* except bees.

Article 5.13.2.

Notes for guidance on the use of the veterinary certificate1. General

The certificate should be completed in capital letters to ensure legibility. To confirm an option, mark the box with a cross (X). No portion of the certificate should be left blank in a manner that would allow unauthorised amendment. Non-applicable fields should be deleted with a line through the text. Information provided on the certificate should be correct at the time of issuance of the certificate.

2. Part I. Details of consignment for export

Country:	Name of the country issuing the certificate.
Box I.1.	Name and full address of the natural or legal person dispatching the consignment. It is recommended to provide contact information, such as telephone and fax numbers or e-mail address.
Box I.2.	The certificate reference number used by the Veterinary Authority of the country issuing the certificate.
Box I.3.	Name of the Veterinary Authority.

Box I.4.	Name and full address of the natural or legal person to whom the consignment is destined.
Box I.5.	Name of the country from which the consignment is being exported. <u>“ISO code” refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization.</u> It is also recommended to provide the country’s International Standards Organization code see http://www.iso.org/iso/english-country-names-and-code-elements .
Box I.6.	Name of the zone or compartment of origin, if given in part III of the certificate (in accordance with Chapter 4.3. of the <i>Terrestrial Code</i>).
Box I.7.	Name of the country of destination. <u>“ISO code” refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization.</u> It is also recommended to provide the country’s International Standards Organization code see http://www.iso.org/iso/english-country-names-and-code-elements .
Box I.8.	Name of the zone or compartment of destination, if given in part III of the certificate (in accordance with Chapter 4.3 of the <i>Terrestrial Code</i>).
Box I.9.	Name and full address of the place(s) from which the animals are being exported; and official approval or registration number when required.
Box I.10.	Name of the air, land or sea facility from which the consignment is being shipped.
Box I.11.	Date of departure and, if known, expected time of departure.
Box I.12.	Identify the means of transport if known at the time of issuance of the certificate. The flight number, airline and airport designation (for air transport). The name and address of the carrier (for road transport). <u>The name and contact details of the emergency contact person.</u>
Box I.13.	Name of border post to which the consignment is directed. It is also recommended to provide the border post’s United Nations Code for Trade and Transport Locations – see http://live.unece.org/cefact/locode/service/location.html
Box I.14.	If the species is listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), provide permit number(s).
Box I.15.	Description of animals. World Customs Organization HS Code, if known, see: www.wcoomd.org .
Box I.16.	Total number of animals.

Box I.17.	Temperature around the shipping container should generally be maintained in the range 10–28°C during shipment. For animals with different requirements, the specific temperature range should be listed here.
Box I.18.	The total number of units (e.g. boxes, cages or stalls) in which the animals in the consignment are being transported.
Box I.19.	Identification of the containers and seal numbers, if provided.
Box I.20.	<p>Details of the nature of the animals.</p> <p>Provide: species (scientific name); identification system; identification number or other relevant details; quantity and, if required, strain or stock designation, sex, and age or weight. When available, international designation conventions should be used, see for example:</p> <p>http://www.informatics.jax.org/mgihome/nomen/strains.shtml</p> <p>http://www.informatics.jax.org/mgihome/nomen/gene.shtml .</p> <p>For animals with an official international animal passport, the passport number should also be provided.</p>

3. Part II. Classification of pathogen free status

Box II.	<p><u>Conventional animals</u> are those for which the presence or absence of specific microorganisms and parasites is unknown due to the absence of testing, treatment or vaccination. This category includes wild-caught animals and domestic animals maintained under uncontrolled microbiological conditions.</p> <p><u>Specific Pathogen Free (SPF) animals</u> are free of one or more parasites or infectious microorganisms. SPF animals can be further subdivided into two categories:</p> <p>a) <u>Conditioned SPF animals</u> have undergone testing, treatment and/or vaccination to ensure the absence of one or more parasites or microbial agents. The agents are most commonly of human or agricultural significance or are species-specific infectious agents that are capable of producing significant clinical disease or research effects. Conditioned SPF animals are often not maintained in specialised housing to prevent introduction of other infectious agents and are usually shipped in unfiltered containers. Larger species such as nonhuman primates, dogs, and cats are often maintained as conditioned SPF animals.</p>
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Annex XXI (contd)

Box II. (contd)	b) <u>Barrier raised SPF animals</u> have been raised in the absence of one or more parasites or microbial agents in specialised facilities to exclude these agents as well as agents of agricultural and human significance. Their pathogen free status has been established either by testing each individual animal or by sampling representative animals from the colony. Filtered SPF shipping containers are required for transport of these animals as are special procedures and equipment for packing, unpacking, and handling them. This subcategory also includes animals that are either axenic (microbe free) or possess only a few well defined species of microorganisms. They must be produced and maintained in a sterile environment (usually isolators) without contact with human, animal, or environmental commensal infectious microorganisms.
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4. Part III. Zoosanitary information

Box III.	Complete this part in accordance with the requirements agreed between the Veterinary Authorities of the importing and exporting countries in accordance with the recommendations in the <i>Terrestrial Code</i> . Attestation of fitness for transportation subject to any conditions or special requirements stated in the certificate.
Box III.a.	Certificate reference number: see box I.2.
Official veterinarian	Name, address, official position, date of signature and official stamp of the Veterinary Services for the country of export.

— Text deleted

Article 5.13.3.

Model veterinary certificate for international trade in laboratory animals

COUNTRY:

Part I: Details of dispatched consignment	I.1. Consignor: Name:		I.2. Certificate reference number:		
	Address:		I.3. Veterinary Authority:		
	I.4. Consignee: Name:				
	Address:				
	I.5. Country of origin:		ISO code*	I.6. Zone or compartment of origin**:	
	I.7. Country of destination:		ISO code*	I.8. Zone or compartment of destination**:	
	I.9. Place of origin: Name:				
	Address:				
	I.10. Place of shipment:		I.11. Date of departure:		
	I.12. Primary means of transport:		I.13. Expected border post:		
Aeroplane <input type="checkbox"/>		Relevant details	I.14. CITES permit No(s)**:		
Road vehicle <input type="checkbox"/>					
Vessel <input type="checkbox"/>					
I.15. Description of animals:		I.16. Total number of animals:			
*HS Code if known :					
I.17. Temperature		I.18. Total number of units:			
I.19. Identification of container/seal number:					
I.20. Details of the nature of the animals and quantity of each:					
Species (Scientific name)		Identification system			
Identification number/details					
Strain/Stock (use international designation if known)*		Passport number(s) if issued *			
Age or Weight					
Sex					

* Optional

** If referenced in Part III.

Annex XXI (contd)**COUNTRY:**

Zoosanitary information	II.a. Certificate reference number:
	<p>II Pathogen Free Status</p> <p>Conventional <input type="checkbox"/></p> <p>Conditioned SPF <input type="checkbox"/></p> <p>Barrier raised SPF <input type="checkbox"/></p> <p>Other – specify <input type="checkbox"/></p> <p>III. Fitness for transportation</p> <p>The undersigned Official Veterinarian certifies that the consignment described above is fit for transport, subject to any conditions specified below, and that the animals satisfy the following zoosanitary requirements:</p> <p>Special conditions for transport: YES <input type="checkbox"/> NO <input type="checkbox"/></p> <div style="border: 1px solid black; padding: 10px; min-height: 150px;"> <p>If there are special conditions for transport, provide complete information of these conditions.</p> </div>
	<p>Name and address (in capital letters):</p> <p>Date:</p> <p>Stamp:</p>
	<p>Official position:</p> <p>Signature:</p>

CHAPTER 7.8.

USE OF ANIMALS IN RESEARCH AND
EDUCATION**EU position**

The EU wishes to thank the OIE for its efforts to introduce a new Article 7.8.10 on transportation of animals used for research and education under Chapter 7.8 and recognises that some of the EU comments were incorporated in the proposed text for adoption. However, the EU regrets that three comments of importance were not taken into account.

The EU would like to support the adoption of this modified chapter provided that the EU comment on the introductory paragraph of Article 7.8.10 is taken into account. If a specific reference is made to the requirements under Chapters 7.3. and 7.4., it is equally necessary to highlight the genuine need for an exemption to these. In exceptional cases, there may be justifiable reasons to transport animals whose fitness for transport is compromised due to the scientific procedures that they are intended for. This has to be acknowledged and specific attention paid to the needs of these animals.

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 XXII (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.

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 primarily responsibility for the project and should include a description of the following elements, where relevant:

- a) the scientific or educational aims, including consideration of the relevance of the experiment to human or animal health or *welfare*, the environment, or the advancement of biological knowledge;
- b) an informative, non-technical (lay) summary may enhance understanding of the project and facilitate the ethical review of the proposal by allowing full and equitable participation of members of the oversight body or committees who may be dealing with matters outside their specific field. Subject to safeguarding confidential information, such summaries may be made publicly available;
- c) the experimental design, including justification for choice of species, source and number of *animals*, including any proposed reuse;
- d) the experimental procedures;

- e) methods of handling and restraint and consideration of refinements such as animal training and operant conditioning;
- f) the methods to avoid or minimise pain, discomfort, distress, suffering or lasting impairment of physical or physiological function, including the use of anaesthesia or analgesia and other means to limit discomfort such as warmth, soft bedding and assisted feeding;
- g) application of humane endpoints and the final disposition of *animals*, including methods of euthanasia;
- h) consideration of the general health, husbandry and care of the species proposed to be used, including environmental enrichment and any special housing requirements;
- i) ethical considerations such as the application of the Three Rs and a harm/benefit analysis; the benefits should be maximised and the harms, in terms of pain and distress, should be minimised;
- j) an indication of any special health and safety risks; and
- k) resources/infrastructure necessary to support the proposed work (e.g. facilities, equipment, staff trained and found competent to perform the procedures described in the proposed project).

The oversight body has a critical responsibility in determining the acceptability of project proposals, taking account of the *animal welfare* implications, the advancement of knowledge and scientific merit, as well as the societal benefits, in a risk-based assessment of each project using live *animals*.

Following approval of a project proposal, consideration should be given to implementing an independent (of those managing the projects) oversight method to ensure that animal activities conform with those described in the approved project proposal. This process is often referred to as post approval monitoring. Such monitoring may be achieved through animal observations made during the conduct of routine husbandry and experimental procedures; observations made by the veterinary staff during their rounds; or by inspections by the oversight body, which may be the local committee, *animal welfare* officer, compliance/quality assurance officer or government inspector.

- l) the duration of approval of a project should normally be defined and progress achieved should be reviewed in considering renewal of a project approval.

2. Facility inspection

There should be regular inspections of the facilities, at least annually. These inspections should include the following elements:

- a) the *animals* and their records, including cage labels and other methods of animal identification;
- b) husbandry practices;
- c) maintenance, cleanliness and security of the facility;
- d) type and condition of caging and other equipment;
- e) environmental conditions of the *animals* at the cage and room level;
- f) procedure areas such as surgery; necropsy and animal research laboratories;
- g) support areas such as washing equipment; animal feed, bedding and drug storage locations;

- h) occupational health and safety concerns.

Principles of *risk management* should be followed when determining the frequency and nature of inspections.

3. Ethical evaluation

The ethical evaluation reflects the policies and practices of the institution in complying with regulations and relevant guidance. It should include consideration of the functioning of the local committee; training and competency of staff; veterinary care; husbandry and operational conditions, including emergency plans; sourcing and final disposition of *animals*; and occupational health and safety. The programme should be reviewed regularly. A requirement for the components of such a programme should be included in relevant regulations to empower the *Competent Authority* to take appropriate action to ensure compliance.

Article 7.8.5.

Assurance of training and competency

An essential component of the animal care and use programme is the assurance that the personnel working with the *animals* are appropriately trained and competent to work with the species used and the procedures to be performed, including ethical considerations. A system (institutional, regional or national) to assure competency should be in place, which includes supervision during the training period until competence has been demonstrated. Continuing professional and paraprofessional educational opportunities should be made available to relevant staff. Senior management, given their overarching responsibility for the animal care and use programme, should be knowledgeable about issues related to the competence of staff.

1. Scientific staff

Researchers using *animals* have a direct ethical and legal responsibility for all matters relating to the *welfare* of the *animals* in their care. Due to the specialised nature of animal research, focused training should be undertaken to supplement educational and experiential backgrounds of scientists (including visiting scientists) before initiating a study. Focused training may include such topics as the national or local regulatory framework and institutional policies. The laboratory *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 XXII (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 XXII (contd)8. Transport, importation and exportation

Animals should be transported under conditions that are appropriate to their physiological and behavioural needs and microbiological pathogen free status, with care to ensure appropriate physical containment of the *animals* as well as exclusion of contaminants. The amount of time *animals* spend on a journey should be kept to a minimum. It is important to ensure that there is a well constructed journey plan, with key staff identified who have responsibility for the *animals* and that relevant documentation accompanies *animals* during transport to avoid unnecessary delays during the journey from the sender to the receiving institution.

9. Risks to biosecurity

In order to minimise the risk of contamination of *animals* with unwanted infectious microorganisms or parasites that may compromise the health of *animals* or make them unsuitable for use in research, the microbiological status of the *animals* should be determined and regularly assessed. Appropriate biocontainment and bioexclusion measures should be practised to maintain their health status and, if appropriate, measures taken to prevent their exposure to certain human or environmental commensals.

Article 7.8.8.

Physical facility and environmental conditions

A well-planned, well-designed, well-constructed, and properly maintained facility should include animal holding rooms as well as areas for support services such as for procedures, surgery and necropsy, cage washing and appropriate storage. An animal facility should be designed and constructed in accordance with all applicable building standards. The design and size of an animal facility depend on the scope of institutional research activities, the *animals* to be housed, the physical relationship to the rest of the institution, and the geographic location. For indoor housing, non-porous, non-toxic and durable materials should be used which can be easily cleaned and sanitised. *Animals* should normally be housed in facilities designed for that purpose. Security measures (e.g. locks, fences, cameras, etc.) should be in place to protect the *animals* and prevent their escape. For many species (e.g. rodents), environmental conditions should be controllable to minimise physiological changes which may be potentially confounding scientific variables and of *welfare* concern.

Important environmental parameters to consider include ventilation, temperature and humidity, lighting and noise:

1. Ventilation

The volume and physical characteristics of the air supplied to a room and its diffusion pattern influence the ventilation of an *animal's* primary enclosure and are thus important determinants of its microenvironment. Factors to consider when determining the air exchange rate include range of possible heat loads; the species, size, and number of *animals* involved; the type of bedding or frequency of cage changing; the room dimensions; and the efficiency of air distribution from the secondary to the primary enclosure. Control of air pressure differentials is an important tool for biocontainment and bioexclusion.

2. Temperature and humidity

Environmental temperature is a physical factor which has a profound effect on the *welfare* of *animals*. Typically, animal room temperature should be monitored and controlled. The range of daily fluctuations should be appropriately limited to avoid repeated demands on the *animals'* metabolic and behavioural processes to compensate for large changes in the thermal environment as well as to promote reproducible and valid scientific data. Relative humidity may also be controlled where appropriate for the species.

3. Lighting

Light can affect the physiology, morphology and behaviour of various *animals*. In general, lighting should be diffused throughout an animal holding area and provide appropriate illumination for the *welfare* of the *animals* while facilitating good husbandry practices, adequate inspection of *animals* and safe working conditions for personnel. It may also be necessary to control the light/dark cycle.

4. Noise

Separation of human and animal areas minimises disturbance to animal occupants of the facility. Noisy *animals*, such as dogs, pigs, goats and nonhuman primates, should be housed in a manner which ensures they do not adversely affect the *welfare* of quieter *animals*, such as rodents, rabbits and cats. Consideration should be given to insulating holding rooms and procedure rooms to mitigate the effects of noise sources. Many species are sensitive to high frequency sounds and thus the location of potential sources of ultrasound should be considered.

Article 7.8.9.

Husbandry

Good husbandry practices enhance the health and *welfare* of the *animals* used and contributes to the scientific validity of animal research. Animal care and accommodation should, as a minimum, demonstrably conform to relevant published animal care, accommodation and husbandry guidelines and regulations.

The housing environment and husbandry practices should take into consideration the normal behaviour of the species, including their social behaviour and age of the *animal*, and should minimise stress to the *animal*. During the conduct of husbandry procedures, personnel should be keenly aware of their potential impact on the *animals' welfare*.

1. Transportation

~~Transportation is a typically stressful experience. Therefore, every precaution should be taken to avoid unnecessary stress through inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. Consignments of *animals* should be accepted into the facility without avoidable delay and, after inspection, should be transferred to clean cages or pens and be supplied with feed and water as appropriate. Social *animals* should be transported, where appropriate, in established pairs or groups and maintained in these on arrival. See Article 7.8.10.~~

2. Acclimatisation

Newly received *animals* should be given a period for physiological and behavioural stabilisation before their use. The length of time for stabilisation will depend on the type and duration of transportation, the age and species involved, place of origin, and the intended use of the *animals*. Facilities should be available to isolate *animals* showing signs of ill health.

Annex XXII (contd)3. Cages and pens

Cages and pens should be made out of material that can be readily cleaned and decontaminated. Their design should be such that the *animals* are unlikely to injure themselves. Space allocations should be reviewed and modified as necessary to address individual housing situations and animal needs (for example, for prenatal and postnatal care, obese *animals*, and group or individual housing). Both the quantity and quality of space provided is important. Whenever it is appropriate, social *animals* should be housed in pairs or groups, rather than individually, provided that such housing is not contraindicated by the protocol in question and does not pose an undue risk to the *animals*.

4. Enrichment

Animals should be housed with a goal of maximising species appropriate behaviours and avoiding or minimising stress induced behaviours. One way to achieve this is to enrich the structural and social environment of the *animals* and to provide opportunities for physical and cognitive activity. Such provision should not compromise the health and safety of the *animals* or people, nor interfere with the scientific goals.

5. Feeding

Provision should be made for each *animal* to have access to feed to satisfy its physiological needs. Precautions should be taken in packing, transporting, storing and preparing feed to avoid chemical, physical and microbiological contamination, deterioration or destruction. Utensils used for feeding should be regularly cleaned and, if necessary, sterilised.

6. Water

Uncontaminated potable drinking water should normally be available at all times. Watering devices, such as drinking tubes and automatic watering systems, should be checked daily to ensure their proper maintenance, cleanliness, and operation.

7. Bedding

Animals should have appropriate bedding provided, with additional nesting material if appropriate to the species. Animal bedding is a controllable environmental factor that can influence experimental data and *animal welfare*. Bedding should be dry, absorbent, non-dusty, non-toxic and free from infectious agents, vermin or chemical contamination. Soiled bedding should be removed and replaced with fresh material as often as is necessary to keep the *animals* clean and dry.

8. Hygiene

The successful operation of a facility depends very much on good hygiene. Special care should be taken to avoid spreading infection between *animals* through fomites, including through personnel traffic between animal rooms. Adequate routines and facilities for the cleaning, washing, decontamination and, when necessary, sterilisation of cages, cage accessories and other equipment should be established. A very high standard of cleanliness and organisation should also be maintained throughout the facility.

9. Identification

Animal identification is an important component of record keeping. *Animals* may be identified individually or by group. Where it is desirable to individually identify *animals*, this should be done by a reliable and the least painful method.

10. Handling

Staff dealing with *animals* should have a caring and respectful attitude towards the *animals* and be competent in handling and restraint. Familiarising *animals* to handling during routine husbandry and procedures reduces stress both to *animals* and personnel. For some species, for example dogs and non-human primates, a training programme to encourage cooperation during procedures can be beneficial to the *animals*, the animal care staff and the scientific programme. For certain species, social contact with humans should be a priority. However, in some cases handling should be avoided. This may be particularly the case with wild *animals*. Consideration should be given to setting up habituation and training programmes suitable for the *animals*, the procedures and length of projects.

Article 7.8.10.

Transportation

Transportation is a typically stressful experience for *animals*. Therefore, every precaution should be taken to avoid unnecessary stress through 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. 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 should be in place and the name of an emergency contact person should be prominently displayed on the *container*.

EU comment

The EU proposes to amend the above paragraph as follows:

"Transportation is a typically stressful experience for animals. Therefore, transport of animals should be kept to the minimum necessary to reduce welfare costs to the animals. Every precaution should be taken to avoid unnecessary stress through 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 intended for. No additional suffering should be imposed by the transport of such animals unless justified and particular attention should be paid to any additional care which may be required. 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 should be in place and the name of an emergency contact person should be prominently displayed on the container"

Justification

This section should first state the basic principle that transport of animals should be kept to a minimum necessary due to added welfare cost to the animals. More importantly, since a specific reference is now added to Chapters 7.3. and 7.4., it needs to be highlighted that contrary to the requirements in those Chapters, there may be genuine, justifiable reasons to transport animals whose welfare is compromised for the

purposes of research. Consequently, it is necessary to emphasise that particular attention is paid to the welfare needs of these animals.

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 method**, 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 **to accomplish 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 **by the veterinarian**:
 - i) Some *animals*, such as (e.g. genetically altered *animals*) may have special requirements **that should be addressed in the *journey plan***.
 - ii) Issues of biosecurity and bioexclusion, (e.g. through *container* design and handling) **should be addressed in the *journey plan***.
4.
 - 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) **Where compatible, social *animals* should be transported in established pairs or groups and maintained in these on arrival.**

EU comments

The EU proposes adding a new point 3bis as follows:

"3bis. Vehicles or containers in which animals are transported should be clearly and visibly marked indicating the presence of live animals. Where animals have special requirements or biosecurity status, specific handling or management instructions should be provided within the journey plan and clear warnings marked on the vehicle/container, where appropriate."

Justification

Whilst certain guidelines e.g. IATA may require this, animals transported by other means and not protected by commercial transportation guidance/law should be identified as carrying live animals for any emergency purposes and for safety of any inspectors and where necessary a warning on vehicle about checking for additional handling/management issues in journey plan before opening container/vehicle.

45. In accordance with OIE Chapters 7.23 to and 7.4 and IATA regulations, an appropriate environment (e.g. 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.

56. 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 8.2.

INFECTION WITH AUJESZKY'S DISEASE VIRUS**EU position**

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

Article 8.2.1.

General provisions

Pigs are the natural host for Aujeszky's disease (AD) virus, although it can infect cattle, sheep, cats, dogs and rats causing fatal *disease*. The definition of pig includes all varieties of *Sus scrofa*, both domestic and *wild*.

For the purposes of the *Terrestrial Code*, AD is defined as an *infection* of domestic pigs and or *captive wild* pigs which are under direct human supervision or control.

For the purposes of this chapter, a distinction is made between domestic pig and *captive wild* pig populations on the one hand, and *wild pig* and *feral pig* populations on the other hand.

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

A Member should not impose trade bans in response to a notification of *infection* with AD virus in *wild* and *feral* pigs according to Article 1.1.3. of the *Terrestrial Code*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.2.3., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the AD status of the *exporting country* or *zone*.

Article 8.2.2.

Determination of the AD status of a country or zone

The AD free or provisionally free status of a country or *zone* can only be determined after considering the following criteria in domestic and wild pigs, as applicable:

1. AD is notifiable in the whole country, and all clinical signs suggestive of AD should be subjected to field and or *laboratory* investigations;
2. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of AD;
3. the *Veterinary Authority* should have current knowledge of, and authority over, all domestic and *captive wild* pigs establishments in the country or *zone*;
4. the *Veterinary Authority* should have current knowledge about the population and habitat of *wild* and *feral* pigs in the country or *zone*;
5. appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs, is in place; this may be achieved through a *surveillance* programme in accordance with Chapter 1.4.

Annex XXIII (contd)

Article 8.2.3.

Safe commodities

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

1. *fresh meat* of domestic and *wild* pigs not containing offal (head, and thoracic and abdominal viscera);
2. *meat products* of domestic and *wild* pigs not containing offal (head, and thoracic and abdominal viscera);
3. products of animal origin not containing offal (head, and thoracic and abdominal viscera).

Article 8.2.4.

AD free country or zone1. Qualification

- a) A country or *zone* may be considered free from the *disease* without formally applying a specific *surveillance* programme (historical freedom) if the *disease* has not been reported for at least 25 years, and if for at least the past 10 years:
 - i) it has been a *notifiable disease*;
 - ii) an early detection system has been in place;
 - iii) measures to prevent the introduction of the AD virus into the country or *zone* have been in place;
 - iv) no *vaccination* against the *disease* has been carried out;
 - v) *infection* is not known to be established in *wild and feral swine pigs*, or **appropriate** measures have been implemented to prevent any transmission of the AD virus from *wild and feral swine pigs* to domestic and captive wild pigs.
- b) A country or *zone* which does not meet the conditions of the above paragraph may be considered free from AD when:
 - i) animal health regulations to control the movement of *commodities* with the exception of those listed in Article 8.2.3. in order to prevent the introduction of *infection* into the *establishments* of the country or *zone* have been in place for at least two years;
 - ii) *vaccination* against AD has been banned for all domestic and captive wild pigs in the country or *zone* for at least two years unless there are means, validated to OIE standards (Chapter 2.1.2. of the Terrestrial Manual), of distinguishing between vaccinated and infected pigs;

Annex XXIII (contd)

- iii) if AD has never been reported in the country or *zone*, serological surveys, with negative results, have been conducted on a representative sample of all pig *establishments* in conformity with the recommendations in Chapter 1.4. at an acceptable level of confidence, no more than three years prior to qualification; the serological surveys should be directed at the detection of antibodies to the whole virus, and based on the breeding pig population or, for *establishments* that contain no breeding pigs, on a comparable number of fattening pigs; or
- iv) if AD has been reported in the country or *zone*, a *surveillance* and control programme has been in place to detect every infected *establishment* and eradicate AD from it; the *surveillance* programme should be carried out in conformity with the recommendations in Chapter 1.4. and demonstrate that no *establishments* within the country or *zone* have had any clinical, virological or serological evidence of AD for at least two years.
- v) In countries or *zones* with *wild and feral swine pigs*, measures should be implemented to prevent any transmission of the AD virus from *wild and feral swine pigs* to domestic and *captive wild* pigs.

2. Maintenance of free status

In order to maintain its free status, a country or *zone* should comply with the following requirements:

- a) periodic serological surveys directed at the detection of antibodies to the whole AD virus should be carried out on a statistically significant number of breeding pigs, in conformity with the recommendations in Chapter 1.4.;
- b) the importation of the *commodities* with the exception of those listed in Article 8.2.3. into the country or *zone* is carried out in conformity with the import conditions contained in the relevant Articles of the present chapter;
- c) the ban on AD *vaccination* remains in force;
- d) appropriate measures aimed at preventing the transmission of the AD virus from *wild and feral swine pigs* to domestic *and captive wild* pigs remain in force.

3. Recovery of free status

Should an AD *outbreak* occur in an *establishment* of a free country or *zone*, the status of the country or *zone* may be restored if either:

- a) all the pigs in the outbreak infected epidemiological units have been slaughtered; and, during and after the application of this measure, an epidemiological investigation including clinical examination, and serological and/or virological testing has been carried out in all pig *establishments* which have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within a prescribed radius from the outbreak infected epidemiological units, demonstrating that these *establishments* are not infected; or
- b) *vaccination* with gE- deleted vaccines has been applied and:
 - i) a serological testing procedure (differential ELISA) has been implemented in the *establishments* where *vaccination* has been applied to demonstrate the absence of *infection*;

Annex XXIII (contd)

- ii) the movement of pigs from these *establishments* has been banned, except for immediate *slaughter*, until the above procedure has demonstrated the absence of *infection*;
- iii) during and after the application of the measures described in points i) to ii) above, a thorough epidemiological investigation including clinical examination and serological ~~and~~ or virological testing has been carried out in all pig *establishments* which have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within a prescribed radius from the *outbreak*, demonstrating that these *establishments* are not infected.

Article 8.2.5.

AD provisionally free country or zone1. Qualification

A country or *zone* may be considered as provisionally free from AD if the following conditions are complied with:

- a) animal health regulations to control the movement of *commodities* with the exception of those listed in Article 8.2.3. in order to prevent the introduction of *infection* into the *establishments* of the country or *zone* have been in place for at least two years;
- b) if AD has never been reported in the country or *zone*, a serological survey, with negative results, has been conducted on a representative sample of all pig *establishments* in conformity with the recommendations in Chapter 1.4. (but not at an acceptable level of confidence); the serological survey should be directed at the detection of antibodies to the whole virus, and based on the breeding pig population or, for *establishments* that contain no breeding pigs, on a comparable number of fattening pigs; or
- c) if AD has been reported in the country or *zone*, a *surveillance* and control programme has been in place to detect infected *establishments* and eradicate AD from these *establishments*, the *herd* prevalence rate in the country or *zone* has not exceeded one percent for at least three years (the sampling procedure described in point 1e) of the definition of 'AD free establishment' should be applied within the *establishments* of the country or *zone*), and at least 90 percent of the *establishments* in the country or *zone* are qualified free;
- d) in countries or *zones* with *wild and feral swine pigs*, appropriate measures should be taken to prevent any transmission of the AD virus between *wild and feral swine pigs* and domestic and captive wild pigs.

2. Maintenance of provisionally free status

In order to maintain its provisionally free status, a country or *zone* should comply with the following requirements:

- a) the measures described in points 1b) and 1d) above should be continued;
- b) the percentage of infected *establishments* remains < one percent;

- c) the importation of the *commodities* with the exception of those listed in Article 8.2.3. into the country or *zone* is carried out in conformity with the import conditions contained in the relevant articles of the present chapter.

3. Recovery of provisionally free status

Should the percentage of infected *establishments* exceed one percent in a provisionally free country or *zone*, the status of the country or *zone* is cancelled and may be restored only once the percentage of infected *establishments* has remained < one percent for at least six months, and this result is confirmed by a serological survey conducted in conformity with point 1c) above.

Article 8.2.6.

AD infected country or zone

For the purposes of this chapter, countries and *zones* which do not fulfil the conditions to be considered free or provisionally free of AD should be considered as infected.

Article 8.2.7.

AD free establishment

1. Qualification

To qualify as free from AD, an *establishment* should satisfy the following conditions:

- a) it is under the control of the *Veterinary Authority*;
- b) no clinical, virological or serological evidence of AD has been found for at least one year;
- c) the introduction of pigs, semen and embryos ~~✓~~ or ova into the *establishment* is carried out in conformity with the import conditions for these *commodities* contained in the relevant articles of the present chapter;
- d) *vaccination* against AD has not been carried out in the *establishment* for at least 12 months, and any previously vaccinated pigs are free from gE antibodies;
- e) a representative sample of breeding pigs from the *establishment* has been subjected, with negative results, to serological tests to the whole AD virus, applying a sampling procedure set out in conformity with the recommendations in Chapter 1.4.; these tests should have been carried out on two occasions, at an interval of two months; for *establishments* that contain no breeding pigs, the tests should be carried out only once on a comparable number of fattening or weaning pigs;
- f) a *surveillance* and control programme has been in place to detect infected *establishments* located within a prescribed radius from the *establishment* and no *establishment* is known to be infected within this *zone*.

2. Maintenance of free status

For *establishments* located in an infected country or *infected zone*, the testing procedure described in point 1e) above should be carried out every four months.

For *establishments* located in a provisionally free country or *zone*, the testing procedure described in point 1e) above should be carried out every year.

Annex XXIII (contd)3. Recovery of free status

Should a free *establishment* become infected, or should an *outbreak* occur within a prescribed radius from a free *establishment*, the free status of the *establishment* should be suspended until the following conditions are met:

- a) in the infected *establishment*:
 - i) all the pigs in the *establishment* have been slaughtered, or
 - ii) at least 30 days after removal of all infected *animals*, all breeding *animals* have been subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of 2 months;
- b) in other *establishments* located within the prescribed radius: a number of breeding pigs from each *establishment* has been subjected, with negative results, to serological tests to the whole AD virus (non vaccinated *establishments*) or to gE antibodies (vaccinated *establishments*), applying the sampling procedure described in point 1e) above.

Article 8.2.8.

Recommendations for importation from AD free countries or zonesFor domestic and captive wild pigs

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

1. showed no clinical sign of AD on the day of shipment;
2. come from an *establishment* located in an AD free country or *zone*;
3. have not been vaccinated against AD.

Article 8.2.9.

Recommendations for importation from AD provisionally free countries or zonesFor domestic and captive wild pigs for breeding or rearing

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

1. showed no clinical sign of AD on the day of shipment;
2. have been kept exclusively in AD free *establishments* since birth;
3. have not been vaccinated against AD;
4. were subjected to a serological test to the whole AD virus, with negative results, within 15 days prior to shipment.

Annex XXIII (contd)

Article 8.2.10.

Recommendations for importation from AD infected countries or zonesFor domestic and captive wild pigs for breeding or rearing

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

1. showed no clinical sign of AD on the day of shipment;
2. were kept exclusively in AD free *establishments* since birth;
3. have not been vaccinated against AD;
4. were isolated in the *establishment* of origin or a *quarantine station*, and were subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of not less than 30 days between each test, the second test being performed during the 15 days prior to shipment.

Article 8.2.11.

Recommendations for importation from AD provisionally free countries or zones or AD infected countries or zonesFor domestic and captive wild pigs for slaughter

The pigs should be transported directly from the place of shipment to the slaughterhouse/ abattoir for immediate slaughter.

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

1. a *surveillance* and control programme is in place in the country or *zone* to detect infected *establishments* and eradicate AD;
2. the *animals*:
 - a) are not being eliminated as part of an eradication programme;
 - b) showed no clinical sign of AD on the day of shipment;
 - c) i) have been kept exclusively in AD free *establishments* since birth; or
 - ~~e~~—ii) have been vaccinated against AD at least 15 days prior to shipment.

[Note: Appropriate precautions should be taken both by the exporting country and the importing country to ensure that the pigs are transported directly from the place of shipment to the abattoir for immediate slaughter.]

Article 8.2.12.

Recommendations for importation from AD free countries or zones

For wild and feral pigs swine

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

1. showed no clinical sign of AD on the day of shipment;
2. were captured in an AD free country or *zone*;
3. have not been vaccinated against the *disease*;
4. were isolated in a *quarantine station*, and were subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of not less than 30 days between each test, the second test being performed during the 15 days prior to shipment.

Article 8.2.13.

Recommendations for importation from AD free countries or zonesFor semen of pigs

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

1. the donor *animals*:
 - a) showed no clinical sign of AD on the day of collection of the semen;
 - b) were kept in an *establishment* or *artificial insemination centre* located in an AD free country or *zone* at the time of semen collection;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.2.14.

Recommendations for importation from AD provisionally free countries or zonesFor semen of pigs

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

1. the donor *animals*:
 - a) have been kept for at least four months prior to semen collection in an *artificial insemination centre* which has the status of AD free *establishment*, and where all boars are subjected to a serological test to the whole AD virus, with negative results, every four months;
 - b) showed no clinical sign of AD on the day of collection;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.2.15.

Recommendations for importation from AD infected countries or zonesFor semen of pigs

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

1. the donor *animals*:
 - a) were kept in an AD free *establishment* for at least six months prior to entering the *artificial insemination centre*;
 - b) have been kept for at least four months prior to semen collection in the *artificial insemination centre* which has the status of AD free *establishment*, and where all boars are subjected to a serological test to the whole AD virus, with negative results, every four months;
 - c) were subjected to a serological test to the whole AD virus, with negative results, within 10 days prior to or 21 days after semen collection;
 - d) showed no clinical sign of AD on the day of collection;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.2.16.

Recommendations for importation from AD free countries or zonesFor *in vivo* derived embryos of pigs

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

1. the donor females:
 - a) showed no clinical sign of AD on the day of collection of the embryos;
 - b) were kept in an *establishment* located in an AD free country or *zone* prior to collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.2.17.

Recommendations for importation from AD provisionally free countries or zonesFor *in vivo* derived embryos of pigs

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

Annex XXIII (contd)

1. the donor females:
 - a) showed no clinical sign of AD on the day of collection of the embryos;
 - b) were kept in an AD free *establishment* for at least three months prior to collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.2.18.

Recommendations for importation from AD infected countries or zonesFor *in vivo* derived embryos of pigs

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

1. the donor females:
 - a) showed no clinical sign of AD on the day of collection of the embryos;
 - b) were kept in an AD free *establishment* for at least three months prior to collection;
 - c) were subjected to a serological test to the whole AD virus, with negative results, within ten days prior to collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.2.19.

Recommendations for importation from AD free countries or zonesFor offal (head, and thoracic and abdominal viscera) of pigs or products containing pig offal

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of offal or products containing pig offal comes from *animals* which come from *establishments* located in an AD free country or *zone*.

Article 8.2.20.

Recommendations for importation from AD provisionally free countries or zones or from AD infected countries or zonesFor offal (head, and thoracic and abdominal viscera) of pigs

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

1. which have been kept in an AD free *establishment* since birth;
2. which have not been in contact with *animals* from *establishments* not considered free from AD during their transport to the approved *abattoir* and therein.

Article 8.2.21.

Recommendations for importation from AD provisionally free countries or zones or from AD infected countries or zonesFor products containing pig offal (head, and thoracic and abdominal viscera)

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

1. either the entire consignment of offal used to prepare the products complied with the conditions referred to in Article 8.2.20.; or
2. the products have been processed to ensure the destruction of the AD virus; and
3. the necessary precautions were taken after processing to avoid contact of the products with any source of AD virus.

— Text deleted

CHAPTER 1.6.

PROCEDURES FOR SELF DECLARATION AND
FOR OFFICIAL RECOGNITION BY THE OIE**EU position**

The EU supports the adoption of this modified chapter and has a comment.

Article 1.6.1.

General principles

Members may wish to make a self declaration as to the freedom of a country, *zone* or *compartment* from an OIE *listed disease*. The Member may inform the OIE of its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim. The OIE does not publish self declaration for bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), rinderpest, and contagious bovine pleuropneumonia (CBPP) and African horse sickness (AHS).

EU comment

The OIE may publish the Member's claim for a self declaration, but importing countries should recognise this status even if not published by the OIE, as long as the conditions of the relevant chapters are fulfilled. Thus, in order to avoid unjustified barriers to trade, the EU asks the OIE either to inform again its Members of the procedures (this could be part of an introductory chapter to the Code) or at least to add in the paragraph above the fact that the claimed status may be published on the OIE website.

Members may request official recognition by the OIE as to:

1. the risk status of a country or *zone* with regard to BSE;
2. the freedom of a country or *zone* from FMD, with or without vaccination;
3. the freedom of a country from rinderpest;
4. the freedom of a country or *zone* from CBPP;
5. the freedom of a country or *zone* from AHS.

The OIE does not grant official recognition for other *diseases*.

In these cases, Members should present documentation setting out the compliance of the *Veterinary Services* of the applicant country or *zone* with the provisions of Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code* and with the provisions of the relevant *disease* chapters in the *Terrestrial Code* and the *Terrestrial Manual*.

When requesting official recognition of disease status, the Member should submit to the OIE Scientific and Technical Department a dossier providing the information requested (as appropriate) in Articles 1.6.3. (for BSE), 1.6.4. (for FMD), 1.6.5. (for rinderpest), ~~or~~ 1.6.6. (for CBPP) or 1.6.6. bis (for AHS).

The OIE framework for the official recognition and maintenance of disease status is described in Resolution N° XXII (administrative procedures) and Resolution N° XXIII (financial obligations) adopted during the 76th General Session in May 2008.

Article 1.6.2. [No change]

Article 1.6.3. [No change]

Article 1.6.4. [No change]

Article 1.6.5. [No change]

Article 1.6.6. [No change]

Article 1.6.6.bis

Questionnaire on African horse sickness

AHS FREE COUNTRY

Report of a Member which applies for recognition of status, under Chapter 12.1. of the *Terrestrial Animal Health Code* (2010), as an AHS free country

Please address concisely the following topics. National legislation, regulations and Veterinary Administration Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a. Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to AHS introduction. Provide a map identifying the factors above.

- b. Equine sectors. Provide a general description of the equine sectors and their relative economic importance in the country. Outline any recent significant changes observed within the sector grouping(s) (if relevant documents are available, please attach).
 - i. Sport and race horses
 - ii. Breeding stock equids equidae
 - iii. Working and production equids equidae (including horses for slaughter)
 - iv. Leisure equids equidae
 - v. *Captive wild, wild and feral equids equidae*.
2. Description of equine equid population
- a. Demographics of domestic equids equidae. What is the equine equidae population by species within the various sectors? Provide a description of the methods of animal identification, holding and individual animal registration systems if in place. How are they distributed (e.g. density, etc.)? Provide tables and maps as appropriate.
 - b. Wildlife demographics. What *captive wild, wild or feral equids equidae* are present in the country? Provide estimates of population sizes and geographic distribution. ~~What are the measures in place to prevent contact between domestic and captive wild, wild or feral equidae?~~
3. Veterinary system
- a. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to AHS.
 - b. *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Services* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how *Veterinary Services* supervise and control all AHS related activities. Provide maps and tables wherever possible.
 - c. Role of farmers, keepers, industry, regulatory bodies, and other relevant groups in AHS *surveillance* and control (include a description of training and awareness programmes on AHS).
 - d. Role of private veterinary profession in AHS *surveillance* and control.
 - e. Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS Pathway
4. AHS eradication
- a. History. Provide a description of the AHS history in the country if applicable, date of first detection, origin of *infection*, date of eradication (date of last *case*), and serotypes present.
 - b. Strategy. Describe how AHS was controlled and eradicated (e.g. isolation of cases, *stamping-out policy*, zoning), provide time frame for eradication.
 - c. Vaccines and vaccination. What type of vaccine was used? What equine species were vaccinated? Were vaccinated animals marked or was *vaccination* recorded in a unique identification document?

- d. Legislation, organisation and implementation of the AHS eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines were used and give a brief summary.
- e. Animal identification. Are equids equidae identified (individually or at a group level)?
- f. Movements of equids equidae. How are movements of equids equidae controlled in the country? Provide evidence on the effectiveness of equidae identification and movement controls of equids. Please provide information on pastoralism, transhumance and related movements.
- g. Leisure and competition movements of equids equidae. How are movements of competition and leisure equids equidae controlled in the country. Please provide information on systems including any use of registration. Provide information on any events that include international movements of equids equidae.
- h. Describe the market systems for equids equidae, in particular, if markets require the international movement of equids equidae.

5. AHS diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3., and 2.5.1. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a. Is AHS laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.
- b. Provide an overview of the AHS approved laboratories, in particular to address the following points:
 - i. Details on the types of tests undertaken.
 - ii. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO that exist in, or planned for, the laboratory system.
 - iii. Give details of participation in inter-laboratory validation tests (ring tests).
 - iv. Describe biosecurity measures applied, particularly in the case where live virus is handled.

6. AHS surveillance

Provide documentary evidence that *surveillance* for AHS in the country complies with the provisions of Articles 12.1.11. to 12.1.13. of the *Terrestrial Code*, and Chapter 2.5.1. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a. Clinical suspicion. What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom), is there a compensation system in place and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for AHS, species, type of sample, testing method(s) and results (including differential diagnosis).

- b. Surveillance. Are the following undertaken?
- i. Serological surveillance
 - ii. Virological surveillance
 - iii. Sentinel animals
 - iv. Vector surveillance.

If so, provide detailed information on the survey designs. How frequently are they conducted? Which were the equine species included? Are *wildlife* species included? Provide a summary table indicating detailed results, for at least the past 2 years. Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of equids equidae examined and samples tested. Provide details on the methods selected and applied for monitoring the performance of the *surveillance* system.

7. AHS prevention

- a. Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or *zones* that have been taken into account (e.g. size, distance from adjacent border to infected equids equidae)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

If the AHS free country borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent and/or *vectors*, taking into consideration the seasonal *vector* conditions and existing physical, geographical and ecological barriers.

- b. Import control procedures

From what countries or *zones* does the country authorize the import of equids equidae or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such equids equidae and products, and subsequent internal movement?

What import conditions (e.g. quarantine) and test procedures are required? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports, temporary admissions or re-entry of equids equidae and their products for at least the past 2 years, specifying country or *zone* of origin and volume.

- i. Provide a map with the number and location of ports, airports and land crossings. Is the service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the *Competent Authority*. Describe the communication systems between the *Competent Authority* and the border inspection posts, and between border inspection posts.
- ii. Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
 - Equids Equidae,
 - genetic material (semen, ova and embryos of the equine species),

- equine derived (by-)products and biological.

iii. Describe the action available under legislation, and actually taken, when an illegal introduction is detected. Provide information on detected illegal introduction.

8. Control measures and contingency planning

- a. Give details of any written guidelines, contingency plans (including information on vaccine banks) available to the Competent Authority Veterinary Services for dealing with suspected or confirmed *cases* of AHS.
- b. In the event of a suspected or confirmed AHS *outbreak*:
 - i. is quarantine imposed on premises with suspicious *cases*, pending final diagnosis?
 - ii. are movement restrictions applied on suspicion?
 - iii. describe the sampling and testing procedures used to identify and confirm presence of the causative agent;
 - iv. describe the actions taken to control the disease situation in and around any holdings found to be infected with AHS;
 - v. describe the control and/or eradication procedures (e.g. *vaccination*, modified stamping-out);
 - vi. describe the procedures used to confirm that an *outbreak* has been successfully controlled and/or eradicated, including conditions for restocking;
 - vii. give details of any compensation made available when equids ~~equidae~~ are killed, for *disease* control and/or eradication purposes.

9. Compliance with the *Terrestrial Code*

- a. In addition to the documentary evidence that the provisions of Article 12.1.2 are properly implemented and supervised, the Delegate of the country must submit a declaration stating:
 - i. The section under paragraph 1 (of Article 12.1.2.) on the base of which the application is made;
 - ii. there has been no *outbreak* of AHS during the past 12 months;
 - iii. no systematic routine *vaccination* against AHS has been carried out during the past 12 months;
- b. and that vaccinated equids ~~equidae~~ were imported in accordance with Chapter 12.1.

10. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 12.1.2. of the *Terrestrial Code* and provide detailed information as specified in sections 4(a), b), c and 6, and highlight any measures introduced to prevent a recurrence of the infection under section 7 of this questionnaire. Information in relation to other sections need only be supplied if relevant.

AHS FREE ZONE

Report of a Member which applies for recognition of status, under Chapter 12.1. of the *Terrestrial Animal Health Code* (2010), as an AHS free zone

Please address concisely the following topics. National legislation, regulations and Veterinary Administration Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a. Geographical factors. Provide a general description of the country and the zone including physical, geographical and other factors that are relevant to AHS introduction. Provide a map identifying the factors above. The boundaries of the zone must be clearly defined, including a protection zone, if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone (and of the protection zone) established in accordance with Chapter 4.3.
- b. Equine sectors. Provide a general description of the equine sectors and their relative economic importance in the country and the zone. Outline any recent significant changes observed within the sector grouping(s) (if relevant documents are available, please attach).
 - i. Sport and race horses
 - ii. Breeding stock equids equidae
 - iii. Working and production equids equidae (including horses for slaughter)
 - iv. Leisure equids equidae
 - v. *Captive wild, wild and feral equids equidae*.

2. Description of equine equidae population

- a. Demographics of domestic equids equidae. What is the equine equidae population by species within the various sectors in the country and the zone? Provide a description of the methods of animal identification, holding and individual animal registration systems in the country and the zone if in place. How are they distributed (e.g. density, etc.)? Provide tables and maps as appropriate.
- b. Wildlife demographics. What *captive wild, wild or feral equids equidae* are present in the country and the zone? Provide estimates of population sizes and geographic distribution. ~~What are the measures in place to prevent contact between domestic and captive wild, wild or feral equidae?~~

3. Veterinary system

- a. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to AHS.
- b. *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Services* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how *Veterinary Services* supervise and control all AHS related activities in the country and in the zone. Provide maps and tables wherever possible.
- c. Role of farmers, keepers, industry, regulatory bodies, and other relevant groups in AHS *surveillance* and control (include a description of training and awareness programmes on AHS).

- d. Role of private veterinary profession in AHS *surveillance* and control.

4. AHS eradication

- a. History. Provide a description of the AHS history in the country and *zone*, if applicable, date of first detection, origin of *infection*, date of eradication in the *zone* (date of last *case*), and serotypes present.
- b. Strategy. Describe how AHS was controlled and eradicated in the *zone* (e.g. isolation of cases, *stamping-out policy*, zoning), provide time frame for eradication.
- c. Vaccines and vaccination. What type of vaccine was used in the *zone* and the rest of the country? What equine species were vaccinated? Were vaccinated *animals* marked or was *vaccination* recorded in a unique identification document?
- d. Legislation, organisation and implementation of the AHS eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines were used and give a brief summary.
- e. Animal identification. Are equids equidae identified (individually or at a group level)?
- f. Movements of equids equidae. How are movements of equids equidae controlled in, and between *zones* of the country? Provide evidence on the effectiveness of equidae identification of equids and movement controls in the *zone*. Please provide information on pastoralism, transhumance and related movements.
- g. Leisure and competition movements of equids equidae. How are movements of competition and leisure equids equidae controlled in the country and the *zones*? Please provide information on systems including any use of registration. Provide information on any events that include international movements of equids equidae.
- h. Describe the market systems for equids equidae in the country and the *zones*, in particular, if markets require the international movement of equids equidae.

5. AHS diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3., and 2.5.1. of the *Terrestrial Manual* are applied in the country and the *zone*. In particular, the following points should be addressed:

- a. Is AHS laboratory diagnosis carried out in the country and the *zone*? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed.
- b. Provide an overview of the AHS approved laboratories, in particular to address the following points:
 - i. Details on the types of tests undertaken.
 - ii. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO that exist in, or planned for, the laboratory system.
 - iii. Give details of participation in inter-laboratory validation tests (ring tests).
 - iv. Describe biosecurity measures applied, particularly in the case where live virus is handled.

Annex XXIV (contd)6. AHS surveillance

Provide documentary evidence that *surveillance* for AHS in the *zone* complies with the provisions of Articles 12.1.11. to 12.1.13. of the *Terrestrial Code*, and Chapter 2.5.1. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a. Clinical suspicion. What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom), is there a compensation system in place and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for AHS, species, type of sample, testing method(s) and results (including differential diagnosis) from the *zone*.
- b. Surveillance. Are the following undertaken?
 - i. Serological surveillance
 - ii. Virological surveillance
 - iii. Sentinel animals
 - iv. Vector surveillance.

If so, provide detailed information on the survey designs. How frequently are they conducted? Which were the equine species included? Are *wildlife* species included? Provide a summary table indicating detailed results, for at least the past 2 years. Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of equids equidae examined and samples tested. Provide details on the methods selected and applied for monitoring the performance of the *surveillance* system.

7. AHS prevention

- a. Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and/or *zones* that have been taken into account (e.g. size, distance from adjacent border to infected equids equidae)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*.

If the AHS free *zone* is established in an AHS infected country or borders an infected country or *infected zones*, describe the animal health measures implemented to effectively prevent the introduction of the agent and/or *vectors*, taking into consideration the seasonal vector conditions and existing physical, geographical and ecological barriers.

- b. Import control procedures. From what countries or *zones* does the country authorize the import of equids equidae or their products into the free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such equids equidae and products, and subsequent internal movement? What import conditions (e.g. quarantine) and test procedures are required? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports, temporary admissions or re-entry of equids equidae and their products to the free *zone* for at least the past 2 years, specifying country or *zone* of origin and volume.

Annex XXIV (contd)

- i. Provide a map with the number and location of ports, airports and land crossings in the *zone*. Is the service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the *Competent Authority*. Describe the communication systems between the *Competent Authority* and the border inspection posts, and between border inspection posts.
- ii. Describe the regulations, procedures, type and frequency of checks at the points of entry into the *zone* ~~and/or~~ for their final destination, concerning the import and follow-up of the following:
 - equids equidae,
 - genetic material (semen, ova and embryos of the equine species),
 - equine derived (by-)products and biologicals.
- iii. Describe the action available under legislation, and actually taken, when an illegal introduction into the *zone* is detected. Provide information on detected illegal introductions into the *zone*.

8. Control measures and contingency planning

- a. Give details of any written guidelines, contingency plans (including information on vaccine banks) available to the ~~Competent Authority~~ Veterinary Services for dealing with suspected or confirmed *cases* of AHS in the country and the *zone* (including the *protection zone* if applicable).
- b. In the event of a suspected or confirmed AHS *outbreak* in the *zone*:
 - i. is quarantine imposed on premises with suspicious *cases*, pending final diagnosis?
 - ii. are movement restrictions applied on suspicion?
 - iii. describe the sampling and testing procedures used to identify and confirm presence of the causative agent;
 - iv. describe the actions taken to control the disease situation in and around any holdings found to be infected with AHS;
 - v. describe the control ~~and/or~~ eradication procedures (e.g. *vaccination*, modified stamping-out);
 - vi. describe the procedures used to confirm that an *outbreak* has been successfully controlled ~~or~~ eradicated, including conditions for restocking;
 - vii. give details of any compensation made available when equids equidae are killed, for *disease control* ~~or~~ eradication purposes.

9. Compliance with the *Terrestrial Code*

- a. In addition to the documentary evidence that the provisions of Article 12.1.2 are properly implemented and supervised, the Delegate of the country must submit a declaration stating:

Annex XXIV (contd)

- i. The section under paragraph 1 (of Article 12.1.2.) on the base of which the application is made
 - ii. there has been no *outbreak* of AHS during the past ~~1224~~ months in the *zone*;
 - iii. no **systematic routine** vaccination against AHS has been carried out during the past 12 months in the *zone*;
- b. and that vaccinated equids equidae were imported into the *zone* in accordance with Chapter 12.1.
10. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 12.1.2. of the *Terrestrial Code* and provide detailed information as specified in sections 4 (a), (b), (c) and 6 and highlight any measures introduced to prevent a recurrence of the *infection* under Section 7 of this questionnaire.

Article 1.6.7.

Questionnaire on foot and mouth disease

COUNTRY WITH AN OIE ENDORSED OFFICIAL CONTROL PROGRAMME FOR FMD
 Report of a Member which applies for the OIE endorsement of status-its official control programme for FMD,
 under Chapter 8.5. of the *Terrestrial Code* (2011),
 as a Member with an endorsed official control programme for FMD

Please address concisely the following topics. National **regulations** laws, **regulation** and Veterinary **Authority Administration** directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) **Geographical factors**. Provide a general description of **geographical factors in** the country and any *zones*, including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that, although not adjacent, present a risk for the introduction of *disease*.
- b) If the endorsed plan is gradually implemented to specific parts of the country, the boundaries of the *zone(s)* should be clearly defined, including the *protection zone*, if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone(s)*.
- c) Provide a general description of the livestock industry in the country and any *zones*.

2. Veterinary system

- a) **Legislation:** Provide a list and summary of all relevant veterinary legislation in relation to the FMD control programme.
- b) **Veterinary Services:** Provide documentation on the compliance of the *Veterinary Services* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the ~~veterinary services~~ *Veterinary Services* supervise and control all FMD related activities in the country and any *zones*. Provide maps and tables wherever possible.
- c) Provide a description on the involvement and the participation of industry, producers, farmers, including subsistence and small scale producers, community animal health workers and the role of the private veterinary profession in FMD *surveillance* and control. Include a description of training and awareness programmes on FMD.
- d) Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS Pathway.

3. FMD control

- a) Provide a description of the FMD history in the country and any *zones*, including date of first detection, origin of *infection*, date of implementation of the control programme in the country and any *zones*, and types and subtypes of the FMD virus present.
- b) Describe the general epidemiology of FMD in the country and the surrounding countries or *zones* highlighting the current knowledge and gaps.
- c) Describe how FMD is controlled in the country or any *zones*. **Submit a detailed plan on the measures to control and eventually eradicate FMD in the country. Include the timelines of the control programme and the performance indicators to assess the efficacy of the control measures and plan.**
- d) Provide a description of the legislation, organisation and implementation of the FMD control programme. Indicate if detailed operational guidelines exist and give a brief summary. **Describe the funding for the control programme and annual budgets for the duration of the control programme.**
- e) Provide information on what types of vaccines are used and which species are vaccinated. Provide information on the licensing process of the vaccines used. Describe the vaccination programme in the country and in any *zones*, including records kept, and provide evidence to show its effectiveness, **such as (e.g. vaccination coverage, population immunity, etc.). Provide details on the studies carried out to determine the population immunity, including the study design. Provide details, if applicable, on a proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual* to enable demonstration of absence of virus circulation.**
- f) Provide a description of the methods of *animal identification* (at the individual or group level), *herd* registration and traceability; and how the movements of *animals* and products are assessed and controlled, including movement of infected *animals* to *slaughter*. Describe the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe measures to prevent introduction of the virus from neighbouring countries or *zones* and through trade.

Annex XXIV (contd)

4. FMD surveillance

Provide documentary evidence on whether *surveillance* for FMD in the country complies with the provisions of Articles 8.5.42. to 8.5.47. and Article 8.5.49. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Describe the criteria for raising a suspicion of FMD and the procedure to notify (by whom and to whom) and what penalties are involved for failure to report.
- b) Describe how clinical *surveillance* is conducted, including which levels of the livestock production system are included in clinical *surveillance*, such as (e.g. farms, markets, fairs, *slaughterhouse*, check points, etc.). Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested in diagnostic laboratories. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators. Explain whether serological and virological surveys are conducted and, if so, how frequently and for what purpose.
- c) Provide a summary table indicating, for at least the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide procedural details on follow-up actions taken on suspicious and positive results.
- d) Provide information on livestock demographics and economics, including the susceptible animal population by species and production systems in the country and the *zone*. Identify how many *herds*, *flocks*, etc. of each susceptible species are in the country and how they are distributed, such as (e.g. *herd* density, etc.). Provide tables and maps as appropriate.
- e) Provide information on the demographics and migration patterns of FMD susceptible *wildlife* species, including which susceptible species are present in the country and any *zones*. Provide estimates of population sizes and geographic distribution. Identify whether susceptible *wildlife* are included in *surveillance*. Identify the measures in place to prevent contact between domestic and susceptible *wildlife*.
- f) Identify the livestock slaughter, marketing and collection centres. Provide information on the patterns of livestock movement within the country, including how *animals* are transported and handled during these transactions.

5. FMD laboratory diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of laboratories approved by the competent authority to diagnose FMD. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. If applicable, indicate the laboratory(ies) where samples originating from any *zone* are diagnosed. Is there regular submission of samples from the country or *zone* to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the standards and methods described in the *Terrestrial Manual*?

Annex XXIV (contd)

- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
 - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system.
 - ii) Give details on participation in inter-laboratory validation tests (ring tests).
 - iii) Is live virus handled?
 - iv) Biosecurity measures applied.
 - v) Details of the type of tests undertaken.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country. In particular provide details on:

- a) Coordination with neighbouring countries, trading partners and other countries within the same region. Identify relevant factors about the adjacent countries and *zones* that should be taken into account such as (e.g. size, distance from adjacent borders to affected herds or animals, surveillance carried in adjacent countries). Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*. Describe the measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation of the agent within the country or *zone* and through trade.
- b) What measures are taken to limit access of susceptible domestic, feral and wild animals to waste products of animal origin? Are there controls in place for the feeding of swill containing animal products to pigs? If so provide information on the extent of the practice, and describe controls and *surveillance* measures.
- c) Provide information on countries or *zones* from which the country authorises the import of susceptible *animals* or their products into the country or *zone*. Describe the criteria applied to approve such countries or *zones*, the controls applied on entry of such *animals* and products, and subsequent internal movement. Describe the import conditions and test procedures required. Advise whether imported *animals* of susceptible species are required to undergo a quarantine or isolation period, and if so, the duration and location of quarantine. Advise whether import permits and health certificates are required. Describe any other procedures used. Provide summary statistics on imports of susceptible *animals* and their products for at least the past two years, specifying country or *zone* of origin, the species and the number or volume.
 - i) Provide a map with the number and location of ports, airports and land crossings. Advise whether the service responsible for import controls is part of the official services, or if it is an independent body. If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central veterinary services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

Annex XXIV (contd)

- ii) Provide a description on the methods used for the safe disposal of waste food from international traffic, who is responsible to supervise this and provide a summary, for the past two years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and ~~for~~ their final destination, concerning the import and follow up of the following:
 - animals,
 - genetic material (semen and embryos),
 - animal products,
 - veterinary medicinal products, i.e. biologics,
 - other livestock related goods potentially contaminated with FMDV including bedding, litter and feeds.
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports, if available.

7. Control measures and emergency response

- a) Give details of any written guidelines, including emergency response plans, available to the ~~official services~~ Veterinary Services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Advise whether quarantine is imposed on premises with suspicious *cases*, pending final diagnosis and any other procedures followed in respect of suspicious *cases*.
- c) In the event of a FMD *outbreak*:
 - i) provide a detailed description of procedures that are followed in case of an *outbreak* including forward and backward tracing;
 - ii) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
 - iii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;
 - iv) indicate the control ~~and/or~~ eradication procedures, such as (e.g. vaccination, stamping-out, partial *slaughter* ~~or~~ vaccination, movement control, control of *wildlife*, pastured livestock and livestock as pets, control of the livestock waste, campaign to promote awareness of farmers, etc.) that would be taken;
 - v) describe the procedures used to confirm that an *outbreak* has been successfully controlled ~~or~~ eradicated, including any restrictions on restocking;
 - vi) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control or eradication purposes and their prescribed timetable.

Annex XXIV (contd)8. Official control programme for FMD submitted for OIE endorsement

Submit a detailed plan on the measures, in addition to those described in point 3, for the control and eventual eradication of FMD in the country, including:

a) objectives,

b) expected status to be achieved

c) timelines of the control programme

d) performance indicators, including methods for measurement and verification

e) description of the funding for the control programme and annual budgets for its duration

f) details, if applicable, on a proposed timeline for the transition to the use of vaccines, which are fully compliant with in the *Terrestrial Manual* in order to enable demonstration of absence of virus circulation.

89. Recovery of status

Countries applying for recovery of the official endorsement of the national FMD control programme should provide updated information in compliance with the provisions of Article 8.5.48. of the *Terrestrial Code*.

— Text deleted

CHAPTER 8.10.

INFECTION WITH RABIES VIRUS**EU position**

The EU thanks the OIE and supports in general the adoption of this modified chapter but has one important comment.

Article 8.10.1.

General provisions

For the purpose of the *Terrestrial Code*,

1. Rabies is a *disease* caused by ~~one~~ any member of the *Lyssavirus* genus; the *Rabies virus* (formerly referred to as classical rabies virus; genotype-1). All mammals including human are susceptible to infection. ~~Carnivora and Chiroptera are the reservoirs for rabies.~~

~~For the purposes of the *Terrestrial Code*:~~

- ~~24. A case is any animal infected with the *Rabies virus* species;~~
- ~~32. The incubation period for rabies is variable, and but will be considered to be less than 6 months or less. . and The infective period for dogs, cats and ferrets is considered to start 10 days before the onset of the first apparent clinical signs.~~

Globally, the most common source of exposure of humans to rabies virus is the dog. Other mammals, particularly members of the Orders Carnivora and Chiroptera, also present a risk.

The aim of this chapter is to mitigate the risk ~~related to~~ of rabies to human and animal health and to prevent the for international spread of the disease ~~trade and non-commercial movements of rabies susceptible species.~~

For the purpose of the *Terrestrial Code*, a country that does not fulfil the requirements in Article 8.10.2. is considered to be infected with *Rabies virus*.

~~The most important species for international trade purposes are domestic carnivores (primarily dogs [*Canis familiaris*], cats [*Felis catus*] and ferrets [*Mustela putorius furo*]) and also include domestic livestock (equids, ruminants and suids).~~

~~Rabies can be suspected based on clinical signs or history of exposure to a rabid animal. Confirmation requires antigen detection or virus isolation. Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.~~

~~Members are encouraged to~~ should implement and maintain a programme for the management of stray dog populations consistent with Chapter 7.7.

Article 8.10.2.

Rabies free country

A country may be considered free from rabies when:

1. the *disease* is notifiable and any change in the epidemiological situation or relevant events ~~are~~ should be reported in accordance with Chapter 1.1.;
2. an ~~effective~~ ongoing system of *disease surveillance* ~~in accordance with Chapter 1.4.~~ has been in operation for the last two years, with a minimum requirement being an on-going early detection programme to ensure investigation and reporting of rabies suspect *animals*;
3. regulatory measures for the prevention of rabies are implemented consistent with the recommendations in ~~the Terrestrial Code this chapter,~~ including ~~effective procedures~~ for the importation of *animals* domestic dogs, cats and ferrets;
4. no *case* of indigenously acquired *rabies virus* infection has been confirmed during the past two years;

EU comment

Typographical error in point above (should read "two years")

5. no imported *case* ~~reservoir~~ species in the Orders ~~of~~ Carnivora or Chiroptera has been confirmed outside a *quarantine station* for the past six months;
6. an imported human *case* of rabies ~~does~~ will not affect the rabies free status.

Members should implement and maintain a programme for the management of stray dog populations consistent with Chapter 7.7.

~~Article 8.10.3.~~

Country free from dog to dog transmission of rabies

A country may be considered free from dog to dog transmission of rabies when:

1. the *disease* is notifiable and any change in the epidemiological situation or relevant events are reported in accordance with Chapter 1.1.;
2. an effective system of *disease surveillance* has been in operation for the last 2 years, with a minimum requirement being an on going early detection programme to ensure investigation and reporting of rabies suspect *animals*;
3. regulatory measures for the prevention and control of rabies are implemented consistent with the recommendations in this chapter, including vaccination, identification and effective procedures for the importation of domestic dogs, cats and ferrets;
4. thorough epidemiological investigations have demonstrated no *case* of dog to dog transmission of rabies during the past 2 years.

Members should implement and maintain a programme for the management of stray dog populations consistent with Chapter 7.7.

Article 8.10.43.

Recommendations for importation from rabies free countries

For domestic mammals, and captive wild mammals

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

Annex XXV (contd)

1. showed no clinical sign of rabies ~~the day prior to or~~ the day prior to or on the day of shipment;
2. and either:
 - a) were kept since birth or at least six months prior to shipment in a ~~the~~ free country; or
 - b) were imported in conformity with the regulations stipulated in Articles 8.10.75, 8.10.86, 8.10.97, or 8.10.408.

Article 8.10.54.

Recommendations for importation from rabies free countries

For wild mammals

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

1. showed no clinical sign of rabies ~~the day prior to or~~ the day prior to or on the day of shipment;
2. and either:
 - a) have been captured at a distance that precludes any contact with animals in an infected country. The distance should be defined according to the biology of the species exported, including home range and long distance movements. ~~and remained in a rabies free country, at a sufficient distance, based on the biology of species, including home range, from any infected country. The distance should be defined according to the species exported and the reservoir species in the neighbouring infected countries;~~ or
 - b) were have been kept in captivity for the six months prior to shipment in a rabies free country.

Article 8.10.6

Recommendations for importation of dogs from countries free from dog to dog transmission of rabies

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

1. were kept for at least the 6 months prior to shipment in a country free from dog to dog transmission of rabies;
2. were permanently identified (e.g., by a microchip or tattoo) and the identification number should be stated in the *certificate*;
3. received, prior to shipment, a valid anti rabies vaccination in accordance with the *Terrestrial Manual*, or revaccination if applicable, in accordance with the recommendations of the manufacturer;
4. showed no clinical sign of rabies ~~the day prior to or~~ on the day of shipment;

Article 8.10.75.

Recommendations for importation of dogs, cats and ferrets from countries considered infected with rabies

Veterinary Authorities should require the presentation of an *international veterinary certificate* complying with the model of Chapter 5.11, attesting that the *animals*:

1. showed no clinical sign of rabies ~~the day prior to or~~ the day prior to or on the day of shipment;
2. were permanently identified and their identification number stated in the certificate;

AND EITHER:

2. ~~were permanently identified (e.g., by a microchip or tattoo) and their identification number should be stated in the certificate; and~~
3. ~~received, prior to shipment, a valid anti-rabies vaccination~~ were vaccinated or revaccinated ~~if applicable, in accordance with the recommendations of the manufacturer;~~ The vaccine should have been produced and used ~~in accordance with the Terrestrial Manual; or revaccination if applicable, in accordance with the recommendations of the manufacturer; vaccination and~~
4. ~~were subjected not less than 3 months and not more than 24 12 months prior to shipment to an antibody titration test as prescribed in the Terrestrial Manual with a positive result of at least 0.5IU/ml;~~

EU comment

It is important to specify here in the Chapter that the antibody titration test should be performed in a laboratory approved and monitored by the *Veterinary Authority* as regards diagnostic tests required for international trade, by adding that the test should be carried out by a *laboratory* (italicised in order to make reference to the definition in the Glossary). Indeed, the indication in the model certificate, referring to an "official diagnostic laboratory", as such is not regarded as sufficient in this respect.

The EU therefore suggests amending the sentence above as follows:

"were subjected not less than 3 months and not more than 12 months prior to shipment to an antibody titration test carried out as prescribed in the Terrestrial Manual with a positive result of at least 0.5IU/ml by a laboratory;"

OR

5. ~~have not been vaccinated against rabies or do not meet all the conditions set out in points 2, 3 and 4 above;~~ in such cases, the *animals* should be were quarantined for six months prior to export.

EU comment

For consistency with the rest of the Code, the word "quarantined" should be replaced by "kept in a *quarantine station*".

Article 8.10.86.

Recommendations for importation of domestic ruminants, equids, camelids and suids from countries considered infected with rabies

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

1. showed no clinical sign of rabies ~~the day prior to or~~ the day prior to or on the day of shipment.
2. were permanently identified (e.g. by ear tag, microchip or tattoo) and the identification number should be stated in the certificate;
3.
 - a) were kept for the 6 months prior to shipment in an establishment where there has been no case of rabies was reported for at least 12 months prior to shipment;

or

 - b) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer. The using a vaccine was produced and used in accordance with the Terrestrial Manual.

~~Article 8.10.9.~~

~~Recommendations for importation of domestic equids from countries considered infected with rabies~~

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

- ~~1.~~ showed no clinical sign of rabies the day prior to or on the day of shipment;
- ~~2.~~ and either:
 - a) ~~were kept for the 6 months prior to shipment in an establishment where no contact with reservoir species was maintained and where no case of rabies was reported for at least 12 months prior to shipment; or~~
 - b) ~~were vaccinated as prescribed in the Terrestrial Manual.~~

~~Article 8.10.10.~~

Recommendations for importation from countries considered infected with rabies

For rodents and lagomorphs born and reared in a biosecure facility

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

1. showed no clinical sign of rabies on the day of shipment;
2. were kept since birth in a biosecure facility where there has been no case of rabies was reported for at least 12 months prior to shipment.

~~Article 8.10.11.~~

~~Recommendations for importation from countries considered infected with rabies~~

for captive wild animals (other than non human primates and captive wild carnivores)

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

- ~~1.~~ showed no clinical sign of rabies the day prior to or on the day of shipment;

2. were kept since birth, or for the 6 months prior to shipment, in an *establishment* where no contact with reservoir species and where no *case* of rabies was reported for at least 12 months prior to shipment.

Article 8.10.12g.

Recommendations for importation of wildlife from countries considered infected with rabies

~~for wild and feral animals (other than non-human primates and Chiroptera)~~

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

1. showed no clinical sign of rabies ~~the day prior to or~~ **the day prior to or** on the day of shipment;
2. were kept for the 6 months prior to shipment in an *establishment* where separation from susceptible ~~wild animals and feral animals~~ was maintained and where **there has been** no *case* of rabies ~~was reported~~ for at least 12 months prior to shipment.

~~Article 8.10.13.~~

Recommendations for importation from countries considered infected with rabies

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

~~for captive non-human primates~~

1. ~~the animals~~ showed no clinical sign of rabies ~~the day prior to or~~ on the day of shipment;
2. ~~quarantine measures were applied in accordance with Chapter 5.9. and Chapter 6.11.~~

 — Text deleted

CHAPTER 5.11.

RABIES
 MODEL INTERNATIONAL VETERINARY
 CERTIFICATE FOR INTERNATIONAL
MOVEMENT OF DOMESTIC DOGS (*Canis*
familiaris), AND CATS (*Felis catus*)
AND FERRETS (*Mustela putorius furo*)
 ORIGINATING FROM COUNTRIES CONSIDERED
INFECTED WITH RABIES INFECTED
COUNTRIES

EU position

The EU thanks the OIE and supports the adoption of this modified chapter but has some comments.

I. OWNER

Name:
 Address:

II. DESCRIPTION

Species of animal:
 Age or date of birth:
 Sex:
 Breed:
 Colour:
 Coat type and marking/Distinguishing marks:

Identification number, and location on the animal and date of marking (tattoo or other permanent method of identification) (see note 1)

III. ADDITIONAL INFORMATION

Country of origin:

 Countries visited
 over the past six months ~~2 years~~
 as declared by the owner
 (give dates)

Annex XXV (contd)

IV. VACCINATION (Rabies)

I the undersigned declare herewith that I have vaccinated seen evidence that the animal described in Part II has been vaccinated against rabies as shown below. The animal was found to be healthy on the day of vaccination.

EU comment

The EU acknowledges the fact that in some countries the certifying veterinarian is not the one who has vaccinated the animal and thus accepts the proposed change to reflect this. However, in other countries the certifying veterinarian indeed is the one who has vaccinated the animal, which is not reflected in the text as it is proposed now.

Therefore, the EU suggests amending the sentence as follows:

"I the undersigned declare herewith that I have vaccinated the animal described in Part II or that I have seen evidence that the animal described in Part II has been vaccinated against rabies as shown below."

Date of vaccination (dd/mm/yy)	Name of inactivated virus vaccine (see note 2)	1. Manufacturing laboratory 2. Batch number 3. Expiry date	Name (in capital letters) and signature of the veterinarian (see note 6)
		1..... 2..... 3.....	

PERIOD OF VALIDITY OF VACCINATION FOR INTERNATIONAL MOVEMENT (see note 3)		Name (in capital letters) and signature of the <u>Certifying Official</u> Veterinarian (see note 6)
from (dd/mm/yy)	to (dd/mm/yy)	
— — —		

Annex XXV (contd)

V. SEROLOGICAL TESTING (Rabies)

I the undersigned declare herewith that ~~I have taken~~ a blood sample has been taken from the animal described in Part II ~~and have received with~~ the following result from the official diagnostic laboratory which ~~has~~ carried out the ~~neutralising~~ antibody titration test (see note 4).

Date of sampling (dd/mm/yy)	Name and address of the official diagnostic laboratory	Result of the antibody titration test (in International Units [IU]/ml)	Name (in capital letters) and signature of the veterinarian (see note 6)

PERIOD OF VALIDITY OF SEROLOGICAL TESTING FOR INTERNATIONAL MOVEMENT (see note 4)		Name (in capital letters) and signature of the <u>Certifying Official</u> Veterinarian (see note 6)
from (dd/mm/yy)	to (dd/mm/yy)	

Annex XXV (contd)

VI. CLINICAL EXAMINATION (Rabies)

I, the undersigned declare herewith that I have examined on the date indicated below the animal described in Part II and have found it to be free from clinical signs of rabies ~~be clinically healthy~~ (see note 5).

EU comment

Similarly to the vaccination under point IV above, the clinical examination may in some countries not be performed by the certifying veterinarian, but by a veterinarian. Therefore, the EU suggests taking this possibility into account by amending the introductory sentence as follows:

"I the undersigned declare herewith that I have examined the animal described in Part II on the date indicated below or that I have seen evidence that that animal was examined on that date, and that the animal was found to be free from clinical signs of rabies (see note 5)."

Furthermore, in analogy to points IV and V above, the second column with the name and signature of the veterinarian should be deleted also from the table under this point, as it is not necessary since the certifying veterinarian declares having examined himself or having seen evidence that the animal in question was examined.

Date (dd/mm/yy)	Name (in capital letters) and signature of the veterinarian (see note 6)	Name (in capital letters) and signature of the <u>Certifying Official</u> Veterinarian (<u>see note 6</u>)

NOTE

1. The identification number should be by a permanent marking. The identification number It should be stated in the certificate should should and be identical to that ~~which can be found~~ on the animal. When electronic identification is used, the type of microchip and the name of the manufacturer should be specified.
2. Only vaccines produced in that comply compliance with the recommendations of the *Terrestrial Manual* should be used ~~inactivated virus vaccines are authorised for international movements of dogs and cats.~~
3. ~~In the case of a primary Vaccination or re-vaccination should be carried out in accordance with the recommendations of the manufacturer the animal should have been vaccinated not less than 6 months and not more than 1 year prior to its introduction into the importing country; the vaccination should have been carried out when the animal was at least 3 months old.~~

~~In the case of a booster vaccination, the animal should have been vaccinated not more than 1 year prior to its introduction into the importing country.~~

4. When serological testing is required, the animal should have been subjected not less than 3 months and not more than 2412 months prior to its introduction into the importing country, to an antibody titration test. It should be, carried out by an official diagnostic laboratory approved by the Competent Authority of the exporting country, as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5IU/ml with positive result in accordance with the *Terrestrial Manual*. The animal's serum should contain at least 0.5 International Units (IU)/ml.

EU comment

For clarity reasons, the EU suggests changing the order of clauses in the sentence above as follows:

"When serological testing is required, the animal should have been subjected not less than 3 months and not more than 12 months prior to its introduction into the importing country, to an antibody titration test, carried out as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5IU/ml by an official diagnostic laboratory approved by the Competent Authority of the exporting country".

5. The clinical examination referred to in Part VI of the certificate must be carried out ~~within 48 hours as per the requirements in Chapter 8.10 of shipment.~~

EU comment

The EU suggests stating the reference to the requirements as to the clinical examination in the point 5 above more precisely, by replacing the words "Chapter 8.10" by the words "Article 8.10.5".

The Competent Authority of the importing country may require the placing of the animals which do not comply with any of the above-mentioned conditions in a quarantine station located on its territory; the conditions of stay in quarantine are laid down by the legislation of the importing country.

6. ~~The certification should be undertaken in accordance with Chapters 5.1. and 5.2. of the *Terrestrial Code*. If the veterinarian whose name and signature appear on the certificate is not an official veterinarian, his signature must be authenticated in the relevant column by the signature and stamp of an official veterinarian. The expression 'Official Veterinarian' means a civil service veterinarian or a specially appointed veterinarian, as authorised by the Veterinary Authority of the country.~~
7. If so required, the certificate should be written in the language of the importing country. In such circumstances, it should also be written in a language understood by the certifying veterinarian.

— Text deleted

UNOFFICIAL VERSION

CHAPTER 4.14.

OFFICIAL HEALTH CONTROL OF BEE DISEASES
HYGIENE AND DISEASE SECURITY PROCEDURES
IN APIARIES

EU position

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

Article 4.14.1**Purpose**

This chapter is intended to set out guidelines for official health control of bee diseases. These are needed for the control of endemic bee diseases at the country level and to detect incursions of exotic diseases, thereby ensuring safe international trade of bees, bee products and used apicultural equipment associated with beekeeping. The guidelines are designed to be general in nature and more specific recommendations or requirements are made in Chapters 9.1. to 9.6. dealing with specific on bee diseases.

Article 4.14.2.**Overview**

In each country or region, official health control of bee diseases should include:

- a) official registration of the apiaries by the Veterinary Authority or by the Competent Authority in the whole country or region;
- b) an organisation for permanent health surveillance;
- c) approval of breeding apiaries for export trade;
- d) measures for cleaning, disinfection and disinfestation of apicultural equipment;
- e) 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 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 include.

1) the GPS coordinates of specific apiaries, or

the mapping of specific apiaries on gridded maps of municipalities or regions;

2) the time of year when *apiary* sites are most likely to contain colonies;

3) the average number of hives expected in a given *apiary*;

4) 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 4.14.24.

Organisation for permanent official sanitary surveillance of apiaries

Veterinary Authorities of countries are requested to regulate the organisation for permanent official sanitary surveillance of *apiaries*.

Permanent official sanitary surveillance of *apiaries* should be under the authority of the *Veterinary Authority* 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 a representative number 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 unexpected visits to *apiaries* may be where breeding or transport operations are carried out for specific purposes including trade or transfer to other regions, or any other purpose whereby *diseases* could be spread, as well as to *apiaries* located in the vicinity;
 - e) special visits for sanitary surveillance to sectors where breeding *apiaries* have been approved for export purposes;
2. collect the samples required for the diagnosis of contagious *diseases* and despatch them to an official laboratory; the results of laboratory examinations must should be communicated within the shortest delay to the *Veterinary 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 contagious *disease*.

Article 4.14.35.

Conditions for approval of breeding apiaries for export trade

Veterinary Authorities of exporting countries are requested to regulate the conditions for approval of breeding *apiaries* for export trade.

The apiaries ~~must~~ should:

1. ~~be situated in the centre of an area defined as follows and in which:~~
 - a) ~~no case of varroosis has been reported for at least the past 2 years within a radius of 50 kilometres;~~
 - b) ~~no case of any other contagious disease of bees included in this Terrestrial Code has been reported for at least the past 8 months within a radius of 5 kilometres;~~
2. have received, for at least the past 2 years, visits by a health inspector and adviser, carried out at least once a year using a risk-based approach at least 3 two times a year (in spring, during the breeding period and the most appropriate periods for detection of listed diseases of bees in autumn). During these visits, there should be a , for the systematic examination of at least 10% of the hives containing bees and of all the used apicultural equipment (especially stored combs), and for the collection of samples to be sent to an official laboratory and, depending on the situation of the importing and exporting countries, no positive results were reported to the Veterinary Authorities for the relevant bee listed diseases of bees included in the Terrestrial Code;
2. be regularly systematically be sampled within seven days of shipment and, depending on the epidemiological situation of the importing and exporting countries, and found free from for the relevant bee listed diseases of bees included in the Terrestrial Code. 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 ~~must~~ should:

3. immediately notify the *Veterinary Authority* of any suspicion of a contagious listed disease of bees in the breeding *apiary* and in other apiaries epidemiologically linked apiaries in the vicinity;
4. not introduce into the *apiary* any bee (including pre-imago larval stages) or used apicultural equipment material or product originating from another *apiary* unless that apiary is recognised by the Veterinary 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 health control has been previously performed by the Veterinary Authority;
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 ~~40~~ 30 days, during the breeding and despatch period, appropriate samples from breeding material, brood combs, bees (including possibly separately raised accompanying bees) queen-bees and or queen-bees bees (including possibly separately raised accompanying bees), to be sent to a an official laboratory and all the positive results officially reported to the Competent Authority.

Article 4.14.46.

Conditions for sanitation and disinfection or disinfection of apicultural equipment

Veterinary Authorities of exporting 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.

Annex XXVI (contd)

1. Any apicultural equipment kept in an *establishment* which has been recognised as being affected with a contagious *disease* of bees ~~shall~~ should be subjected to sanitary measures ensuring the elimination of pathogens.
2. In all cases, these measures comprise the initial cleaning ~~and scraping~~ of the equipment, followed by sanitation or *disinfection* or disinfection depending on the *disease* concerned.
3. ~~The kind of equipment (hives, small hives, combs, extractor, small equipment, appliances for handling or storage) shall also be taken into account in the choice of procedures to be applied.~~
34. Any Infected infested or contaminated equipment which cannot be subjected to the above-mentioned measures ~~must~~ should ~~must~~ should be destroyed, preferably by burning. ~~Any equipment in bad condition, especially hives, as well as larvae in combs affected with varroosis, American foulbrood or European foulbrood, must~~ should be destroyed by burning.
45. The products and means used for sanitation and *disinfection* or disinfection ~~shall~~ should be accepted ~~recognised~~ as being effective by the *Veterinary Authority*. They ~~shall~~ 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.
6. ~~When these procedures are not performed, the products shall be kept away from the bees and any contact with apicultural equipment and products must~~ should be prevented.
7. ~~Waste water from the cleaning, sanitation and disinfection of apicultural equipment shall be kept away from the bees at all times and disposed of in a sewer or in an unused well.~~

Article 4.14.57.

Preparation of the international veterinary certificate for export

This certificate covers hives containing bees, swarms, consignments of bees (worker bees or drones), queen bees (with accompanying bees), brood-combs, royal cells, used apicultural equipment and bee products, etc.

This document ~~shall~~ should be prepared in accordance with the model contained in Chapter 5.10. and taking into account the specific disease (chapters 9.1. to 9.6. related to on bee diseases.

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CHAPTER 10.4.

**AVIAN INFLUENZA INFECTION WITH VIRUSES
OF NOTIFIABLE AVIAN INFLUENZA**

EU position

The EU would support the adoption of this modified chapter, but only on the condition that the word "notifiable" is added between "low pathogenicity" and "avian influenza" in the proposed new point 1 of Article 10.4.1. Indeed, the proposed sentence is contradictory to the current Code Chapter 1.2.3. and cannot be accepted as such.

Article 10.4.1.

General provisions

1. Highly pathogenic avian influenza in birds and low pathogenicity avian influenza in poultry, as defined below, should be notified in accordance with the *Terrestrial Code*.

21. For the purposes of the *Terrestrial Code*, notifiable avian influenza in its notifiable form (NAI) is defined as an *infection* of *poultry* caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75 percent mortality) as described below. NAI viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) and low pathogenicity notifiable avian influenza (LPNAI):

- a) HPNAI viruses have an IVPI in 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;
- b) LPNAI are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.

2. *Poultry* is defined as 'all domesticated birds, including backyard *poultry*, used for the production of *meat* or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.

3. For the purposes of the *Terrestrial Code*, the *incubation period* for NAI shall be 21 days.

4. 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.

5. Antibodies to H5 or H7 subtype of NAI virus, which have been detected in *poultry* and are not a consequence of vaccination, have to be immediately investigated. In the case of isolated serological positive results, NAI *infection* may be ruled out on the basis of a thorough epidemiological and laboratory investigation that does not demonstrate further evidence of NAI *infection*.

Annex XXVII (contd)

6. The following defines the occurrence of *infection* with NAI virus:
- a) HPNAI virus has been isolated and identified as such or viral RNA specific for HPNAI has been detected in *poultry* or a product derived from *poultry*; or
 - b) LPNAI virus has been isolated and identified as such or viral RNA specific for LPNAI has been detected in *poultry* or a product derived from *poultry*.
7. For the purposes of the *Terrestrial Code*, 'NAI free establishment' means an *establishment* in which the *poultry* have shown no evidence of NAI *infection*, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.
8. Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.
9. 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 HPAI and LPAI virus 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* has been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.

Annex XXVII (contd)

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*, three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.
2. In the case of LPNAI *infections*, *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

A country, *zone* or *compartment* may be considered free from HPNAI when:

1. it has been shown that HPNAI *infection* in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, although its LPNAI status may be unknown; or
2. when, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33., it does not meet the criteria for freedom from NAI but any NAI virus detected has not been identified as HPNAI virus.

The *surveillance* may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, 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 XXVII (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 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 HPNAI free country, *zone* or *compartment* since they were hatched;

Annex XXVII (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 compartment

For hatching eggs of poultry

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

1. the eggs came from a NAI free country, *zone* or *compartment*;
2. the eggs were derived from parent *flocks* which had been kept in a NAI free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
3. 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 10.4.11.

Recommendations for importation from a HPNAI free country, zone or compartment

For hatching eggs of poultryAnnex XXVII (contd)

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

1. the eggs came from a HPNAI free country, *zone* or *compartment*;
2. the eggs were derived from parent *flocks* which had been kept in a NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the eggs have had their surfaces 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 NAIIV;
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 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 HPNAI free country, *zone* or *compartment*;
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 compartment

For poultry semen

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

1. showed no clinical sign of NAI on the day of semen collection;
2. were kept in a NAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.17.

Recommendations for the importation from a HPNAI free country, zone or compartment

For poultry semen

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

1. showed no clinical sign of HPNAI on the day of semen collection;
2. were kept in a HPNAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.18.

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:

Annex XXVII (contd)

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

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 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 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
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);

Annex XXVII (contd)

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.

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 in eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of AI virus 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 in meat

The following times for industry standard temperatures are suitable for the inactivation of AI virus 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.

Annex XXVII (contd)

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*.

Article 10.4.28.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:
 - a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease* or NAI *infection* should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspect *cases* of NAI to a *laboratory* for NAI diagnosis as described in the *Terrestrial Manual*;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
2. The NAI *surveillance* programme should:
 - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious *cases*. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of NAI to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected *cases* of NAI should be investigated immediately. As suspicion cannot 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.

Annex XXVII (contd)

An effective *surveillance* system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is NAIV. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from NAIV *infection* should, in consequence, provide details of the occurrence of suspicious *cases* and how they were investigated and dealt with. This should include

the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 10.4.29.

Surveillance strategies

1. Introduction

The target population for *surveillance* aimed at identification of *disease* and *infection* should cover all the susceptible *poultry* species within the country, *zone* or *compartment*. Active and passive *surveillance* for NAI should be ongoing. The frequency of active *surveillance* should be at least every 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 NAIIV *infection* 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 NAIIV *infection* 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 NAIIV *infection* in a specific *zone* or *compartment*, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone* or *compartment*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member 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/*infection* history and the different species in the target population.

Annex XXVII (contd)

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

The principles involved in *surveillance* for *disease/infection* are technically well defined. The design of *surveillance* programmes to prove the absence of NAIIV *infection/circulation* needs to be carefully followed to avoid producing results that are either insufficiently reliable, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

2. Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of NAI at the *flock* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory *disease* or a drop in egg production, is important for the early detection of NAIIV *infection*. In some cases, the only indication of LPNAIV *infection* may be a drop in feed consumption or egg production.

Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of NAI suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should have restrictions imposed upon it until NAI *infection* is ruled out.

Identification of suspect *flocks* is vital to the identification of sources of NAIIV and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that NAIIV 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*.

Annex XXVII (contd)

4. Serological surveillance

Serological *surveillance* aims at the detection of antibodies against NAIIV. Positive NAIIV antibody test results can have four possible causes:

- a) natural *infection* with NAIIV;
- 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 NAIIV 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 NAIIV *infection* is present in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

5. Virological and serological surveillance in vaccinated populations

The *surveillance* strategy is dependent on the type of vaccine used. The protection against AI is haemagglutinin subtype specific. Therefore, two broad vaccination strategies exist: 1) inactivated whole AI viruses, and 2) haemagglutinin expression-based vaccines.

In the case of vaccinated populations, the *surveillance* strategy should be based on virological and/or serological methods and clinical *surveillance*. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, AI virus antibody free birds and clearly and permanently identified. Sentinel birds should be used only if no appropriate *laboratory* procedures are available. The interpretation of serological results in the presence of vaccination is described in Article 10.4.33.

Article 10.4.30.

Documentation of NAI or HPNAI free status1. Members declaring freedom from NAI or HPNAI for the country, zone or compartment: additional surveillance procedures

In addition to the general conditions described in above mentioned articles, a Member declaring freedom from NAI or HPNAI for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter, to demonstrate absence of NAIV or HPNAIV *infection*, during the preceding 12 months in susceptible *poultry* populations (vaccinated and non-vaccinated). This requires the support of a *laboratory* able to undertake identification of NAIV or HPNAIV *infection* through virus detection and antibody tests described in the *Terrestrial Manual*. This *surveillance* may be targeted to *poultry* population at specific risks linked to the types of production, possible direct or indirect contact with wild birds, multi-age *flocks*, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding and poor biosecurity measures in place.

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

Vaccination to prevent the transmission of HPNAI virus may be part of a *disease* control programme. The level of *flock* immunity required to prevent transmission will depend on the *flock* size, composition (e.g. species) and density of the susceptible *poultry* population. It is therefore impossible to be prescriptive. The vaccine 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.

Article 10.4.31.

Countries, zones or compartments declaring that they have regained freedom from NAI or HPNAI following an outbreak: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member declaring that it has regained country, *zone* or *compartment* freedom from NAI or HPNAI virus *infection* should show evidence of an active *surveillance* programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*. This will require *surveillance* incorporating virus detection and antibody tests described in the *Terrestrial Manual*. The use of sentinel birds may facilitate the interpretation of *surveillance* results.

A Member declaring freedom of country, *zone* or *compartment* after an *outbreak* of NAI or HPNAI (with or without vaccination) should report the results of an active *surveillance* programme in which the NAI or HPNAI susceptible *poultry* population undergoes regular clinical examination and active *surveillance* planned and implemented according to the general conditions and methods described in these recommendations.

The *surveillance* should at least give the confidence that can be given by a randomized representative sample of the populations at risk.

Article 10.4.32.

NAI free establishments within HPNAI free compartments: additional surveillance procedures

The declaration of NAI free *establishments* requires the demonstration of absence of NAIV *infection*. Birds in these *establishments* should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these recommendations. The frequency of testing should be based on the risk of *infection* and at a maximum interval of 21 days.

Article 10.4.33.

The use and interpretation of serological and virus detection tests

Poultry infected with NAI virus produce antibodies to haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will not be covered in this chapter. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct and blocking ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI), ELISA and neutralization (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies to the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype AI viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of AI viruses.

EU comment

Since there are 16 haemagglutinin subtypes, figures 1 and 2 should be updated to "H 8-16" instead of "H 8-15".

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*.

Annex XXVII (contd)

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

1. The follow-up procedure in case of positive test results if vaccination is used

In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on NAI-vaccinated *poultry*. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated *animals*.

- a) Inactivated whole AI virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If *poultry* in the population have antibodies to NP/M and were vaccinated with inactivated whole AI virus vaccine, the following strategies should be applied:
 - i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating AI virus *infection*, specific HI tests should be performed to identify H5 or H7 AI virus *infection*;
 - ii) if vaccinated with inactivated whole AI virus vaccine containing homologous NA to field virus, the presence of antibodies to NSP could be indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins;
 - iii) if vaccinated with inactivated whole AI virus vaccine containing heterologous NA to field virus, presence of antibodies to the field virus NA or NSP would be indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.
- b) Haemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect AI *infection*. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

2. The follow-up procedure in case of positive test results indicative of infection for determination of infection due to HPNAI or LPNAI virus

The detection of antibodies indicative of a NAI virus *infection* as indicated in point a)i) above will result in the initiation of epidemiological and virological investigations to determine if the *infections* are due to HPNAI or LPNAI viruses.

Annex XXVII (contd)

Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of AI virus, by virus isolation and identification, and/or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting *infection* by AI virus and the method is described in the *Terrestrial Manual*. All AI virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens and/or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as HPNAI, LPNAI or LPAI (not notifiable) viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as HPNAI or LPNAI viruses. The antigen detection systems, because of low sensitivity, are best suited for screening clinical field *cases* for *infection* by Type A influenza virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

EU comment

The EU recommends that the sentence above beginning by "The antigen detection systems" be revised. Indeed, because of low sensitivity, negative results, even in the case of screening clinical field cases, would not mean that the virus is not present. This must also be reflected in the decision tree in figure 2.

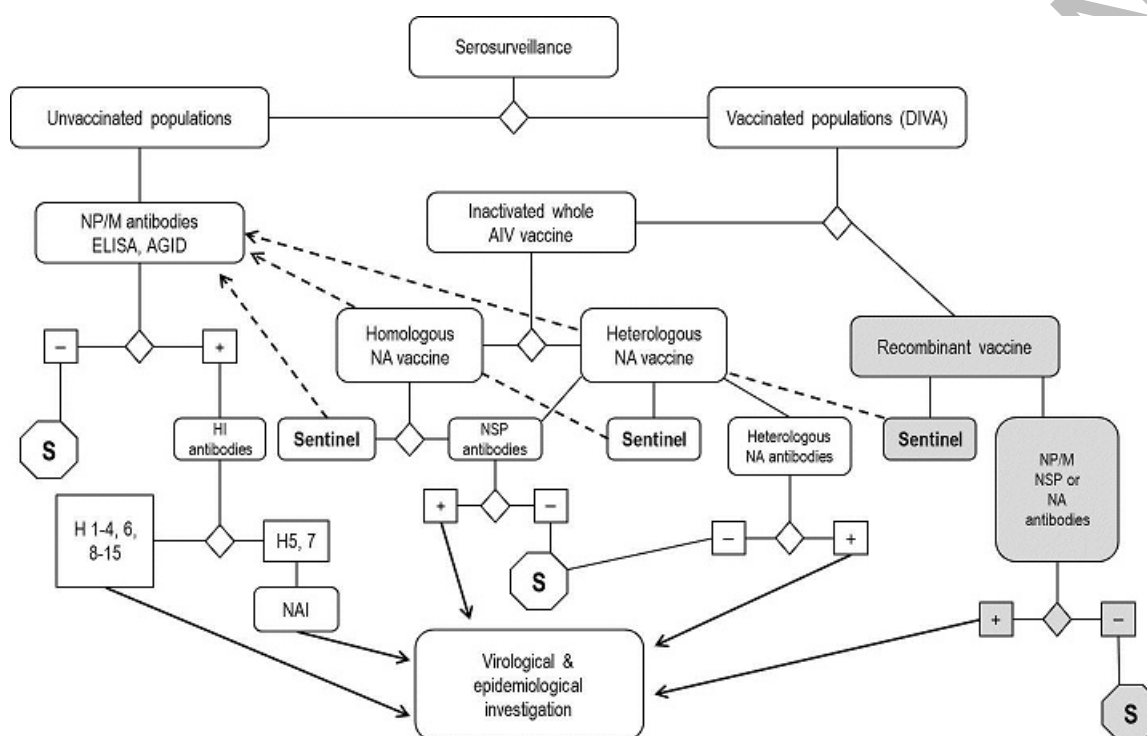
Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

- a) characterization of the existing production systems;
- b) results of clinical *surveillance* of the suspects and their cohorts;
- c) quantification of vaccinations performed on the affected sites;
- d) sanitary protocol and history of the affected *establishments*;
- e) control of *animal identification* and movements;
- f) other parameters of regional significance in historic NAIIV 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*.

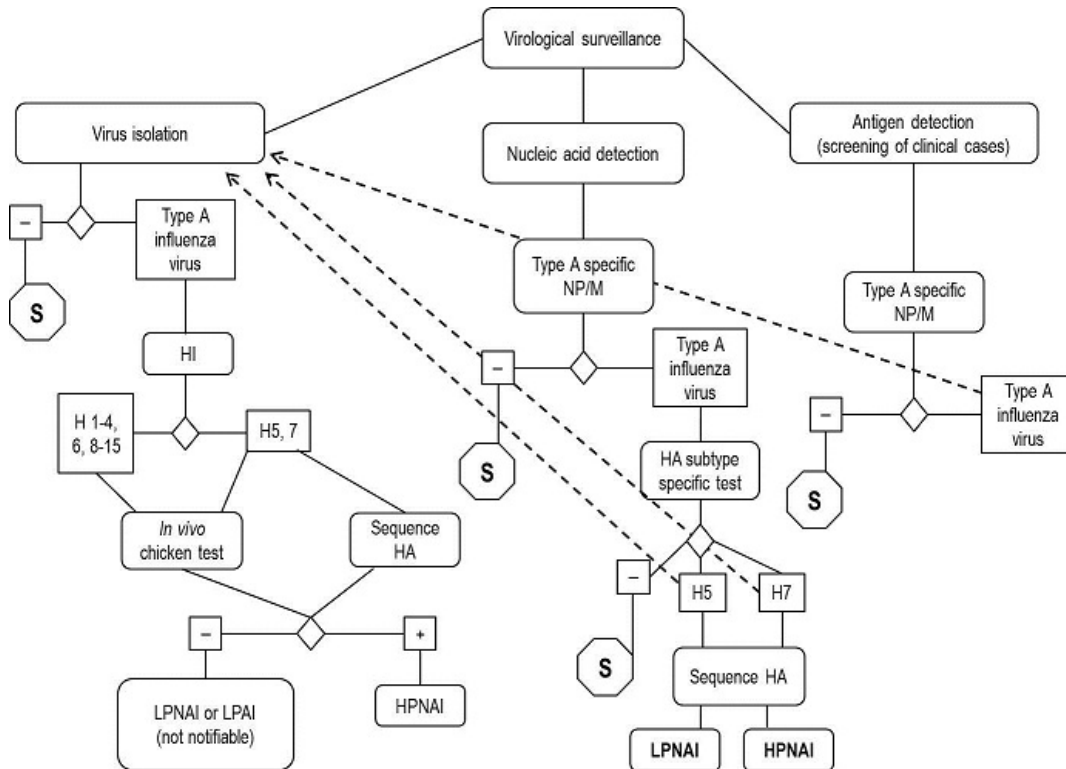
Fig. 1. Schematic representation of laboratory tests for determining evidence of NAI infection through or following serological surveys



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 NAI

Annex XXVII (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 NAI

— Text deleted

CHAPTER 12.1.

**INFECTION WITH AFRICAN HORSE
SICKNESS VIRUS****EU position**

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

The EU will carefully scrutinize how the notion of "adjacent" will be handled in practice by the *ad hoc* Group on Official Disease Status Recognition. The EU is willing to propose expertise for this group. Point 2 of Article 12.1.2, linked with Article 12.1.4 virtually imply that at the time of adoption of the chapter, all OIE Member Countries will be considered infected and will have to perform surveillance, except if they are "not adjacent", which is not defined either. Thus the role of the *ad hoc* Group and the guidance of the SCAD in interpreting the term "adjacent" will be crucial.

Article 12.1.1.

General provisions

For the purposes of the *Terrestrial Code*, the *infective period* for African horse sickness virus (AHSV) shall be 40 days for domestic horses. Although critical information is lacking for some species, this chapter applies to all equidae.

All countries or ~~zones neighbouring adjacent to, or considered to be at risk from,~~ a country or *zone* not having free status should determine their AHSV status from an ongoing *surveillance* programme. Throughout the chapter, *surveillance* is in all cases understood as being conducted as described in ~~Chapter 4.4.~~ Article 12.1.11. to 12.1.13.

The following defines a *case* of African horse sickness (AHS):

1. AHSV has been isolated and identified from an equid or a product derived from that equid; or
2. viral antigen or viral RNA specific to one or more of the serotypes of AHSV has been identified in samples from one or more equids showing clinical signs consistent with AHS, or epidemiologically linked to a suspected or confirmed *case*; or
3. serological evidence of active infection with AHSV by detection of seroconversion with production of antibodies to structural or nonstructural proteins of AHSV that are not a consequence of *vaccination* have been identified in one or more equids that either show clinical signs consistent with AHS, or epidemiologically linked to a suspected or confirmed *case*.

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

Article 12.1.2.

AHSV free country or zone

1. A country or *zone* may be considered free from AHSV when African horse sickness (AHS) is notifiable in the whole country, systematic *vaccination* is prohibited, importation of equids ~~equidae~~ and their semen, oocytes or embryos are carried out in accordance with this chapter, and either:

- a) historical freedom as described in Chapter 1.4. has demonstrated no evidence of AHSV in the country or *zone*; or
- b) the country or *zone* has not reported any *case* of AHS for at least 2 years and is not adjacent to a country or *zone* not having a free status an infected country or *zone*; or
- c) a *surveillance* programme has demonstrated no evidence of AHSV in the country or *zone* for at least 1224 months and includes a complete season of *vector* activity; or
- d) the country or *zone* has not reported any *case* of AHS for at least 40 days and a *surveillance* programme has demonstrated no evidence of *Culicoides* likely to be competent AHSV *vectors* for at least 2 years in the country or *zone*.
2. An AHS free country or *zone* adjacent to an infected country or *infected zone* should include a *zone* in which *surveillance* is conducted in accordance with Articles 12.1.11. to 12.1.13. *Animals* within this *zone* should be subjected to continuing *surveillance*. The boundaries of this *zone* should be clearly defined, and should take account of geographical and epidemiological factors that are relevant to AHS transmission.
23. An AHSV free country or *zone* will not lose its free status through the importation of vaccinated or seropositive equids equidae and their semen, oocytes or embryos from infected countries or *infected zones*, provided these imports are carried out in accordance with this chapter.
4. To qualify for inclusion in the existing list of AHSV free countries or *zones*, a Member should:
- a) have a record of regular and prompt animal disease reporting;
- b) send a declaration to the OIE stating:
- i) the section under paragraph 1 on the base of which the application is based ~~made~~;
- ii) no systematic routine *vaccination* against AHS has been carried out during the past 12 months in the country or *zone*;
- iii) equids equidae are imported in accordance with paragraph 3 above this chapter;
- c. supply documented evidence that:
- i) *surveillance* for both AHS and AHSV infection in accordance with Articles 12.1.11. to 12.1.13 is in operation applied;
- ii) regulatory measures for the early detection, prevention and control of AHS have been implemented.
5. The Member will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 4b)ii) and iii) and 4c) ii) above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1., and in particular, formally state that:
- 1a). there has been no *outbreak* of AHS during the past 12 months in the country or *zone*;
- 2b) no evidence of AHSV infection has been found during the past 12 months in the country or *zone*.

Article 12.1.3.

AHSV seasonally free zone

1. An AHSV seasonally free *zone* is a part of an infected country or an *infected zone* in which for part of a year, ongoing *surveillance* and monitoring consistently demonstrated neither evidence of AHSV transmission nor the evidence of the presence of adult *Culicoides* likely to be competent AHSV vectors.
2. AHS is notifiable in the whole country.
23. For the application of Articles 12.1.6., 12.1.8. and 12.1.9., the seasonally free period is:
 - a) taken to commence the day following the last evidence of AHSV transmission and of the cessation of activity of adult *Culicoides* likely to be competent AHSV vectors as demonstrated by an ongoing *surveillance* programme, and
 - b) taken to conclude either:
 - i) at least 40 days before the earliest date that historical data show AHSV activity has recommenced; or
 - ii) immediately when current climatic data or data from a *surveillance* and monitoring programme indicate an earlier resurgence of activity of adult *Culicoides* likely to be competent AHSV vectors.
34. An AHSV seasonally free *zone* will not lose its free status through the importation of vaccinated or seropositive equids *equidae* and their semen, oocytes or embryos from infected countries or *infected zones*, provided these imports are carried out in accordance with this chapter.

Article 12.1.4.

AHSV infected country or zone

For the purpose of this chapter, ~~a~~An AHSV infected country or *infected zone* is one that does not fulfil the requirements to qualify as either AHSV free country or *zone* or AHSV seasonally free *zone* in which the conditions of Article 12.1.2. or Article 12.1.3. do not apply.

Article 12.1.4.bis.

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

In the event of limited *outbreaks* within an AHS free country or *zone*, including within a *protection zone*, a single *containment zone*, which includes all *cases*, and should be large enough to contain any potentially infected vectors, can be established for the purpose of minimizing the impact on the entire country or *zone*. For this to be achieved, the *Veterinary Authority* should provide documented evidence that:

1. the *outbreaks* are limited based on the following factors:
 - a) immediately on suspicion, a rapid response including notification has been made;
 - b) standstill of movements of equids *equidae* has been imposed, and effective controls on the movement of equids *equidae* and their products mentioned specified in this chapter are in place;
 - c) epidemiological investigation (trace-back, trace-forward) has been completed;
 - d) the *infection* has been confirmed;
 - e) the *primary outbreak* and likely source of the *outbreak* has been identified;

- f) all cases have been shown to be epidemiologically linked;
- g) no new cases have been found in the containment zone within a minimum of two infectious-infective periods as defined in Article 12.1.1.;
- 2. the equids equidae within the containment zone should be clearly identifiable as belonging to the containment zone;
- 3. increased passive and targeted surveillance in accordance with Articles 12.1.11. to 12.1.13. has increased in the rest of the country or zone and has not detected any evidence of infection;
- 4. animal health measures that effectively prevent the spread of AHS to the rest of the country or zone, taking into consideration the establishment of a protection zone within the containment zone, the seasonal vector conditions and existing physical, geographical and ecological barriers;
- 5. ongoing surveillance in accordance with Articles 12.1.11. to 12.1.13. is in place in the containment zone.

The free status of the areas outside the containment zone is suspended pending the establishment of the containment zone in accordance with points 1 to 5 above. The free status of the areas outside the containment zone could be reinstated irrespective of the provisions of Article 12.1.4.tris, once the containment zone is recognised by the OIE.

The recovery of the AHS free status of the containment zone should follow the provisions of Article 12.1.4.tris.

Article 12.1.4.tris.

Recovery of free status

When an AHS outbreak occurs in an AHS free country or zone, to regain the free status, the following provisions of Article 12.1.2. apply ~~waiting period required to regain the status of AHS free country or zone, irrespective of whether emergency vaccination has been applied:~~

- 1. If emergency vaccination is not carried out, the conditions of Article 12.1.2. paragraph 1b), 1c) or 1d) apply; or
- 2. if emergency vaccination is carried out, a waiting period of 24 months after the last case and completion of the emergency vaccination has elapsed, during which surveillance applied in accordance with Articles 12.1.11. to 12.1.13. has shown no evidence of AHSV infection.

Article 12.1.5.

Recommendations for importation from AHSV free countries ~~that are neither neighbouring nor considered to be at risk from an AHSV infected country or infected zones~~

for equidae equids

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

- 1. showed no clinical sign of AHS on the day of shipment;
- 2. have not been vaccinated against AHS within the last 40 days;
- 3. were kept in an AHSV free country or zone since birth or for at least 40 days prior to shipment;
- 4. either:

- a) did not transit through an ~~infected country or infected zone~~ during transportation to the place of shipment; or
- b) were protected from attacks ~~by~~ from *Culicoides* at all times when transiting through an ~~infected country or infected zone~~.

Article 12.1.6.

Recommendations for importation from ~~AHSV free countries or free zones or from AHSV seasonally free zones (during the seasonally free period) that are neighbouring or are considered to be at risk from an AHSV infected country or infected zone~~

for equidae equids

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

1. showed no clinical signs of AHS on the day of shipment;
2. have not been vaccinated against AHS within the last 40 days;
3. and either
 - a. were kept in an AHSV ~~free country, free zone or~~ seasonally free ~~zone~~ during the seasonally free period since birth or for at least 40 days prior to shipment; or
 - 4b. ~~in a country or zone considered to be at risk, were held in quarantine isolation in a vector-protected establishment for at least 40 days prior to shipment and protected at all times from attacks by Culicoides; and~~
 - ai. for a period of at least 28 days and a serological test according to the *Terrestrial Manual* to detect antibodies to the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the vector protected establishment quarantine station; or
 - bii. for a period of at least 40 days and serological tests according to the *Terrestrial Manual* to detect antibodies against AHSV were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after introduction into the vector protected establishment quarantine station; or
 - ei. for a period of at least 14 days and an agent identification tests according to the *Terrestrial Manual* ~~were was~~ carried out with a negative results on a blood samples collected ~~on two occasions with an interval of not less than 14 days between collection, the first sample being collected at least 7 days after introduction into the vector-protected establishment quarantine station~~;
54. were protected from attacks ~~by~~ from *Culicoides* at all times ~~during transportation (including to and at the place of shipment)~~ when transiting through an infected zone.

Annex XXVIII (contd)

Article 12.1.7.

Recommendations for importation from AHSV infected countries or zonesfor equidae equids

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

1. showed no clinical sign of AHS on the day of shipment;
2. have not been vaccinated against AHS within the last 40 days;
3. were held ~~continuously during the quarantine period of at least 40 days, in isolation in a vector-proof protected establishment quarantine station and protected at all times from attacks by *Culicoides*; and~~
 - a) for a period of at least 28 days and a serological test according to the *Terrestrial Manual* to detect antibodies to the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the ~~vector-protected establishment quarantine station~~;
or
 - b) for a period of at least 40 days and serological tests according to the *Terrestrial Manual* to detect antibodies against AHSV were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after introduction into the ~~vector-protected establishment quarantine station~~;
or
 - c) for a period of at least 14 days and an agent identification tests according to the *Terrestrial Manual* ~~were was~~ carried out with a negative results on a blood samples collected ~~on two occasions with an interval of not less than 14 days between collection, the first sample being collected at least 7 days after introduction into the~~ ~~vector-protected establishment quarantine station~~;
or
 - d) for a period of at least 40 days and were vaccinated, at least 40 days before shipment, in accordance with the *Terrestrial Manual* against all serotypes whose presence in the source population has been demonstrated through a surveillance programme in accordance with Articles 12.1.12 and 12.1.13, and were identified in the accompanying certification as having been vaccinated;
4. were protected from attacks by *Culicoides* at all times during transportation (including transportation to and at the *place of shipment*).

Article 12.1.8.

Recommendations for the importation of equid equine semen

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

1. showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;
2. had not been immunised against AHS with a live attenuated vaccine within 40 days prior to the day of collection;

3. were either:
 - a) kept in an AHSV free country or free *zone* or from an AHSV seasonally free *zone* (during the seasonally free period) for at least 40 days before commencement of, and during collection of the semen, or
 - b) kept in an AHSV free vector-~~proof~~ protected *artificial insemination centre* throughout the collection period, and subjected to either:
 - i) a serological test according to the *Terrestrial Manual* to detect antibody to the AHSV group, carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of semen; or
 - ii) agent identification tests according to the *Terrestrial Manual* carried out with negative results on blood samples collected at commencement and conclusion of, and at least every 7 days, during semen collection for this consignment.

Article 12.1.9.

Recommendations for the importation of *in vivo* derived equine equid embryos ~~or~~ oocytes

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

1. the donor animals:
 - a) showed no clinical sign of AHS on the day of collection of the embryos ~~or~~ oocytes and for the following 40 days;
 - b) had not been immunised against AHS with a live attenuated vaccine within 40 days prior to the day of collection;
 - c) were either:
 - i) kept in an AHSV free country or free *zone* or from an AHSV seasonally free *zone* (during the seasonally free period) for at least 40 days before commencement of, and during collection of the embryos ~~or~~ oocytes, or
 - ii) kept in an AHSV free vector-~~proof~~ protected *collection centre* throughout the collection period, and subjected to either:
 - a serological test according to the *Terrestrial Manual* to detect antibody to the AHSV group carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of embryos ~~or~~ oocytes; or
 - agent identification tests according to the *Terrestrial Manual* carried out with negative results on blood samples collected at commencement and conclusion of, and at least every 7 days during embryos ~~or~~ oocytes collection for this consignment;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7. or Chapter 4.9., as relevant;
3. semen used to fertilize the oocytes, complies at least with the requirements in Article 12.1.8.

Annex XXVIII (contd)

Article 12.1.10.

Protecting animals from *Culicoides* attack**1. Vector-protected establishment or facility**

The *establishment* or facility should be approved by the Veterinary Authority and the means of protection of the *establishment* or facility should at least comprise the following;

- a) Appropriate physical barriers at entry and exit points, for example double-door entry-exit system;
- b) openings of the building are vector screened with mesh of appropriate gauge aperture size (under study) impregnated regularly with an approved insecticide according to manufacturers' instruction;
- c) vector surveillance and control within and around the building;
- d) measures to limit breeding sites for vectors in vicinity of the establishment or facility;
- e) Standard Operating Procedure, including description of back-up and alarm systems, for operation of the establishment or facility and transport of horses to the place of loading.

2. During transportation

When transporting equids through AHSV infected countries or AHSV *infected zones*, Veterinary Authorities should require strategies to protect animals from attacks by *Culicoides* during transport, taking into account the local ecology of the vector.

a) Transport by road:

Potential *risk management* strategies include a combination of:

- 4i. treating animals with chemical repellents prior to and during transportation, in sanitized vehicles treated with appropriate residual contact insecticide;
- 2ii. loading, transporting and unloading animals at times of low vector activity (i.e. bright sunshine and low temperature);
- 3iii. ensuring vehicles do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;
- 4iv. darkening the interior of the vehicle, for example by covering the roof and/or sides of vehicles with shade cloth;
- 5v. monitoring for vectors at common stopping and offloading points to gain information on seasonal variations;
- 6vi. using historical, ongoing and/or AHS modelling information to identify low risk ports and transport routes.

b) Transport by air:

Prior to loading the equids, the crates, containers or jetstalls are sprayed with an insecticide approved in the country of dispatch.

Crates, containers or jet stalls in which equidae equids are being transported and the cargo hold of the aircraft must be sprayed with an approved insecticide just after the doors to the aircraft are closed and prior to takeoff, or immediately prior to the closing of the aircraft doors after loading.

In addition, during any stop over in countries or zones not free of AHS, prior to, or immediately after the opening of any aircraft door and until all doors are closed prior to takeoff, netting of appropriate aperture gauge size (under study) impregnated with an approved insecticide must be placed over all crates, containers or jetstalls.

Article 12.1.11.

Surveillance: introduction

Articles 12.1.11. to 12.1.13. define the principles and provide a ~~guide~~ guidance on the *surveillance* for AHS, complementary to Chapters 1.4. ~~and, for vectors, complementary to Chapter 1.5,~~ applicable to Members seeking to determine their AHSV status. ~~This may be for the entire country or zone. Guidance for Members seeking free status following an outbreak and for the maintenance of AHS status is also provided.~~

AHS is a *vector-borne infection* transmitted by a limited number of species of *Culicoides* insects. Unlike the related bluetongue virus, AHSV is so far geographically restricted to sub Saharan Africa with periodic excursions into North Africa, southwest Europe, the Middle East and adjacent regions of Asia. An important component of AHSV epidemiology is vectorial capacity which provides a measure of *disease risk* that incorporates *vector* competence, abundance, seasonal incidence, biting rates, survival rates and the extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context.

According to this chapter, a Member demonstrating freedom from AHSV infection for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter. This requires the support of a *laboratory* able to undertake identification of AHSV infection through the virus detection and antibody tests described in the *Terrestrial Manual*.

Susceptible ~~captive wild, feral and wild equid~~ equine populations should be included in the *surveillance* programme.

For the purposes of *surveillance*, a *case* refers to an equid infected with AHSV.

The purpose of *surveillance* is to determine if a country or *zone* is free from AHSV or if a *zone* is seasonally free from AHSV. *Surveillance* deals not only with the occurrence of clinical signs caused by AHSV, but also with evidence of infection with AHSV in the absence of clinical signs.

Annex XXVIII (contd)

The following defines the occurrence of AHSV infection:

1. AHSV has been isolated and identified as such from an equid or a product derived from that equid, or
2. viral antigen or viral RNA specific to one or more of the serotypes of AHSV has been identified in samples from one or more equids showing clinical signs consistent with AHS, or epidemiologically linked to a confirmed or suspected *case*, or
3. serological evidence of active infection with AHSV by detection of seroconversion with production of antibodies to structural or nonstructural proteins of AHSV that are not a consequence of *vaccination* have been identified in one or more equids that either show clinical signs consistent with AHS, or epidemiologically linked to a suspected *case*.

Article 12.1.12.

Surveillance: general conditions and methods

1. A *surveillance* system should be under the responsibility of the *Veterinary Authority*. In particular the following should be in place:
 - a) a formal and ongoing system for detecting and investigating *outbreaks of disease*;
 - b) a procedure for the rapid collection and transport of samples from suspect *cases* of AHS to a *laboratory* for AHS diagnosis as described in the *Terrestrial Manual*;
 - c) a system for recording, managing and analysing diagnostic, epidemiologic and *surveillance* data.
2. The AHS *surveillance* programme should:
 - a) in a country ~~or~~ *zone*, free or seasonally free, include an early warning system for reporting suspicious *cases*. Persons who have regular contact with equids, as well as diagnosticians, should report promptly any suspicion of AHS to the *Veterinary Authority*. An effective *surveillance* system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is AHS. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected *cases* of AHS should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*;
 - b) conduct random or targeted serological and virological *surveillance* appropriate to the *infection* status of the country or *zone* in accordance with Chapter 1.4.

Article 12.1.13.

Surveillance strategies

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

Annex XXVIII (contd)

A Member should justify the *surveillance* strategy chosen as appropriate to detect the presence of AHSV infection in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. horses). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. donkeys).

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

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

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size, expected prevalence and diagnostic sensitivity of the tests determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence, in particular, needs to be based on the prevailing or historical epidemiological situation.

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

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

The principles for *surveillance* for *disease* ~~+~~ or *infection* are technically well defined. *Surveillance* programmes to prove the absence of AHSV infection ~~+~~ or circulation, need to be carefully designed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

1. Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of AHS in equids particularly during a newly introduced *infection*. In horses, clinical signs may include pyrexia, oedema, hyperaemia of mucosal membranes and dyspnoea.

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

2. Serological surveillance

Serological *surveillance* of equine ~~equid~~ populations is an important tool to confirm absence of AHSV transmission in a country or *zone*. The species tested should reflect the local epidemiology of AHSV infection, and the equine species available. Management variables that may reduce the likelihood of *infection*, such as the use of insecticides and animal housing, should be taken into account when selecting equids to be included in the *surveillance* system.

Annex XXVIII (contd)

Samples should be examined for antibodies against AHSV using tests prescribed in the *Terrestrial Manual*. Positive AHSV antibody tests results can have four possible causes:

- a) natural *infection* with AHSV;
- b) *vaccination* against AHSV;
- c) maternal antibodies;
- d) positive results due to the lack of specificity of the test.

It may be possible to use sera collected for other purposes for AHSV *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of AHSV infection should not be compromised.

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

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

Serological *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with an infected country or *infected zone*, based upon geography, climate, history of *infection* and other relevant factors. The *surveillance* should be carried out over a distance of at least 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of AHSV. An AHSV free country or *zone* may be protected from an adjacent infected country or *infected zone* by a *protection zone*.

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

3. Virological surveillance

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

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

- a) to identify virus circulation in at risk populations;
- b) to confirm clinically suspect *cases*;
- c) to follow up positive serological results;
- d) to better characterize the genotype of circulating virus in a country or *zone*.

4. Sentinel animals

Sentinel animals are a form of targeted *surveillance* with a prospective study design. They comprise groups of unexposed equids that are not vaccinated and are managed at fixed locations and observed and sampled regularly to detect new AHSV infections.

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

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

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting AHSV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid confounding factors sentinel groups should comprise animals selected to be of similar age and susceptibility to AHSV infection. The only feature distinguishing groups of sentinels should be their geographical location. Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

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

Definitive information on AHSV circulating in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required sentinels should be sampled at sufficiently frequent intervals to ensure that some samples are collected during the period of viraemia.

5. Vector surveillance

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

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

Annex XXVIII (contd)

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

Vector surveillance should be based on scientific sampling techniques. The choice of the number and types of traps to be used in *vector surveillance* and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

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

The use of a *vector surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low *vector infection* rates mean that such detections can be rare. Other *surveillance* strategies are preferred to detect virus circulation.

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CHAPTER 12.6.

INFECTION WITH EQUINE INFLUENZA VIRUS**EU position**

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

Article 12.6.1.

General provisions

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

This chapter deals not only with the occurrence of clinical signs caused by equine influenza virus (EIV), but also with the presence of *infection* with EIV in the absence of clinical signs.

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

For the purposes of the *Terrestrial Code*, the *infective period* for EI shall be 21 days.

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 12.6.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the EI status of the equine population of the *exporting country, zone or compartment*.

Article 12.6.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any EIV related conditions, regardless of the EI status of the equine population of the *exporting country, zone or compartment*:

1. equine semen;
2. *in vivo* derived equine embryos collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant (under study).

Article 12.6.3.

Determination of the EI status of a country, a zone or a compartment

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

1. the outcome of a *risk assessment* identifying all risk factors and their historic relevance;
2. whether EI is notifiable in the whole country, an on-going EI awareness programme is in place, and all notified suspect occurrences of EI are subjected to field and, where applicable, *laboratory* investigations;

- appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in domestic equids.

Article 12.6.4.

EI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from EI provided the *disease* is notifiable in the whole country and it shows evidence, through an effective *surveillance* programme, planned and implemented according to the general principles in Chapter 1.4., that no *case* of EI occurred in the past two years. The *surveillance* may need to be adapted to parts of the country, *zone* or *compartment* depending on historical or geographical factors, industry structure, population data, movements of equids within and into the country, *zone* or *compartment*, *wild equine* equid populations or proximity to recent *outbreaks*.

A country, *zone* or *compartment* seeking freedom from EI, in which *vaccination* is practised, should also demonstrate that EIV has not been circulating in the population of domestic *feral* and *wild* equids during the past 12 months, through *surveillance*, in accordance with Chapter 1.4. In a country in which *vaccination* is not practised, *surveillance* may be conducted using serological testing alone. In countries where *vaccination* is practised, the *surveillance* should include agent identification methods described in the *Terrestrial Manual* for evidence of *infection*.

A country, *zone* or *compartment* seeking freedom from EI should apply appropriate movement controls to minimise the risk of introduction of EIV in accordance with this chapter.

If an *outbreak* of clinical EI occurs in a previously free country, *zone* or *compartment*, free status can be regained 12 months after the last clinical *case*, providing that *surveillance* for evidence of *infection* has been carried out during that twelve-month period in accordance with Chapter 1.4.

Article 12.6.5.

Recommendations for the importation of domestic equids for immediate slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the domestic equids showed no clinical sign of EI on the day of shipment.

Article 12.6.6.

Recommendations for the importation of domestic equids for unrestricted movement

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

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

OR

- came from a country, *zone* or *compartment* not known to be free from EI, were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and
- were immunised according to the recommendations of the manufacturer's instructions with a vaccine complying with the standards described in the *Terrestrial Manual* between 21 and 90 days before shipment either with a primary course or a booster; information on their *vaccination* status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12.

Annex XXIX (contd)

For additional security, countries that are free of EI or undertaking an eradication programme may also request that the domestic equids were tested negative for EIV by an agent identification test for EI described in the *Terrestrial Manual* conducted on samples collected on two occasions at 7 to 14 days and less than 5 days before shipment.

Article 12.6.7.

Recommendations for the importation of domestic equids which will be kept in isolation (see Article 12.6.1.)

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

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

OR

2. showed no clinical sign of EI in any premises in which the domestic equids had been resident for the 21 days prior to shipment nor on the day of shipment; and
3. were immunised according to the recommendations of the manufacturer's instructions with a vaccine complying with the standards described in the *Terrestrial Manual*; information on their *vaccination* status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12.

Article 12.6.8.

Recommendations for the importation of fresh meat of equids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *fresh meat* came from equids which had been subjected to ante- and post-mortem inspections as described in Chapter 6.2.

 — Text deleted

CHAPTER 12.9.

INFECTION WITH EQUINE VIRAL ARTERITIS VIRUS**EU position****The EU thanks the OIE and supports the adoption of this modified chapter.**

Article 12.9.1.

General provisions

For the purposes of the *Terrestrial Code*, equine viral arteritis (EVA) is defined as an *infection* of domestic equids and feral members of the family, Equidae with equine arteritis virus (EAV).

This chapter deals not only with the occurrence of clinical signs caused by equine arteritis virus (EAV), but also with the presence of *infection* with EAV in the absence of clinical signs. For the purposes of this chapter, isolation is defined as the separation of domestic equids from those of a different EVA health status, utilising appropriate biosecurity measures, with the objective of preventing the transmission of *infection*.

The *infective period* for equine viral arteritis (EVA) shall be 28 days for all categories of equids ~~equine~~ except sexually mature stallion where the *infective period* may be for the life of the *animal*. Because the *infective period* may be extended in the case of virus shedding in semen, the status of seropositive stallions should be checked to ensure that they do not shed virus in their semen.

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

Article 12.9.2.

Recommendations for the importation of uncastrated male equid ~~equines~~

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animals* showed no clinical sign of EVA on the day of shipment and during the 28 days prior to shipment and met one of the following requirements:

1. were isolated for the 28 days prior to shipment and were subjected, to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on a single blood sample collected during the 21 days prior to shipment with negative result; or
2. were subjected between six and nine months of age to a test for EVA, as prescribed in the *Terrestrial Manual*;

EITHER:

a) with a negative result,

OR

- b) ~~with a positive result, followed at least 14 days later by a second test showing~~ carried out on two blood samples collected at least 14 days apart with a stable or decreasing titre; and were; immediately vaccinated ~~for~~ against EVA and regularly revaccinated according to the recommendations of the manufacturer's instructions; or
3. met the following requirements:
- were isolated; and
 - not earlier than seven days of commencing isolation were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results; and
 - were then immediately vaccinated; and
 - were kept separated from other equids equidae for 21 days following *vaccination*; and
 - were revaccinated regularly according to the recommendations of the manufacturer's instructions; or
4. have been subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on a blood sample with positive results and then: either
- were subsequently test mated to two mares within six months prior to shipment which were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or
 - were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected during the six months prior to shipment; or
 - were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within six months after the blood sample was tested, then immediately vaccinated, and revaccinated regularly in accordance with the recommendations of the manufacturer's instructions.

Article 12.9.3.

Recommendations for the importation of equids equines other than uncastrated males

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animals* showed no clinical sign of EVA on the day of shipment ~~and were kept in an establishment where no animals have shown any signs of EVA for the 28 days prior to shipment~~; and

EITHER

- were kept in an *establishment* where no *animals* have shown any signs of EVA for the 28 days prior to shipment; and
 - were subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on blood samples collected either once within 21 days prior to shipment with negative result, or on two occasions at least 14 days apart within 28 days prior to shipment, which demonstrated stable or declining antibody titres; or
 - were regularly vaccinated according to the recommendations of the manufacturer's instructions;

OR

- were isolated for the 28 days prior to shipment and during this period the *animals* showed no sign of EVA.

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Article 12.9.4.

Recommendations for the importation of equine semen

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the animal donors were kept for the 28 days prior to semen collection in an *establishment* where no equid equine has shown any clinical sign of EVA during that period and showed no clinical sign of EVA on the day of semen collection; and

1. were subjected between six and nine months of age to a test for EVA, as prescribed in the *Terrestrial Manual*;

Either:

- a) with a negative result,

OR

- b) with a positive result, followed at least 14 days later by a second test showing on two blood samples collected at least 14 days apart with a stable or decreasing titre;

and were immediately vaccinated for EVA and regularly revaccinated according to the recommendations of the manufacturer's instructions; or

2. were isolated and not earlier than seven days of commencing isolation were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, immediately vaccinated for EVA, kept for 21 days following vaccination separated from other equids equidae and regularly revaccinated according to the recommendations of the manufacturer's instructions; or
3. were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results within 14 days prior to semen collection, and had been separated from other equids equidae not of an equivalent EVA status for 14 days prior to blood sampling until the end of semen collection; or
4. have been subjected to a test for EVA as prescribed in the *Terrestrial Manual* carried out on a blood sample with positive results and then: either
 - a) were subsequently test mated to two mares within six months prior to semen collection, which were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* with negative results on blood samples collected at the time of test mating and again 28 days after the test mating; or
 - b) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within six months prior to collection of the semen to be exported; or
 - c) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within six months after the blood sample was collected tested, then immediately vaccinated, and revaccinated regularly; or

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5. for frozen semen, were subjected with negative results either:
- a) to a test for EVA as prescribed in the *Terrestrial Manual* carried out on a blood sample taken not earlier than 14 days and not later than 12 months after the collection of the semen for export; or
 - b) to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* carried out on an aliquot of the semen collected immediately prior to processing or on an aliquot of semen collected within 14 to 30 days after the first collection of the semen to be exported.

— Text deleted

**FUTURE WORK PROGRAMME FOR THE
TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

EU comments

The EU would encourage the TAHSC to take up work on an introductory chapter to the Code (see also general comments).

Moreover, the EU would like the OIE TAHSC to include in its work programme a partial revision of the Chapter 14.9 of the Terrestrial Code regarding Scrapie. This request is justified by the following elements of epidemiological, scientific or trade relevance.

1. Like BSE, scrapie is a prion disease characterized by a long incubation period, a lack of approved in vivo diagnostic method, and a real potential for sporadic occurrence. It therefore appears that, just as for BSE, the notion of negligible risk should be preferred to scrapie freedom. The EU proposes that the articles 14.9.3, 14.9.4 and 14.9.5 especially, as well as the rest of chapter 14.9 where necessary, be amended accordingly.

2. Article 14.9.5, part 2 lays down that the subsequent "conditions must be complied with for at least seven years" to allow an establishment the possibility to be granted a scrapie free status (or rather "negligible scrapie risk status", see previous point). The EU is of the opinion that this seven years constraint is disproportionate and unduly restrictive. It appears that it may have been chosen by analogy with the BSE chapter provisions. However, whereas the usual incubation period is 4-5 years with BSE, it is only of approximately 2 to 3 years in scrapie, depending on the genetic susceptibility profile of the animals; the breeding and production cycles are also much shorter in small ruminants than in cattle. We therefore propose that consideration should be given to amend the code to shorten the period of seven years.

3. Article 14.9.6 lays down the same recommendations for importation from countries or zones not considered free from scrapie of sheep and goats for breeding as well as for rearing. Whereas these stringent provisions make sense for breeding animals (except for the point raised above under paragraph 2), the EU is of the opinion that applying the same conditions to animals intended for rearing, including fattening for a limited period before slaughter, is overly restrictive and disproportionate. Based on the fact that animals for fattening will not breed or give birth, the EU considers that article 14.9.6 should cover breeding and rearing animals other than for fattening, and that importation of animals for fattening should be covered by the provisions of article 14.9.7 presently covering animals for slaughter.

4. Article 14.9.8 and 14.9.9: EFSA opinion of 6 January 2010 (Scientific Opinion on Risk of transmission of TSEs via semen and embryo transfer in small ruminants (sheep and goats) concluded that the risk of TSE transmission associated with semen and embryos collected from Classical Scrapie incubating sheep and goats ranges from negligible to low. The EU therefore proposes the following:

- to modify the introductory phrase of Article 14.9.9 to cover all embryos, not only in vivo derived sheep embryos.
- to amend article 14.9.8 to apply to semen similar provisions as laid down in 14.9.9 for embryos.

5. It is scientifically recognised since several years that some polymorphisms of the PRNP gene are associated with differences in the phenotypic expression of prion diseases in sheep (incubation period, physiopathology and clinical signs). This association has led to the implementation at EU level of eradication / control measures in scrapie infected flocks based on a selective elimination of genetically susceptible animals and the exemption of application of some regular movement restrictions to the genetically resistant animals. The appropriateness of these measures has been confirmed in the EFSA opinion on the breeding program for TSE resistance in sheep of 13 July 2006. The EU would like to see chapter 14.9 acknowledge the genetic susceptibility/resistance to scrapie in sheep as a valid additional tool to manage the risk associated with movements of live sheep and their germinal products.

Topic		
Action	How to be managed	Status (Feb 2012)
Restructuring of the <i>Terrestrial Code</i>		
Harmonisation of <i>Terrestrial</i> and <i>Aquatic Codes</i>		
1. Work with AAHSC towards harmonisation, as appropriate, of the Codes	TAHSC & ITD	1. Ongoing
2. CH rename by disease agents		2. Ongoing
Listed disease		
Criteria for listing	TAHSC & SCAD & AHG	Revised CH for adoption
CWD		
Decision on listing (new CH)	TAHSC & SCAD	On hold
PRRS		
New CH	SCAD	Pending new info on diagnostics
Evaluation of VS and OIE PVS pathway		
Inclusion of legislation aspect	TAHSC & ITD	Modified new CH for adoption
CSF		
Official recognition CSF	SCAD/AHG	Pending production of draft + Q
AHS		
Official recognition	SCAD&TAHSC	Revised CH & Q for adoption
FMD		
Revise chapter including wildlife	SCAD&TAHSC	Pending production of draft CH Q (official control programme) for adoption
RP		
Global freedom era	SCAD&TAHSC&AHG	Pending development of the Joint FAO/OIE Advisory Committee on Rinderpest
Other <i>Terrestrial Code</i> texts in need of revision		
Pet food certificate CH	TAHSC	On hold
Update CH on Brucellosis	AHG/SCAD&TAHSC	MC to AHG
Update CH on Rabies	SCAD&TAHSC	Revised CH for adoption
Update CH on Bee diseases	AHG/SCAD&TAHSC	Revised CH 4.14. for adoption Others to be reviewed by AHG

Update CH on PPR	SCAD and TAHSC	MC to AHG
CH on EHD	SCAD and TAHSC	On hold
Update CH on SVD	SCAD&TAHSC	Pending SCAD revision
Update CH on ASF(SURV)	SCAD	Pending SCAD revision
CH on Paratuberculosis	BSC (diagnostic test) & STD (guidance document)	On hold pending further development in diagnostics

Animal production food safety		
1. Salmonellosis Update biosecurity procedures CH	APFSWG & AHG	1. Modified draft CH proposed for adoption
2. Zoonotic parasitic diseases a. <i>Trichinella</i> spp. b. Echinococcosis c. <i>Taenia solium</i>	AHG & TAHSC	a. MC to AHG b. revised text for MC c. On hold
Animal welfare		
New texts: 1. Laboratory animals 2. Livestock production systems a. Broiler b. General principles c. Beef cattle	AWWG & AHGs TAHSC supervision	1. Modified CH proposed for adoption (new article on transport and new model certificate) 2. a. On hold b. Draft article 7.1.4. for adoption c. Draft CH for adoption
Horse diseases		
Brainstorming meeting in March 2012	SCAD&TAHSC	
Collection and processing of equine semen		
Convene an <i>ad hoc</i> Group		
OIE policy on wildlife		
Draft policy	TAHSC with WG on Wildlife & SCAD	MC to be reviewed
Invasive alien species		
Guidance on RA	TAHSC&SCAD	Guidelines to be on the OIE website
Compartmentalisation		
Generic Checklist	TAHSC&SCAD	to be reviewed
Veterinary products (AMR)		
1. Updating CH 6.7 & 6.8. 2. Updating CH6.9 3. Updating CH 6.10	TAHSC&SCAD&AHG	1. Draft texts to adoption 2. MC to AHG 3. Proposed for MC

Note: MC; Member comments, CH: chapter, Q: questionnaire, SURV: surveillance, ITD: International Trade Department, S&T Dept: Scientific & Technical Department

UNOFFICIAL VERSION

ITEM, ANNEX, CHAPTER NUMBERS AND CURRENT STATUS

Item	Annex	Chapter	Title	Provided for comments	GS80
1			General comments		D
3	3		Glossary		A
4	4	1.1.	Notification of diseases and epidemiological information		A
	5	1.2.	Criteria for listing diseases	Feb 11	A
5	6	1.4.	Animal health surveillance		A
17, 26	24	1.6.	Procedures for self declaration and for official recognition by the OIE		A
6	7	2.1.	Import risk analysis	Sep 11	A
7	8	3.2.	Evaluation of veterinary services	Sep 11	A
	9	3.3.	Communication	Sep 11	A
	10	3.4.	Veterinary legislation	Sep 10	A
	30		Report of <i>ad hoc</i> Group on veterinary legislation		I
35	11	4.4.	Application of compartmentalisation		A
			Generic checklist		
8	12	4.6.	Collection and processing of bovine, small ruminant and porcine semen	Sep 11	A
		4.7.	Collection and processing of <i>in vivo</i> derived embryos from livestock and horses		
9	13	5.3.	OIE procedures relevant to the SPS Agreement of the WTO		A
10	14	6.4.	Biosecurity procedures in poultry production	Sep 11	A
	15	13.2.	Rabbit haemorrhagic disease	Sep 11	A
11	16	6.7.	Harmonisation of national antimicrobial resistance surveillance and monitoring programmes	Feb 11	A
	17	6.8.	Monitoring of the quantities of antimicrobials used in animal husbandry		
		6.9.	Responsible and prudent use of antimicrobial	Sep 11	E
	31	6.10.	Risk assessment for antimicrobial resistance		C
12	18	6.11.	Zoonoses transmissible from non-human primates		A
13	19	7.1.	Introduction to the recommendation for AW (General principle for production system)	Sep 11	A
	20	7.X.	Beef cattle production system	Sep09	A
	21	5.13	Model health certificate for Laboratory animals	Sep 11	A
	22	7.8.	Use of animals in research and education	Sep 11	A
	32		AWWG work programme		I
14	23	8.2.	Aujeszky's disease	Sep 11	A
15		8.3.	Bluetongue	Sep 11	E
16	33	8.4.	Echinococcosis (<i>E. granulosus</i>)	Feb 11	C
		NEW	Echinococcosis (<i>E. multilocularis</i>)		C
		8.13.	<i>Trichinella</i> infection	Feb 11	E
	34		Report of <i>ad hoc</i> Group on Zoonotic Parasites		I

Annex XXXVII (contd)

Item	Annex	Chapter	Title	Provided for comments	GS80	
17		8.5.	Foot and mouth disease		E	
	24	1.6.	Questionnaire on foot and mouth disease (Article 1.6.7.)		A	
18	25	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>)	Sep10	A	
19		8.12.	Rinderpest	Sep 11	E	
20		8.15.	Vesicular stomatitis	Sep 11	E	
21	26	4.14.	Hygiene and disease security procedures in apiaries	Sep10	A	
		9.1. 9.2. 9.3. 9.4. 9.5. 9.6.	Acarapisosis of honey bees American foulbrood of honey bees European foulbrood of honey bees Small hive beetle infestation (<i>Aethina tumida</i>) <i>Tropilaelaps</i> infestation of honey bees Varroosis of honey bees	Sep09	E	
	22	27	10.4	Avian influenza		A
	23		10.9.	Newcastle disease		
	24		11.3.	Brucellosis	Sep 11	E
	25		11.12.	Lumpy skin disease	Sep 11	E
26	28	12.1	African horse sickness	Sep10	A	
	24	1.6.	Questionnaire on African horse sickness (Article 1.6.6.bis)			
	29	12.6. 12.9.	Equine influenza Equine viral arteritis	Sep 11	A	
27		14.8.	Peste des petits ruminants	Sep 11	E	
28		15.2.	Classical swine fever	Sep10	E	
29		New	Epizootic haemorrhagic disease		D	
30	35		Minimum competencies of day1 graduates	Sep10	I	
			Report of <i>ad hoc</i> Group on VE		I	
31	36		Report of APFSWG		I	
32	37		Work Programme		C	
33	38		Guidelines for assessing the risk of non-native animal species becoming invasive		I	

A: proposed for adoption at 80th General Session, C: For Member comments, E: under expert consultation (*ad hoc* Groups, Specialist Commissions etc.), D: deferred to Sep 2012 meeting, I: For Member information.

List of abbreviations	
AAHSC	Aquatic Animal Health Standards Commission
AHS	African horse sickness
APFSWG	Animal Production Food Safety Working Group
AWWG	Animal Welfare Working Group
EHD	Epizootic haemorrhagic disease
FMD	Foot and mouth disease
PPR	Peste des petits ruminants
PRRS	Porcine reproductive and respiratory syndrome
SCAD	Scientific Commission for Animal Diseases
TAHSC	Terrestrial Animal Health Standards Commission
VE	Veterinary Education