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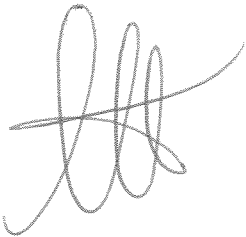

Dear Director General,

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 82nd General Session in May 2014 in Paris.

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

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

Yours sincerely,

Spiros Doudounakis Director Animal Health OIE Delegate Greece	Bernard Van Goethem Director for Veterinary and International Affairs European Commission, DG Health and Consumers
	

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Annexes: 2

Copy: All Directors / Chief Veterinary Officers of the EU 28 and Iceland, Liechtenstein, Norway, Switzerland, and Montenegro, FYROM, Serbia and Turkey.



Organisation
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Health

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Mundial
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ANNEX 1

Original: English

February 2014

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

Paris, 11–20 February 2014

EU comments

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

A number of general comments on this report of the February 2014 meeting of the Code Commission as well as the intended positions of the EU on the draft Terrestrial Code chapters proposed for adoption at the 82nd OIE General Session are inserted in the text below, while specific comments are inserted in the text of the respective annexes of the report.

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

The OIE Terrestrial Animal Health Standards Commission (the Code Commission) met at the OIE Headquarters in Paris from 11 to 20 February 2014. The list of participants is attached as [Annex I](#).

The Code Commission thanked the following Member Countries for providing written comments on draft texts circulated after the Commission's September meeting: Argentina, Australia, Bangladesh, Belarus, Canada, Chile, China, Chinese Taipei, Costa Rica, Guatemala, Japan, Kazakhstan, Mexico, New Zealand, Norway, Russia, South Africa, Switzerland, Thailand, the Philippines, the United States of America (USA), Uruguay, the 28 Member States of the European Union (EU), the African Union–Interafrican Bureau for Animal Resources (AU-IBAR) on behalf of the OIE Delegates of Africa, and the Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA). Comments were also received from the Comité Veterinario Permanente del Cono Sur (CVP). In addition, the International Embryo Transfer Society (IETS) and the International Coalition for Farm Animal Welfare (ICFAW) submitted comments.

The Code Commission reviewed Member Countries' comments that had been submitted by 10 January 2014 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 '~~strike through~~' and may be found in the Annexes to the report. Amendments made at the February 2014 meeting are highlighted with a coloured background in order to distinguish them from those made previously. All Member Countries' comments were considered by the Code Commission. However, because of the very large volume of work, the Commission was not able to draft a detailed explanation of the reasons for accepting or not every proposal received. Member Countries are reminded that if comments are resubmitted without modification or new justification, the Commission will not, as a rule, repeat previous explanations for decisions. The Commission encourages Member Countries to refer to previous reports when preparing comments on longstanding issues. The Commission also draws the attention of Member Countries to those instances where the Scientific Commission for Animal Diseases (the Scientific Commission) has addressed Member Countries' comments and proposed amendments. In such cases, the rationale for such amendments is described in the Scientific

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Commission's report and the Code Commission encourages Member Countries to review its report together with those of the Scientific Commission and *ad hoc* groups.

Member Countries should note that texts in Part A of this report are proposed for adoption at the 82nd General Session in May 2014. Texts in Part B are submitted for comment by Member Countries and comments received will be addressed during the Commission's meeting in September 2014. The reports of meetings (Working Group and *ad hoc* Groups) and other related documents are attached for information in Part B of this report.

The Code Commission again strongly encourages Member Countries to participate in the development of the OIE's international standards by submitting comments on this report, and prepare to participate in the process of adoption at the General Session. Comments should be submitted as specific proposed text changes, supported by a structured rationale. Proposed deletions should be indicated in '~~strike through~~' 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 8 August 2014** to be considered at the September 2014 meeting of the Code Commission. All comments should be sent to the OIE International Trade Department at: trade.dept@oie.int.

A. MEETING WITH THE DIRECTOR GENERAL

The Code Commission met Dr Bernard Vallat, the Director General of the OIE, on 11 February 2014 to discuss several key topics as follows.

1. Coordination among Specialist Commissions

Dr Alejandro Thiermann noted that the participation of the Code Commission members as observers in relevant *ad hoc* Group meetings has proven very useful in ensuring early alignment of the work of *ad hoc* Groups with the needs of the Code Commission. It was also agreed that the welcome return to scheduling overlapping Scientific and Code Commission meetings to allow joint meetings in both February and September 2014 will enable greater cohesion and alignment of the work of both Commissions. Dr Vallat also noted that the imminent appointment of Deputy Director General Dr Evans will contribute to improve coordination between the Specialist Commissions and relevant OIE Headquarters' departments.

2. High health status horse subpopulation

Dr Vallat outlined the background to the current work programme with the Fédération Equestre Internationale (FEI) and the International Federation of Horseracing Authorities (IFHA). The expectation is that once the concept and principles are adopted, more detailed guidelines will be developed as needed. The Code Commission welcomed this approach and agreed with the importance of highlighting and applying existing standards to facilitate temporary movement of these high health status horses.

The growing issue of smuggling and necessary controls at border inspection posts was also discussed.

B. ADOPTION OF THE AGENDA

The adopted agenda of the meeting is attached as [Annex II](#).

C. REPORT ON THE JOINT MEETING OF THE CODE COMMISSION AND THE SCIENTIFIC COMMISSION (14th February)

The Code Commission and the Scientific Commission met together on 14th February to discuss various issues of mutual interest. The minutes of this joint meeting are attached as [Annex III](#).

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

Item 1. General comments of Member Countries

General comments were received from Australia, Bangladesh, Japan, New Zealand, the Philippines, and AU-IBAR on behalf of the OIE Delegates of Africa.

Under this item, the Code Commission noted Member Countries' endorsement of the proposals in the report of the September 2014 meeting.

In response to a Member Country's comment on the consistency and accuracy of the use of the terms embryos/oocytes, embryos/ova and embryos throughout the *Terrestrial Code*, it was agreed that the International Trade Department would identify where these terms are used, and seek an expert's advice on

which term is appropriate in each instance for review by the Code Commission at its September 2014 meeting.

A Member Country observed an inconsistency in the way commodities are classified as safe amongst various chapters of the *Terrestrial* and *Aquatic Codes*. The Code Commission proposed that ‘safe commodities’ in each chapter should refer to those commodities that, regardless of the specific disease status of the exporting country or zone, are safe for trade without treatment or with generic treatments such as canning, pasteurisation, ante- and post-mortem inspection, etc. Commodities that require pathogen specific treatment are excluded. The Code Commission will take this into consideration as chapters are reviewed, and liaise with the OIE Aquatic Animal Health Standards Commission (the Aquatic Animals Commission) as appropriate.

EU comment

The EU supports efforts to draft recommendations on safe commodities in a consistent manner across the Terrestrial Code, and that these should be regardless of the disease situation of the exporting country or zone. However, the EU is of the opinion that in principle safe commodities by their very nature should only be those commodities that are safe without any treatment, be it generic or specific, i.e. they do not contain the infectious agent. Indeed, a commodity that requires heat treatment or ante- and post-mortem inspection should not be regarded as “safe”, as the “safety” would depend not on the nature of the commodity itself but require the proper performance of a risk mitigation treatment.

In this context, it is not clear what exactly is meant by a “pathogen specific treatment”, which according to the Code Commission would exclude a commodity from being regarded as a “safe commodity”, as opposed to a generic treatment such as canning or pasteurisation.

Finally, the EU suggests defining “safe commodity” in the glossary, as that term is used in several disease specific chapters of the Code.

In response to a Member Country’s concern on variations to the cycle of standard development, including shorter than normal periods for consultation on draft texts, the Code Commission agreed that the OIE should minimise such irregularities.

EU comment

The EU commends the Code Commission on its intention to minimise shorter than normal periods for consultation on draft texts. However, the EU notes that several draft amended Code chapters are circulated to member countries for the first time with this February 2014 meeting report, yet are proposed for adoption in May 2014.

While the EU does not wish to create delays implementing important changes in the OIE Code, in general we would ask the OIE to stick to the established standard setting procedures and not to propose modifications of Code chapters for adoption without having circulated these proposed amendments for at least one round of member country comments.

Reference is made to the EU comment on the Code Commission’s work programme (cf. Annex XL).

In response to a Member Country’s observation on the inconsistent use of the terms ‘disinsection’ ‘disinsectisation’, and ‘disinfestation’ in the *Terrestrial Code*, the Commission recognised each of these terms has a specific meaning and requested the International Trade Department to review where these terms are used in the *Terrestrial Code*, and provide recommendations for appropriate amendments for the Code Commission to consider at its September 2014 meeting. The Code Commission recognised that the title of Chapter 4.13. should be ‘disinsection’ rather than ‘disinsectisation’, as this is the term used by WHO, IATA and numerous other organisations, and proposes that amendment.

Item 2. Horizontal issues

a) User's Guide

Comments were received from Argentina, Australia, China, EU, New Zealand, Switzerland, and AU-IBAR on behalf of the OIE Delegates of Africa.

In response to a Member Country's comment requesting definition of the term 'standard', the Code Commission recalled the clarification of this issue made in the report of the February 2013 Code Commission report as follows:

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

The Commission accepted a Member Country's suggestion to amend point 2 of the introduction to use the active voice and improve readability, but rejected Member Countries' suggestion to replace "ones" with "pathogenic agents" in the same point as inferior syntax.

The Commission accepted Member Countries' suggestion to delete unnecessary words from the end of point 3 of the introduction.

The Commission accepted the OIE Headquarters' suggestion to insert new point 5 into the introduction to remind readers that the *Terrestrial Code* is available on the OIE website.

The Code Commission made additional changes to improve harmonisation with the *Aquatic Animal Health Code* (the *Aquatic Code*) where appropriate.

A Member Country's comment on the use of the *Terrestrial Code* triggered a discussion on those instances in which there are no recommendations on a specific issue in the *Terrestrial Code*. The Code Commission considered that the absence of recommendations does not mean that measures may not be applied. For example, the absence of a recommendation on trade in a particular chapter does not mean that the commodity in question should not be traded. Also, absence of an entire chapter on a specific disease does not mean a Member Country may not apply animal health measures relevant to the disease in question to protect its territory. However, such measures should be based on a risk analysis. The Code Commission drafted a new point 4 in Section A to clarify this point.

With respect to point 4 of Section B, the Code Commission agreed with Member Countries' view that the meaning of 'to justify import measures which result in a higher level of protection than would be achieved by measures based on existing OIE trade standards' is not clear. The Code Commission revised the text to clarify that its focus is on the extent to which different measures restrict trade.

The Code Commission did not accept a Member Country's proposal to change 'disinsection' to 'disinfestation' in point 6 of Section B as these terms are not synonyms. 'Disinsection' is a broader term than 'disinfestation'.

In response to Member Countries' comments, the Code Commission modified the language of points 9 and 10 of Section B to improve clarity and readability, and accepted a Member Country's suggestion to correct the Spanish version of point 10.

The Code Commission accepted Member Countries' suggestions to improve wording and grammar of the text in Section C on Notification, Diagnostic tests and vaccines, and Prevention and control. It rejected a Member Country's suggestion to add 'infestations' to the text on Prevention and control for Chapters 4.5. to 4.11. since these chapters deal with semen and embryos for which only 'diseases' and 'infections' are relevant.

The Code Commission accepted a Member Country's suggestion to split the text in Section C 3 on Prevention and Control referring to Chapters 6.4. and 6.5. into separate sentences and delete an unnecessary phrase from the end of the sentence referring to Chapter 6.5.

The Code Commission agreed with a Member Country's comment on the first paragraph of Section C 4 on Trade requirements to improve the structure of the sentence. It also accepted another comment on the text with respect to safe commodities to use stronger and more direct wording about expectations.

In Section C 5 on International Veterinary Certificates, the Code Commission accepted, but modified, Member Countries' comments to improve sentence structure, grammar and readability.

Similarly, the Code Commission accepted, but modified, a Member Country's suggestion to improve sentence structure in the text in Section C 6 on Guidance notes for importers and exporters.

The revised User's Guide is attached as Annex IV to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU thanks the OIE for having taken its previous comments into account. However, the EU does not support the adoption of this modified user's guide as proposed. Comments are inserted in the text of Annex IV that should be taken into account before adoption.

b) General obligations related to certification

The Code Commission accepted the OIE Headquarters' suggestion to reword Article 5.1.2. points 1 and 2 to improve clarity.

The revised Chapter 5.1., as attached in Annex V, is presented for adoption at the 82nd General Session in May 2014.

The EU does not support the adoption of this modified chapter as proposed. Comments are inserted in the text of Annex V that should be taken into account before adoption.

The EU notes that this amended chapter is proposed for adoption in May 2014 without having previously been circulated for member comments. Reference is made to the EU's general comment included in the introduction of the Code Commission report.

c) Harmonisation of articles on disease status determination

The Commission agreed with the OIE Headquarters' suggestion to harmonise currently inconsistent language in various chapters introducing the criteria to be applied to determine the disease status of a country or zone. It decided to use 'should be determined on the basis of' instead of other phrases for the recommendation to the Veterinary Authority and to use 'is' instead of 'should be' for the criteria, which are facts. These amendments will be incorporated as and when other changes are proposed in the relevant chapters.

Item 3 Glossary

Comments were received from Argentina, Belarus, Chile, EU, Kazakhstan, New Zealand, Russia, Switzerland, USA and OIRSA.

The Code Commission accepted Member Countries' suggestions to improve the clarity and specificity of the definition of emerging disease, but rejected one comment suggesting the additions of further text to specify the types of changes of a known pathogenic agent as too restrictive. Similarly it rejected Member Countries' suggestion to replace 'pathogenic' with 'aetiologic', which it considered a less specific adjective.

The Code Commission accepted the OIE Headquarters' suggestion to add 'scientific' to the definition of risk assessment.

For the definition of 'stamping out' the Code Commission accepted a Member Country's suggestion to replace 'premises' with 'establishment' (which is defined in the glossary), and suggested improvements to the Spanish version but rejected a Member Country's suggestion to add 'Total' to the term 'Stamping out' as unnecessary since 'modified stamping out' is defined.

In response to Member Countries' divergent and irreconcilable comments on the definition of 'veterinarian', the Code Commission noted that none of the proposed changes could be applied to all Member Countries, given that many Member Countries do not yet have Veterinary Statutory Bodies or education requirements for veterinarians specified in legislation. The Code Commission also noted that this issue is likely to be considered further in progressing the recommendation from the 2013 OIE Global Conference on Veterinary Education and the Role of the Veterinary Statutory Body to develop a global register of Veterinary Education Establishments. Considering these points, the Code Commission decided not to propose any change to the current definition of 'veterinarian'.

The revised Glossary is attached as [Annex VI](#) to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU in general supports the adoption of this modified glossary. Comments are inserted in the text of Annex VI.

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

Comments were received from Argentina, Australia, EU, New Zealand, South Africa, Switzerland, USA and AU-IBAR on behalf of the OIE Delegates of Africa.

The Code Commission accepted Member Countries' suggestion to differentiate obligatory notification and voluntary information in the title of Chapter 1.1.

It also accepted Member Countries' suggestion to add reference to Article 1.1.3. bis to Articles 1.1.2. point 2, and 5.

The Code Commission accepted Member Countries' suggestions to re-arrange the wording of Article 1.1.2. points 4 and 5 to improve readability.

The Code Commission decided to refer Member Countries' questions and comments on the formatting of reports to the OIE Information Department to review and report back to the September 2014 meeting of the Commission.

The Code Commission rejected Member Countries' suggestion to replace the word 'unusual' with 'novel' or 'new' in Article 1.1.3. point e as too restrictive given that new or novel may be interpreted as the first occurrence only at either global or individual country level.

The Code Commission rejected Member Countries' suggestion to split Article 1.1.3. point d into two paragraphs as unnecessary.

The Code Commission rejected a Member Country's suggestion to require notification in Article 1.1.3. bis point 1 within 24 hours, since an emerging disease is extremely unlikely to be recognised as such within 24 hours of first occurrence. The Code Commission reflected that it can take weeks or months before it is realised that an observed disease is new and emerging as described in the glossary. It also noted that the WAHIS notification system ensures all Member Countries are notified of a new emerging disease report as soon as the information is confirmed.

The Code Commission accepted a Member Country's suggestion to re-format Article 1.1.3. bis point 2 to improve readability.

The Code Commission rejected Member Countries' suggestion to reference 'event closure' in Article 1.1.3. bis point 2, since this situation is included in the existing provisions referencing 'eradication' or 'sufficiently stable'.

Similarly, the Code Commission rejected as unnecessary a Member Country's suggestion to add to this chapter language already provided in the WAHIS instructions.

The revised Chapter 1.1. is attached as [Annex VII](#) to be presented for adoption at the 82nd General Session in May 2014.

EU position**The EU thanks the OIE and supports the adoption of this modified chapter.****Item 5 Criteria for listing diseases****a) Criteria for the inclusion of diseases, infections and infestations on the OIE list (Chapter 1.2.)**

Comments were received from Argentina, Australia, China, EU, Guatemala, Japan, Russia, Switzerland, USA, AU-IBAR on behalf of the OIE Delegates of Africa and OIRSA.

The Code Commission rejected Member Countries' requests to retain Swine Vesicular Disease and Vesicular Stomatitis as listed diseases, as none provided an adequate rationale based on the listing criteria of Article 1.2.2. Justification for the delisting of these two diseases is provided in the following extract from a submission from a Member Country:

Swine vesicular disease**International spread**

Swine vesicular disease virus (SVDV) is exceptionally stable outside the host and indirect contacts such as transport vehicles or waste feeding play an important role in the spread of disease (Hedger and Mann, 1989). Experimental inoculation or exposure to a contaminated environment is followed by the rapid development of viraemia (Dekker *et al.*, 1995).

The between farm spread of SVD is mainly related to movements of infected animals or contaminated trucks, but also to the introduction of contaminated material or persons (EFSA, 2012).

Maes *et al.* (2008) noted that artificial insemination using SVDV-infected semen failed to transmit disease to sows. Similarly, van Rijn *et al.* (2004) were unable to isolate virus directly from the semen of boars artificially infected with SVDV intravenously although virus isolation carried out following the blind passage of semen samples in cell culture did detect SVDV. PCR testing of semen from artificially infected boars gave weak positive results, suggesting low numbers of SVDV RNA (van Rijn *et al.*, 2004).

Country freedom

Many countries, several with general or targeted surveillance, report that SVD has never occurred (OIE, 2012).

SVD first emerged in Italy in 1966 (Nardelli *et al.*, 1968) and was subsequently diagnosed in a number of European countries (Lubroth *et al.*, 2006; Sabirovic *et al.*, 2009; Sabirovic *et al.*, 2010a; Sabirovic *et al.*, 2010b).

The disease is likely to be present in various parts of eastern Asia; the last reported case of SVD from the Far East being in Taiwan in 2000 (EFSA, 2012).

Significant mortality

Infection of pigs with SVDV results in vesicular lesions whose severity may be heavily influenced by environmental factors (Hedger and Mann, 1989). These lesions may be accompanied by fever, lack of appetite and general malaise.

Recovery from infection is usually complete in 2–3 weeks, with the only evidence of infection being a dark, horizontal line on the hoof where growth has been temporarily interrupted. Disease caused by mild strains may remain unobserved, particularly in pigs kept on grass or housed on deep straw. Younger animals are more severely affected, although mortality due to SVD is very rare. Nervous signs have been reported, but are unusual. Recent outbreaks of SVD have been characterised by less severe or no clinical signs; infection has been detected when samples are tested for a serosurveillance programme or for export certification (OIE, 2008).

Diagnosis

Where a vesicular condition is seen in pigs, the demonstration by enzyme-linked immunosorbent assay (ELISA) of SVD viral antigen in a sample of lesion material or vesicular fluid is sufficient for a positive diagnosis. If the quantity of lesion material submitted is not sufficient (less than 0.5 g), or if the test results are negative or inconclusive, a more sensitive test, such as the reverse transcription polymerase chain reaction (RT-PCR) or isolation of virus (VI) in porcine cell cultures, may be used. If any inoculated cultures subsequently develop a cytopathic effect, the demonstration of SVD viral antigen by ELISA or by RT-PCR will suffice to make a positive diagnosis. Subclinical infection may be detected by random sampling of pen-floor faeces followed by identification of SVD viral genome using RT-PCR or VI tests (OIE, 2008).

Serological tests can be used to help confirm clinical cases as well as to identify subclinical infections. Specific antibody to SVD virus can be identified using the microneutralisation test or ELISA. Although the microneutralisation test requires 2–3 days to complete, it remains the definitive test for antibody to SVD virus. A small proportion (up to 0.1%) of normal, uninfected pigs will react positively in serological tests for SVD. The reactivity of these singleton reactors is transient, so that they can be differentiated from infected pigs by resampling of the positive animal and its cohorts (OIE, 2008).

Conclusion

SVD is not associated with human infection, significant morbidity or mortality in domestic animals, or significant morbidity or mortality in wildlife. Using the criteria in Article 1.2.2. for determining if a disease should be listed, SVD should not be included in the OIE list.

References

- Dekker A., Moonen P., de Boer-Luijtz E.A. Terpstra C. (1995).** Pathogenesis of swine vesicular disease after exposure of pigs to an infected environment. *Veterinary Microbiology*, 45, 234–50.
- EFSA (2012).** Scientific Opinion on Swine Vesicular Disease and Vesicular Stomatitis. *EFSA Journal* 10, 2631.
- Hedger R.S. and Mann J.A. (1989).** Swine vesicular disease virus. In Pensaert MB (ed) *Virus Infections of Vertebrates, Volume 2. Virus Infections of Porcines*. Pp 241–50, Elsevier Science Publishers.
- Lubroth J., Rodríguez L. and Dekker A. (2006).** Vesicular diseases. In: Straw BE, Zimmerman JJ, D’Allaire S, Taylor DJ (eds) *Diseases of Swine 9th Edition*, pp 517–35, Blackwell Publishing.
- Maes D., Nauwynck H., Rijsselaere T., Mateusen B., Vyt P., de Kruif A. and Van Soom A. (2008)** Diseases in swine transmitted by artificial insemination: An overview. *Theriogenology*, 70, 1337–45.
- Nardelli L., Lodetti E., Gualandi G.L., Burrows R., Goodridge D., Brown F. and Cartwright B. (1968).** A foot and mouth disease syndrome in pigs caused by an enterovirus. *Nature*, 219, 1275–6.
- OIE (2012).** **WAHID interface.**
http://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/Diseasedistributionmap
- OIE (2008) Swine vesicular disease.** *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*. Chapter 2.8.9. Available at:
http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/2.08.09_SVD.pdf
- Sabirovic M., Roberts H., Papadopoulou C., Lopez M., Hancock R. and Calistri P. (2009).** International disease monitoring, July to September 2009. *Veterinary Record*, 165, 552–5.
- Sabirovic M., Roberts H., Lopez M., Hancock R. (2010a).** International disease monitoring, October to December 2009. *Veterinary Record*, 166, 160–2.
- Sabirovic M., Roberts H., Lopez M. and Hancock R. (2010b).** International disease monitoring, January to March. *Veterinary Record*, 166, 483–6.

van Rijn P.A., Wellenberg G.J., der Honing R.H., Jacobs L., Moonen P.L.J.M. and Feitsma H. (2004). Detection of economically important viruses in boar semen by quantitative RealTime PCR technology. *Journal of Virological Methods*, 120, 151–60.

Vesicular stomatitis

International spread

Vesicular stomatitis is primarily an insect-borne virus but it can also be transmitted by contact (Lubroth *et al.*, 2006). Outbreaks of disease occur sporadically in the USA and are always associated with insect transmission (Lubroth *et al.*, 2006; Rodriguez 2002; Rodriguez *et al.*, 1996). The virus is found in epithelial tissues of the mouth, nose, coronary region of the hooves, teats and lymph nodes (Lubroth *et al.*, 2006). It is not found in blood (Lubroth *et al.*, 2006). There are no references to it being excreted in semen. There is no evidence of a carrier state in cattle, horses, or swine (EFSA, 2012), suggesting that international spread through trade in animals is highly unlikely.

Country freedom

Vesicular stomatitis is restricted to the Americas, but in the past it has also been reported in France (1915 and 1917) and in South Africa (1886 and 1897) (EFSA, 2012).

Significant mortality

Infection in animals generally is typified by a short febrile period and full recovery. The incubation period is short, ranging from 2 to 8 days after infection with an average of 3–5 days. The most common early signs are excessive salivation and drooling. The disease is characterised by vesicles, papules, erosions and ulcers. Vesicles are caused by the action of the virus on the tongue, lips, buccal mucosa, teats, and in the coronary band epithelium of cattle, horses, pigs and many other species of domestic and wild animals. Vesicular lesions in horses generally occur on the upper surface of the tongue, lips, around nostrils, corners of the mouth, and gums. Lesions in horses may also be expressed as crusting scabs on the muzzle, lips or ventral abdomen. Affected pigs usually first show signs of lameness caused by foot lesions (EFSA, 2012).

Observational studies on outbreaks indicated several subclinical infections with limited observed clinical signs, both in equidae and cattle. The mortality is negligible. The data on production losses are limited, but they seem to be variable (EFSA, 2012).

In humans, vesicular stomatitis is an acute, self-limiting infection with signs similar to influenza. The incubation period is usually 3 to 4 days, but it can be as short as 24 hours or as long as 6 days. The symptoms can include fever, muscle aches, headache and malaise. Vesicles are rare, but can occasionally be found on the mouth, lips or fingers. Deaths have not been reported, and most people recover without complications in 4 to 7 days (EFSA, 2012).

Diagnosis

Vesicular stomatitis virus can be readily isolated by the inoculation of several tissue culture systems, unweaned mice or embryonated chicken eggs. Viral RNA can be detected from epithelial tissue and vesicular fluid by conventional and real-time reverse transcriptase polymerase chain reaction (PCR). Viral antigen can be identified by an indirect sandwich enzyme-linked immunosorbent assay (IS-ELISA) which is the least expensive and most rapid test. The complement fixation (CF) test is also a good alternative. The virus neutralisation (VN) test may be used, but it is elaborate and time-consuming (OIE, 2010).

Convalescent animals develop serotype-specific antibodies within 4–8 days of infection that are demonstrated by a liquid-phase blocking ELISA (LP-ELISA), a competitive ELISA (C-ELISA) and VN. Other tests are CF, agar gel immunodiffusion and counter immunoelectrophoresis (OIE, 2010).

Conclusion

Natural transmission of vesicular stomatitis to humans is recognised although subsequent disease is inconsequential. Infection is not associated with significant morbidity or mortality in domestic

animals, or significant morbidity or mortality in wildlife. Using the criteria in Article 1.2.2., vesicular stomatitis should **not** be included in the OIE list.

References

EFSA (2012). Scientific Opinion on Swine Vesicular Disease and Vesicular Stomatitis. *EFSA Journal* 10, 2631.

Lubroth J., Rodriguez L. and Dekker A. (2006). Vesicular stomatitis. *In*: Straw B.E., Zimmerman J.J., D’Allaire S. & Taylor D.J. (eds), *Diseases of Swine*. 9th edition, Pp. 525–535, Blackwell Publishing, Ames, Iowa.

OIE (2010). Vesicular stomatitis. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*. Chapter 2.1.19 Available at: http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/2.01.19_VESICULAR_STOMITIS.pdf

Rodriguez L.L. (2002). Emergence and re-emergence of vesicular stomatitis in the United States. *Virus Research*, 85(2), 211–219.

Rodriguez L.L., Fitch W.M. and Nichol S.T. (1996). Ecological factors rather than temporal factors dominate the evolution of vesicular stomatitis virus. *Proceedings of the National Academy of Sciences USA*, 93(23), 13030–13035.

The Code Commission also rejected a Member Country’s suggestion to amend Article 1.2.2. point 3 b) because the proposed amendment would not add any value to the existing text.

The Code Commission rejected Member Countries’ suggestion to reinsert the previous point 5 of Article 1.2.2. because the new Article 1.1.3. bis clarifies the requirements for notification of emerging diseases, and Article 1.2.2. provides the criteria by which all diseases, including emerging diseases, are considered for listing.

In response to a Member Country’s question as to why ‘Infection with *Trichinella* spp.’ remains a listed disease, the Code Commission noted that point 2 of Article 1.2.2. applies to populations of susceptible animals rather than an entire country; and in the case of *Trichinella* spp. there are countries which could demonstrate freedom of populations of susceptible animals from particular species of *Trichinella*.

The Code Commission accepted Member Countries’ suggestion to replace ‘Rift Valley Fever’ with ‘Infection with Rift Valley Fever Virus’ in Article 1.2.3. point 1 and similarly in point 6 to replace ‘Newcastle disease’ with ‘Infection with Newcastle disease virus’.

The Commission rejected Member Countries’ suggestion to revert to a single listing of avian influenza, as it considers the current dual listing helps distinguish the different obligations with respect to detection of avian influenza viruses in poultry, and detection of influenza A viruses of high pathogenicity in birds other than poultry.

In response to a Member Country’s suggestion to review the listing criteria, without providing any rationale, the Code Commission recalled that the current listing criteria were reviewed and adopted only recently, in 2011.

The revised Chapter 1.2., together with the deletion of Chapters 8.16. and 15.4., is attached as [Annex VIII](#) to be presented for adoption at the 82nd General Session in May 2014.

EU position

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

b) Report of the ad hoc Group on Schmallenberg virus infection and the Scientific Commission’s view on it

The Code Commission noted that the *ad hoc* group had rigorously assessed Schmallenberg virus against the criteria for listing and agreed with the *ad hoc* group's well-supported conclusion that Schmallenberg virus does not meet the criteria in Article 1.2.2.

Item 6 Import risk analysis (Chapter 2.1.)

Comments received from Australia, China, EU and Switzerland.

The Code Commission accepted a Commission member's proposal to delete 'potential' from the term 'potential hazard' throughout the chapter where the hazard has clearly been recognised (and therefore use of the qualifier 'potential' is redundant). This change is logical and aligns with the terminology used in the OIE *Handbook on Import Risk Analysis* and with Codex Alimentarius Commission.

In response to Member Countries' suggestion to change the title of the chapter to reflect the point that risk analysis is no longer restricted to imports, the Code Commission agreed to reflect on this issue and re-consider how it may be dealt with at their September 2014 meeting.

In response to a Member Country's request to reinsert language referring to the SPS Agreement in Article 2.1.1., the Code Commission noted that this language is now in Chapter 5.3., and does not need to be duplicated here.

The Code Commission accepted Member Countries' and OIE Headquarters' editorial comments to improve clarity in Articles 2.1.1., 2.1.5. and 2.1.6.

The revised Chapter 2.1. is attached as Annex IX to be presented for adoption at the 82nd General Session in May 2014.

EU position

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

Item 7 Support for Veterinary Services

The Code Commission was updated on the Global Conference on Veterinary Education and the Role of Veterinary Statutory Body held in December 2013. It was also updated on activities under the OIE PVS Pathway.

Item 8 Semen and embryos

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

Comments were received from Australia, New Zealand and Switzerland.

In response to Member Countries' comments highlighting inconsistencies between Chapter 4.6. and some disease-specific chapters, the Code Commission recommended that Chapter 4.6. should be referred to an expert for review, and then reconsidered at the September 2014 meeting of the Code Commission.

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

Comments were received from Australia, EU and IETS.

The Code Commission recalled that a Member Country's comments concerning the process used by the IETS to determine categorisation of agents subsequently adopted in the *Terrestrial Code* was dealt with at its September 2013 meeting and, demonstrating that process in action, the Code Commission added Q fever (*Coxiella burnetii*) to category 4 on the basis of the reference:

Fieni *et al.* (2013). Can *Coxiella burnetii* be transmitted by embryo transfer in goats? *Theriogenology*, **80** (6), 571–575.

Similarly, the Code Commission moved porcine circovirus type 2 to category 3 on the basis of the reference:

Bielanski A., Algire J. *et al.* (2013). Non transmission of porcine circovirus 2 (PCV 2) by embryo transfer. *Theriogenology*, **80** (2), 77–83.

The revised Chapter 4.7. is attached as Annex X to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU in general supports the adoption of this modified chapter. Some comments are inserted in the text of Annex X, seeking consistency with the nomenclature of diseases in Chapter 1.2. and the corresponding disease specific chapters of the Code.

The EU notes that this amended chapter is proposed for adoption in May 2014 without having previously been circulated for member comments. Reference is made to the EU's general comment included in the introduction of the Code Commission report.

Item 9 Trade measures, import/export procedures and veterinary certification

a) Certification procedures (Chapter 5.2.)

Comments were received from EU.

The Code Commission accepted proposed amendments to Article 5.2.4. point 1 to better describe the procedures for electronic certification.

The revised Chapter 5.2. is attached as Annex XI to be presented for adoption at the 82nd General Session in May 2014.

EU position

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

The EU notes that this amended chapter is proposed for adoption in May 2014 without having previously been circulated for member comments. Reference is made to the EU's general comment included in the introduction of the Code Commission report.

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

Based on the proposal by the OIE Headquarters, the Code Commission amended reference to the *Terrestrial Code* chapters on model veterinary certificates in this chapter.

The revised Chapter 5.4. is attached as Annex XII to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU supports the adoption of this modified chapter.

Item 10 Antimicrobial resistance

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

Comments were received from EU, Norway and Switzerland.

The Code Commission accepted a Member Country's suggestion to replace the words 'animal husbandry' with 'animals' in the opening paragraph of Article 6.6.1., and to replace the words 'entire animal sector' with 'all animal sectors' at the end of the third paragraph of the same article to more clearly indicate that pets and non-food producing animals are included in this objective.

The revised Chapter 6.6. is attached as Annex XIII to be presented for adoption at the 82nd General Session in May 2014.

EU position

<p>The EU thanks the OIE and supports the adoption of this modified chapter.</p>

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

Comments were received from Australia, China, EU, Norway, Switzerland and USA.

Many detailed comments were received on this chapter, and these have been referred to *ad hoc* group experts to address. Amendments proposed as a result of these comments will be submitted for Member Countries' review and comment at a later date.

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

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

The Code Commission noted that this chapter had been thoroughly revised and adopted in May 2013, with a few pending points.

The Code Commission agreed with a Member Country's observation of incorrect editing of the plural for agents and products in a number of places in the previous draft, and made the necessary corrections.

The Code Commission agreed with a Member Country's suggestion to delete the unnecessary words 'as far as possible' from Article 6.9.2. point 3.

The Code Commission rejected a Member Country's suggestion to add the qualifying words 'biologically active' to 'residues' in Article 6.9.2. point 5 as unnecessary detail.

Similarly the Code Commission rejected a Member Country's suggestion to add the words 'when indicated' to the end of point 2 d of Article 6.9.3. as unnecessary qualification.

The Code Commission rejected a Member Country's suggestion to add the words 'strive to' and delete the words 'that all' from Article 6.9.3. point 9 as contrary to the prudent use objective of this chapter.

In response to a Member Country's question on who may be designated 'authorised persons' in Article 6.9.3. point 9 c, the Code Commission advised this is a matter for the relevant Competent Authorities to manage.

In response to a Member Country's observation, the Code Commission corrected the cross reference article points of Article 6.9.4. point 4 and 5, Article 6.9.5. point 3, and Article 6.9.6. point 6.

The Code Commission rejected a Member Country's suggestion to include a new sentence in Article 6.9.6. related to a veterinarian's independence, impartiality, integrity and objectivity as these points are all addressed in Chapter 3.1.

The Code Commission agreed with a Member Country's suggestion to delete the unnecessary word 'ideally' from Article 6.9.6. point 2 a.

In response to a Member Country's request for improved clarity the Code Commission amended Article 6.9.8. point 3.

The revised Chapter 6.9. is attached as Annex XIV to be presented for adoption at the 82nd General Session in May 2014.

<p>EU position</p>

<p>The EU in general supports the adoption of this modified chapter. A specific comment is inserted in the text of Annex XIV, and a general comment is included in the EU's comment on the work programme of the Code Commission.</p>
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d) Risk assessment for antimicrobial resistance arising from the use of antimicrobial agents in animals (Chapter 6.10.)

Comments were received from Australia, China, EU, Switzerland, USA and AU-IBAR on behalf of the OIE Delegates of Africa

The Code Commission accepted a Member Country's suggestion to re-arrange the first paragraph of point 1 of Article 6.10.1. to more clearly highlight the points of emphasis. It rejected a Member Country's request to replace the word 'non-therapeutic' with 'production' as unnecessary.

The Code Commission accepted a Member Country's suggestions to improve the grammar of Article 6.10.1. point 5. However, they rejected the suggestion to delete the last paragraph of this point as they consider this usefully cross references this article to Chapter 2.1.

In Article 6.10.2. the Code Commission rejected a Member Country's suggestion to replace 'release assessment' with 'entry assessment' in point 3 because in this case the hazard is released. They accepted Member Countries' suggestions to add 'entertainment' to the category of animal species considered, and to clarify the reference to sex in this point. However, the Code Commission and the *ad hoc* group rejected a Member Country's suggestion to merge the clause on data on extra-label and off-label use with the clause on data on trends in *antimicrobial* use in point 3, since data on extra-label and off-label use are often difficult to obtain and insufficient to recognise usage trends. In the 9th indent of the list of factors to be considered in the release assessment, the Code Commission changed 'animal species' to 'animal host' in response to a Member Country's suggestion.

The Code Commission rejected a Member Country's request to replace the term probability with 'likelihood' in the chapeau text of Article 6.10.2. point 4 since, as noted on page 1 of the *OIE Handbook on Import Risk Analysis for Animals and Animal Products*, these are interchangeable terms.

In the list of factors to be considered in the exposure assessment (Article 6.10.2. point 4), the Code Commission accepted a Member Country's suggestion to delete the unnecessary words 'or other exposure' from the 2nd and 3rd indents, and to add the words 'that have the capacity to become established in the animals, thus leading to contamination of foods of animal origin' to the 5th indent. They rejected a Member Country's request to specify the type of waste referred to in the 10th indent as unnecessary and potentially restrictive.

In the list of factors to be considered in the consequence assessment (Article 6.10.2. point 5), the Code Commission accepted a Member Country's suggestion to reword the indent on 'microbial dose' to improve clarity, and to amend the text on deaths to include 'reduced life expectancy' and 'compared with deaths linked to sensitive organisms of the same species'.

In the list of factors to be considered in the risk estimation (Article 6.10.2. point 6) the Code Commission accepted Member Countries' suggestions to add 'pregnant' to the subpopulations listed in the second indent', to amend the text on deaths in the 5th indent as in point 5, and to add 'and cost' to the 7th indent on availability.

The Code Commission rejected a Member Country's suggestion to add substantial new text suggesting lists of final outputs that may be included for quantitative and qualitative risk assessments to point 6 of Articles 6.10.2. and 6.10.3., since the chapter with the existing articles has already been adopted, and the adopted chapter format aligns with Chapter 2.1.

The Code Commission amended Article 6.10.2. point 7 a to align with the change proposed in Article 2.1.6.

In response to comments from a Member Country and the *ad hoc* group, the Code Commission amended Article 6.10.2. point 7 b to improve clarity.

The Code Commission rejected a Member Country's suggestion to delete the words 'due to antimicrobial usage in animals' in Article 6.10.3. since those words align this article with the scope of the chapter.

Clauses in Article 6.10.3. that are identical to those in Article 6.10.2. were amended in response to Member Countries' comments so that the clauses in both articles remain aligned.

The revised Chapter 6.10. is attached as Annex XV to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU thanks the OIE for having taken its previous comment into account. While in general supporting the adoption of this modified chapter, the EU cannot accept the newly proposed changes in point 1 of Article 6.10.1. The EU comments on that point, inserted in the text of Annex XV, should be taken into account before adoption. Further comments are inserted in the text of Annex XV.

Item 11 Animal welfare

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

Comments were received from Argentina, Australia, Canada, EU, Japan, New Zealand, Switzerland, USA, AU-IBAR on behalf of the OIE Delegates of Africa and the International Coalition for Animal Welfare .

The Code Commission acknowledged the excellent Member Country and NGO participation and contribution of suggestions and comments on this draft chapter, despite the shorter than normal period for comment on this draft. Unfortunately a number of the comments offered no supporting rationale which made them difficult for both the Code Commission and the *ad hoc* Group to evaluate. Comments with no supporting rationale or obvious logic were rejected.

The Code Commission refers Member Countries and NGOs to the excellent report of the *ad hoc* Group on Animal welfare and dairy cattle production systems for detailed responses to comments and suggestions received, and reminds Member Countries that bibliographic references included in the draft chapter will be removed when the chapter is adopted.

In response to the question from the *ad hoc* Group on the need for a definition of ‘calf’, the Code Commission agreed that no definition of ‘calf’ is required for this chapter (or previously adopted chapters) as the term is used with its standard dictionary meaning.

The Code Commission noted that some of the requests for additional detail to be included in the chapter were overly prescriptive, or could not be accurately assessed and were therefore inappropriate for inclusion in this chapter.

In response to Member Countries’ concerns about the development of this chapter leading to the imposition of unjustified trade barriers, the Code Commission reiterated that the objectives for developing the chapters on animal welfare and various production systems are to develop science-based animal welfare standards that are globally applicable and should, therefore, assist in overcoming any unjustified trade barriers based on animal welfare. It is not the presence of animal welfare chapters in the *Terrestrial Code* that leads to trade barriers; it is the existence of animal welfare concerns. The animal welfare chapters are designed to address such concerns.

The Code Commission edited the draft chapter to be consistent with established Code structure, format and content. In this context, the list of criteria or measurables in Article 7.X.4. was expanded to include all measurables cited in subsequent articles.

In response to a Member Country’s question on the scope of ‘system design’ in Article 7.X.5. point 1, the Code Commission advised that system design is understood to include structure and management. To clarify this point, the words ‘and management’ were added to the heading of point 1 in this article.

The Code Commission referred Member Countries’ and the *ad hoc* group’s requests for inclusion of specific threshold levels for ammonia concentration (Article 7.X.5. point 1c to experts for advice (as for the same question in Chapter 7.10.).

In response to Member Countries’ request to include a specific noise threshold in Article 7.X.5. point 1d, the Code Commission considered that the current text and suggested outcome-based measurables give sufficient guidance.

The revised Chapter 7.X. is attached as Annex XXXIV for Member Countries’ comment.

EU comment

The EU comments on this draft new chapter will be conveyed to the OIE by 8 August 2014.

The Code Commission endorsed the report of the OIE *ad hoc* Group, which is attached in [Annex XXXV](#) for Member Country information.

b) Restructuring of Chapters 7.5. and 7.6.

i) Slaughter of animals (Chapter 7.5.)

Comments were received from Australia, Canada, Chile, China, EU, New Zealand, Norway, Switzerland, Thailand, USA and the International Coalition for Animal Welfare,.

The Code Commission recalled that Chapters 7.5. and 7.6. were circulated for consideration of removal or retention of the extensive tables and figures included in both chapters. There is clear support for retention of the tables and figures in this article.

The Code Commission also noted that many Member Countries and NGOs had used the opportunity of circulation of these chapters to put forward a large number of comments on text already adopted, many of which repeat comments and suggestions previously rejected by the World Assembly of Delegates.

Considering this history, the Code Commission decided to address new comments only, and refer clauses and articles where there is clearly significant divergence of opinion between the various Member Countries and NGOs to the Animal Welfare Working Group (or experts) for consideration.

The Code Commission rejected a Member Country's request for 'slaughter of seals' to be included in this chapter, since seals are killed for their fur rather than slaughtered, and are therefore beyond the scope of the chapter. Note: 'slaughter' is a defined term which is clearly not applicable to the killing of seals in the wild.

In response to a Member Country's request to include slaughter without stunning standards in this chapter, the Code Commission noted that provisions for slaughter without stunning are already included.

The Code Commission accepted Member Countries' suggestions to delete the word 'conveyer' from Article 7.5.1. points 4b and 4f.

The Code Commission accepted a NGO's suggestion to include 'and water' in Article 7.5.2. point 3c, and Article 7.5.4. point 6.

The Code Commission accepted a Member Country's suggestion to amend the Spanish version of Article 7.5.3. point 1.

The Code Commission accepted Member Countries' requests to modify the captions of the figures showing stunning methods wherever necessary to unambiguously distinguish the figures for penetrative captive bolt stunning and non-penetrative captive bolt stunning.

The Code Commission also accepted Member Countries' suggestion to clarify the species applicability of the text on signs for correct stunning using a mechanical instrument at the end of Article 7.5.7. point 2.

Member Countries' and a NGO's comments on the figures and diagrams for stunning, a Member Country's request for stunning diagrams for farmed deer and camelids, and Member Countries' and a NGO's comments on electrical stunning were all referred to the Animal Welfare Working Group for consideration.

The revised draft of Chapter 7.5. will be circulated for Member Countries' comment when the Code Commission has received the advice of the Animal Welfare Working Group on those matters referred to it.

ii) Killing of animals for disease control purposes (Chapter 7.6.)

Comments were received from Australia, Chile, China, EU, New Zealand, Switzerland, USA and the International Coalition for Animal Welfare.

The Code Commission rejected Member Countries' and a NGO's suggestion to add further indicators of death to the list in Article 7.6.1. point 7 since this is not an exhaustive list, and they consider the current list sufficient for the purpose of this standard. The Code Commission also noted that *rigor mortis* usually takes some time to develop and so is not particularly applicable to the case in point.

A Member Country's suggestion to include 'monitoring animal welfare and biosecurity procedures' in the responsibilities for animal killing personnel and carcass disposal personnel in Article 7.6.3. was also rejected as the Commission considers the inclusion of this item in the responsibilities for animal handlers in this article is sufficient for the purpose of this standard.

A Member Country's request to add further text dealing with the planning of 'killing' to Article 7.6.4. was also rejected as unnecessary given the text already present in the chapeau text of this article.

Member Countries' and a NGOs' suggestions to add further detail to Article 7.6.6. points 1e and 4 were rejected as unnecessary detail given the text already includes the clause 'should only be used by properly trained and competent marksmen'.

The Code Commission accepted Member Countries' requests to modify the captions of the figures showing stunning methods wherever necessary to unambiguously distinguish the figures for penetrative captive bolt stunning and non-penetrative captive bolt stunning (corresponding with the same amendments made in Chapter 7.5.).

Member Countries' request to change the species age parameters in Article 7.6.8. point 2 on the basis of a 1996 reference was rejected because the current text is supported by a more recent EFSA report referenced to Finnie *et al.*, 2000.

In response to a Member Country's comment the reference point of Article 7.6.8. point 5 was changed from 'a maximum weight of 10 Kg' to 'a maximum age of 6 months' to align with the introduction to this article.

A NGO's request to add further detail to Article 7.6.9. point 2c was rejected, given the comprehensive nature of the text 'competent personnel who are appropriately trained' already included in that point.

In response to a Member Country's comment, the Code Commission changed 'cattle' to 'calves' in the table in Article 7.6.10. point 2a to align with the tables in Article 7.6.5.

Member Countries' suggestion to add text indicating 'that neither cervical dislocation nor decapitation should be used routinely....' after the title of Article 7.6.17. was rejected as unnecessary duplication of the text already included in the second paragraph of Article 7.6.17. point 1a.

In response to a Member Country's request for a reference to support the weight parameters given in Article 7.6.17. point 1, the Code Commission cites; "Practical Slaughter of Poultry – A Guide for the Small Producer" 2nd edition: 18–19 (Humane Slaughter Association).

Member Countries' and a NGO's comments on the figures and diagrams for stunning, a Member Country's request for inclusion of text on killing horses for disease control, and Member Countries and a NGO's comments on electrical stunning, Member Countries' comments on the use of CO₂ and low density foam with inert gas, were all referred to the Animal Welfare Working Group for consideration.

The revised draft of Chapter 7.6. will be circulated for Member Countries' comment when the Code Commission has received the advice of the Animal Welfare Working Group on those matters referred to them.

c) Animal welfare and broiler chicken production systems (Chapter 7.10.)

Comments were received from Australia, Chile, China, EU, Norway, Switzerland, USA, the International Coalition for Animal Welfare, and a member of the OIE Animal Welfare Working Group.

The Code Commission rejected the suggestion from a Member Country and a NGO to change the definition of broiler in this chapter because the current definition was adopted by consensus in 2013, following rejection of earlier definitions. The Commission also noted that most of the animal welfare issues of broiler chickens do not apply to village chickens.

The Code Commission also rejected a Member Country's suggestion to replace 'day old birds' with 'day old chicks', given the World Assembly of Delegates' choice of 'day old birds', which is also defined in the Glossary.

In response to a Member Country's suggestion, the Code Commission removed the sentence 'Broilers in commercial flocks should be assessed for gait anomalies' from point 2 of Article 7.10.3., and introduced similar generic wording to the opening chapeau text of Article 7.10.3., so that the recommendation applies to the entire article, rather than gait abnormalities only.

A NGO's request to reinstate text now located at Article 7.10.4. point 2e in Article 7.10.3. was rejected as an unnecessary duplication.

Minor changes were made to Article 7.10.3. points 6c and 8a in response to Member Countries' comments.

A Member Country's request to introduce a clause to the effect that 'acceptable performance criteria may not necessarily be an indicator of good welfare' was rejected as unnecessary, and inconsistent with standard Code format.

Article 7.10.3. point 8b was amended in response to Member Countries' suggestion that the point should cover a broader range of situations, and the Code Commission noted that the key point is the reference to expected feed conversion rate in the specific situation. As pointed out by Member Countries there are situations where higher than expected feed conversion rates can be an indicator of welfare problems, and other situations where higher feed conversion rates can be an indicator of improved welfare.

The Code Commission rejected a Member Country's suggestion to include variation in bird weight or size as a new measurable, as that can be adequately addressed in the growth rate measurable.

The Code Commission accepted a Member Country's suggestion to specifically include 'contact dermatitis' in Article 7.10.3. point 9.

The Code Commission referred questions from a Member Country, an Animal Welfare Working Group member and a NGO on what is an adequate period of darkness and continuous light, what is an appropriate upper reference point for ammonia concentration, and what is an appropriate upper reference point for carbon dioxide, to experts for advice.

The Code Commission amended the language of Article 7.10.4. point 2f in response to Member Countries' and a NGO's comments.

A NGO's suggestion to direct Article 7.10.4. point 2g to breeders rather than broilers was rejected as unnecessary given the opening sentence that feather pecking and cannibalism are rarely seen in broilers because of their young age.

Similarly a Member Country's suggestion to include a new measurable for 'level of activity and movement' was rejected as unnecessary given the option to measure those indicators under the behaviour measurables in Article 7.10.4. point 2h.

The Code Commission expanded Article 7.10.4. point 2i to take account of a Member Country's comments.

The Code Commission rejected Member Countries' suggestion to delete growth rate from the factors to consider in choice of broiler strain (Article 7.10.4. point 2k) because it is an important factor, as described in Article 7.10.3. (performance).

In response to Member Countries and a NGO's comments requesting reinsertion of the examples in Article 7.10.4. point 2k, the Code Commission recalled that World Assembly of Delegates had declined to adopt this chapter with the clause containing those examples.

The Code Commission accepted a Member Country's suggestion to amend the language of Article 7.10.4. point 2m.

The Code Commission rejected a Member Country's suggestion to change 'emergency killing procedures' to 'killing for disease control procedures' in Article 7.10.4. point 2n, since this point applies to all emergency killing situations, not just those associated with disease control.

A Member Country's and a NGO's suggestion to add text referring to listed disease outbreak situations to Article 7.10.4. point 2o, to space requirements during transport to Article 7.10.4. point 2q, and a new outcome-based measurable for injury rate to Article 7.10.4. point 2q, were rejected as those matters are all addressed elsewhere in the *Terrestrial Code*.

The revised Chapter 7.10. is attached as Annex XVI to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU can support the adoption of this modified chapter but strongly recommend that the OIE considers inserting the two sentences proposed for Article 7.10.4.(2)(k). We would also ask that sentence order of the first paragraph of Article 7.10.3. be altered.

d) Disaster management and preparedness

i) Veterinary Services (Chapter 3.1.)

Comments were received from China, EU, Norway and Switzerland.

The Code Commission modified Article 3.1.2. point d in response to Member Countries' comments. The Commission also noted that the order of example procedures and standards listed in Article 3.1.2. point 9 should not be considered to be an order of priority or importance.

The revised Chapter 3.1. is attached as Annex XVII to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU thanks the OIE for taking our comment into account and supports the adoption of this modified chapter.

ii) Evaluation of Veterinary Services (Chapter 3.2.)

Comments were received from EU and Norway.

The Code Commission rejected Member Countries' request to specifically reference 'animal welfare surveillance' in the capabilities listed in Article 3.2.3. point 3 since this is not a widely recognised capability distinct from the epidemiologic capability already included.

Similarly the Code Commission rejected Member Countries' request to add the words 'unless there are effective electronic communications which preclude this need' to the end of Article 3.2.6. point 2a as too restrictive to the wide range of benefits of co-location.

Member Countries' suggestion to add a point 'd) Animal welfare research centres' to Article 3.2.6. was referred to the Animal Welfare Working Group for consideration.

Article 3.2.7. point 1 was amended to take account of Member Countries' suggestions.

In response to Member Countries' suggestions the Code Commission also inserted 'animal welfare' at multiple points through the chapter, and referred their more detailed suggestions for

referencing animal welfare in this chapter to the Animal Welfare Working Group for deeper consideration of how animal welfare in those settings is appropriately referenced throughout the chapter.

The revised Chapter 3.2. is attached as Annex XVIII to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU thanks the OIE for taking some of its comments into account while referring several of them to the OIE Animal Welfare Working Group for deeper consideration. The EU can support the adoption of this modified chapter but looks forward to the outcome of the Working Group's deliberations.

iii) Communication (Chapter 3.3.)

Comments were received from EU, Norway, and AU-IBAR on behalf of the OIE Delegates of Africa.

The Code Commission rejected Member Countries' suggestion to replace 'combined' with 'mutually supportive' in Article 3.3.2. point 2, and to amend the language of Article 3.3.4. since they considered both suggestions significantly diminished the intention of text previously adopted by the World Assembly of Delegates.

On the basis of Member Countries' comments the Code Commission amended the newly proposed text of Article 3.3.2. point 2 to correspond with the same amendment made in Chapter 3.1, Article 3.1.2. point 9.

The revised Chapter 3.3. is attached as Annex XIX to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU thanks the OIE for taking our comment into account and supports the adoption of this modified chapter.

Item 12 Harmonisation of three vector-borne diseases

a) Infection with African horse sickness virus (Chapter 12.1.)

Comments were received from Australia, China, EU, Norway, Switzerland, USA and AU-IBAR on behalf of the OIE Delegates of Africa.

A Member Country's request for the OIE to convene a small group of experts to examine the implications of a recently published study demonstrating persistent infection in naturally infected or partially immune horses was referred to the Scientific Commission for consideration.

A Member Country's request to change the definition of the disease was rejected as the text proposed was inconsistent with the title of the chapter.

The Code Commission accepted Member Countries' and the Scientific Commission's request to replace 'infection' with 'case' in Article 12.1.1. points 2 and 3.

Member Countries' request to add a new clause e to Article 12.1.2. point1 to cover 'continental' historical freedom was rejected as historical freedom should be demonstrated on a country-by-country basis.

In response to Member Countries' request to qualify the surveillance requirements of Article 12.1.2. point 2, the Code Commission added the words 'as relevant' to the end of this clause.

The Code Commission accepted a Member Country's suggestion to amend the language of Article 12.1.2. point 4 to be consistent with the title of this article.

To avoid ambiguity and supporting the recommendation of the *ad hoc* Group and the Scientific Commission, the Code Commission added the words ‘in accordance with Article 1.4.6.’ to the end of Article 12.1.2. point 4 c i.

In response to Member Countries’ request for an explanation of the deletion of the previous Article 12.1.3. AHSV seasonally free zone, the Code Commission advised that this article was deleted because the OIE process for official recognition of AHS freedom does not recognise seasonal freedom. The commission also noted that as explained in the proposed new text in User’s guide (see Annex IV), absence of recommendation in the *Terrestrial Code* does not mean that the Veterinary Authorities may not apply appropriate measures.

The Code Commission rejected a Member Country’s request to revert to the previous (now deleted) text of Article 12.1.4. point 1 e, and noted that all clauses of Article 12.1.4. point 1 must be addressed. In the context of this request, it is important that both clauses e and f are addressed, and it may not always be possible to pinpoint the first case of an outbreak.

The Code Commission accepted a Member Country’s request to add the word ‘infection’ to Article 12.1.4. point 5.

The Code Commission agreed with the Scientific Commission that it is preferable to keep the outcome focus in Article 12.1.10. point 1b, rather than specific insect and mesh sizes as requested by a Member Country.

The Code Commission re-formatted Article 12.1.12., and edited Articles 12.1.11., 12.1.12., and 12.1.13. to improve clarity and for consistency with other surveillance articles in the *Terrestrial Code*.

The revised Chapter 12.1. is attached in [Annex XX](#) to be presented for adoption at the 82nd General Session in May 2014.

EU position

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

b) Harmonisation of three vector-borne diseases (bluetongue, epizootic haemorrhagic disease and African horse sickness)

The Code Commission and the Scientific Commission agreed that prior to circulation of the revised chapters on bluetongue and epizootic haemorrhagic disease, the Scientific and Technical Department and the International Trade Department would clarify the outstanding differences to be examined by the Scientific Commission and the Code Commission at their September meetings. The Code Commission expects that these revised chapters will be circulated to Member Countries with the September 2014 Code Commission report.

Item 13 Zoonotic parasites

a) Infection with *Trichinella* spp. (Chapter 8.14.)

Comments were received from Argentina, Australia, China, Chinese Taipei, EU, New Zealand and Switzerland.

In response to a Member Country’s request for additional articles pertaining to country and zone freedom, the Code Commission recalled again that experts were unable to develop generic guidelines for country or zone freedom applicable to all species of *Trichinella* (as would be expected with the expanded scope of the new chapter). However, as explained in the User’s Guide, the absence of such articles does not preclude Member Countries from developing their own case for population, zone or country freedom (or negligible risk status) for individual *Trichinella* species.

The Code Commission accepted a Member Country’s suggestion to delete a redundant ‘and’ from the third paragraph of Article 8.14.1.

The Code Commission rejected a Member Country’s suggestion to add other species to the definition of *Trichinella* infection for this chapter, since the chapter is deliberately focused on epidemiologically significant species which determines the scope of recommendations to Veterinary Authorities with respect to

notification, status requirements, prevention and control, trade conditions, etc. Species susceptibility to infection by itself is, therefore, insufficient reason to include a host species in the definition of infection in specific chapters.

The Code Commission rejected a Member Country's suggestion to restrict the scope of Article 8.14.3. point b to preventing waste of animal origin only to 'being fed to pigs' as being too narrow.

The Code Commission accepted a Member Country's suggestion to amend the Spanish language in point 3 of Article 8.14.4. replacing 'dispone de datos' with 'tenga conocimiento'. In addition the English text of the same point was modified reading 'the *Veterinary Authority* has current knowledge of the distribution of susceptible species of *wildlife*' in order to harmonise the language on this clause with similar requirements in other chapters (e.g. ASF, CSF). The Code Commission also noted that this clause should not be interpreted as meaning that precise knowledge of the distribution of all susceptible species over the whole country is required.

The Code Commission rejected a Member Country's suggestion to delete Article 8.14.6. point 2c, since a standard on inactivation of *Trichinella larvae* is being developed by the Codex Alimentarius Commission, and once approved will be cross referenced in this OIE standard. The Code Commission also noted that as long as this clause is qualified with 'under study' it is not considered part of the standard.

The revised Chapter 8.14. is attached in Annex XXI to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU supports the adoption of this modified chapter.

b) Infection with *Taenia solium* (Chapter X.X.)

The Code Commission reviewed the *ad hoc* Group report, and the draft text. It made minor editorial amendments to the draft chapter to align it with established format.

The Code Commission noted that the listing name of the disease in Chapter 1.2. would need to be amended when this chapter is adopted.

The proposed new draft Chapter X.X. is attached as Annex XXXVI for Member Countries' comments.

EU comment

The EU comments on this draft new chapter will be conveyed to the OIE by 8 August 2014.

The Code Commission endorsed the Report of the Meeting of the OIE *ad hoc* Group on Porcine Cysticercosis, which is attached in Annex XXXVII for Member Country information.

Item 14 Foot and mouth disease (Chapters 8.6. and 1.6.)

The Code Commission received the latest extensive revision of this chapter from the Scientific Commission during the course of their meeting. In discussion with the Scientific Commission and the Director General, it was agreed that the Code Commission should complete its review of the revised chapter at their September 2014 meeting. The revised chapter will then be circulated for Member Countries' review and comment with the September 2014 Code Commission meeting report, with a view to having the finished text ready to propose for adoption at the 83rd General Session in 2015.

Item 15 Infection with Rift valley fever virus (Chapter 8.12.)

Comments were received from EU, Switzerland and USA.

The Code Commission gratefully acknowledges a Member Country's thanks and congratulations to the *ad hoc* Group on Rift Valley Fever. The Member Country concerned noted: "The proposed changes in the Code chapter drew comments and questions from our experts, but the answers could all be found in the report of the *ad hoc* Group. It is a very clear report that explains the rationale for the changes and provides references."

In response to a Member Country's question, the Code Commission clarified that the reference to ruminants in Article 8.12.1. point 2 does not include camelids. It also rejected Member Countries' suggestions to include dromedary and Bactrian camels in the definition of Rift Valley Fever, since the *ad hoc* group considered that camels do not play a significant epidemiological role in Rift Valley Fever, and mere susceptibility to infection is insufficient basis to include them in this chapter definition. For further explanation of this point, Member Countries are referred to the *ad hoc* group report appended to the September 2013 Scientific Commission report.

The Code Commission changed the words, as appropriate, 'animals' to 'ruminants' to align with the definition of Article 8.12.1. point 2.

In response to Member Countries' requests to change the infective period for Rift Valley Fever throughout the chapter, the Code Commission referred Member Countries to the *ad hoc* group report appended to the September 2013 Code Commission report where the infective period of 14 days is fully justified.

The Commission also refers Member Countries seeking clarification of "an incidence substantially exceeding that during the inter-epizootic period" to the *ad hoc* group report. *Veterinary Authorities* are left to define this term taking account of the considerations highlighted in the *ad hoc* group report.

In response to a Member Country's comment, the Code Commission changed the word 'may' to 'can' in Article 8.12.1. point 7.

In response to Member Countries' comments, the Code Commission specified 'point 1 of Article 1.4.6.' in Article 8.12.3. point 1 and split the second point of the same article into two separate points to acknowledge the fact that *Veterinary Services* are not responsible for surveillance in humans. In reviewing this article, the Commission also noted the possibility of detecting an imported case in the absence of an epizootic.

In response to Member Countries' suggestion to list predisposing factors or examples in Article 8.12.4., both the Code Commission and the Scientific Commission agreed that such a list does not fit the established Code format and structure, and should be sought in more detailed references beyond the scope of this chapter.

Member Countries' request to insert additional words on isolation requirements in Article 8.12.8. point 3b was considered unnecessary additional detail.

The Code Commission amended the title of Article 8.12.10.bis, and re-worded point 3 to improve its grammar. Following Member Countries' suggestion, the Code Commission moved this article after Article 8.12.1.2. to align with other disease specific chapters.

The Code Commission rejected Member Countries' suggestion to specify temperature and time recommendations for pasteurisation in Article 8.12.13., since there are multiple temperature and time combinations in regular use which are available elsewhere, and the current presentation is consistent with similar recommendations of other chapters in the *Terrestrial Code*.

The Code Commission accepted Member Countries' suggestion to note that examination of vectors for the presence of RVFV is not recommended in Article 8.12.14.

The revised Chapter 8.12. is attached as Annex XXII to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU does not support the adoption of this modified chapter as proposed. Comments are inserted in the text of Annex XXII which should be taken into account before adoption.

Item 16 Tularemia (Chapter 8.15.)

The Code Commission accepted the OIE Headquarters' suggestion for minor reformatting of Article 8.15.3.

The revised Chapter 8.15. is attached as Annex XXIII to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU in general supports the adoption of this modified chapter. However, the chapter seems in need of a more thorough review. This should include *inter alia* a case definition and a change in the title of the chapter (to “Infection with *Francisella tularensis*”).

In general, the EU would favour an in depth review of disease specific chapters that have not been amended for some time, in line with the prioritised work programme of the Code Commission, instead of making small *ad hoc* revisions related to certain language issues.

Item 17. Infection with *Brucella abortus*, *B. melitensis* and *B. suis* (Chapter 8.X.)

Comments were received from Australia, Canada, China, Ecuador, EU, New Zealand, Russia, Switzerland, USA and AU-IBAR on behalf of OIE Delegates of Africa. Member Countries are urged to read the *Report of the OIE Ad Hoc Group on Brucellosis* for supporting rationale for the changes proposed to this chapter.

The Code Commission agreed with Member Countries’ suggestion to improve the title of the chapter.

The Code Commission included ‘caribou’ in point 5 of Article 8.X.1. following a convincing a Member Country’s suggestion.

In response to a Member Country request to keep three *Brucella* species separate in different chapters, the Code Commission reiterated the fact that, majority of Member Countries had been in favour of combining three species in one chapter before an *ad hoc* Group launched review of the chapter in XXX.

The Code Commission also did not agree with a Member Country proposing to specify test as ‘OIE prescribed’ when referred in this chapter because Article 8.X.1. clarifies that standards for diagnostic tests are described in the Terrestrial Manual.

The Code Commission did not agree with a Member Country’s suggestion to exclude European hares from the definition of ‘animals’ for the purpose of this chapter because the *ad hoc* Group and Scientific Commission considered that this species has epidemiological importance.

A Member Country’s proposal to replace ‘identification’ with ‘confirmation’ in the definition of infection was not accepted as the Code Commission considered identification of *Brucella* in a sample is adequate to defining *Brucella* infection. In the same point, the Code Commission changed ‘animal or a product derived from that animal’ to ‘a sample from an animal’ for simplification and clarification.

A Member Country comment suggesting a sentence to exclude research animals from the definition of infection was not taken because the Code Commission was of the view that research facilities are considered equivalent to ‘*quarantine station*’ defined in the Glossary, in which the presence of infection does not affect the disease status of the country or zone.

Agreeing with a Member Country comment, the Code Commission deleted ‘, *zone, herd or flock*’ from the introductory text of Article 8.X.2.

The Code Commission did not accept a Member Country’s proposal to include *in vivo* derived bovine embryos in the safe commodities, as IETS does not consider bovine embryos pose negligible risk with respect to all *B. species*.

The Code Commission added an article on historical freedom following a Member Country’s suggestion.

The Code Commission agreed with a Member Country’s suggestion to re-order the points of Articles 8.X.3. through 8.X.8. and 8.X.11. with respect to the requirements for qualification as free status.

It also made several changes in these articles for improved clarity and better syntax in response to Member Country comments.

The Code Commission did not agree with a Member Country proposing a more generic recommendation with respect to regular and periodic testing in Articles 8.X.3., 8.X.5., 8.X.6., 8.X.7. and 8.X.8. as the Commission considered it necessary to provide specific guidance to Member Countries.

The Code Commission also did not take a Member Country's suggestion to add 'under official veterinary control' in the first requirement for qualifying as freedom in all relevant articles, because official veterinary control is ensured in the subsequent requirements.

The Code Commission accepted a suggestion from several Member Countries to change the titles of Articles 8.X.9. and 8.X.10. for better syntax and consistency among articles.

The Code Commission agreed with a Member Country's suggestion to add the words 'with negative results' to Article 8.X.9. point 1c iv.

A Member Country's proposal to include Article 8.X.9. point 1c vi in the requirements for maintaining the free status laid down in Article 8.X.9. point 2a was not accepted by the Code Commission because point 1c vi is required when establishing freedom rather than maintaining the status.

The Code Commission, the Scientific Commission and the *ad hoc* group rejected a Member Country's suggestion that the tests in Article 8.X.9. point 1c vi, Article 8.X.10. point 1b vi, and Article 8.X.11. point 3b be separated by a parturition season, since there may not be a defined 'parturition season' for these species in many countries.

The Code Commission did not accept a Member Country's recommendation for including in the qualification requirements for free status with vaccination the use of official animal identification devices to enable permanent identification of vaccinated animals. However, text was modified to ensure that vaccinated animals are permanently identified as such.

The Code Commission clarified the text referring to animals, herds and flocks throughout this chapter.

The Code Commission declined Member Countries' request to amend the language of Article 8.X.10, point 1 vi, and noted that Member Countries need to consider age, vaccination, and testing history when interpreting results to prove herd or flock freedom with vaccination.

A Member Country's comments suggesting change in the title of Article 8.X.11. was not accepted due to the inconsistent format against other articles.

In response to a Member Country comment, the Code Commission amended point 2 of Article 8.X.12. to clarify that the investigation has been performed within 60 days of disease confirmation.

A Member Country's request to add a new section on a process to regain pig herd freedom from *Brucella* infection was rejected as the measures proposed are not applicable to pigs. Member Countries are referred to the *ad hoc* group report for further background to this issue.

In response to a Member Countries' comment, the Code Commission replaced 'eliminated' with 'culled' for clarity in several articles.

In response to a Member Countries' comment on point 2 of Article 8.X.16., the Code Commission added reference to Chapter 4.5. With this amendment, the Code Commission declined another Member Country request to revert point 3 of the same article.

Article 8.X.21. was deleted because the entire digestive tract is recognised as a safe commodity.

The revised Chapter 8.X. is attached as Annex XXIV to be presented for adoption at the 82nd General Session in May 2014. The Commission noted that this revised chapter would replace Chapters 11.3., 14.1. and 15.3. upon the adoption.

EU position

The EU thanks the OIE and in general supports the adoption of this new chapter. Some comments are inserted in the text of Annex XXIV.

Item 18 Infection with avian influenza viruses (Chapter 10.4.)

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

The Code Commission accepted Member Countries' suggestions to remove a redundant word from Article 10.4.14., and correct grammar in Article 10.4.20.

The Code Commission accepted Member Countries' suggestion to remove pasteurisation from Article 10.4.21. point 2 on the grounds that the term 'pasteurisation' is normally used in reference to food products.

It also accepted a Member Country's suggestion to specify 'moist heat' treatment in Article 10.4.21. point 2.

In response to Member Countries' comments questioning the inclusion of provisions for fumigation with formalin and irradiation in Articles 10.4.22. and 10.4.23., the Code Commission acknowledged that the references previously provided to support these treatments were inadequate and now offers the following reference to correct that omission:

De Benedictis P. *et al.* (2007). *Inactivation of Avian Influenza Viruses by Chemical Agents and Physical Conditions: A Review. Zoonoses and Public Health*, **54**, 51–68.

The Code Commission also noted that these measures are already successfully applied by several Member Countries and that the recommendation to include these measures in both of these articles had been endorsed by the Scientific Commission.

The Code Commission rejected Member Countries' suggestion to include a time period in Article 10.4.24. point 2c as unnecessary because inactivation is achieved once the specified temperature is attained.

The Code Commission accepted Member Countries' and Commission Members' suggestions to correct syntax and grammar, and improve clarity in Articles 10.4.25., 10.4.26., 10.4.27., and 10.4.28., 10.4.31. and 10.4.32.

The Code Commission also accepted a Member Country's suggestion to delete 'infected compartment' from Article 10.4.28., since compartments are, by definition, only maintained when they are free from infection.

The Code Commission rejected a Member Country's suggestion to delete the words 'and water' from Article 10.4.29. point 2, since in the context of this clause inclusion of reduced water consumption is given as one of a number of possible indicators of infection.

The Code Commission referred a Member Country's comment suggesting an increase in the number of recognised haemagglutinin and neuraminidase subtypes in Article 10.4.33. to the Biological Standards Commission for review and advice.

The revised Chapter 10.4. is attached as [Annex XXV](#) to be presented for adoption at the 82nd General Session in May 2014.

EU position

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

Item 19 Newcastle disease (Chapter 10.9.)

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

The Code Commission accepted Member Countries' suggestion to change the title of this chapter to 'Infection with Newcastle disease virus'.

The Code Commission accepted Member Countries' suggestion to remove pasteurisation from Article 10.9.16. point 2 on the grounds that the term 'pasteurisation' is normally used in reference to food products.

It also accepted a Member Country's suggestion to specify 'moist heat' treatment in Article 10.9.16. point 2.

In response to Member Countries' comments questioning the inclusion of provisions for fumigation with formalin and irradiation in Articles 10.9.17. and 10.9.18., the Code Commission noted that these measures are already successfully applied by several Member Countries, and that the recommendation to include these measures in both of these articles had been endorsed by the Scientific Commission.

The Code Commission rejected a Member Country's suggestion to include x-log kill data in brackets to the inactivation methods listed in Article 10.9.17. point 2, as this information is simply not available for the application of these inactivation methods in industrial settings.

The Code Commission accepted Member Countries' and Commission Members' suggestions to correct syntax and grammar, and improve clarity in Articles 10.9.22., 10.9.23., and 10.9.24., and 10.9.25.

The revised Chapter 10.9. is attached as Annex XXVI to be presented for adoption at the 82nd General Session in May 2014.

EU position

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

Item 20 Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia) (Chapters 11.8. and 1.6.)

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

In response to a Member Country's request for clarification of the list of susceptible species the Code Commission replaced the word 'cattle' with 'bovids' which includes cattle (*Bos indicus* and *Bos Taurus*) and yaks (*Bos grunniens*), and aligned the remainder of the chapter with this nomenclature.

The Code Commission accepted a Member Country's request for additional language in Article 11.8.7. which is provided as new point b.

The Code Commission amended several articles to correct syntax and grammar, and improve clarity.

The Code Commission accepted a Member Country's suggestion to use more specific language in Article 1.6.12. point 7c iv.

The revised Chapters 11.8. and 1.6. are attached as Annex XXVII to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU supports the adoption of this modified chapter.

Item 21 Equine diseases

a) High health status horse subpopulation (draft Chapter 4.X.)

Comments were received from Argentina, Australia, Chile, EU, New Zealand, Norway, South Africa, Switzerland, Uruguay and USA.

The Code Commission received extensive comments on this draft chapter, including significant contradictory positions. The Code Commission also sought advice from the Scientific Commission which believes that the most significant comments can be addressed sufficiently well to propose this chapter for adoption in May 2014.

Both the Code Commission and the Scientific Commission reiterated the point that the purpose of this chapter is to set the concept framework without giving implementation details. These details will be developed in the future, either as guidelines or *Terrestrial Code* chapters, as appropriate. The intention is to focus this chapter on key principles and concepts that Member Countries can adopt as a platform to guide future development of those agreed principles and concepts.

With this philosophy, the Code Commission reviewed all Member Countries' comments, and made significant amendments which should make this chapter adoptable.

Member Countries' comments requesting incorporation of 'high performance' in the title and Article 4.X.1. were rejected as the Code Commission considers the provisions of this chapter should be determined on the

basis of health status rather than performance. The Code Commission also noted that since the scope of this chapter is restricted to international competition, the concept of high performance is implicit.

In response to a Member Countries' comment on the opening paragraph of Article 4.X.1., the Code Commission added 'certified by the Veterinary Authorities' to clarify the *Veterinary Authorities*' role in certification of the health status of this population. However, the Commission rejected other proposed amendments because the purpose of this chapter is to set the concept framework without details.

A Member Country's request to replace 'high health' with 'negligible risk' was rejected because that suggested language does not accurately describe this population.

In response to Member Countries' suggestions the second paragraph of Article 4.X.1. was modified as follows: '... biosecurity measures to create and maintain a functional separation between horses within the defined subpopulation and all other equids at all times.' The Code Commission noted that the responsibility for creation and maintenance of a functional separation rests with the Member Country, and further details should be developed within the international biosecurity plan.

Member Countries' comments requesting more detail in Article 4.X.1. were not accepted, given the intent to focus this chapter on principles and concepts.

The Code Commission noted that horses are expected to belong to this compartment (or subpopulation) for only a part of their lives.

- a) In response to Member Countries' comments, Article 4.X.2. point 1 was amended to improve clarity, and now reads: 'Each horse in the *subpopulation* is subjected to specific measures to establish and maintain its health status and preserve that of the other horses in the subpopulation.'
- b) These measures comprise a specific set of laboratory tests, treatments and vaccinations appropriate to the disease status of the horse's region of origin, regions visited and the regions that it will visit. Records of all treatments and vaccinations, and results of tests and clinical inspections are documented in an individual passport that complies with Chapter 5.12.'

Member Countries' request to include reference to continual veterinary supervision in point 1 of Article 4.X.2. was rejected, as that is covered in point 3b of this article.

Member Countries' comments requesting clarification of *Veterinary Services* authority with respect to identification and issuing passports were rejected since these points are addressed in Chapters 4.1 and 4.2., which apply in all situations.

Article 4.X.2. point 2a was amended to read: 'Each horse bears a permanent unique identifier' in response to Member Countries' comments.

Member Countries' request to add the words 'information on' to Article 4.X.2. point 2b was accepted for accuracy.

Article 4.X.2. point 2c was amended to read: 'Each horse has an attachment to its passport that identifies it as a member of the high health status *subpopulation*' on the basis of a Member Country's comment for clarification.

A Member Country's request for additional detail in Article 4.X.2. point 2d was rejected on the grounds that all relevant information should be included in the passport.

Article 4.X.2. point 3a was amended to clarify the record details required, the words 'all official' were replaced with 'any' and a new sentence cross referenced to Chapter 5.2. was added to clarify the purposes of certification. Member Countries' request that each veterinarian examination referred to in this point should be undertaken by an *official veterinarian* was rejected as impractical.

The Code Commission also noted that each Member Country is free to apply additional measures to suit their circumstances for management of the subpopulation.

In response to Member Countries' comments, the Code Commission clarified Article 4.X.2. point 3b to indicate that the international biosecurity plan referenced in this point is expected to be approved by the importing and exporting *Veterinary Authorities* in accordance with relevant recommendations of the OIE.

A Member Country's request to delete 'continual' from Article 4.X.2. point 3b was rejected because continual does not mean 'uninterrupted'.

Member Countries' request to replace 'authorised *veterinarian*' with '*official veterinarian*' in Article 4.X.2. 3b was rejected because 'authorised' still requires a process of authorisation, but with potentially more flexibility than the process for authorisation of an *official veterinarian*.

Member Countries' request to insert 'training' into Articles 4.X.1. and 4.X.2. was rejected because training is an integral part of competition.

In response to Member Countries' comments the Code Commission amended Article 4.X.2. points 3c and 3d to include reference to the international Biosecurity Plan.

The Code Commission rejected Member Countries' request to add a new point to Article 4.X.2. on an equine disease free zone as beyond the scope of the current chapter.

In response to Member Countries' comments the Code Commission amended Article 4.X.3. to read 'Organisations that are responsible for ensuring compliance with this chapter should be approved by the *Veterinary Authorities*. *Veterinary Authorities* are also.....equestrian events and for their return to their country of origin.'

Member Countries' request for a timeline for development of the biosecurity guidelines was referred to the Director General and the Scientific Commission for advice.

The Code Commission also noted that the 'biosecurity guidelines' referred to in the last paragraph of Article 4.X.3. are not the same as the 'international Biosecurity Plan' referred to in Article 4.X.2. point b. To emphasise this distinction it amended the last paragraph of Article 4.X.2. point b to read:

'*Veterinary Authorities* are encouraged to recognise the international Biosecurity Plan developed by the FEI and the IFHA on the basis of the relevant OIE guidelines (under study).'

The Code Commission noted that the OIE, FEI, and IFHA are working together to develop the biosecurity guidelines referred to in Article 4.X.3.

The proposed new draft Chapter 4.X. is attached as Annex XXVIII to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU thanks the OIE for having taken some of its comments into account. The EU confirms its general support for the concept outlined in this chapter. Whilst recognising the importance of advancing the concept, the EU nevertheless has some continuing concerns about the situation where this conceptual chapter is proposed for early adoption without having developed and agreed the necessary chapters or guidelines that would make it understandable and thus implementable in a common and consistent way by member countries.

It is difficult for the EU to fully endorse such a new conceptual chapter in the absence of the required implementation guidelines and standards. We note that indeed, the draft chapter contains references to an international biosecurity plan developed by the industry and to OIE biosecurity guidelines concerning which we do not have any information.

However, the EU notes the importance of adopting this first chapter as a strong sign of support from the OIE World Assembly and the OIE member countries for the overall concept of the High Health Status Horse Subpopulation (HHS), and as an incentive to keep the momentum for finalising the work of the relevant *ad hoc* group.

The EU is confident that this concept, which is in line with the concept of compartmentalisation described in Chapter 4.4. of the Code, will greatly facilitate the temporary international movement of competition horses to the benefit of the horse industry and member countries alike. The EU furthermore understands that there will be opportunity to fine-tune and further improve this chapter, once adopted, as has been customary for newly adopted Terrestrial Code chapters in recent years.

Thus notwithstanding the concerns identified above, the EU supports the adoption of this new Code chapter at the OIE General Session in May 2014.

Specific comments are inserted in the text of Annex XXVIII.

b) Infection with equid herpesvirus 1 (Equine rhinopneumonitis) (Chapter 12.8.)

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

In response to Member Countries comments, the title of this chapter was amended to align with the nomenclature committee of the International Committee on Taxonomy of Viruses.

The Code Commission disagreed with Member Countries' rationale for re-wording Article 12.8.1., and retained the current version which is clinically accurate.

The Commission accepted Member Countries' suggestion to delete 'and during the 21 days prior to shipment' from Article 12.8.2. point 1 since a clinical presentation such as nasal discharge, which is one of the clinical signs of EHV1, is a common non-specific clinical sign for several equine diseases and could therefore make it difficult to certify this clause if this phrase were retained.

The revised Chapter 12.8. is attached as [Annex XXIX](#) to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU in general supports the adoption of this modified chapter. Some comments are inserted in the text of Annex XXIX.

However, the chapter seems in need of a more thorough review. In general, the EU would favour an in depth review of disease specific chapters that have not been amended for some time, in line with the prioritised work programme of the Code Commission, instead of making small *ad hoc* revisions as a follow-up to certain changes elsewhere in the Code.

c) Infection with equine arteritis virus (chapter 12.9.)

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

In response to suggestions from a Member Country, the Code Commission checked and revised the use of the acronym EVA throughout the chapter and, to avoid confusion, removed the acronym EAV from the chapter.

Suggestions from Member Countries to replace the word 'sign' with 'signs' in Article 12.9.2., and the word 'donors' with 'stallions' in Article 12.9.4. were rejected as unnecessary.

The revised Chapter 12.9. is attached as [Annex XXX](#) to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU supports the adoption of this modified chapter.

d) Glanders (Chapter 12.10.)

The Code Commission agreed with the Scientific Commission that resolution of the outstanding issues concerning tests that can be used to define an infection with *Burkholderia mallei* is an essential prerequisite to detailed consideration of this draft text. The Code Commission will review this draft chapter in detail when those diagnostic issues have been resolved by the Biological Standards Commission.

Item 22 Infection with peste des petits ruminants virus (Chapter 14.8.)

Comments were received from EU, New Zealand, Switzerland, AU-IBAR on behalf of the OIE Delegates of Africa and OIRSA.

The Code Commission agreed with Member Countries' suggestion to split point 1c of Article 14.8.3. into two points (c and d) to deal with the issues of vaccination and importation separately.

The Code Commission rejected Member Countries' suggestion to introduce a new point to deal with historical freedom in point 1 of Article 14.8.3., since historical freedom should be demonstrated on a country-by-country basis. Point 2a of the same article covers the requirement for historical freedom.

The Code Commission added a new clause to Article 14.8.3. point 2b ii in response to a Member Country's suggestion for consistency and full respect of the *Terrestrial Code* when applying for freedom status.

With respect to a Member Country's suggestion to amend the temperature specified in Article 14.8.26. from 20°C to 12°C, the Commission sought the Scientific Commission's advice on justification.

The Commission also made syntax, and grammar changes to Articles 14.8.27., 14.8.28., 14.8.31. and 14.8.32. to improve clarity of these articles.

The revised Chapter 14.8. is attached as Annex XXXI to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU supports the adoption of this modified chapter.

Item 23 Classical swine fever (Chapter 15.2.)

In agreement with the Scientific Commission, the Code Commission decided not to circulate minor amendments to this chapter for Member Countries' review pending an update of the *Terrestrial Manual* to include DIVA vaccination.

Item 24. Infection with porcine reproductive and respiratory syndrome (Chapter X.X.)

The Commission reviewed the *ad hoc* group reports (which Member Countries are urged to read when examining the draft chapter) and the draft text. It made amendments to the draft chapter to align it with established Code format.

The proposed new draft Chapter X.X. is attached as Annex XXXVIII for Member Countries' comments.

EU comment

The EU comments on this draft new chapter will be conveyed to the OIE by 8 August 2014.

Item 25. Report of the Animal Production and Food Safety Working Group meeting

Dr Gillian Mylrea, Deputy Head of the International Trade Department, updated the Code Commission on the activities of the Working Group. The Code Commission endorsed the report of the Group, which is attached in Annex XXXIX for Member Country information.

Item 26 Update of the Code Commission work programme

Comments were received from EU.

The Code Commission reviewed and updated its work programme, taking account of Member Countries' comments within the Code Commission's scope, and work completed.

The revised work programme is attached as Annex XL for Member Countries' comments.

EU comment

The EU thanks the OIE Code Commission for providing its detailed revised work programme for member country comments, which it supports, and thanks the Code Commission for having taken into account some suggestions previously made by the EU.

Specific comments are inserted in Annex XL.

Item 27 Review of applications for recognition as an OIE collaborating centre

The Code Commission reviewed the dossiers submitted by the following applicants for recognition as OIE Collaborating Centres (CC) and recommended that the OIE presents them for adoption at the 82nd General Session in May 2014:

- a) CC for food-borne parasites in Asian-Pacific region (China);
- b) CC for food-borne zoonotic parasites in Europe region (France).

The Commission encouraged the applicants to closely collaborate each other and with the one in Canada on the same topic as well.

The Code Commission requested that the OIE contacts another applicant for recognition as a CC to provide additional detailed information so that the Commission can review the application in depth at its September 2014 meeting.

Item 28. Other issues

a) Prevention, detection and control of *Salmonella* in poultry (Chapter 6.5.)

The Code Commission reviewed Chapter 6.5. and made amendments to Articles 6.5.7., 6.5.8. and 6.5.9. to take account of the point that this chapter is intended primarily for disease control rather than trade.

The revised chapter is appended as Annex XXXII to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU in general supports the adoption of this modified chapter. Some comments are inserted in the text of Annex XXXII for consideration by the Code Commission at its next meeting.

b) General recommendations on disinfection and disinsectisation (Chapter 4.13.)

As discussed in Item 1 (General comments), the Code Commission proposed to amend the title of Chapter 4.13.

The revised chapter is appended as Annex XXXIII to be presented for adoption at the 82nd General Session in May 2014.

EU position

The EU supports the adoption of this modified chapter.

Item 29 Proposed dates for 2014 meetings

The September 2014 meeting is scheduled for September 9–18, and the February 2015 meeting for February 10–19.



.../Annexes

USER'S GUIDE

EU position

The EU thanks the OIE for having taken its previous comments into account. However, the EU does not support the adoption of this modified user's guide as proposed. Comments are inserted in the text below that should be taken into account before adoption.

A. Introduction

- 1) The OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) sets out standards for the improvement of terrestrial animal health and welfare and veterinary public health worldwide. The purpose of this guide is to advise the Veterinary Authorities of OIE Member Countries on how to use the *Terrestrial Code*.
- 2) Veterinary Authorities should use the standards in the *Terrestrial Code* should be used by the Veterinary Authorities of Member Countries to set up measures providing for early detection, reporting, notification and control of pathogenic agents, including zoonotic ones, in terrestrial animals (mammals, birds and bees) and preventing their spread via international trade in animals and animal products, while avoiding unjustified sanitary barriers to trade.
- 3) The OIE standards are based on the most recent scientific and technical information and available techniques. Correctly applied, the OIE standards they protect provide for animal health and welfare and veterinary public health during production and trade in animals and animal products to take place with an optimal level of animal and veterinary public health safety, based on the most recent scientific information and available techniques.
- 4) The absence of chapters, articles or recommendations on particular aetiological agents or commodities does not mean that Veterinary Authorities may not apply appropriate animal health and welfare measures.

EU position

The EU agrees with the addition of this new point. However, it should be clarified what is meant by “appropriate measures”, otherwise this statement could be misunderstood as an invitation by the OIE for member countries to establish excessive or arbitrary measures. Therefore, the EU suggests adding the following wording to the point above:

“These measures should be based on an import risk analysis performed in accordance with OIE standards.”

- 5) The complete text of the *Terrestrial Code* is available on the OIE website and may be downloaded from: <http://www.oie.int>.

B. *Terrestrial Code* content

- 1) Key terms and expressions used in more than one chapter in the *Terrestrial Code* are defined in the Glossary. The reader should be aware of the definitions given in the Glossary When reading and using the *Terrestrial Code*, the Veterinary Authorities of Member Countries should be aware of the definitions given in the Glossary. Defined terms appear in italics. In the on-line version of the *Terrestrial Code*, a hyperlink leads to the relevant definition.
- 2) The term '(under study)' is found in some rare instances, with reference to an article or part of an article. This means that this part of the text has not yet been adopted by the World Assembly of OIE Delegates and the particular provisions are thus not yet part of the *Terrestrial Code*.

- 3) The standards in the chapters of Section 1 are designed for the implementation of measures for the diagnosis, surveillance and notification of pathogenic agents. The standards include procedures for notification to the OIE, tests for international trade, and procedures for the assessment of the health status of a country, of zone or compartment.
- 4) The standards in the chapters of Section 2 are designed for to guide the importing country in conducting import risk analysis used by an importing country in the absence of OIE trade standards. The importing country may also use these standards or to justify import measures which result in are more trade restrictive a higher level of protection than would be achieved by measures based on more stringent than existing OIE trade standards.
- 5) The standards in the chapters of Section 3 are designed for the establishment, maintenance and evaluation of quality Veterinary Services, including veterinary legislation and communication. These standards are intended to assist the Veterinary Services of Member Countries to meet their objectives of improving terrestrial animal health and welfare and veterinary public health, as well as to establish and maintain confidence in their international veterinary certificates.
- 6) The standards in the chapters of Section 4 are designed for the implementation of measures for the prevention and control of pathogenic agents. Measures in this section include through animal identification, traceability, zoning, compartmentalisation, disposal of dead animals, disinfection, disinsection ~~disinsectisation~~ and general hygiene precautions. Some chapters address the specific sanitary measures to be applied for the collection and processing of semen and embryos of animals.
- 7) The standards in the chapters of Section 5 are designed for the implementation of general sanitary measures for trade. In particular, chapters address veterinary certification and the measures applicable by the exporting, transit and importing countries, ~~especially Members of the World Trade Organization (WTO).~~ Section 5# also includes a range of model veterinary certificates to be used as a harmonised basis for international trade.
- 8) The standards in the chapters of Section 6 are designed for the implementation of preventive measures in animal production systems. These measures are intended, to assist Member Countries in meeting their veterinary public health objectives. This They includes ante- and post-mortem inspection, control of hazards in feed, biosecurity at the animal production level, and the control of antimicrobial resistance in animals.
- 9) The standards in the chapters of Section 7 are designed for the implementation of animal welfare measures. The standards cover, including those at the level of production, transport, and slaughter or killing, as well as. Additional standards address the animal welfare aspects of stray dog population control and the use of animals in research and education.
- 10) The standards in each of the chapters of Sections 8 to 15 are designed to prevent the aetiological agents of OIE listed diseases, infections or infestations from being introduced into an importing country. The standards taking into account the nature of the traded commodity, the animal health status of the exporting country, zone or compartment, and the risk reduction measures applicable to each commodity.

These standards assume that the agent is either not present in the importing country or is the subject of a control or eradication programme. Sections 8 to 15 each relate to the host species of the pathogenic agent: multiple species or single species of the families Apidae, Aves, Bovidae, Equidae, Leporidae, Caprinae and Suidae. Some chapters include specific measures to prevent and control the infections of global concern. Although the OIE aims to include a chapter for each OIE listed disease, not all OIE listed diseases have been covered yet by a specific chapter. This is work in progress, depending on available scientific knowledge and the priorities set by the World Assembly.

C. Specific issues

1) Notification

Chapter 1.1. describes Member Countries' obligations under the OIE Organic Statutes. Although only listed and emerging diseases, as prescribed in Chapter 1.1., are compulsorily notifiable. Member Countries are encouraged to also provide information to the OIE on other animal health event of epidemiological significance.

Chapter 1.2. describes the criteria for the inclusion of a disease, infection or infestation in the OIE List and gives the updated list. Diseases are divided into nine categories, depending of based on the host species of the aetiological agents.

2) Diagnostic tests and vaccines

The use of specified diagnostic tests and vaccines in *Terrestrial Code* chapters is recommended with a reference to the relevant section in the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereafter referred to as the *Terrestrial Manual*). Chapter 1.3. provides a table summarising the recommended diagnostic tests for OIE listed diseases. Experts responsible for F facilities responsible used for disease diagnosis and vaccine production should be fully conversant with the standards in the *Terrestrial Manual*.

3) Prevention and control

Chapters 4.5. to 4.11. describe the measures which should be implemented during collection and processing of semen and embryos of animals, including micromanipulation and cloning, in order to prevent animal health risks, especially when trading these commodities. Although this the measures relates principally to OIE listed diseases or infections, general standards apply applies to all health risks. Moreover, in Chapter 4.7. diseases that are not listed diseases are included, and marked as such, mentioned for the information of OIE Member Countries.

EU comment

Please replace “relates” by “relate” in the second sentence of the point above (grammar).

Chapter 4.14. addresses the specific issue of the control of bee diseases and some of its trade implications. This chapter should be read in conjunction with the specific bee disease chapters in Section 9.

Chapter 6.4. is designed for the implementation of general biosecurity measures in intensive poultry production, whereas Chapter 6.5. gives an example of a specific on-farm prevention and control plan for the non-listed food borne pathogen *Salmonella* in poultry, including standards for introduction of live poultry and hatching eggs.

Chapter 6.11. deals specifically with the zoonotic risk associated with the movements of non-human primates and gives standards for certification, transportation and import conditions of these animals.

4) Trade requirements

International trade animal health measures should be based on OIE standards. A Member Country may authorise the importation of animals or animal products into its territory under conditions more or less restrictive than those recommended by the *Terrestrial Code*. To scientifically justify more trade restrictive measures However, where the conditions are more restrictive, the importing country they should conduct be scientifically justified by a risk analysis conducted in accordance with OIE standards, as described in Chapter 2.1. For Members of the WTO should refer to meet their obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), international trade animal health measures should be based on an OIE standard or an import risk analysis.

EU comment

In order to improve readability, the first sentence of the paragraph above should be amended as follows:

“International trade Animal health measures related to international trade should be based on OIE standards.”

Chapters 5.1. to 5.3. describe the obligations and ethics in international trade. Veterinary Authorities and all veterinarians directly involved in international trade should be familiar with these chapters, These chapters which also provide guidance for informal mediation by the OIE.

The OIE aims to include an article listing the commodities that are considered safe for trade without the imposition of pathogen-specific sanitary measures, regardless of the status of the country or zone for the agent in question, at the beginning of each disease-specific chapter relating to a specific aetiological agent in Sections 8 to 15 an article listing the commodities that are considered safe for trade regardless of the status of the country or zone for the agent in question. This is a work in progress and some chapters do not yet contain articles listing safe commodities. In those chapters, where such a list of safe commodities is present, the importing countries should be not apply trade restrictions applied to the listed such commodities in relation with respect to the agent in question.

EU position

The EU does not support the amendment of the paragraph above as proposed. Indeed, as explained in the EU's general comment included in the introduction of the Code Commission report, "safe commodities" in principle should only be those commodities that are safe *per se*, without requiring any risk mitigation treatment, be it specific or unspecific. In this context, it is unclear what is meant by "pathogen specific sanitary measures".

Therefore, in the first sentence of the paragraph above, the words "without the imposition of pathogen-specific sanitary measures" should be deleted.

As the concept of safe commodities is an important element of the OIE standards in relation to international trade, the EU suggests having an in depth reflection and discussion on this concept both within the OIE and among Member Countries, which ideally would lead to a commonly agreed definition of the term "safe commodity" to be included in the glossary.

5) International veterinary certificates

An international veterinary certificate is an official document the Veterinary Authority of an exporting country drawn up by the Veterinary Authority of an exporting country in accordance with Chapter 5.1. and Chapter 5.2., Certificates list describing the animal health requirements and, where appropriate, public health requirements for the exported commodity. The quality of the exporting country's Veterinary Services is essential in providing assurances to trading partners regarding the safety of exported animals and products. This includes the Veterinary Services' ethical approach to the provision of veterinary certificates and their history in meeting their notification obligations, is essential in providing assurance to trading partners regarding the safety of exported animals and products.

International veterinary certificates underpin international trade and provide assurances to the importing country regarding the health status of the animals and products imported. The measures prescribed should take into account the health status of both exporting and importing countries and be based upon the standards in the *Terrestrial Code*.

The following steps should be taken when drafting international veterinary certificates:

- a) list the diseases, infections or infestations for which the importing country is justified in seeking protection in regards to its own disease status. Importing countries should not impose measures in regards to diseases that occur in their own territory but are not subject to official control or eradication programmes;
- b) for commodities capable of transmitting these diseases, infections or infestations through international trade, the importing country should apply the articles addressing the commodity in question in the relevant disease-specific chapters. The application of the articles should be, adapted to the disease status of the exporting country, zone or compartment. Such status should be established according to Article 1.4.6. the articles except when articles of the relevant disease chapter specify otherwise, or to Chapter 1.4. when there are no such articles;
- c) when preparing international veterinary certificates, the importing country should endeavour to use terms and expressions in accordance with the definitions given in the Glossary. As stated in Article 5.2.3., international veterinary certificates should be kept as simple as possible and should be clearly worded, to avoid misunderstanding of the importing country's requirements;

- d) Chapters 5.10. to 5.12. contain provide model certificates as a further guidance to Member Countries, and model certificates that should be used as a baseline.

6) Guidance notes for importers and exporters

Veterinary Authorities are recommended to prepare 'guidance notes' to assist importers and exporters
To provide understand a clear understanding of trade requirements, it is advisable that Veterinary Authorities of Member Countries prepare 'guidance notes' to assist importers and exporters. These notes should identify and explain the trade conditions, including the measures to be applied before and after export, during transport and unloading, relevant legal obligations and operational procedures. The guidance notes should advise on all details to be included in the health certification accompanying the consignment to its destination. Exporters should also be reminded of the International Air Transport Association rules governing air transport of animals and animal products. The guidance notes should advise on all details to be included in the health certification accompanying the consignment to its destination.

— Text deleted.

CHAPTER 5.1.

GENERAL OBLIGATIONS RELATED TO
CERTIFICATION**EU position**

The EU does not support the adoption of this modified chapter as proposed. Comments are inserted in the text below that should be taken into account before adoption.

The EU notes that this amended chapter is proposed for adoption in May 2014 without having previously been circulated for member comments. Reference is made to the EU's general comment included in the introduction of the Code Commission report.

Article 5.1.1.

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

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

These requirements should be included in the model certificates approved by the OIE which are included from Chapters 5.10. to 5.12.

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

The certification requirements should not include conditions for *diseases* that are not transmitted by the *commodity* concerned. The certificate should be signed in accordance with the provisions of Chapter 5.2.

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

Article 5.1.2.

Responsibilities of the importing country

- 1) The import requirements included in the *international veterinary certificate* should assure that *commodities* introduced into the *importing country* comply with the standards of the OIE. *Importing countries* should restrict their requirements to those **recommended in the relevant standards of the OIE, necessary to achieve the national appropriate level of protection. If there are no such standards or if the country wishes to establish are more trade restrictive stricter measures, these than the standards of the OIE, they** should be based on an *import risk analysis*.

EU position

While in general supporting the redrafting proposed above, the EU is of the opinion that the new text does not reflect well the reason for establishing more trade restrictive

measures than those recommended by OIE standards. Indeed, the primary purpose is not the wish of the importing country to establish more trade restrictive measures *per se*. In line with the principles of the SPS agreement, it is rather the choice to maintain the appropriate level of protection chosen by the importing country which is the essential element for establishing import requirements that go beyond what is recommended by OIE standards, while at the same time keeping trade restrictions to the minimum necessary to achieve that chosen level of protection. This should properly be reflected in the text, in order to avoid any possible misunderstandings that might inadvertently encourage countries to set unjustified barriers to trade.

Therefore, the EU suggests amending the paragraph above as follows:

“If there are no such standards or if the country ~~wishes to~~ chooses to establish maintain a higher level of protection resulting in more trade restrictive measures, these should be scientifically justified and based on an import risk analysis.”

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

EU position

As the term “trade restrictive” is not appropriate for measures applied within the importing country, the EU suggests the following alternative wording in the paragraph above:

“The measures imposed on imports to manage the *risks* posed by a specific pathogen or *disease* should not be ~~more trade restrictive~~ stricter than the measures applied as part of the *official control programme* operating within the *importing country.*”

- 3) The *international veterinary certificate* should not include measures against pathogens or *diseases* which are not OIE listed, unless the *importing country* has demonstrated through *import risk analysis*, carried out in accordance with Section 2., that the pathogen or *disease* poses a significant *risk* to the *importing country*.
- 4) The transmission by the *Veterinary Authority* of certificates or the communication of import requirements to persons other than the *Veterinary Authority* of another country, necessitates that copies of these documents are also sent to the *Veterinary Authority*. This important procedure avoids delays and difficulties which may arise between traders and *Veterinary Authorities* when the authenticity of the certificates or permits is not established.

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

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

Article 5.1.3.

Responsibilities of the exporting country

- 1) An *exporting country* should, on request, supply the following to *importing countries*:
- a) information on the animal health situation and national animal health information systems to determine whether that country is free or has *zones* or *compartments* free from *listed diseases*, including the regulations and procedures in force to maintain its free status;

- b) regular and prompt information on the occurrence of *notifiable diseases*;
 - c) details of the country's ability to apply measures to control and prevent the relevant *listed diseases*;
 - d) information on the structure of the *Veterinary Services* and the authority which they exercise according to Chapters 3.1. and 3.2.;
 - e) technical information, particularly on biological tests and vaccines applied in all or part of the national territory.
- 2) *Veterinary Authorities* of *exporting countries* should:
- a) have official procedures for authorisation of certifying *veterinarians*, defining their functions and duties as well as conditions of oversight and accountability, including possible suspension and termination of the authorisation;
 - b) ensure that the relevant instructions and training are provided to certifying *veterinarians*;
 - c) monitor the activities of the certifying *veterinarians* to verify their integrity and impartiality.
- 3) The *Veterinary Authority* of the *exporting country* is ultimately accountable for veterinary certification used in *international trade*.

Article 5.1.4.

Responsibilities in case of an incident related to importation

- 1) *International trade* involves a continuing ethical responsibility. Therefore, if within the recognised *incubation periods* of the various *diseases* subsequent to an export taking place, the *Veterinary Authority* becomes aware of the appearance or reappearance of a *disease* which has been specifically included in the *international veterinary certificate*, there is an obligation for this *Authority* to notify the *importing country*, so that the imported *commodities* may be inspected or tested and appropriate action be taken to limit the spread of the *disease* should it have been inadvertently introduced.
- 2) If a *disease* condition appears in imported *commodities* within a time period after importation consistent with the recognised *incubation period* of the *disease*, the *Veterinary Authority* of the *exporting country* should be informed so as to enable an investigation to be made, since this may be the first available information on the occurrence of the *disease* in a previously free *herd*. The *Veterinary Authority* of the *importing country* should be informed of the result of the investigation since the source of *infection* may not be in the *exporting country*.
- 3) In case of suspicion, on reasonable grounds, that an official certificate may be fraudulent, the *Veterinary Authority* of the *importing country* and *exporting country* should conduct an investigation. Consideration should also be given to notifying any third country(ies) that may have been implicated. All associated consignments should be kept under official control, pending the outcome of the investigation. The *Veterinary Authorities* of all countries involved should fully cooperate with the investigation. If the certificate is found to be fraudulent, every effort should be made to identify those responsible so that appropriate action can be taken according to the relevant legislation.

— Text deleted.

GLOSSARY

EU position

The EU in general supports the adoption of this modified glossary. Comments are inserted in the text below.

For the purposes of the *Terrestrial Code*:

Emerging disease

means a new occurrence in an animal of a disease, infection or infestation, causing which has a significant impact on animal or public health, of a disease, infection or infestation resulting from: the evolution or

- ≡ a change of an known existing pathogenic agent, ~~a known infection or infestation~~ or its spreading to a new geographic area or species population; or
- ≡ a previously unrecognised pathogenic agent or *disease* diagnosed for the first time and which has a significant impact on animal or public health.

Risk assessment

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

Stamping-out policy

means carrying out under the authority of the *Veterinary Authority*, on confirmation of a *disease*, the *killing* of the *animals* which are affected and those suspected of being affected in the *herd* and, where appropriate, those in other *herds* which have been exposed to *infection* by direct animal to animal contact, or by indirect contact of a kind likely to cause the transmission of with the causal pathogen. All susceptible *animals*, vaccinated or unvaccinated, on an infected premises establishments should be killed and their carcasses destroyed by burning or burial, or by any other method which will eliminate the spread of *infection* through the carcasses or products of the *animals* killed.

This policy should be accompanied by the cleansing and *disinfection* procedures defined in the *Terrestrial Code*.

The terms *modified stamping-out policy* should be used in communications to the OIE whenever the above animal health measures are not implemented in full and details of the modifications should be given.

EU comment

As regards destroying of carcasses, in addition to burning and burial, the option of rendering should be envisaged, as now this is a frequently used method of carcass disposal. In addition, a reference to Chapter 4.12. “Disposal of dead animals” could be included in the definition. Furthermore, the word “on” before “infected establishments” should be replaced by “in” (grammar).

The EU therefore suggests amending the sentence as follows:

“[...] All susceptible *animals*, vaccinated or unvaccinated, ~~on~~ in infected *establishments* should be killed and their carcasses destroyed by rendering, burning or burial, or by any other method described in Chapter 4.12, which will eliminate the spread of infection through the carcasses or products of the animals killed”.

Finally, the term *modified stamping-out policy* is not well defined in the glossary, as the definition of that term refers back to the definition of *stamping-out policy*, in which the modifications are not explicitly mentioned, i.e. member countries are free to modify the *stamping-out policy* as they see fit without any further details given in the glossary definition. This may lead to confusion in the disease specific chapters whenever the term *modified stamping-out policy* is used. Therefore the EU wonders whether a definition of *modified stamping-out* in the glossary and the use of the italicised term in the Code are at all necessary. Instead, the concept of modified-stamping out policy and the implications for notifications and other communications with the OIE could also be explained elsewhere in the Code, e.g. in the chapter on notification of diseases. Reference is made to the EU comment in the draft new chapter on PRRS.

— Text deleted.

CHAPTER 1.1.

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

EU position

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

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, Member Countries 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) Member Countries shall make available to other Member Countries, through the OIE, whatever information is necessary to minimise the spread of important animal *diseases*, and their aetiological agents, and to assist in achieving better worldwide control of these *diseases*.
- 2) To achieve this, Member Countries shall comply with the *notification* requirements specified in Article 1.1.3. and 1.1.3.bis
- 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) The detection of the aetiological agent of a listed disease in an animal should be reported, even in the absence of clinical signs. Recognising that scientific knowledge concerning the relationship between *diseases* and their aetiological agents is constantly developing and that the presence of an aetiological agent does not necessarily imply the presence of a *disease*, Member Countries shall ensure, through their reports, that they comply with the spirit and intention of point 1 above. This means that the detection of the aetiological agent of a listed disease in an animal should be reported, even in the absence of clinical signs disease.
- 5) In addition to notifying new findings in accordance with Articles 1.1.3. and 1.1.3.bis, Member Countries shall also provide information on the measures taken to prevent the spread of *diseases*, *infections* and *infestations*; Information shall including include quarantine measures and restrictions on the movement of *animals*, animal products, biological products and other miscellaneous objects which could by their nature be responsible for their transmission. 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 fax or e-mail, within 24 hours, of any of the following events:
 - a) first occurrence of a *listed disease*, *infection* or *infestation* in a country, a *zone* or a *compartment*;

- b) re-occurrence of a *listed disease, infection or infestation* in a country, a *zone* or a *compartment* following a the final report that declared the *outbreak* ended;
 - c) first occurrence of a new strain of a pathogen of a *listed disease, infection or infestation* in a country, a *zone* or a *compartment*;
 - d) a sudden and unexpected change increase in the distribution, or increase in incidence or virulence of, or morbidity or mortality of caused by, the aetiological agent of a *listed disease, infection or infestation* prevalent present 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 occurrence of a listed disease, infection or infestation in an unusual host species (including host range, pathogenicity, strain) in particular if there is a zoonotic impact;~~
- 2) weekly reports subsequent to a *notification* under point 1 above, to provide further information on the evolution of the event which justified the *notification*. These reports should continue until the *disease, infection or infestation* has been eradicated or the situation has become sufficiently stable so that six-monthly reporting under point 3 will satisfy the obligation of the Member Country; ~~in any for each event notified case~~, a final report on the event should be submitted;
 - 3) six-monthly reports on the absence or presence, and evolution of *listed diseases, infections or infestations* and information of epidemiological significance to other Member Countries;
 - 4) annual reports concerning any other information of significance to other Member Countries.

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

Article 1.1.3.bis

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

- 1) a notification through WAHIS or by fax or e-mail, when an emerging disease has been detected in a country, a zone or a compartment;
- 2) periodic reports subsequent to a notification of for an emerging disease, as described under point 1. These should continue until:
 - a) the disease, infection or infestation has been eradicated; or
 - b) the situation becomes sufficiently stable; or
 - c) sufficient scientific information is available to determine whether it meets the criteria for listing.

Article 1.1.4.

- 1) The *Veterinary Authority* of a country in which an *infected zone* was located shall inform the *Headquarters* when this zone is free from the *disease, infection or infestation*.
- 2) An *infected zone* for a particular *disease, infection or infestation* shall be considered as such until a period exceeding the *infective period* specified in the *Terrestrial Code* has elapsed after the last reported case, and when full prophylactic and appropriate animal health measures have been applied to prevent possible reappearance or spread of the *disease, infection or infestation*. These measures will be found in detail in the various chapters of Volume II of the *Terrestrial Code*.
- 3) A Member Country may be considered to regain freedom from a specific *disease, infection or infestation* when all relevant conditions given in the ~~relevant chapters of the~~ *Terrestrial Code* have been fulfilled.

- 4) The *Veterinary Authority* of a Member Country which sets up one or several *free zones* shall inform the *Headquarters* 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 Country.

Article 1.1.5.

- 1) Although Member Countries are only required to notify *listed diseases, infections and infestations and emerging diseases*, they are encouraged to inform the OIE of other important animal health events.
- 2) The *Headquarters* shall communicate by e-mail or World Animal Health Information Database (WAHID) to *Veterinary Authorities* all *notifications* received as provided in Articles 1.1.2. to 1.1.4. and other relevant information.

— Text deleted.

CHAPTER 1.2.

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

EU position

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

Article 1.2.1.

Introduction

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

Article 1.2.2.

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

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

AND

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

AND

3)

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

OR

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

OR

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

AND

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

OR

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

Article 1.2.3.

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

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

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

- Anthrax
- Bluetongue
- Brucellosis (*Brucella abortus*)
- Brucellosis (*Brucella melitensis*)
- Brucellosis (*Brucella suis*)
- Crimean Congo haemorrhagic fever
- Epizootic haemorrhagic disease
- Equine encephalomyelitis (Eastern)
- Foot and mouth disease
- Heartwater
- Infection with Aujeszky's disease virus
- Infection with *Echinococcus granulosus*
- Infection with *Echinococcus multilocularis*
- Infection with rabies virus
- Infection with rinderpest virus
- Infection with *Trichinella* spp.
- Japanese encephalitis
- New World screwworm (*Cochliomyia hominivorax*)
- Old World screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- **Infection with** Rift Valley fever **virus**
- Surra (*Trypanosoma evansi*)
- Tularemia
- ~~Vesicular stomatitis (under study)~~
- West Nile fever.

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

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

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

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

Annex VIII (contd)

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

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

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

- African swine fever
- Infection with classical swine fever virus
- Nipah virus encephalitis
- Porcine cysticercosis
- Porcine reproductive and respiratory syndrome
- ~~Swine vesicular disease (under study)~~
- Transmissible gastroenteritis.

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

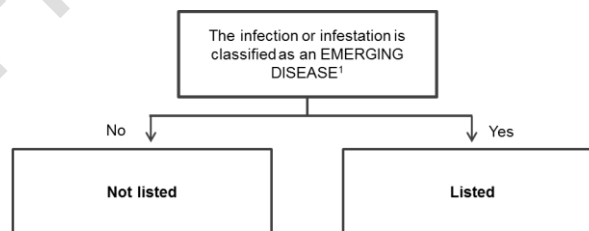
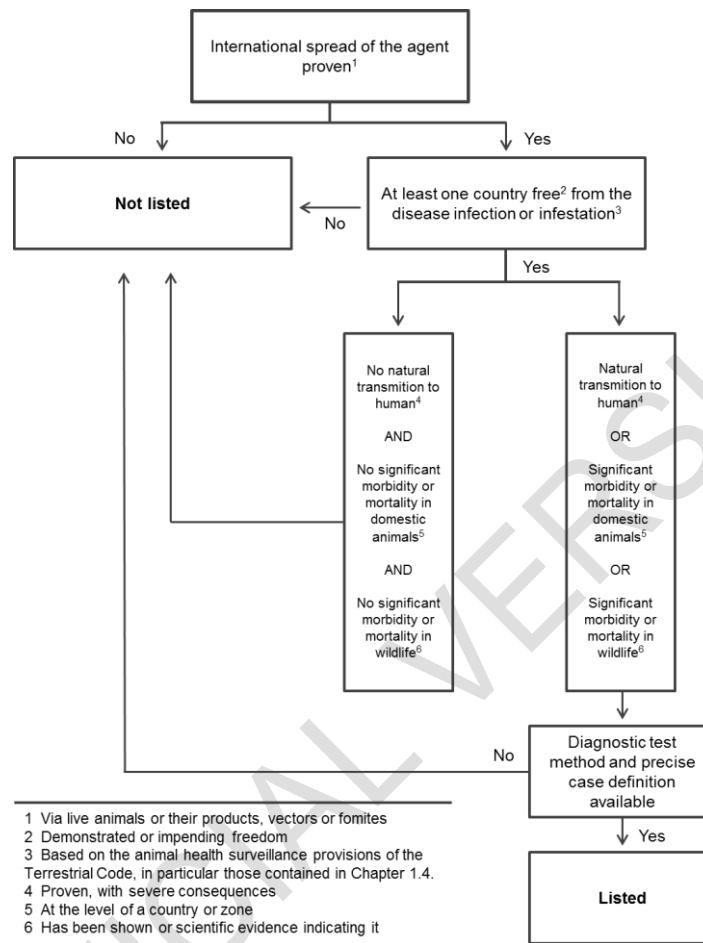
- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Avian mycoplasmosis (*Mycoplasma gallisepticum*)
- Avian mycoplasmosis (*Mycoplasma synoviae*)
- Duck virus hepatitis
- Fowl typhoid
- Infection with avian influenza viruses ~~and~~

Annex VIII (contd)

- ≡ Infection with influenza A viruses of high pathogenicity in birds other than poultry including wild birds
 - Infectious bursal disease (Gumboro disease)
 - Infection with Newcastle disease virus
 - Pullorum disease
 - Turkey rhinotracheitis.
- 7) The following are included within the category of lagomorph *diseases and infections*:
- Myxomatosis
 - Rabbit haemorrhagic disease.
- 8) The following are included within the category of bee *diseases, infections and infestations*:
- Infection of honey bees with *Melissococcus plutonius* (European foulbrood)
 - Infection of honey bees with *Paenibacillus larvae* (American foulbrood)
 - Infestation of honey bees with *Acarapis woodi*
 - Infestation of honey bees with *Tropilaelaps* spp.
 - Infestation of honey bees with *Varroa* spp. (Varroosis)
 - Infestation with *Aethina tumida* (Small hive beetle).
- 9) The following are included within the category of other *diseases and infections*:
- Camelpox
 - Leishmaniosis.

Annex VIII (contd)

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

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~~CHAPTER 8.16.~~~~VESICULAR STOMATITIS~~~~Article 8.16.1.~~~~General provisions and safe commodities~~

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

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

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

- ~~1) *milk and milk products*;~~
- ~~2) *hides and skins*;~~
- ~~3) *meat and meat products*;~~
- ~~4) *tallow*;~~
- ~~5) *gelatine and collagen*.~~

~~Article 8.16.2.~~~~VS free country~~

~~A country may be considered free from VS when:~~

- ~~1) *VS is notifiable in the country*;~~
- ~~2) *no clinical, epidemiological or other evidence of VS has been found during the past two years*.~~

~~Article 8.16.3.~~~~Trade in commodities~~

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

~~Article 8.16.4.~~~~Recommendations for importation from VS free countries~~

~~For domestic cattle, sheep, goats, pigs and horses~~

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

- ~~1) *showed no clinical sign of VS on the day of shipment*;~~
- ~~2) *were kept in a VS free country since birth or for at least the past 21 days*.~~

~~Annex VIII (contd)~~

Article 8.16.5.**Recommendations for importation from VS free countries**For wild bovine, ovine, caprine, porcine and equine animals and deer

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

- 1) showed no clinical sign of VS on the day of shipment;
- 2) come from a VS free country;

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

- 3) were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;
- 4) were protected from insect vectors during quarantine and transportation to the *place of shipment*.

Article 8.16.6.**Recommendations for importation from countries considered infected with VS**For domestic cattle, sheep, goats, pigs and horses

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

- 1) showed no clinical sign of VS on the day of shipment;
- 2) were kept, since birth or for the past 21 days, in an *establishment* where no case of VS was officially reported during that period;
- 3) were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;
- 4) were protected from insect vectors during quarantine and transportation to the *place of shipment*.

Article 8.16.7.**Recommendations for importation from countries considered infected with VS**For wild bovine, ovine, caprine, porcine and equine animals and deer

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

- 1) showed no clinical sign of VS on the day of shipment;
- 2) were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;
- 3) were protected from insect vectors during quarantine and transportation to the *place of shipment*.

~~Article 8.16.8.~~~~Recommendations for importation from VS free countries or zones~~~~For in vivo derived embryos of ruminants, swine and horses~~~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:~~

- ~~1) the donor females were kept in an establishment located in a VS free country or zone at the time of collection;~~
- ~~2) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.~~

~~Article 8.16.9.~~~~Recommendations for importation from countries or zones considered infected with VS~~~~For in vivo derived embryos of ruminants, swine and horses~~~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:~~

- ~~1) the donor females:

 - ~~a) were kept for the 21 days prior to, and during, collection in an establishment where no case of VS was reported during that period;~~
 - ~~b) were subjected to a diagnostic test for VS, with negative results, within the 21 days prior to embryo collection;~~~~
- ~~2) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.~~

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Annex VIII (contd)

~~CHAPTER 15.4.~~~~SWINE VESICULAR DISEASE~~~~Article 15.4.1.~~~~General provisions~~

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

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

~~Article 15.4.2.~~~~SVD free country~~

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

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

~~Article 15.4.3.~~~~SVD infected zone~~

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

- ~~1) at least 60 days have elapsed after the confirmation of the last case and the completion of a stamping-out policy and disinfection procedures, or~~
- ~~2) 12 months have elapsed after the clinical recovery or death of the last affected animal if a stamping-out policy was not practised.~~

~~Article 15.4.4.~~~~Trade in commodities~~

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

- ~~1) domestic and wild pigs;~~
- ~~2) semen of pigs;~~
- ~~3) fresh meat of domestic and wild pigs;~~
- ~~4) meat products of domestic and wild pigs which have not been processed to ensure the destruction of the SVD virus;~~
- ~~5) products of animal origin (from pigs) intended for use in animal feeding or for agricultural or industrial use which have not been processed to ensure the destruction of the SVD virus;~~
- ~~6) products of animal origin (from pigs) intended for pharmaceutical or surgical use which have not been processed to ensure the destruction of the SVD virus;~~

Annex VIII (contd)

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

Article 15.4.5.

Recommendations for importation from SVD free countries

For domestic pigs

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

- 1) showed no clinical sign of SVD on the day of shipment;
- 2) were kept in an SVD free country since birth or for at least the past six weeks.

Article 15.4.6.

Recommendations for importation from SVD free countries

For wild pigs

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

- 1) showed no clinical sign of SVD on the day of shipment;
- 2) come from an SVD free country;

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

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

Article 15.4.7.

Recommendations for importation from countries considered infected with SVD

For domestic pigs

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

- 1) showed no clinical sign of SVD on the day of shipment;
- 2) were kept since birth, or for the past six weeks, in an *establishment* where no case of SVD was officially reported during that period, and that the *establishment* was not situated in an *SVD infected zone*;
- 3) were kept in a *quarantine station* for the 28 days prior to shipment, and were subjected to the virus neutralisation test for SVD with negative results during that period.

Article 15.4.8.

Recommendations for importation from countries considered infected with SVD

For wild pigs

Annex VIII (contd)

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

- ~~1) showed no clinical sign of SVD on the day of shipment;~~
- ~~2) were kept in a quarantine station for the 28 days prior to shipment, and were subjected to the virus neutralisation test for SVD with negative results during that period.~~

~~Article 15.4.9.~~

~~Recommendations for importation from SVD free countries~~~~For semen of pigs~~

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

- ~~1) the donor animals:

 - ~~a) showed no clinical sign of SVD on the day of collection of the semen;~~
 - ~~b) were kept in an SVD free country for not less than six weeks prior to collection;~~~~
- ~~2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.~~

~~Article 15.4.10.~~

~~Recommendations for importation from countries considered infected with SVD~~~~For semen of pigs~~

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

- ~~1) the donor animals:

 - ~~a) showed no clinical sign of SVD on the day of collection of the semen, and were subjected to the virus neutralisation test for SVD with negative results;~~
 - ~~b) were kept in the exporting country for the 28 days prior to collection, in an establishment or artificial insemination centre where no case of SVD was officially reported during that period, and that the establishment or artificial insemination centre was not situated in an SVD infected zone;~~~~
- ~~2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.~~

~~Article 15.4.11.~~

~~Recommendations for importation from SVD free countries~~~~For fresh meat of pigs~~

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

- ~~1) have been kept in an SVD free country since birth or for at least the past 28 days;~~
- ~~2) have been slaughtered in an approved abattoir, and have been subjected to ante and post-mortem inspections for SVD with favourable results.~~

Annex VIII (contd)

~~Article 15.4.12.~~~~Recommendations for importation from countries considered infected with SVD~~~~For fresh meat of pigs~~

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

- ~~1) have not been kept in an SVD infected zone;~~
- ~~2) have been slaughtered in an approved abattoir not situated in an SVD infected zone, and have been subjected to ante- and post-mortem inspections for SVD with favourable results.~~

~~Article 15.4.13.~~~~Recommendations for importation from countries considered infected with SVD~~~~For meat products of pigs~~

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

- ~~1) the entire consignment of meat products comes from animals which have been slaughtered in an approved abattoir and have been subjected to ante- and post-mortem inspections for SVD with favourable results;~~
- ~~2) the meat products have been processed to ensure the destruction of the SVD virus;~~
- ~~3) the necessary precautions were taken after processing to avoid contact of the meat with any source of SVD virus.~~

~~Article 15.4.14.~~~~Recommendations for importation from SVD free countries~~~~For products of animal origin (from pigs) intended for use in animal feeding or for agricultural or industrial use~~

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that these products come from animals which have been kept in an SVD free country since birth or for at least the past 6 weeks.~~

~~Article 15.4.15.~~~~Recommendations for importation from SVD free countries~~~~For products of animal origin (from pigs) intended for pharmaceutical or surgical use~~

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

- ~~1) have been kept in an SVD free country since birth or for at least the past six weeks;~~
- ~~2) have been slaughtered in an approved abattoir, and have been subjected to ante- and post-mortem inspections for SVD with favourable results.~~

Annex VIII (contd)~~Article 15.4.16.~~~~Recommendations for importation from countries considered infected with SVD~~~~For meal and flour from blood, meat, defatted bones, hooves and claws (from pigs)~~

~~Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the SVD virus.~~

~~Article 15.4.17.~~~~Recommendations for importation from countries considered infected with SVD~~~~For bristles (from pigs)~~

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

~~Article 15.4.18.~~~~Recommendations for importation from countries considered infected with SVD~~~~For fertilisers of animal origin (from pigs)~~

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

- ~~1) do not come from an *SVD infected zone*; or~~
- ~~2) have been processed to ensure the destruction of the SVD virus.~~

~~Article 15.4.19.~~~~Recommendations for importation from countries considered infected with SVD~~~~For products of animal origin (from pigs) intended for pharmaceutical or surgical use~~

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

- ~~1) have been processed to ensure the destruction of the SVD virus;~~
- ~~2) come from *animals* which have not been kept in an *SVD infected zone*;~~
- ~~3) come from *animals* which have been slaughtered in an approved *abattoir* and have been subjected to ante and post-mortem inspections for SVD with favourable results.~~

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CHAPTER 2.1.

IMPORT RISK ANALYSIS

EU position

The EU thanks the OIE and 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*.

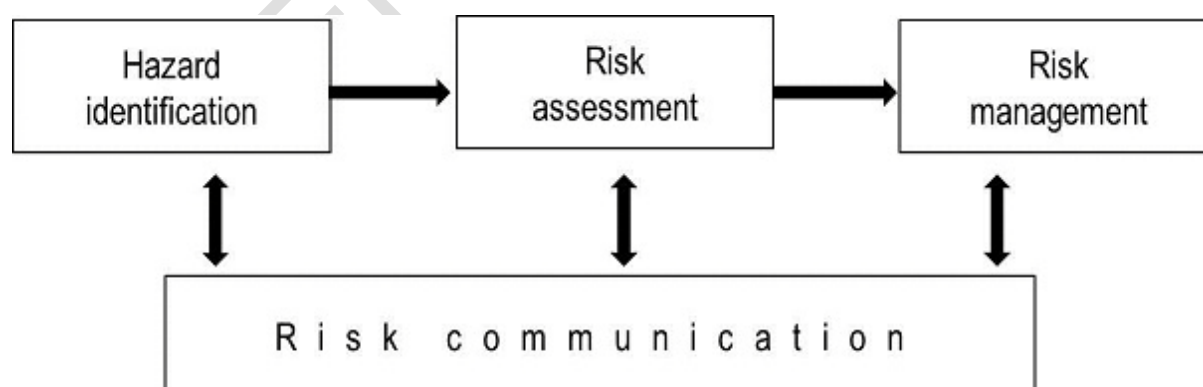
The principal aim of import *risk analysis* is to provide *importing countries* with an objective and defensible method of assessing the *disease risks* associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, biological products and *pathological material*. 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 that 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 IX (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 assessment

Entry assessment consists of describing the biological pathway(s) necessary for an importation activity to 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 assessment describes the probability of the '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 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 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) 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 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 IX (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 assessment, exposure assessment, and consequence assessment to produce overall measures of *risks* associated with the *hazards* identified at the outset. Thus risk estimation takes into account the whole of the *risk* pathway from *hazard* identified to unwanted outcome.

For a quantitative assessment, the final outputs may include:

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

Article 2.1.5.

Principles of risk management

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

Article 2.1.6.

Risk management components

- 1) Risk evaluation - the process of comparing the *risk* estimated in the *risk assessment* with the reduction in risk expected from the proposed risk management measures Member Country'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 Countries appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood 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 IX (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 4.7.

**COLLECTION AND PROCESSING OF *IN VIVO*
DERIVED EMBRYOS FROM LIVESTOCK AND
EQUIDS**

EU position

The EU in general supports the adoption of this modified chapter. Some comments are inserted in the text below, seeking consistency with the nomenclature of diseases in Chapter 1.2. and the corresponding disease specific chapters of the Code.

The EU notes that this amended chapter is proposed for adoption in May 2014 without having previously been circulated for member comments. Reference is made to the EU's general comment included in the introduction of the Code Commission report.

Article 4.7.1.

Aims of control

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

Article 4.7.2.

Conditions applicable to the embryo collection team

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

- 1) The team should be approved by the *Competent Authority*.
- 2) The team should be supervised by a team *veterinarian*.
- 3) The team *veterinarian* is responsible for all team operations which include verification of donor health status, sanitary handling and surgery of donors and *disinfection* and hygienic procedures.
- 4) Team personnel should be adequately trained in the techniques and principles of *disease* control. High standards of hygiene should be practiced to preclude the introduction of *infection*.
- 5) The collection team should have adequate facilities and equipment for:
 - a) collecting embryos;
 - b) processing and treatment of embryos at a permanent site or mobile laboratory;
 - c) storing embryos.

These facilities need not necessarily be at the same location.

- 6) The embryo collection team should keep a record of its activities, which should be maintained for inspection by the *Veterinary Authority* for a period of at least two years after the embryos have been exported.

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

Article 4.7.3.

Conditions applicable to processing laboratories

A processing laboratory used by the embryo collection team may be mobile or permanent. It is a facility in which embryos are recovered from collection media, examined and subjected to any required treatments such as washing and being examined and prepared for freezing and storage.

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

Additionally:

- 1) The processing laboratory should be under the direct supervision of the team *veterinarian* and be regularly inspected by an *Official Veterinarian*.
- 2) While embryos for export are being handled prior to their storage in ampoules, vials or straws, no embryos of a lesser health status should be processed.
- 3) The processing laboratory should be protected against rodents and insects.
- 4) The processing laboratory should be constructed with materials which permit its effective cleansing and *disinfection*. This should be done frequently, and always before and after each occasion on which embryos for export are processed.

Article 4.7.4.

Conditions applicable to the introduction of donor animals

1. Donor animals

- a) The *Veterinary Authority* should have knowledge of, and authority over, the *herd/flock* from which the donor *animals* have been sourced.
- b) The donor *animals* should not be situated in a *herd/flock* subject to veterinary restrictions for OIE *listed disease* or pathogens for relevant species (see Chapter 1.2.), other than those that are in International Embryo Transfer Society (IETS) Category 1 for the species of embryos being collected (see Article 4.7.14.).
- c) At the time of collection, the donor *animals* should be clinically inspected by the team *veterinarian*, or by a *veterinarian* responsible to the team *veterinarian* and certified to be free of clinical signs of *diseases*.

2. Semen donors

- a) Semen used to inseminate donor *animals* artificially should have been produced and processed in accordance with the provisions of Chapter 4.6.
- b) When the donor of the semen used to inseminate donor females for embryo production is dead, and when the health status of the semen donor concerning a particular infectious *disease* or *diseases* of concern was not known at the time of semen collection, additional tests may be required of the inseminated donor female after embryo collection to verify that these infectious *diseases* were not transmitted. An alternative may be to test an aliquot of semen from the same collection date.

- c) Where natural service or fresh semen is used, donor sires should meet the health conditions set out in Chapter 4.6. as appropriate to the species.

Article 4.7.5.

Risk management

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

- 1) The first phase, which is applicable to *diseases* not included in Category 1 of the IETS categorisation (Article 4.7.14.), comprises the risk potential for embryo contamination and depends on:
 - a) the disease situation in the *exporting country or zone*;
 - b) the health status of the *herds or flocks* and the donors from which the embryos are collected;
 - c) the pathogenic characteristics of the specified disease agents that are of concern to the *Veterinary Authority of the importing country*.
- 2) The second phase covers risk mitigation by use of internationally accepted procedures for processing of embryos which are set out in the IETS Manual. These include the following:
 - a) The embryos should be washed at least ten times with at least 100-fold dilutions between each wash, and a fresh pipette should be used for transferring the embryos through each wash.
 - b) Only embryos from the same donor should be washed together, and no more than ten embryos should be washed at any one time.
 - c) Sometimes, for example when inactivation or removal of certain viruses, such as bovine herpesvirus-1 and Aujeszky's disease virus, is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual.
 - d) The zona pellucida of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free of adherent material.
 - e) All shipments of embryos should be accompanied by a statement signed by the team veterinarian certifying that these embryo processing procedures have been completed.
- 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 *herd or flock* based on the recognised *incubation periods* of the *diseases* of concern to determine retrospectively the health status of donors whilst the embryos are stored (in species where effective storage by cryopreservation is possible) in the *exporting country*;
 - b) testing of embryo-collection (flushing) fluids and non-viable embryos, or other samples such as blood, in a laboratory for presence of specified disease agents.

Annex X (contd)

Article 4.7.6.

Conditions applicable to the collection and storage of embryos1. Media

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

2. Equipment

- a) All equipment used to collect, handle, wash, freeze and store embryos should ideally be new or at least sterilised prior to use as recommended in the IETS Manual.
- b) Used equipment should not be transferred between countries for re-use by the embryo collection team.

Article 4.7.7.

Optional tests and treatments

- 1) The testing of samples can be requested by an *importing country* to confirm the absence of pathogenic organisms that may be transmitted via *in vivo* derived embryos, or to help assess whether the degree of quality control of the collection team (with regard to adherence to procedures as described in the IETS Manual) is at an acceptable level.

Samples may include:

- a) Non-viable embryos and oocytes

Where the viable, zona pellucida intact embryos from a donor are intended for export, all non-fertilised oocytes and degenerated or zona pellucida compromised embryos collected from that donor should be washed according to the IETS Manual and pooled for testing if requested by the *importing country*. Non-viable embryos and oocytes from the donor should be processed and stored together.

- b) Embryo collection (flushing) fluids

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

- c) Washing fluids

The last four washes of the embryos and oocytes should be pooled according to the IETS Manual.

- d) Samples

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

Annex X (contd)

- 2) When treatment of the viable embryos is modified to include additional washings with the enzyme trypsin (see point 2c) in Article 4.7.5.), the procedure should be carried out according to the IETS Manual. 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 a treatment is not always beneficial and it should not be regarded as a general disinfectant. It may also have adverse effects on embryo viability, for instance in the case of equine embryos where the embryonic capsule could be damaged by the enzyme.

Article 4.7.8.

Conditions applicable to the storage and transport of embryos

- 1) The embryos for export should be stored in sealed sterile ampoules, vials or straws under strict hygienic conditions at a storage place approved by the *Veterinary Authority* of the *exporting country* where there is no risk of contamination of the embryos.
- 2) Only embryos from the same individual donor should be stored together in the same ampoule, vial or straw.
- 3) The embryos should if possible, depending on the species, be frozen, stored with fresh liquid nitrogen in cleaned and sterilised tanks or containers under strict hygienic conditions at the approved storage place.
- 4) Ampoules, vials or straws should be sealed at the time of freezing (or prior to export where cryopreservation is not possible), and they should be clearly identified by labels according to the standardised system recommended in the IETS Manual.
- 5) Liquid nitrogen containers should be sealed under the supervision of the *Official Veterinarian* prior to shipment from the *exporting country*.
- 6) Embryos should not be exported until the appropriate veterinary certificates are completed.

Article 4.7.9.

Procedure for micromanipulation

When micromanipulation of the embryos is to be carried out, this should be done after completion of the treatments described in point 2 of Article 4.7.5. and conducted in accordance with Chapter 4.9.

Article 4.7.10.

Specific conditions applicable to porcine embryos

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

The development of effective cryopreservation methods for the storage of zona pellucida-intact porcine embryos is still at a very early stage.

Article 4.7.11.

Specific conditions applicable to equine embryos

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

Annex X (contd)

Article 4.7.12.

Specific conditions applicable to camelid embryos

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

Article 4.7.13.

Specific conditions applicable to cervid embryos

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

Article 4.7.14.

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

Based on the conclusions of the IETS, the following listed *diseases* and pathogenic agents are categorised into four categories, which applies only to *in vivo* derived embryos.

EU comment

To avoid confusion between OIE listed and non-listed diseases, the EU suggests deleting the word “listed” in the paragraph above, which is not in italics, refers to IETS listed diseases and is not necessary.

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 (pigs): trypsin treatment required

EU comment

For reasons of consistency, the EU suggests amending the names of the diseases in this chapter in line with recent and currently proposed nomenclature changes in the list of diseases in Chapter 1.2. and the corresponding disease specific chapters of the Code, as follows:

“– Infection with Aujeszky's disease virus (pigs): trypsin treatment required”.

- Bluetongue (cattle)
- Bovine spongiform encephalopathy (cattle)
- *Brucella abortus* (cattle)

EU comment

With reference to the comment above, the following amendment is proposed:

“– **Infection with *Brucella abortus* (cattle)**”.

- Enzootic bovine leukosis
- Foot and mouth disease (cattle)
- Infectious bovine rhinotracheitis: trypsin treatment required

EU comment

For reasons of consistency with the wording of Chapter 1.2., the following amendment is proposed:

“– **Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis: trypsin treatment required**”.

- Scrapie (sheep).

2. Category 2

- a) Category 2 *diseases* are those for which substantial evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual, 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.

EU comment

With reference to the comment above, the following amendment is proposed:

“– **Infection with ~~C~~lassical swine fever virus**”.

3. Category 3

- a) Category 3 *diseases* or pathogenic agents are those for which preliminary evidence indicates that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual, 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:
 - Atypical scrapie (not a *listed disease*)
 - Bovine immunodeficiency virus (not a *listed disease*)
 - Bovine spongiform encephalopathy (goats) (not a *listed disease* of goats)
 - Bovine viral diarrhoea virus (cattle)
 - *Campylobacter fetus* (sheep) (not a *listed disease* of sheep)
 - Foot and mouth disease (pigs, sheep and goats)
 - *Haemophilus somnus* (cattle) (not a *listed disease*)

- Maedi-visna (sheep)
- *Mycobacterium paratuberculosis* (cattle)
- *Neospora caninum* (cattle) (not a *listed disease*)
- Ovine pulmonary adenomatosis (not a *listed disease*)
- Porcine reproductive and respiratory disease syndrome (PRRS)
- Porcine circovirus (type 2) (pigs) (not a *listed disease*)
- Rinderpest (cattle)

EU comment

With reference to the comment above, the following amendment is proposed:

“– Infection with Rinderpest virus (cattle)”.

- Swine vesicular disease.

EU comment

As the OIE proposes delisting swine vesicular disease, the EU suggests adding the parenthesis indicating it is not a listed disease, in case Chapter 1.2. is adopted by the World Assembly as proposed, as follows:

“– Swine vesicular disease (not a *listed disease*)”.

4. Category 4

- a) Category 4 *diseases* or pathogenic agents are those for which studies have been done, or are in progress, that indicate:
 - i) that no conclusions are yet possible with regard to the level of transmission risk; or
 - ii) the risk of transmission via embryo transfer might not be negligible even if the embryos are properly handled according to the IETS Manual between collection and transfer.
- b) The following *diseases* or pathogenic agents are in category 4:
 - African swine fever
 - Akabane (cattle) (not a *listed disease*)
 - Bovine anaplasmosis
 - Bluetongue (goats)
 - Border disease (sheep) (not a *listed disease*)
 - Bovine herpesvirus-4 (not a *listed disease*)
 - *Chlamydia psittaci* (cattle, sheep)
 - Contagious equine metritis
 - Enterovirus (cattle, pigs) (not a *listed disease*)
 - Equine rhinopneumonitis

EU comment

With reference to the comment above, the following amendment is proposed:

“– Infection with equid herpesvirus 1 (Equine rhinopneumonitis)”.

- Equine viral arteritis

EU comment

With reference to the comment above, the following amendment is proposed:

“– **Infection with Equine viral arteritis virus**”.

- *Escherichia coli* 09:K99 (cattle) (not a listed disease)
- *Leptospira borgpetersenii* serovar *hardjobovis* (cattle) (not a listed disease)
- *Leptospira* sp. (pigs) (not a listed disease)
- Lumpy skin disease
- *Mycobacterium bovis* (cattle)
- *Mycoplasma* spp. (pigs)
- Ovine epididymitis (*Brucella ovis*)
- **Q fever (*Coxiella burnetii*)**
- Parainfluenza-3 virus (cattle) (not a listed disease)
- Parvovirus (pigs) (not a listed disease)
- **Porcine circovirus (type 2) (pigs) (not a listed disease)**
- Scrapie (goats)
- *Tritrichomonas foetus* (cattle)
- *Ureaplasma* and *Mycoplasma* spp. (cattle, goats) (not a listed disease)
- Vesicular stomatitis (cattle, pigs).

EU comment

As the OIE proposes delisting vesicular stomatitis, the EU suggests adding the parenthesis indicating it is not a listed disease, in case Chapter 1.2. is adopted by the World Assembly as proposed, as follows:

“– **Vesicular stomatitis (cattle, pigs) (not a listed disease).**”.

-
- Text deleted.

CHAPTER 5.2.

CERTIFICATION PROCEDURES

EU position

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

The EU notes that this amended chapter is proposed for adoption in May 2014 without having previously been circulated for member comments. Reference is made to the EU's general comment included in the introduction of the Code Commission report.

Article 5.2.1.

Protection of the professional integrity of the certifying veterinarian

Certification should be based on the highest possible ethical standards, the most important of which is that the professional integrity of the certifying *veterinarian* should be respected and safeguarded according to Chapters 3.1. and 3.2.

It is essential to include in any requirements only those specific statements that can be accurately and honestly signed by a certifying *veterinarian*. For example, these requirements should not include certification of an area as being free from *diseases* other than *notifiable diseases*, or the occurrence of which the signing *veterinarian* is not necessarily informed about. It is unacceptable to ask for certification for events which will take place after the document is signed when these events are not under the direct control and supervision of the signing *veterinarian*.

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

The note of guidance referred to in Article 5.1.1. is not only to inform the signing *veterinarian* but also to safeguard professional integrity.

Article 5.2.2.

Certifying veterinarians

Certifying *veterinarians* should:

- 1) be authorised by the *Veterinary Authority* of the *exporting country* to sign *international veterinary certificates*;
- 2) only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party;
- 3) sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the certifying *veterinarian* should have verified or be in possession of that documentation before signing;
- 4) have no conflict of interest in the commercial aspects of the *animals* or animal products being certified and be independent from the commercial parties.

Article 5.2.3.

Preparation of international veterinary certificates

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

- 1) Certificates should be designed so as to minimize the potential for fraud including use of a unique identification number, or other appropriate means to ensure security. Paper certificates should bear the signature of the certifying *veterinarian* and the official identifier (stamp) of the issuing *Veterinary Authority*. Each page of a multiple page certificate should bear the unique certificate number and a number indicating the number of the page out of the total number of pages. Electronic certification procedures should include equivalent safeguards.
- 2) Certificates should be written using terms that are simple, unambiguous and as easy to understand as possible, without losing their legal meaning.
- 3) If so required, certificates should be written in the language of the *importing country*. In such circumstances, they should also be written in a language understood by the certifying *veterinarian*.
- 4) Certificates should require appropriate identification of *animals* and animal products except where this is impractical (e.g. *day-old birds*).
- 5) Certificates should not require a *veterinarian* to certify matters that are outside his/her knowledge or which he/she cannot ascertain and verify.
- 6) Where appropriate, when presented to the certifying *veterinarian*, certificates should be accompanied by notes of guidance indicating the extent of enquiries, tests or examinations expected to be carried out before the certificate is signed.
- 7) The text of a certificate should not be amended except by deletions which should be signed and stamped by the certifying *veterinarian*.
- 8) The signature and stamp should be in a colour different from that of the printing of the certificate. The stamp may be embossed instead of being a different colour.
- 9) Replacement certificates may be issued by a *Veterinary Authority* to replace certificates that have been, for example, lost, damaged, contain errors, or where the original information is no longer correct. These replacements should be provided by the issuing authority and be clearly marked to indicate that they are replacing the original certificate. A replacement certificate should reference the number and the issue date of the certificate that it supersedes. The superseded certificate should be cancelled and, where possible, returned to the issuing authority.
- 10) Only original certificates are acceptable.

Article 5.2.4.

Electronic certification

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

EU comment

For consistency and clarity reasons, the EU suggests replacing the word “documentation” by the words “exchange of data”. Indeed, as referred to in points a) and b) below, what are exchanged electronically are data and not documents.

- a) Systems providing electronic certificates normally provide an interface with the commercial organisation marketing the commodity for provision of information to the certifying authority. The certifying veterinarian should have access to all information such as laboratory results and animal identification data.
- b) When exchanging electronic certificates and in order to fully utilise electronic data exchange the Veterinary Authorities should use internationally standardised language, message structure and exchange protocols. Guidance for electronic certification in standardised World Wide Web

Consortium (WC3) Extensible Markup Language (XML schemas) as well as secure exchange mechanisms between *Veterinary Authorities* is provided by the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT).

EU comment

In point b) above, the EU proposes deleting the words “World Wide Web Consortium (WC3)” as they are not necessary. Furthermore, the word “schemas” after “XML” should be deleted as it could be misunderstood. Indeed, the exchange of data is performed in XML, while the schema file is used to control whether the exchange of data has been performed accordingly.

Finally, the EU suggests adding a point c) pertaining to security. The wording proposed below is consistent with that contained in the CODEX “Guidelines for design, production, issuance and use of generic official certificates” (CAC/GL 38-2001).

“c) Secure method of electronic data exchange must be ensured by digital authentication of the certificates, encryption, non-repudiation mechanisms, controlled and audited access and firewalls.”

- 2) Electronic certificates may be in a different format but should carry the same information as conventional paper certificates.
- 3) The *Veterinary Authority* should have in place systems for the security of electronic certificates against access by unauthorised persons or organisations.
- 4) The certifying *veterinarian* should be officially responsible for the secure use of his/her electronic signature.

 — Text deleted.

CHAPTER 5.4.

ANIMAL HEALTH MEASURES APPLICABLE BEFORE
AND AT DEPARTURE**EU position**

The EU supports the adoption of this modified chapter.

Article 5.4.1.

Animals for breeding, rearing or slaughter

- 1) Countries should only authorise the exportation from their territory of *animals for breeding or rearing* or *animals for slaughter* which are correctly identified and which meet the requirements of the *importing country*.
- 2) Biological tests and/or *vaccinations* required by the *importing country* should be carried out in accordance with the recommendations in the *Terrestrial Code* and *Terrestrial Manual*, as well as *disinfection* and *disinfestation* procedures.
- 3) Observation of the *animals* before leaving the country may be carried out either in the *establishment* where they were reared, or in a *quarantine station*. The *animals* should be transported to the *place of shipment* in specially constructed *vehicles*, previously cleansed and, if required, disinfected. This must be done without delay and without the *animals* coming into contact with other susceptible *animals*, unless these *animals* have animal health guarantees similar to those of the transported *animals*. An *international veterinary certificate* should attest that the *animals* have been found to be clinically healthy and of the health status agreed by the *importing country* and *exporting country*.
- 4) The transportation of the *animals for breeding or rearing* or *animals for slaughter* from the *establishment* of origin to the point of departure from the *exporting country* should be carried out in conformity with the conditions agreed between the *importing country* and *exporting country*.

Article 5.4.2.

Semen, embryos, leva oocytes and hatching eggs

Countries should only undertake the export from its territory of:

- 1) semen,
- 2) embryos leva and oocytes,
- 3) *hatching eggs*,

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

Article 5.4.3.

Notification

Countries exporting *animals*, semen, embryos, leva oocytes or *hatching eggs* should inform the country of destination and where necessary the *transit countries* if, after exportation, a *listed disease* occurs within the *incubation period* of that particular *disease*, in the *establishment* of origin, or in an *animal* which was in an *establishment* or in a *market*, at the same time as the exported *animals*.

Article 5.4.4.

Certificate

Before the departure of *animals*, semen, embryos, *ova oocytes*, *hatching eggs* and brood-combs of bees, an *Official Veterinarian* should, within the 24 hours prior to shipment, provide an *international veterinary certificate* conforming with the models approved by the OIE (as shown in Chapters 5.10. to 5.12.) and worded in the languages agreed upon between the *exporting country* and the *importing country*, and, where necessary, with the *transit countries*.

Article 5.4.5.

Live animals

- 1) Before the departure of an *animal* or a consignment of *animals* on an international journey, the *Veterinary Authority* of the port, airport or district in which the *border post* is situated may, if it is considered necessary, carry out a clinical examination of the *animal* or consignment. The time and place of the examination should be arranged taking into account customs and other formalities and in such a way as not to impede or delay departure.
- 2) The *Veterinary Authority* referred to in point 1 above should take necessary measures to:
 - a) prevent the shipment of *animals* affected or suspected of being affected with any *listed disease* or with any other infectious *disease* as agreed by the *importing country* and the *exporting country*;
 - b) avoid entry into the *vehicle* of possible *vectors* or causal agents of *infection*.

Article 5.4.6.

Products of animal origin

- 1) Countries should only authorise the export from their territory of *meat* and products of animal origin intended for human consumption, which are fit for human consumption. They must be accompanied by an *international veterinary certificate* conforming to the models approved by the OIE (as shown in Chapters 5.10. to 5.12.). These must be worded in the languages agreed upon between the *exporting country* and the *importing country*, and, where necessary, with the *transit countries*.
- 2) Products of animal origin intended for use in animal feeding, or for pharmaceutical or surgical or agricultural or industrial use, should be accompanied by an *international veterinary certificate* conforming to the models approved by the OIE (as shown in Chapters 5.10. to 5.12.).

 — Text deleted.

CHAPTER 6.6.

INTRODUCTION TO THE RECOMMENDATIONS FOR
CONTROLLING ANTIMICROBIAL RESISTANCE**EU position****The EU thanks the OIE and supports the adoption of this modified chapter.**

Article 6.6.1.

Objective

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

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

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

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

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

— Text deleted.

CHAPTER 6.9.

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

EU position

The EU in general supports the adoption of this modified chapter. A specific comment is inserted in the text below, and a general comment is included in the EU's comment on the work programme of the Code Commission.

Article 6.9.1.

Purpose

This document provides guidance for the responsible and prudent use of *antimicrobial agents* in veterinary medicine, with the aim of protecting both animal and human health as well as the environment. It defines the respective responsibilities of the *Competent Authority* and stakeholders such as the veterinary pharmaceutical industry, *veterinarians*, animal feed manufacturers, distributors and food animal producers who are involved in the authorisation, production, control, importation, exportation, distribution and use of *veterinary medicinal products* (VMP) containing *antimicrobial agents*(s).

Responsible and prudent use is determined taking into account the specifications detailed in the marketing authorisation and their implementation when *antimicrobial agents* are administered to *animals* and is part of good veterinary and good agricultural practice.

Activities associated with the responsible and prudent use of *antimicrobial agents* should involve all relevant stakeholders.

Coordination of these activities at the national or regional level is recommended and may support the implementation of targeted actions by the stakeholders involved and enable clear and transparent communications.

Article 6.9.2.

Objectives of responsible and prudent use

Responsible and prudent use includes implementing practical measures and recommendations intended to improve animal health and *animal welfare* while preventing or reducing the selection, emergence and spread of antimicrobial-resistant bacteria in *animals* and humans. Such measures include:

- 1) ensuring the rational use of *antimicrobial agents* in *animals* with the purpose of optimising both their efficacy and safety;
- 2) complying with the ethical obligation and economic need to keep *animals* in good health;
- 3) preventing or reducing, **as far as possible**, the transfer of resistant micro-organisms or resistance determinants within animal populations, the environment and between *animals* and humans;
- 4) contributing to the maintenance of the efficacy and usefulness of *antimicrobial agents* used in animal and human medicine;
- 5) protecting consumer health by ensuring the safety of food of animal origin with respect to residues of *antimicrobial agents*.

Annex XIV (contd)

Article 6.9.3.

Responsibilities of the Competent Authority1. Marketing authorisation

All Member Countries should combat the unauthorised manufacture, compounding, importation, advertisement, trade, distribution, storage and use of unlicensed, adulterated and counterfeit products, including bulk active ingredients, through appropriate regulatory controls and other measures.

The *Competent Authority* is responsible for granting marketing authorisation which should be done in accordance with the provisions of the *Terrestrial Code*. It has a significant role in specifying the terms of this authorisation and in providing the appropriate information to *veterinarians* and all other relevant stakeholders.

The *Competent Authority* should establish and implement efficient statutory registration procedures that evaluate the quality, safety and efficacy of VMP containing *antimicrobial agent(s)*. According to Article 3.1.2., the *Competent Authority* should be free from any commercial, financial, hierarchical, political or other pressures which might affect its judgement or decisions.

Member Countries lacking the necessary resources to implement an efficient registration procedure for VMP containing *antimicrobial agent(s)*, and which are importing them, should undertake the following measures:

- a) evaluate the efficacy of administrative controls on the import of these VMP;
- b) evaluate the validity of the registration procedures of the exporting and manufacturing country as appropriate;
- c) develop the necessary technical co-operation with experienced relevant authorities to check the quality of imported VMP as well as the validity of the recommended conditions of use.

The *Competent Authorities* of *importing countries* should request the pharmaceutical industry to provide quality certificates prepared by the *Competent Authority* of the exporting and manufacturing country as appropriate.

Marketing authorisation is granted on the basis of the data submitted by the pharmaceutical industry or applicant and only if the criteria of safety, quality and efficacy are met.

Member Countries are encouraged to apply the existing guidelines established by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

An evaluation of the potential risks and benefits to both *animals* and humans resulting from the use of *antimicrobial agents*, with particular focus on use in food producing animals, should be carried out. The evaluation should focus on each individual *antimicrobial agent* and the findings should not be generalised to the antimicrobial class to which the particular active ingredient belongs. Guidance on usage should be provided for all target species, route of administration, dosage regimens, withdrawal period and different durations of treatment that are proposed.

The *Competent Authority* should expedite the process for new *antimicrobial agent(s)* in order to address a specific need for the treatment of *animal disease*.

2. Quality control of antimicrobial agent(s) and VMP containing antimicrobial agent(s)

Quality controls should be performed:

- a) in compliance with the provisions of *good manufacturing practices*;

Annex XIV (contd)

- b) to ensure that analysis specifications of *antimicrobial agent(s)* used as active ingredients comply with the provisions of registration documentations (such as monographs) approved by the relevant *Competent Authority*;
- c) to ensure that the quality of *antimicrobial agent(s)* in the marketed dosage forms *are is* maintained until the expiry date, established under the recommended storage conditions;
- d) to ensure the stability of *antimicrobial agent(s)* when mixed with feed or drinking water;
- e) to ensure that all *antimicrobial agent(s)* and the VMP containing them are manufactured to the appropriate quality and purity in order to guarantee their safety and efficacy.

3. Assessment of therapeutic efficacy

a) Preclinical trials

i) Preclinical trials should:

- establish the spectrum of activity of *antimicrobial agent(s)* against relevant pathogens and non-pathogens (commensals);
- assess the capacity of the *antimicrobial agent(s)* to select for resistance *in vitro* and *in vivo*, taking into consideration intrinsically resistant and pre-existing resistant strains;
- establish an appropriate dosage regimen (dose, dosing interval and duration of the treatment) and route of administration necessary to ensure the therapeutic efficacy of the *antimicrobial agent(s)* and limit the selection of antimicrobial resistance. Pharmacokinetic and pharmacodynamic data and models can assist in this appraisal.

ii) The activity of *antimicrobial agent(s)* towards the targeted microorganism should be established by pharmacodynamics. The following criteria should be taken into account:

- spectrum of activity and mode of action;
- minimum inhibitory and bactericidal concentrations against recent isolates;
- time- or concentration-dependent activity or co-dependency;
- activity at the site of *infection*.

iii) The dosage regimens allowing maintenance of effective antimicrobial levels should be established by pharmacokinetics. The following criteria should be taken into account:

- bio-availability according to the route of administration;
- distribution of the *antimicrobial agent(s)* in the treated *animal* and concentration at the site of *infection*;
- metabolism;
- excretion routes.

Use of combinations of *antimicrobial agents* should be scientifically supported.

Annex XIV (contd)

b) Clinical trials

Clinical trials in the target animal species should be performed to confirm the validity of the claimed therapeutic indications and dosage regimens established during the preclinical phase. The following criteria should be taken into account:

- i) diversity of the clinical cases encountered when performing multi-centre trials;
- ii) compliance of protocols with good clinical practice;
- iii) eligibility of studied clinical cases, based on appropriate criteria of clinical and bacteriological diagnoses;
- iv) parameters for qualitatively and quantitatively assessing the efficacy of the treatment.

4. Assessment of the potential of antimicrobial agents(s) to select for resistance

Other studies may be requested in support of the assessment of the potential of *antimicrobial agents* to select for resistance. The party applying for market authorisation should, where possible, supply data derived in target animal species under the intended conditions of use.

For this the following may be considered:

- a) the concentration of either active *antimicrobial agents(s)* or metabolites(s) in the gut of the *animal* (where the majority of potential foodborne pathogens reside) at the defined dosage level;
- b) pathway for the human exposure to antimicrobial resistant microorganisms;
- c) the degree of cross-resistance;
- d) the intrinsic and pre-existing, baseline level of resistance in the pathogens of human health concern in both *animals* and humans.

5. Establishment of acceptable daily intake (ADI), maximum residue limit (MRL) and withdrawal periods in food producing animals

- a) When setting the ADI and MRL for an *antimicrobial agent*, the safety evaluation should also include the potential biological effects on the intestinal flora of humans.
- b) The establishment of an ADI for each *antimicrobial agent*, and an MRL for each animal-derived food, should be undertaken before a VMP containing it is granted marketing authorisation.
- c) For all VMP containing *antimicrobial agents(s)*, withdrawal periods should be established for each animal species in order to ensure compliance with the MRLs, taking into account:
 - i) the MRLs established for the *antimicrobial agent* in the target animal edible tissues;
 - ii) the composition of the product and the pharmaceutical form;
 - iii) the dosage regimen;
 - iv) the route of administration.
- d) The applicant should describe methods for regulatory testing of residues in food based on the established marker residues.

6. Protection of the environment

An assessment of the impact of the proposed antimicrobial use on the environment should be conducted.

7. Establishment of a summary of product characteristics for each VMP containing antimicrobial agent(s)

The summary of product characteristics contains the information necessary for the appropriate use of VMP containing *antimicrobial agent(s)* and constitutes the official reference for their labelling and package insert. This summary should contain the following items:

- a) active ingredient and class;
- b) pharmacological properties;
- c) any potential adverse effects;
- d) target animal species and, as appropriate, age or production category;
- e) therapeutic indications;
- f) target micro-organisms;
- g) dosage regimen and route of administration;
- h) withdrawal periods;
- i) incompatibilities and interactions;
- j) storage conditions and shelf-life;
- k) operator safety;
- l) particular precautions before use;
- m) particular precautions for the proper disposal of un-used or expired products;
- n) information on conditions of use relevant to the potential for selection of resistance;
- o) contraindication.

8. Post-marketing antimicrobial surveillance

The information collected through existing pharmacovigilance programmes, including lack of efficacy, and any other relevant scientific data, should form part of the comprehensive strategy to minimise antimicrobial resistance. In addition to this, the following should be considered:

a) General epidemiological surveillance

The surveillance of animal microorganisms resistant to *antimicrobial agent(s)* is essential. The relevant authorities should implement a programme according to Chapter 1.4.

b) Specific surveillance

Specific surveillance to assess the impact of the use of a specific *antimicrobial agent* may be implemented after the granting of marketing authorisation. The surveillance programme should evaluate not only resistance in target animal pathogens, but also in foodborne pathogens, and commensals if relevant and possible. This will also contribute to general epidemiological surveillance of antimicrobial resistance.

Annex XIV (contd)9. Supply and administration of the VMP containing antimicrobial agent(s)

The relevant authorities should ensure that all the VMP containing *antimicrobial agent(s)* used in *animals* are:

- a) prescribed by a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agent(s)* in accordance with the national legislation and under the supervision of a *veterinarian*;
- b) supplied only through licensed or authorised distribution systems;
- c) administered to *animals* by a *veterinarian* or under the supervision of a *veterinarian* or by other authorised persons.

The relevant authorities should develop effective procedures for the safe collection and disposal or destruction of unused or expired VMPs containing *antimicrobial agent(s)*. Their labels should have appropriate instructions for disposal and destruction.

10. Control of advertising

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

- a) complies with the marketing authorisation granted, in particular regarding the content of the summary of product characteristics;
- b) is restricted to a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agent(s)* in accordance with the national legislation and under the supervision of a *veterinarian*.

11. Training on the usage of antimicrobial agents

The training on the usage of *antimicrobial agents* should include all the relevant organisations, such as the *Competent Authority*, pharmaceutical industry, veterinary schools, research institutes, veterinary professional organisations and other approved users such as food animal owners and manufacturers of medicated animal feed. This training should focus on preserving the effectiveness of *antimicrobial agents* and include:

- a) information on *disease* prevention, management and mitigation strategies;
- b) the ability of *antimicrobial agent(s)* to select for resistant microorganisms in *animals* and the relative importance of that resistance to public and animal health;
- c) the need to observe responsible use recommendations for the use of *antimicrobial agent(s)* in animal husbandry in agreement with the provisions of the marketing authorisations;
- d) appropriate storage conditions, proper disposal of unused or expired VMP;
- e) record keeping.

12. Research

The relevant authorities should encourage public- and industry-funded research, for example on methods to identify and mitigate the public health risks associated with specific *antimicrobial agent* uses, or on the ecology of antimicrobial resistance.

Article 6.9.4.

Responsibilities of the veterinary pharmaceutical industry with regards to VMP containing antimicrobial agents~~(s)~~1. Marketing authorisation

The veterinary pharmaceutical industry has responsibilities to:

- a) supply all the information requested by the national *Competent Authority*;
- b) guarantee the quality of this information in compliance with the provisions of good manufacturing, *laboratory* and clinical practices;
- c) implement a pharmacovigilance programme and on request, specific surveillance for bacterial susceptibility and resistance data.

2. Marketing and export

For the marketing and export of VMP containing *antimicrobial agents*~~(s)~~:

- a) only licensed and officially approved VMP containing *antimicrobial agents*~~(s)~~ should be sold and supplied, and then only through licensed/authorised distribution systems;
- b) the pharmaceutical industry should provide quality certificates prepared by the *Competent Authority* of the exporting and manufacturing countries to the *importing country*;
- c) the national regulatory authority should be provided with the information necessary to evaluate the amount of *antimicrobial agents* marketed.

3. Advertising

The veterinary pharmaceutical industry should respect principles of responsible and prudent use and should comply with established codes of advertising standards, including to:

- a) distribute information in compliance with the provisions of the granted authorisation;
- b) discourage the advertising of VMP containing *antimicrobial agents*~~(s)~~ directly to the food animal producer.

EU comment

For consistency with the responsibilities of the Competent Authority concerning the control of advertising (see Art. 6.9.3. point 10 b), the EU suggests amending the point b) above as follows:

“b) ~~discourage the advertising of~~ not advertise VMP containing *antimicrobial agents*~~(s)~~ directly to the food animal producer.”

Indeed, as the Competent Authority must ensure that the advertising of antimicrobial agents is restricted to a veterinarian or other suitably trained person, the veterinary pharmaceutical industry should equally comply with the codes of advertising standards, i.e. not advertise directly to the food animal producer. Merely discouraging the industry from such direct advertising is not enough in this regard.

4. Training

The veterinary pharmaceutical industry should participate in training programmes as defined in point 14 11 of Article 6.9.3.

5. Research

The veterinary pharmaceutical industry should contribute to research as defined in point 45 12 of Article 6.9.3.

Article 6.9.5.

Responsibilities of wholesale and retail distributors

1. Distributors of VMP containing *antimicrobial agents*(s) should only do so on the prescription of a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agents*(s) in accordance with the national legislation and under the supervision of a *veterinarian*. All products should be appropriately labelled.

Annex XIV (contd)

2. The recommendations on the responsible and prudent use of VMP containing *antimicrobial agents*(s) should be reinforced by retail distributors who should keep detailed records of:
 - a) date of supply;
 - b) name of prescriber;
 - c) name of user;
 - d) name of product;
 - e) batch number;
 - f) expiration date;
 - g) quantity supplied;
 - h) copy of prescription.
3. Distributors should also be involved in training programmes on the responsible and prudent use of VMP containing *antimicrobial agents*(s), as defined in point 14 11 of Article 6.9.3.

Article 6.9.6.

Responsibilities of veterinarians

The *veterinarian's* responsibility is to promote public health, animal health and welfare, including identification, prevention and treatment of animal *diseases*. The promotion of sound animal husbandry methods, hygiene procedures, biosecurity and *vaccination* strategies can help to minimise the need for antimicrobial use in food producing *animals*.

Veterinarians should only prescribe *antimicrobial agents*(s) for *animals* under their care.

1. Use of antimicrobial agents(s)

The responsibilities of *veterinarians* are to carry out a proper clinical examination of the *animals*(s) and then:

- a) administer or prescribe *antimicrobial agents*(s) only when necessary and taking into consideration the OIE list of *antimicrobial agents* of veterinary importance;
- b) make an appropriate choice of *antimicrobial agents*(s) based on clinical experience and diagnostic *laboratory* information (pathogen isolation, identification and antibiogram) where possible;
- c) provide a detailed treatment protocol, including precautions and withdrawal times, especially when prescribing extra-label or off-label use.

2. Choosing antimicrobial agents(s)

- a) The expected efficacy of the treatment is based on:
 - i) the clinical experience of the *veterinarians*, their diagnostic insight and therapeutic judgement;
 - ii) diagnostic *laboratory* information (pathogen isolation, identification and antibiogram);
 - iii) pharmacodynamics including the activity towards the pathogens involved;
 - iv) the appropriate dosage regimen and route of administration;
 - v) pharmacokinetics and tissue distribution to ensure that the selected therapeutic agent is effective at the site of *infection*;
 - vi) the epidemiological history of the rearing unit, particularly in relation to the antimicrobial resistance profiles of the pathogens involved.

Should a first-line antimicrobial treatment fail or should the *disease* recur, a second-line treatment should ideally be based on the results of diagnostic tests. In the absence of such results, an appropriate *antimicrobial agent* belonging to a different class or sub-class should be used.

In emergencies, a *veterinarian* may treat *animals* without recourse to an accurate diagnosis and antimicrobial susceptibility testing, to prevent the development of clinical *disease* and for reasons of *animal welfare*.

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

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

A prescription for VMP containing *antimicrobial agents(s)* should indicate precisely the dosage regimen, the withdrawal period where applicable and the amount of VMP containing *antimicrobial agents(s)* to be provided, depending on the dosage and the number of *animals* to be treated.

The extra-label or off-label use of VMP containing *antimicrobial agents(s)* may be permitted in appropriate circumstances and should be in agreement with the national legislation in force including the withdrawal periods to be used, as applicable. It is the *veterinarian's* responsibility to define the conditions of responsible use in such a case including the dosage regimen, the route of administration and the withdrawal period.

The use of compounded VMP containing *antimicrobial agents(s)* and extra-label or off-label use of registered VMP containing *antimicrobial agents(s)* should be limited to circumstances where an appropriate registered product is not available.

4. Recording of data

Records on VMP containing *antimicrobial agents(s)* should be kept in conformity with the national legislation. Information records should include the following:

- a) quantities of VMP used per animal species;
- b) a list of all VMP supplied to each food producing animal holding;
- c) treatment schedules including animal identification and withdrawal period;
- d) antimicrobial susceptibility data;
- e) comments concerning the response of *animals* to treatment;

- f) the investigation of adverse reactions to antimicrobial treatment, including lack of response due to possible antimicrobial resistance. Suspected adverse reactions should be reported to the appropriate regulatory authorities.

Veterinarians should also periodically review farm records on the use of VMP containing *antimicrobial agents*(s) to ensure compliance with their directions or prescriptions and use these records to evaluate the efficacy of treatments.

5. Labelling

All VMP supplied by a *veterinarian* should be labelled according to the national legislation.

6. Training and continued professional development

Veterinary professional organisations should participate in the training programmes as defined in point 44 11 of Article 6.9.3. It is recommended that veterinary professional organisations develop for their members species-specific clinical practice recommendations on the responsible and prudent use of VMP containing *antimicrobial agents*(s).

Article 6.9.7.

Responsibilities of food animal producers

- 1) Food animal producers, with the assistance and guidance of a *veterinarian*, are responsible for implementing animal health and welfare programmes on their farms in order to promote animal health and food safety.
- 2) Food animal producers should:
 - a) draw up a health plan with the attending *veterinarian* that outlines preventive measures (e.g. feedlot health plans, mastitis control plans, endo- and ectoparasite control, *vaccination* programmes and biosecurity measures);
 - b) use VMP containing *antimicrobial agents*(s) only on the prescription of a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agents*(s) in accordance with the national legislation and under the supervision of a *veterinarian*;
 - c) use VMP containing *antimicrobial agents*(s) in accordance with product label instructions, including storage conditions, or the instructions of the attending *veterinarian*;
 - d) isolate sick *animals*, when appropriate, to avoid the transfer of pathogens; dispose of dead or dying *animals* promptly under conditions approved by the relevant authorities;
 - e) address on-farm biosecurity measures and take basic hygiene precautions as appropriate;
 - f) comply with and record the recommended withdrawal periods to ensure that residue levels in animal-derived food do not present a risk for the consumer;
 - g) use VMP containing *antimicrobial agents*(s) within the expiry date and dispose of unused and expired surplus VMP containing *antimicrobial agents*(s) under conditions safe for the environment;
 - h) maintain all the *laboratory* records of bacteriological and susceptibility tests; these data should be made available to the *veterinarian* responsible for treating the *animals*;
 - i) keep adequate records of all VMP containing *antimicrobial agents*(s) used, including the following:
 - i) name of the product and active substance, batch number and expiry date;
 - ii) name of the prescriber and the supplier;
 - iii) date of administration;
 - iv) identification of the *animal* or group of *animals* to which the *antimicrobial agent* was administered;
 - v) clinical conditions treated;
 - vi) dosage;
 - vii) withdrawal periods including the end-date of the withdrawal periods;

- viii) result of *laboratory* tests;
- ix) effectiveness of therapy;
- j) inform the responsible *veterinarian* of recurrent *disease* problems.

3) Training

Food animal producers should participate in the training programmes as defined in point **11 44** of Article 6.9.3. It is recommended that food animal producer organisations work in cooperation with the veterinary professional organisations to implement existing guidelines for the responsible and prudent use of VMPs containing *antimicrobial agents*(s).

Article 6.9.8.

Responsibilities of animal feed manufacturers

- 1) The supply of medicated feed containing *antimicrobial agents* to farmers keeping food producing animals by animal feed manufacturers should be allowed only on the prescription of a *veterinarian*. Alternatively, such medicated feed may be prescribed by other suitably trained persons authorised to prescribe VMP containing *antimicrobial agents*(s) in accordance with the national legislation and under the supervision of a *veterinarian*. Animal feed manufacturers preparing medicated feed should do so following rules put in place by the *Competent Authority* in accordance with the national legislation. All medicated feed and medicated premixes should be appropriately labelled.
- 2) The regulations and recommendations on the responsible and prudent use of VMP containing *antimicrobial agents*(s) should be reinforced by animal feed manufacturers who should keep detailed records.
- 3) Use only approved sources of medications: Animal feed manufacturers preparing medicated feed should ensure that only approved sources of medications are added to feed at a level, **and for a species and** purpose **and species** as permitted by the drug premix label or a veterinary prescription.
- 4) Ensure appropriate labelling with product identification, direction for use and withdrawal time: Animal feed manufacturers preparing medicated feed should ensure that medicated animal feed are labelled with the appropriate information (e.g. level of medication, approved claim, intended species, directions for use, warning, cautions) so as to ensure effective and safe use by the producer.
- 5) Implement appropriate production practices to prevent contamination of other feed: Animal feed manufacturers preparing medicated feed should implement appropriate production practices to avoid unnecessary carry over and unsafe cross contamination of unmedicated feed.

— Text deleted.

CHAPTER 6.10.

**RISK ANALYSIS ~~ASSESSMENT~~ FOR
ANTIMICROBIAL RESISTANCE ARISING FROM
THE USE OF ANTIMICROBIAL AGENTS IN
ANIMALS**

EU position

The EU thanks the OIE for having taken its previous comment into account. While in general supporting the adoption of this modified chapter, the EU cannot accept the newly proposed changes in point 1 of Article 6.10.1. The EU comments on that point, inserted in the text below, should be taken into account before adoption. Further comments are inserted in the text below.

Article 6.10.1.

Recommendations for analysing the risks to animal and human ~~public~~ health from antimicrobial resistant microorganisms of animal origin

1. Introduction

Antimicrobial resistance is a naturally occurring phenomenon and the selection or dissemination of antimicrobial resistance can occur or be influenced by factors other than the use of antimicrobial agents. However, ~~Problems~~ related to antimicrobial resistance are inherently linked to antimicrobial agent use in any environment, including human and non-human usages. ~~However, the selection emergence or dissemination of antimicrobial resistance can occur or be influenced by through factors other than the use of antimicrobial agents.~~

EU position

The EU cannot accept the paragraph above as it now stands. Indeed, the proposed first sentence clearly gives a wrong impression, since it seems to suggest that the use of antimicrobial agents has no or only a minor impact on the selection or emergence of AMR. It is an undisputable scientific fact that the selection of AMR is driven by the use of antimicrobials in both humans and animals. This should be made unequivocally clear in the text. Merely stating that “problems” related to AMR are linked to antimicrobial use without specifying what is meant by the term “problems” is not enough.

Furthermore, the word “non-human” should be replaced by “animal and other”, as this more accurately reflects the scope of this OIE Code chapter.

Thus, the EU suggests the following alternative wording:

“Antimicrobial resistance is a naturally occurring phenomenon ~~and the selection or dissemination of antimicrobial resistance can occur or be influenced by~~ many factors ~~other than the use of antimicrobial agents.~~ However, ~~Problems~~ related to the main driving force for the selection of antimicrobial resistance ~~are inherently linked to~~ is the use of antimicrobial agents use in any environment, including human, and non-human animal and other usages”.

Antimicrobial resistance associated with the use of antimicrobial agents for therapeutic and non-therapeutic purposes may lead to the selection and dissemination of antimicrobial resistant

microorganisms, with a resulting loss of therapeutic efficacy in animal and human medicine of one or several antimicrobial agents.

EU position

For the same reasons stated in the above EU comment, the EU suggests replacing the words “may lead” by the word “has lead” in the paragraph above. Indeed, the notion of “may lead” seems to suggest that the selection and dissemination of AMR may or may not happen further to the use of antimicrobial agents, whereas it is undisputable that it has indeed happened in the past and may happen again in the future. The EU is of the opinion that the term “has lead” better reflects this context.

~~The use of antimicrobial agents for therapy therapeutic and non therapeutic purposes, prophylaxis and growth promotion in animals can reduce their efficacy in animal and human medicine, through the development of antimicrobial resistant strains of pathogenic microorganisms. This risk may be represented by the loss of therapeutic efficacy of one or several antimicrobial agents drugs and includes the selection and dissemination of antimicrobial resistant micro-organisms emergence of multi-resistant micro-organisms.~~

2. Objective

~~For the purpose of this chapter, the principal aim of risk analysis, for the purpose of this chapter, for antimicrobial resistance in micro-organisms from animals is to provide Members Countries with a transparent, objective and scientifically defensible method of assessing and managing the human and animal health risks associated with the selection and dissemination development of resistance arising from the use of antimicrobial agents in animals.~~

~~Guidance on the issue of food-borne antimicrobial resistance related to the non-human use of antimicrobial agents is covered by the Codex Guidelines for risk analysis of food-borne antimicrobial resistance (CAC/GL77-2011).~~

EU comment

The components of risk analysis in this draft Code chapter are not in line with the components in the CODEX Guidelines on risk analysis, which are referred to in the paragraph above. The EU had previously suggested aligning these components in both documents.

This draft Code chapter also deals with risks to human health, which is overlapping the CODEX guidelines on risk analysis, and may lead to confusion. Therefore, the EU suggests coordinating the work in this area of mutual interest between the OIE and CODEX in order to avoid such overlaps in the future.

3. The risk analysis process

~~The principles of risk analysis are described in Chapter 2.1, Section of this Terrestrial Code. The components of risk analysis described in this chapter are hazard identification, risk assessment, risk management and risk communication.~~

~~The chapter includes factors to be considered at various steps of the risk analysis process. These factors are not intended to be exhaustive and not all elements may be applicable in all situations.~~

~~A qualitative risk assessment should always be undertaken. Its outcome will determine whether progression to a quantitative risk assessment is feasible and/or necessary.~~

4. Hazard identification

~~Hazard identification is defined under the OIE Terrestrial Code in Chapter 2.1.~~

For the purpose of this chapter, the *hazard* is the resistant microorganism or resistance determinant that emerges as a result of the use of a specific antimicrobial agent in animals. This definition reflects the development of resistance in a species of pathogenic micro-organisms, as well as the development of a resistance determinant that may be passed from one species of micro-organisms to another potential for resistant microorganisms to cause adverse health effects, as well as the potential for horizontal transfer of genetic determinants between microorganisms. The conditions under which the *hazard* might produce adverse consequences include any scenarios through which humans or *animals* could become exposed to an antimicrobial resistant pathogen which contains that resistance determinant, fall ill and then be treated with an antimicrobial agent that is no longer effective because of the resistance.

5. Risk assessment

The assessment of the *risk* to human and animal health from antimicrobial-resistant microorganisms resulting from the use of antimicrobial agents in *animals* should examine:

- a) the likelihood of emergence of resistant microorganisms arising from the use of an antimicrobial agent(s), or more particularly, dissemination ~~production~~ of the resistance determinants if transmission is possible between microorganisms;
- b) consideration of all pathways and their importance, by which humans and animals could be exposed to these resistant microorganisms or resistance determinants, together with the possible degree likelihood of exposure;
- c) the consequences of exposure in terms of *risks* to human and/or animal health.

The general principles of risk assessment as defined in Chapter 2.1. of the Terrestrial Code applies equally to both qualitative and quantitative risk assessment. At a minimum, a qualitative risk assessment should always be undertaken.

Article 6.10.2.

Analysis of risks to human health

1. Definition of the risk

The *infection* of humans with microorganisms that have acquired resistance to a specific antimicrobial agent due to the antimicrobial usage used in animals, and resulting in the loss of benefit of antimicrobial therapy used to manage the human *infection*.

2. Hazard identification

- Microorganisms that have acquired resistance, (including multiple resistance) arising from the use of an antimicrobial agent(s) in *animals*.
- Microorganisms having obtained a resistance determinant(s) from other microorganisms which have acquired resistance arising from the use of an antimicrobial agent(s) in *animals*.

The identification of the *hazard* ~~must~~ should include consideration of the class or subclass of the antimicrobial agent(s). This definition should be read in conjunction with point 4) of Article 6.10.1.

3. Release assessment

A release assessment describes the biological pathways necessary that may lead to the release of resistant microorganisms or resistance determinants into a particular environment due to ~~for~~ the use of a specific antimicrobial agent in *animals* ~~to lead to the release of resistant micro-organisms or resistance determinants into a particular environment.~~ It also estimates and estimating either qualitatively or quantitatively the probability of that complete process occurring. The release assessment describes the probability of the release of each of the potential *hazards* 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.

The following factors should be considered in the release assessment:

- animal species, category such as food producing, zoo, entertainment or companion animal, and, where appropriate, production type (e.g. such as veal calves or dairy cattle, broilers or laying hens), of animal treated with the antimicrobial agent(s) in question;

EU position

The EU does not favour the addition of the word “entertainment” in the paragraph above. Indeed, it is not clear what is meant by this term, which is not well defined and may lead to confusion. The EU therefore suggests replacing it by the word “circus”.

- number of animals treated, sex, and their age, and their geographical distribution and, where appropriate, sex of these animals;
- prevalence of infection or disease for which the antimicrobial agent is indicated in the target animal population;
- data on trends in antimicrobial agent use and changes in farm production systems;
- data on potential extra-label or off-label use;
- variation in methods and routes of administration of the antimicrobial agent(s);
- dosage regimen (dose, dosing interval and duration of the treatment) including duration of use;
- the pharmacokinetics and relevant or pharmacodynamics/pharmacokinetics of the antimicrobial agent(s);
- micro-organisms developing resistance as a result of the antimicrobial(s) use prevalence of pathogens that are likely to develop acquire resistance in an animal species host;
- prevalence of commensal bacteria which are able to transfer resistance to human pathogens;
- mechanisms and pathways of direct or indirect transfer of resistance;
- potential linkage of virulence attributes and resistance;
- cross-resistance and/or co-resistance with other antimicrobial agents;
- data on trends and occurrence of resistant microorganisms obtained through surveillance of animals, products of animal origin and animal waste products for the existence of resistant micro-organisms.

4. Exposure assessment

An exposure assessment describes the biological pathways necessary for exposure of humans to the resistant microorganisms or resistance determinants released from a given antimicrobial use in *animals*, and estimates the probability of the exposures occurring. 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 and the number, species and other characteristics of the human populations exposed.

The following factors should be considered in the exposure assessment:

- human demographics, including population subgroups, and food consumption patterns, including traditions and cultural practices in with respect to the preparation and storage of food;
- prevalence of resistant microorganisms in food at the point of consumption or other exposure;
- microbial load in contaminated food at the point of consumption or other exposure for quantitative risk assessment;
- environmental contamination with resistant microorganisms;

- occurrence in animal feed of resistant microorganisms in animal feed that have the capacity to become established in the animals, thus leading to contamination of food of animal origin prevalence of animal feed contaminated with resistant micro-organisms;
- transfer cycling of resistant microorganisms and their resistance determinants between humans, animals and the environment;
- ~~steps~~ measures taken for of microbial decontamination of food;
- microbial load in contaminated food at the point of consumption;
- survival capacity and dissemination spread redistribution of resistant microorganisms during the food production process (including slaughtering, processing, storage, transportation and retailing);
- disposal practices for waste products and the likelihood opportunity for human exposure to resistant microorganisms or resistance determinants ~~in~~ through those waste products;
- ~~point of consumption of food (professional catering, home cooking);~~
- ~~variation in consumption and food handling methods of exposed populations and subgroups of the population;~~
- capacity of resistant microorganisms to become established in humans;
- human-to-human transmission of the microorganisms under consideration;
- capacity of resistant microorganisms to transfer resistance to human commensal microorganisms and zoonotic agents;
- amount and type of *antimicrobial agents* used in response to treat humans ~~illness~~;
- pharmacokinetics, ~~(such as~~ such as metabolism, bioavailability and distribution to the gastrointestinal access to intestinal flora.

5. Consequence assessment

A consequence assessment describes the relationship between specified exposures to resistant microorganisms or resistance determinants and the consequences of those exposures. A causal process ~~must~~ 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.

The following factors should be considered in the consequence assessment:

- microbial dose ~~=~~ host response relationships and subsequent host response interactions;
- variation in susceptibility of exposed populations or subgroups of the population;
- variation and frequency of human health effects resulting from loss of efficacy of *antimicrobial agents* and associated costs;
- potential linkage of virulence attributes and resistance;
- ~~changes in human medicinal practices resulting from reduced confidence in antimicrobials;~~
- changes in food consumption patterns due to loss of confidence in the safety of food products and any associated secondary *risks*;
- ~~associated costs;~~

- interference with ~~first-line or /choice~~ antimicrobial therapy in humans;
- ~~importance of the antimicrobial agent in human medicine perceived future usefulness of the antimicrobial (time reference);~~
- prevalence of resistance in human bacterial pathogens under consideration.

6. Risk estimation

A *risk* estimation integrates the results from the release assessment, exposure assessment and consequence assessment to produce overall estimates of *risks* associated with the *hazards*. Thus, *risk* estimation takes into account the whole of the *risk* pathway from *hazard identification* to the unwanted consequences.

The following factors should be considered in the *risk* estimation:

- number of people falling ill and the proportion of that number ~~infected~~ affected with antimicrobial resistant strains of microorganisms;
- adverse effects on vulnerable human sub-population (children, immunocompromised persons, elderly, pregnant, etc.);
- increased severity or duration of infectious *disease*;
- number of person ~~/+or~~ days of illness per year;
- deaths (total per year; probability per year or reduced life expectancy lifetime for a random member of the population or a member of a specific ~~more exposed~~ sub-population) linked to antimicrobial resistant microorganisms when compared with deaths linked to sensitive microorganisms of the same species;
- ~~importance~~ severity of the pathology ~~disease infection~~ caused by the target resistant microorganisms;
- availability and cost ~~existence or~~ absence of alternative antimicrobial therapy;
- potential impact of switching to an alternative antimicrobial agent (e.g. alternatives with potential increased toxicity);
- occurrence ~~incidence~~ of antimicrobial resistance in target pathogens observed in humans;
- ~~consequences of the overall~~ to allow weighted summation of different risk impacts (e.g. illness and hospitalisation).

7. Risk management components options and risk communication

The OIE defines *risk management* as consisting of the steps described below. ~~Risk management options and risk communication have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.~~

a) Risk evaluation – the process of comparing the risk estimated in the risk assessment with the reduction in risk expected from the proposed risk management measures Member Country's appropriate level of protection.

b) Option evaluation

A range of risk management options is available to minimise the emergence and dissemination spread of antimicrobial resistance and these include both regulatory and non-regulatory risk management options, such as the development of codes of practice concerning for the use of antimicrobial agents in animal husbandry. Risk management decisions need to consider fully the implications of these different options for human health and animal health and welfare and also take into account economic considerations and any associated environmental issues. Effective control of animal certain bacterial diseases of animals will can have the dual benefits of reducing the risks to human health linked to associated with both the bacterial pathogen under

consideration and antimicrobial resistance, in cases where the bacterial disease pathogen under consideration has also developed antimicrobial resistance.

c) Implementation

Risk managers should develop an implementation plan that describes how the decision will be implemented, by whom and when National or regional authorities Competent Authorities should ensure an appropriate regulatory framework and infrastructure.

d) Monitoring and review

Risk management options have to should be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

8. Risk communication

Communication with all interested parties should be promoted at the earliest opportunity and integrated into all phases of a risk analysis. This will provide all interested parties, including risk managers, with the better understanding of risk management approaches. Risk communication should be also well documented.

Article 6.10.3.

Analysis of risks to animal health

1. Definition of the risk

The *infection of animals* with microorganisms that have acquired resistance ~~to from the use of a specific antimicrobial agent(s)~~ due to the antimicrobial usage ~~its use~~ in *animals*, and resulting in the loss of benefit of antimicrobial therapy used to manage the animal *infection*.

2. Hazard identification

- Microorganisms that have acquired resistance, (including multiple resistance) arising from the use of an *antimicrobial agent(s)* in *animals*;
- ~~m~~Microorganisms having obtained a resistance determinant(s) from another microorganisms which ~~hasve~~ acquired resistance arising from the use of an *antimicrobial agent(s)* in *animals*.

The *identification of the hazard* ~~must~~ should include considerations of the class or subclass of the *antimicrobial agent(s)*. This definition should be read in conjunction with point 4) of Article 6.10.1.

3. Release assessment

The following factors should be considered in the release assessment:

- animal species, category such as food producing, zoo, entertainment or companion animal and, where appropriate, production type, (e.g. such as veal calves or dairy cattle, broilers or laying hens) treated with the antimicrobial agent(s) in question;

EU position

Again, the EU does not favour the addition of the word “entertainment” in the paragraph above. Indeed, it is not clear what is meant by this term, which is not well defined and may lead to confusion. The EU therefore suggests replacing it by the word “circus”.

- number of *animals* treated, sex, and their age, and their geographical distribution and, where appropriate, sex;

- ~~=~~ prevalence of infection or disease for which the antimicrobial agent is indicated in the target animal population;
- ~~=~~ data on trends in antimicrobial agent use and changes in farm production systems;
- ~~=~~ potential extra-label or off-label use;
- dosage regimen including amounts used and duration of treatment use;
- ~~variation in~~ methods and routes of administration of the antimicrobial agent(s);
- the pharmacokinetics or and relevant pharmacodynamics/ pharmacokinetics of the antimicrobial agent(s);
- site and type of infection;
- development of resistant microorganisms;
- mechanisms and pathways of resistance transfer;
- cross-resistance ~~and/or~~ co-resistance with other antimicrobial agents;
- data on trends and occurrence of resistant microorganisms obtained through surveillance of animals, products of animal origin and animal waste products for the existence of resistant microorganisms.

4. Exposure assessment

The following factors should be considered in the exposure assessment:

- prevalence and trends of resistant microorganisms in clinically ill and clinically unaffected animals;
- occurrence prevalence of resistant microorganisms in feed and in/ the animal environment;
- animal-to-animal transmission of the resistant microorganisms and their resistance determinants (animal husbandry practices methods and movement of animals);
- number/ or percentage of animals treated;
- ~~=~~ dissemination of resistant microorganisms from animals (animal husbandry methods, movement of animals);
- quantity and trends of antimicrobial agent(s) used in animals;
- treatment regimens (dose, route of administration, duration);
- survival capacity of resistant microorganisms and dissemination spread of resistant microorganisms;
- exposure of wildlife to resistant microorganisms;
- disposal practices for waste products and the likelihood opportunity for of animal exposure to resistant microorganisms or resistance determinants in through those products;
- capacity of resistant microorganisms to become established in animals intestinal flora;
- exposure to resistance determinants from other sources such as water, effluent, waste pollution, etc.;
- ~~=~~ dose, route of administration and duration of treatment;

- pharmacokinetics, such as (metabolism, bioavailability, distribution to the gastrointestinal flora access to intestinal flora;
- transfer cycling of resistant microorganisms and their resistance determinants between humans, *animals* and the environment.

5. Consequence assessment

The following factors should be considered in the consequence assessment:

- microbial dose = host response relationships and subsequent host response interactions;
- variation in disease susceptibility of exposed populations and subgroups of the populations;
- variation and frequency of animal health effects resulting from loss of efficacy of *antimicrobial agents* and associated costs;
- potential linkage of virulence attributes and resistance;
- changes in practices resulting from reduced confidence in antimicrobials;
- associated cost;
- perceived future importance usefulness of the drug antimicrobial agent in animal health (see OIE list of antimicrobial agents of veterinary importance) (time reference).

6. Risk estimation

The following factors should be considered in the *risk* estimation:

- additional burden of disease due to antimicrobial resistant microorganisms;
- number of therapeutic failures due to antimicrobial resistant microorganisms;
- increased severity and duration of infectious disease;
- impact on animal welfare;
- estimation of the economic impact and cost on animal health and production;
- economic cost;
- deaths (total per year; probability per year or lifetime reduced life expectancy for a random member of the population or a member of a specific more exposed sub-population) linked to antimicrobial resistant microorganisms when compared with deaths linked to sensitive microorganisms of the same species;
- availability and cost existence or absence of alternative antimicrobial therapy;
- potential impact of switching to an alternative antimicrobial agent, e.g. alternatives with potential increased toxicity;
- estimation of the economic impact and cost on animal health and production;
- incidence of resistance observed in animals.

7. Risk management options components and risk communication

The relevant provisions contained in point 7 of Article 6.9.7, 6.10.2. do apply.

Risk management options and risk communication have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

The relevant recommendations (Articles 2.1.5., 2.1.6. and 2.1.7.) in the *Terrestrial Code* apply.

~~A range of *risk management* options is available to minimize the emergence and spread of antimicrobial resistance and these include both regulatory and non-regulatory *risk management* options, such as the development of codes of practice concerning the use of antimicrobials in animal husbandry. *Risk management* decisions need to consider fully the implications of these different options for human health and animal health and *welfare* and also take into account economic considerations and any associated environmental issues. Effective control of certain bacterial *diseases* of *animals* will have the dual benefit of reducing the *risks* linked to antimicrobial resistance, in cases where the bacterial *disease* under consideration has also developed antimicrobial resistance. Appropriate communication with all stakeholders is essential throughout the *risk assessment* process.~~

8. Risk communication

~~The relevant provisions contained in point 8 of Article 6.9.8- 6.10.2. do apply.~~

— Text deleted

CHAPTER 7.10.

ANIMAL WELFARE AND
BROILER CHICKEN PRODUCTION SYSTEMS**EU position**

The EU can support the adoption of this modified chapter but strongly recommend that the OIE considers inserting the two sentences proposed for Article 7.10.4.(2)(k). We would also ask that sentence order of the first paragraph of Article 7.10.3. be altered.

Article 7.10.1.

Definitions

For the purpose of this chapter:

Broiler

means a bird of the species *Gallus gallus* kept for commercial meat production. Poultry kept in village or backyard *flocks* are not included.

Harvesting

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

Article 7.10.2.

Scope

These recommendations cover the production period from arrival of *day-old birds* on the farm to harvesting the broilers in commercial production systems. Such systems involve confinement of the birds, the application of biosecurity measures, and trade in the products of those birds, regardless of scale of production. These recommendations cover broilers kept in cages, on slatted floors, litter or dirt and indoors or outdoors.

Broiler production systems include:

1. Completely housed system

Broilers are completely confined in a poultry house, with or without environmental control.

2. Partially housed system

Broilers are kept in a poultry house with access to a restricted outdoor area.

3. Completely outdoors system

Broilers are not confined inside a poultry house at any time during the production period but are confined in a designated outdoor area.

This chapter should be read in conjunction with Chapters 7.2., 7.3. and 7.4. on the welfare of the broiler during *transport* to the *slaughterhouse/abattoir*.

Article 7.10.3.

Criteria or measurables for the welfare of broilers

The welfare of broilers should be assessed using outcome-based measurables. The following outcome-

based measurables, specifically animal-based measurables, can be useful indicators of *animal welfare*. The use of these indicators and the appropriate thresholds should be adapted to the different situations where broilers are managed, also taking into account the strain of bird concerned. Consideration should also be given to the resources provided and the design of the system.

EU comment:

The EU can support the inclusion of this first new sentence. However, we would propose to move the final sentence forward so that the paragraph reads:

“The welfare of broilers should be assessed using outcome-based measurables. Consideration should also be given to the resources provided and the design of the system. The following outcome-based measurables, specifically animal-based measurables, can be useful indicators of *animal welfare*. The use of these indicators and the appropriate thresholds should be adapted to the different situations where broilers are managed, also taking into account the strain of bird concerned. ~~Consideration should also be given to the resources provided and the design of the system.~~”

Justification:

It is important to not focus solely on outcome-based measurables as this could lead to unbalanced evaluation of welfare. It is important that such measurables be seen in conjunction with the resources and design of the system and we have for this reason moved the final sentence to emphasise that both need to be considered when assessing the welfare of animals.

Some criteria can be measured in the farm setting, such as gait, mortality and morbidity rates, while others are best measured at the *slaughterhouse/abattoir*. For example, at slaughter *flocks* can be assessed for presence of bruising, broken limbs and other injuries. The age of these lesions can help to determine the source. Back scratching, and contact dermatitis and breast blisters are also easily observed at the *slaughterhouse/abattoir*. Other conditions such as ascites, leg deformities, dehydration and *disease* conditions can also be assessed at *slaughter*. It is recommended that values for welfare measurables be determined with reference to appropriate national, sectoral or perhaps regional norms for commercial broiler production.

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

1. Mortality, culling and morbidity

Daily, weekly and cumulative mortality, culling and morbidity rates should be within expected ranges. Any unforeseen increase in these rates could reflect an *animal welfare* problem.

2. Gait

Broilers are susceptible to developing a variety of infectious and non-infectious musculoskeletal disorders. These disorders may lead to lameness and to gait abnormalities. Broilers that are lame or have gait abnormalities may have difficulty reaching the food and water, may be trampled by other broilers, and may experience pain. Musculoskeletal problems have many causes, including genetics, nutrition, sanitation, lighting, litter quality, and other environmental and management factors. **Broilers in commercial flocks should be assessed for gait abnormalities.** There are several gait scoring systems available.

3. Contact dermatitis

Contact dermatitis affects skin surfaces that have prolonged contact with wet litter or other wet flooring surfaces. The condition is manifested as blackened skin progressing to erosions and fibrosis on the lower surface of the foot pad, at the back of the hocks, and sometimes in the breast area. If severe, the foot and hock lesions may contribute to lameness and lead to secondary *infections*. Validated scoring systems for contact dermatitis have been developed for use in *slaughterhouse/abattoir*.

4. Feather condition

Evaluation of the feather condition of broilers provides useful information about aspects of welfare. Plumage dirtiness is correlated with contact dermatitis and lameness for individual birds or may be associated with the environment and production system. Plumage dirtiness can be assessed as part of on-farm inspections, at the time of harvesting or prior to plucking. A scoring system has been developed for this purpose.

5. Incidence of diseases, metabolic disorders and parasitic infestations

Ill-health, regardless of the cause, is a welfare concern, and may be exacerbated by poor environmental or husbandry management.

6. Behaviour

a) Fear behaviour

Fearful broilers show avoidance of humans, and this behaviour is seen in *flocks* where *animal handlers* walk through the poultry house quickly when performing their tasks rather than moving more slowly while interacting with the broilers. Fearfulness (e.g. of sudden loud noises) can also lead to the broilers piling on top of, and even suffocating, one another. Fearful broilers may be less productive. Validated methods have been developed for evaluating fearfulness.

b) Spatial distribution

Changes in the spatial distribution (e.g. huddling) of the birds may indicate thermal discomfort or the existence of areas of wet litter or uneven provision of light, food or water.

c) Panting and wing spreading

Excessive panting and wing spreading indicates heat stress or poor air quality, such as high levels of ammonia.

d) Dust bathing

Dust bathing is an intricate body maintenance behaviour performed by many birds, including broilers. During dust bathing, broilers work loose material, such as litter, through their feathers. Dust bathing helps to keep the feathers in good condition, which in turns helps to maintain body temperature and protect against skin injury. Reduced dust bathing behaviour in the *flock* may indicate problems with litter or range quality, such as litter or ground being wet or not friable.

e) Feeding, drinking and foraging

Reduced feeding or drinking behaviour can indicate management problems, including inadequate feeder or drinker space or placement, dietary imbalance, poor water quality, or feed contamination. Feeding and drinking behaviour are often depressed when broilers are ill, and intake may be also reduced during periods of heat stress and increased during cold stress. Foraging is the act of searching for food, typically by walking and pecking or scratching the litter substrate; reduced foraging activity could suggest problems with litter quality or presence of conditions that decrease bird movement.

f) Feather pecking and cannibalism

Feather pecking can result in significant feather loss and may lead to cannibalism. Cannibalism is the tearing of the flesh of another bird, and can result in severe injury. These abnormal behaviours have multi-factorial causes.

7. Water and feed consumption

Monitoring daily water consumption is a useful tool to indicate *disease* and other welfare conditions, taking into consideration ambient temperature, relative humidity, feed consumption and other related factors. Problems with the water supply can result in wet litter, diarrhoea, dermatitis or dehydration.

Changes in feed consumption can indicate unsuitability of feed, the presence of *disease* or other welfare problems.

8. Performance

- a) Growth rate (gr) – an index that indicates the average daily gain (gr) of weight per average broiler of a *flock*.
- b) Feed conversion – an index that measures the quantity of feed consumed by a *flock* relative to the total live weight harvested, expressed as the weight of feed required to produce one kg of broiler bodyweight. Higher or lower values than expected may indicate welfare problems.
- c) Liveability – an index that indicates the percentage of broilers present at the end of the production period; more commonly this indicator is measured as its opposite, mortality.

9. Injury rate

The rate of these injuries can indicate welfare problems in the *flock* during production or harvesting. Injuries include those due to other broilers (scratches, feather loss or wounding due to feather pecking and cannibalism) and those due to environmental conditions, such as skin lesions, (e.g. contact dermatitis), and those due to human intervention, such as catching. The most prevalent injuries seen during catching are bruises, broken limbs, dislocated hips, and damaged wings.

10. Eye conditions

Conjunctivitis can indicate the presence of irritants such as dust and ammonia. High ammonia levels can also cause corneal burns and eventual blindness. Abnormal eye development can be associated with low light intensity.

11. Vocalisation

Vocalisation can indicate emotional states, both positive and negative. Interpretation of *flock* vocalisations is possible by experienced *animal handlers*.

Article 7.10.4.

Recommendations

1. Biosecurity and animal health

a) Biosecurity and disease prevention

Biosecurity means a set of measures designed to maintain a *flock* at a particular health status and to prevent the entry (or exit) of specific infectious agents.

Biosecurity programmes should be designed and implemented, commensurate with the best possible *flock* health status and current *disease* risk (endemic and exotic or transboundary) that is specific to each epidemiological group of broilers and in accordance with relevant recommendations found in the *Terrestrial Code*.

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

- i) direct transmission from other *poultry*, domesticated and wild animals and humans,
- ii) fomites, such as equipment, facilities and *vehicles*,
- iii) *vectors* (e.g. arthropods and rodents),
- iv) aerosols,
- v) water supply,

vi) feed.

Outcome-based measurables: incidence of *diseases*, metabolic disorders and parasitic *infestations*, mortality, performance.

b) Animal health management, preventive medicine and veterinary treatment

Animal health management means a system designed to optimise the health and welfare of the broilers. It includes prevention, treatment and control of *diseases* and adverse conditions.

Those responsible for the care of broilers should be aware of the signs of ill-health or distress, such as a change in feed and water intake, reduced growth, changes in behaviour, abnormal appearance of feathers, faeces, or other physical features.

If persons in charge are not able to identify the causes of *disease*, ill-health or distress, or to correct these, or if they suspect the presence of a reportable *disease*, they should seek advice from *veterinarians* or other qualified advisers. Veterinary treatments should be prescribed by a *veterinarian*.

There should be an effective programme for the prevention and treatment of *diseases* consistent with the programmes established by *Veterinary Services* as appropriate.

Vaccinations and treatments should be administered, on the basis of veterinary or other expert advice, by personnel skilled in the procedures and with consideration for the welfare of the broilers.

Sick or injured broilers should be humanely killed as soon as possible. Similarly, killing broilers for diagnostic purposes should be done in a humane manner according to Chapter 7.6.

Outcome-based measurables: incidence of *diseases*, metabolic disorders and parasitic *infestations*, mortality, performance, gait.

2. Environment and management

a) Thermal environment

Thermal conditions for broilers should be appropriate for their stage of development, and extremes of heat, humidity and cold should be avoided. For the growing stage, a heat index can assist in identifying the comfort zones for the broilers at varying temperature and relative humidity levels.

When environmental conditions move outside these zones, strategies should be used to mitigate the adverse effects on the broilers. These may include adjusting ~~higher~~ air speeds, provision of heat, evaporative cooling and adjusting ~~reducing~~ stocking density.

Management of the thermal environment should be checked frequently enough so that failure of the system would be noticed before it caused a welfare problem.

Outcome-based measurables: behaviour, mortality, contact dermatitis, water and feed consumption, performance, feather condition.

b) Lighting

There should be an adequate period of continuous darkness during each 24-hour period to allow the broilers to rest. There should also be an adequate period of continuous light.

The light intensity during the light period should be sufficient and homogeneously distributed to allow the broilers to find feed and water after they are placed in the poultry house, to stimulate activity, and allow adequate inspection.

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

Outcome-based measurables: gait, metabolic disorders, performance, behaviour, eye condition, injury rate.

c) Air quality

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

Ammonia concentration should not routinely exceed 25 ppm at broiler level.

Dust levels should be kept to a minimum. Where the health and welfare of broilers depend on an artificial ventilation system, provision should be made for an appropriate back-up power and alarm system.

Outcome-based measurables: incidence of respiratory *diseases*, metabolic disorders, eye conditions, performance, contact dermatitis.

d) Noise

Broilers are adaptable to different levels and types of noise. However, exposure of broilers to sudden or loud noises should be minimised where possible to prevent stress and fear reactions, such as piling. Ventilation fans, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in such a way that they cause the least possible amount of noise.

Location of farms should, where possible, take into account existing local sources of noise.

Outcome-based measurables: daily mortality rate, morbidity, performance, injury rate, fear behaviour.

e) Nutrition

Broilers should always be fed a diet appropriate to their age and genetics, which contains adequate nutrients to meet their requirements for good health and welfare.

Feed and water should be acceptable to the broilers and free from contaminants at a concentration hazardous to broiler health.

The water system should be cleaned regularly to prevent growth of hazardous microorganisms.

Broilers should be provided with adequate access to feed on a daily basis. Water should be available continuously. Special provision should be made to enable young chicks access to appropriate feed and water.

Broilers that are physically unable to access feed or water should be humanely killed as soon as possible.

Outcome-based measurables: feed and water consumption, performance, behaviour, gait, incidence of *diseases*, metabolic disorders and parasitic *infestations*, mortality, injury rate.

f) Flooring, bedding, resting surfaces and litter quality

The floor of a poultry house should preferably be easy to clean and disinfect.

The provision of loose and dry bedding material is desirable in order to insulate the chicks from the ground and to encourage dust bathing and foraging.

Litter should be managed to minimise any detrimental effects on welfare and health. Poor litter quality can lead to contact dermatitis and breast blisters. Litter should be replaced or adequately treated when required to prevent *disease* in the next *flock*.

Annexe XVI (contd)

Litter quality is partly related to the type of substrate used and partly to different management practices. The type of substrate should be chosen carefully. Litter should be maintained so that it is dry and friable and not dusty, caked or wet. Poor litter quality can result from a range of factors including water spillage, inappropriate feed composition, enteric infections, poor ventilation and overcrowding.

If broilers are kept on slatted floors, where a very humid climate precludes the use of other flooring substrates, the floors should be designed, constructed and maintained to adequately support the broilers, prevent injuries and ensure that manure can fall through or be adequately removed.

To prevent injury and keep them warm, *day-old birds* should be placed on an appropriate type of flooring suitable for their size.

If *day-old birds* are housed on litter, before they enter the poultry house, a layer of uncontaminated substrate, such as wood shavings, straw, rice husk, shredded paper, treated used litter should be added to a sufficient depth to allow normal behaviour and to separate them from the floor.

Outcome-based measurables: contact dermatitis, feather condition, gait, behaviour (dust bathing and foraging), eye conditions, incidence of *diseases*, metabolic disorders and parasitic *infestations*, performance.

g) Prevention of feather pecking and cannibalism

Feather pecking and cannibalism are rarely seen in broilers because of their young age. However, management methods, such as reducing light intensity, providing foraging materials, nutritional modifications, reducing stocking density, selecting the appropriate genetic stock should be implemented where feather pecking and cannibalism are a potential problem.

If these management strategies fail, therapeutic beak trimming is the last resort.

Outcome-based measurables: injury rate, behaviour, feather condition, mortality.

h) Stocking density

Broilers should be housed at a stocking density that allows them to access feed and water and to move and adjust their posture normally. The following factors should be taken into account: management capabilities, ambient conditions, housing system, production system, litter quality, ventilation, biosecurity strategy, genetic stock, and market age and weight.

Outcome-based measurables: injury rate, contact dermatitis, mortality, behaviour, gait, incidence of *diseases*, metabolic disorders and parasitic *infestations*, performance, feather condition.

i) Outdoor areas

Broilers can be given access to outdoor areas as soon as they have sufficient feather cover and are old enough to range safely. There should be sufficient exit areas to allow them to leave and re-enter the poultry house freely.

Management of outdoor areas is important in partially housed and completely outdoors production systems. Land and pasture management measures should be taken to reduce the risk of broilers being infected by pathogens or infested by parasites. This might include limiting the stocking density or using several pieces of land consecutively in rotation.

Annexe XVI (contd)

Outdoor areas should be placed on well drained ground and managed to minimise swampy conditions and mud.

Outdoor areas should provide shelter for broilers and be free from poisonous plants and contaminants.

Protection from adverse climatic conditions should be provided in completely outdoors systems.

Outcome-based measurables: behaviour, incidence of disease, metabolic disorders and parasitic *infestations*, performance, contact dermatitis, feather condition, injury rate, mortality, morbidity.

j) Protection from predators

Broilers should be protected from predators.

Outcome-based measurables: fear behaviour, mortality, injury rate.

k) Choice of broiler strain

Welfare and health considerations, in addition to productivity and growth rate, should be taken into account when choosing a strain for a particular location or production system. ~~For example, broilers selected with faster growth rates may have greater risks of metabolic disorders and contact dermatitis which should be mitigated by relevant management procedures. [Under study]~~

EU comment

With regard to the first sentence the EU strongly supports maintaining growth rate as an element which needs to be addressed. In addition the EU would propose to include a second and third sentence in the above paragraph:

“The conservation and development of genetic lines of broilers, which limit or reduce animal welfare problems, should be encouraged. Examples of such criteria include reduction of risks for metabolic disorders, heat stress and locomotion problems.”

Justification:

These sentences are in line with text proposed for the new chapter on dairy cattle and in part with chapter 7.9 beef cattle production systems. They address a different aspect that related to genetic selection itself but this may impact on the welfare of birds kept for meat production. The new third sentence allows for highlighting some of the resultant negative outcomes for bird welfare without directly linking them to growth rate. The EU has previously submitted scientific references demonstrating the importance of these issues.

Outcome-based measurables: gait, metabolic disorders, contact dermatitis, mortality, behaviour, performance.

l) Painful interventions

Painful interventions, such as beak trimming, toe trimming and dubbing, should not be routinely practised on broilers.

If therapeutic beak trimming is required, it should be carried out by trained and skilled personnel at as early an age as possible and care should be taken to remove the minimum amount of beak necessary using a method which minimises pain and controls bleeding.

Surgical caponisation should not be performed without adequate pain and *infection* control

methods and should only be performed by *veterinarians* or trained and skilled personnel under veterinary supervision.

Outcome-based measurables: mortality, culling and morbidity, behaviour.

m) Handling and inspection

Broilers should be inspected at least daily. Inspection should have three main objectives: to identify sick or injured broilers to treat or cull them, to detect and correct any welfare or health problem in the *flock*, and to pick up dead broilers.

Inspection should be done in such a way that broilers are not unnecessarily disturbed, for example *animal handlers* should move quietly and slowly through the *flock*.

When broilers are handled, they should not be injured or unnecessarily frightened or stressed.

Broilers which have an incurable illness, significant deformity or injury should be removed from the *flock* and killed humanely as soon as possible as described in Chapter 7.6.

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

Outcome-based measurables: behaviour, performance, injury rate, mortality, vocalisation, morbidity.

n) Personnel training

All people responsible for the broilers should have received appropriate training or be able to demonstrate that they are competent to carry out their responsibilities and should have sufficient knowledge of broiler behaviour, handling techniques, emergency killing procedures, biosecurity, general signs of *disease*, and indicators of poor *animal welfare* and procedures for their alleviation.

Outcome-based measurables: all measurables could apply.

o) Emergency plans

Broiler producers should have emergency plans to minimise and mitigate the consequences of natural disasters, *disease outbreaks* and the failure of mechanical equipment. Planning may include the provision of fail-safe alarm devices to detect malfunctions, backup generators, access to maintenance providers, alternative heating or cooling arrangements, ability to store water on farm, access to water cartage services, adequate on-farm storage of feed and alternative feed supply and a plan for managing ventilation emergencies.

The emergency plans should be consistent with national programmes established or recommended by *Veterinary Services*.

p) Location, construction and equipment of farms

The location of broiler farms should be chosen to be safe from the effects of fires and floods and other natural disasters to the extent practical. In addition farms should be sited to avoid or minimise biosecurity risks, exposure of broilers to chemical and physical contaminants, noise and adverse climatic conditions.

Broiler houses, outdoor areas and equipment to which broilers have access should be designed and maintained to avoid injury or pain to the broilers.

Broiler houses should be constructed and electrical and fuel installations should be fitted to minimise the risk of fire and other hazards.

Broiler producers should have a maintenance programme in place for all equipment the failure of which can jeopardise broiler welfare.

q) On farm harvesting

Broilers should not be subject to an excessive period of feed withdrawal prior to the expected *slaughter* time.

Water should be available up to the time of harvesting.

Broilers that are not fit for *loading* or *transport* because they are sick or injured should be killed humanely.

Catching should be carried out by skilled *animal handlers* and every attempt should be made to minimise stress and fear reactions, and injury. If a broiler is injured during catching, it should be killed humanely.

Broilers should not be picked up by their neck or wings.

Broilers should be carefully placed in the *transport container*.

Mechanical catchers, where used, should be designed, operated and maintained to minimise injury, stress and fear to the broilers. A contingency plan is advisable in case of mechanical failure.

Catching should preferably be carried out under dim or blue light to calm the broilers.

Catching should be scheduled to minimise the time to *slaughter* as well as climatic stress during catching, *transport* and holding.

Stocking density in *transport containers* should suit climatic conditions and maintain comfort.

Containers should be designed and maintained to avoid injury, and they should be cleaned and, if necessary, disinfected regularly.

Outcome-based measurables: injury rate, mortality rate at harvesting and on arrival at the *slaughterhouse/abattoir*.

— Text deleted.

CHAPTER 3.1.

VETERINARY SERVICES

EU position

The EU thanks the OIE for taking our comment into account and supports the adoption of this modified chapter.

Article 3.1.1.

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

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

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

These fundamental principles are presented in Article 3.1.2. Other factors affecting quality are described in Volume I of the *Terrestrial Code* (notification, principles of certification, etc.).

The quality of *Veterinary Services*, including *veterinary legislation*, can be measured through an evaluation, whose general principles are described in Article 3.1.3. and in Article 3.1.4.

Recommendations on the evaluation of *Veterinary Services*, including *veterinary legislation*, are described in Chapter 3.2.

A procedure for evaluating *Veterinary Services* by OIE experts, on a voluntary basis, is described in Article 3.1.5.

Article 3.1.2.

Fundamental principles of quality

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

1. Professional judgement

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

2. Independence

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

3. Impartiality

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

4. Integrity

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

5. Objectivity

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

6. Veterinary legislation

Veterinary legislation is prerequisite to support good governance and provide the legal framework for all key activities of the *Veterinary Services*.

Legislation should be suitably flexible to allow for judgements of equivalence and efficient responses to changing situations. In particular, it should define and document the responsibilities and structure of the organisations in charge of the *animal identification system*, control of animal movements, animal disease control and reporting systems, epidemiological *surveillance* and communication of epidemiological information.

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

7. General organisation

The *Veterinary Services* should be able to demonstrate by means of appropriate legislation, sufficient financial resources and effective organisation that they are ~~in a position~~ able to anticipate the requirements for, and have control of, the establishment and application of animal health and *animal welfare* measures, and of international veterinary certification activities.

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

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

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

8. Quality policy

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

9. Procedures and standards

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

- a) programming and management of activities, including international veterinary certification activities;
- b) prevention, control and notification of *disease outbreaks*;
- c) *risk analysis*, epidemiological *surveillance* and zoning;
- d) emergency preparedness for disasters which could have impact on animal health and welfare disaster preparedness
- e) inspection and sampling techniques;
- f) diagnostic tests for animal *diseases*;
- g) preparation, production, registration and control of biological products for use in the diagnosis or prevention of *diseases*;
- h) border controls and import regulations;
- i) *disinfection* and *disinfestation*;
- j) treatments intended to destroy, if appropriate, pathogens in animal products.

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

10. Information, complaints and appeals

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

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

11. Documentation

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

12. Self-evaluation

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

A procedure for evaluating *Veterinary Services* by OIE experts, on a voluntary basis, is described in Article 3.1.5.

13. Communication

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

Annex XVII (contd)14. Human and financial resources

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

Article 3.1.3.

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

Any evaluation of *Veterinary Services* should be conducted having regard to the OIE recommendations on the evaluation of *Veterinary Services* presented in Chapter 3.2.

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

Article 3.1.4.

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

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

The evaluation process should take into account the fundamental principles and other factors of quality laid down in Article 3.1.1. and in Article 3.1.2. It should also take into consideration the specific circumstances regarding quality, as described in Article 3.1.1., prevailing in the countries concerned.

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

In the event of a dispute between two Member Countries over the conduct or the conclusions of the evaluation of the *Veterinary Services*, the matter should be dealt with having regard to the procedures set out in Article 5.3.8.

Article 3.1.5.

Evaluation facilitated by OIE experts under the auspices of the OIE

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

The World Assembly of OIE Delegates endorses a list of approved experts to facilitate the evaluation process.

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

Annex XVII (contd)

The expert(s) facilitate(s) the evaluation of the *Veterinary Services* of the Member Country based on the provisions in Chapter 3.2., using the *OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool)*.

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

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

— Text deleted.

CHAPTER 3.2.

EVALUATION OF VETERINARY SERVICES

EU position

The EU thanks the OIE for taking some of its comments into account while referring several of them to the OIE Animal Welfare Working Group for deeper consideration. The EU can support the adoption of this modified chapter but looks forward to the outcome of the Working Group's deliberations.

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 Country. In applying these recommendations on the evaluation, the *OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool)* should be used.

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

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

of outputs and performance of *Veterinary Services*. Evaluation should take into consideration any quality systems used by *Veterinary Services*.

- 7) An *importing country* has a right of assurance that information on sanitary or zoosanitary situations provided by the *Veterinary Services* of an *exporting country* is objective, meaningful and correct. Furthermore, the *Veterinary Services* of the *importing country* are entitled to expect validity in the veterinary certification of export.
- 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 Member Countries' obligations.
- 2) To complement the evaluation of *Veterinary Services*, the legislative and regulatory framework, the organisational structure and functioning of the *veterinary statutory body* should also be considered.
- 3) Article 3.2.14. outlines appropriate information requirements for:
 - self-evaluation by the *Veterinary Authority* which perceives a need to prepare information for national or international purposes;
 - evaluation by a prospective or actual *importing country* of the *Veterinary Services* of a prospective or actual *exporting country*;
 - verification or re-verification of an evaluation in the course of a visit to the *exporting country* by the *importing country*;
 - evaluation by third parties such as OIE PVS experts or regional organisations.

Article 3.2.3.

Evaluation criteria for the organisational structure of the Veterinary Services

- 1) A key element in the evaluation is the study of the organisation and structure of the official *Veterinary Services*. The *Veterinary Services* should define and set out their policy, objectives and commitment to quality systems and standards. These organisational and policy statements should be described in detail. Organisational charts and details of functional responsibilities of staff should be available for

evaluation. The role and responsibility of the Chief Veterinary Officer/Veterinary Director should be clearly defined. Lines of command should also be described.

- 2) The organisational structure should also clearly set out the interface relationships of government Ministers and departmental Authorities with the Chief Veterinary Officer/Veterinary Director and the *Veterinary Services*. Formal relationships with statutory authorities and with industry organisations and associations should also be described. It is recognised that *Services* may be subject to changes in structure from time to time. Major changes should be notified to trading partners so that the effects of re-structuring may be assessed.
- 3) Organisational components of *Veterinary Services* which have responsibility for key functional capabilities should be identified. These capabilities include epidemiological *surveillance*, *disease control*, import controls, animal disease reporting systems, animal identification systems, traceability systems, animal movement control systems, communication of epidemiological information, training, inspection and certification. Laboratory and field systems and their organisational relationships should be described.
- 4) To reinforce the reliability and credibility of their services, the *Veterinary Services* may have set up quality systems that correspond with their fields of activity and to the nature and scale of activities that they carry out. Evaluation of such systems should be as objective as possible.
- 5) The *Veterinary Authority* alone speaks for the country as far as official international dialogue is concerned. This is also particularly important to cases where zoning and compartmentalisation are being applied. The responsibilities of the *Veterinary Authority* should be made clear in the process of evaluation of *Veterinary Services*.
- 6) The *Veterinary Authority* is defined in the Glossary of the *Terrestrial Code*. As some countries have some relevant roles of the *Veterinary Authority* vested in autonomous sub-national (state/provincial, municipal) government bodies, there is an important need to assess the role and function of these *Services*. Details of their roles, relationship (legal and administrative) to each other and to the *Veterinary Authority* should be available for evaluation. Annual reports, review findings and access to other information pertinent to the animal health activities of such bodies should also be available.
- 7) Similarly, where the *Veterinary Authority* has arrangements with other providers of relevant services such as universities, *laboratories*, information services, etc., these arrangements should also be described. For the purposes of evaluation, it is appropriate to expect that the organisational and functional standards that apply to the *Veterinary Authority* should also apply to the service providers.

Article 3.2.4.

Evaluation criteria for quality systems

- 1) The *Veterinary Services* should demonstrate a commitment to the quality of the processes and outputs of their services. Where services or components of services are delivered under a formal quality systems programme which is based on OIE recommended standards or, especially in the case of laboratory components of *Veterinary Services* other internationally recognised quality standards, the *Veterinary Services* undergoing evaluation should make available evidence of accreditation, details of the documented quality processes and documented outcomes of all relevant audits undertaken.
- 2) Where the *Veterinary Services* undergoing evaluation make large use of formal quality systems in the delivery of their services, it is appropriate that greater emphasis be placed on the outcomes of evaluation of these quality systems than on the resource and infrastructural components of the services.

Annex XVIII (contd)

Article 3.2.5.

Evaluation criteria for human resources

- 1) The *Veterinary Services* should demonstrate that their human resource component includes an integral core of full-time civil service employees. This core should always include *veterinarians*. It should also include administrative officials and *veterinary para-professionals*. The human resources may also include part-time and private sector *veterinarians* and *veterinary para-professionals*. It is essential that all the above categories of personnel be subject to legal disciplinary provisions. Data relating to the resource base of the *Veterinary Services* undergoing evaluation should be available.
- 2) In addition to raw quantitative data on this resource base, the functions of the various categories of personnel in the *Veterinary Services* should be described in detail. This is necessary for analysis and estimation of the appropriateness of the application of qualified skills to the tasks undertaken by the *Veterinary Services* and may be relevant, for example, to the roles of *veterinarians* and *veterinary para-professionals* in field services. In this case, the evaluation should provide assurances that *disease* monitoring is being conducted by a sufficient number of qualified, experienced field *veterinarians* who are directly involved in farm visits; there should not be an over-reliance on *veterinary para-professionals* for this task.
- 3) Analysis of these data can be used to estimate the potential of the *Veterinary Services* to have reliable knowledge of the state of animal health in the country and to support an optimal level of animal disease control programmes. A large population of private *veterinarians* would not provide the *Veterinary Services* with an effective epizootiological information base without legislative (e.g. compulsory reporting of *notifiable diseases*) and administrative (e.g. official animal health surveillance and reporting systems) mechanisms in place.
- 4) These data should be assessed in close conjunction with the other information described in this chapter. For example, a large field staff (*veterinarians* and *veterinary para-professionals*) need fixed, mobile and budgetary resources for animal health activities in the livestock farming territory of the country. If deficiencies are evident, there would be reason to challenge the validity of epizootiological information.

Article 3.2.6.

Evaluation criteria for material resources1. Financial

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

2. Administrative

a) Accommodation

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

b) Communications

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

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

c) Transport systems

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

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

3. Technical

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

a) Cold chain for laboratory samples and veterinary medicines

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

b) Diagnostic laboratories

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

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

Annex XVIII (contd)

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

c) Research

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

Article 3.2.7.

Legislation and functional capabilities1. Animal health, animal welfare and veterinary public health

The *Veterinary Authority* should be able to demonstrate that it has the capacity, supported by appropriate legislation, to anticipate and exercise control over all animal health and welfare matters. These controls should include, where appropriate, compulsory notification of prescribed animal *diseases*, inspection, movement controls through systems which provide adequate traceability, registration of facilities, quarantine of infected premises or areas, testing, treatment, humane killing destruction of infected *animals*, disposal of carcasses, or destruction of 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 zoonosanitary matters. The evaluation should also involve the consideration of administrative instructions to ensure the enforcement of *importing country* requirements during the pre-export period.

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

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

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

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

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

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

Article 3.2.8.

Animal health controls

1. Animal health status

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

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

2. Animal health control

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

Annex XVIII (contd)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.

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.

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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 and welfare organisations. Such a programme should be used in assessing the effectiveness of the Services.

e) Publications

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

f) Formal linkages with sources of independent scientific expertise

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

g) Trade performance history

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

Article 3.2.11.

Participation in OIE activities

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

Article 3.2.12.

Evaluation of the veterinary statutory body1. Scope

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

- a) objectives and functions;
- b) legislative basis for the *veterinary statutory body*, including autonomy and functional capacity;
- c) the composition of the *veterinary statutory body*, including the organisation represented in it;
- 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 policy and the objectives of the *veterinary statutory body*, including details of its power and functions, should be defined, notably with regard to:

- a) the licensing or registration of *veterinarians* and *veterinary para-professionals* to perform the activities of veterinary medicine/science;
- b) the minimum standards of education (initial and continuing) required for degrees, diplomas and certificates entitling the holders thereof to be registered or licensed as *veterinarians* and *veterinary para-professionals*;
- c) the standards of professional conduct and competence of *veterinarians* and *veterinary para-professionals* and ensuring that these standards are met.

3. Evaluation of legislative basis, autonomy and functional capacity

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

Annex XVIII (contd)

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

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

4. Evaluation of the composition of the veterinary statutory body

Detailed descriptions of the composition, rules and conditions for membership, including duration of appointment and representation of interested third parties, public and private, should be available.

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

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

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

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

Article 3.2.13.

- 1) The *Veterinary Services* of a country may undertake self-evaluation against the above criteria for such purposes as national interest, improvement of internal efficiency or export trade facilitation. The way in which the results of self-evaluation are used or distributed is a matter for the country concerned.
- 2) A prospective *importing country* may undertake an evaluation of the *Veterinary Services* of an *exporting country* as part of a *risk analysis* process, which is necessary to determine the sanitary or zoonosanitary measures which the country will use to protect human or animal life or health from *disease* or pest threats posed by imports. Periodic evaluation reviews are also valid following the commencement of trade.
- 3) In the case of evaluation for the purposes of *international trade*, the authorities of an *importing country* should use the principles elaborated above as the basis for the evaluation and should attempt to acquire information according to the model questionnaire outlined in Article 3.2.14. The *Veterinary Services* of the *importing country* are responsible for the analysis of details and for determining the outcome of the evaluation after taking into account all the relevant information. The relative ranking of importance ascribed, in the evaluation, to the criteria described in this chapter will necessarily vary according to case-by-case circumstances. This ranking should be established in an objective and justifiable way. Analysis of the information obtained in the course of an evaluation study should be performed in as objective a manner as possible. The validity of the information should be established and reasonableness should be employed in its application. The assessing country should be willing to defend any position taken on the basis of this type of information, if challenged by the other party.

Article 3.2.14.

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

1. Organisation and structure of Veterinary Services

a) National Veterinary Authority

Organisational chart including numbers, positions and numbers of vacancies.

b) Sub-national components of the Veterinary Authority

Organisational charts including numbers, positions and number of vacancies.

c) Other providers of veterinary services

Description of any linkage with other providers of veterinary services.

2. National information on human resources

a) Veterinarians

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

ii) Numbers of:

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

iii) Animal health:

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

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

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iv) Veterinary public health:

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

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

v) Numbers of veterinarians relative to certain national indices:

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

vi) Veterinary education:

- number of veterinary schools;
- length of veterinary course (years);
- curriculum addressing the minimum competencies of day 1 veterinary graduates and the post-graduate and continuing education topics to assure the delivery of quality veterinary services, as described in the relevant chapter(s) of the *Terrestrial Code*;
- international recognition of veterinary degree.

vii) Veterinary professional associations.

b) Graduate personnel (non-veterinary)

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

c) Veterinary para-professionals employed by the Veterinary Services

i) Animal health:

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

- ii) Veterinary public health:
 - Categories and numbers involved in food inspection on a majority time basis:
 - *meat* inspection: export *meat* establishments with an export function and domestic *meat* establishments (no export function);
 - dairy inspection;
 - other foods.
 - Numbers in import and export inspection.
 - Education or training details.
 - d) Support personnel

Numbers directly available to *Veterinary Services* per sector (administration, communication, transport).
 - e) Descriptive summary of the functions of the various categories of staff mentioned above
 - f) Veterinary, *veterinary para-professionals*, livestock owner, farmer and other relevant associations
 - g) Additional information or comments.
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.

Annex XVIII (contd)4. Administration details

a) Accommodation

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

b) Communications

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

c) Transport

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

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

5. Laboratory services

a) Diagnostic laboratories (laboratories engaged primarily in diagnosis)

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

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

- government operated *laboratories*;
- private *laboratories* authorised by veterinary authority for the purposes of supporting official or officially-endorsed animal health control or public health testing and monitoring programmes and import and export testing.

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

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

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

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

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

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

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

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

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- xi) Reports of independent reviews of the laboratory service conducted by government or private organisations (if available).
 - xii) Strategic and operational plans for the official veterinary laboratory service (if available).
- b) Research laboratories (laboratories engaged primarily in research)
- i) Numbers of veterinary research *laboratories* operating in the country:
 - government operated *laboratories*;
 - private *laboratories* involved in full time research directly related to animal health and veterinary public health matters involving production animal species.
 - ii) Summary of human and financial resources allocated by government to veterinary research.
 - iii) Published programmes of future government sponsored veterinary research.
 - iv) Annual reports of the government research *laboratories*.
6. Veterinary legislation, regulations and functional capabilities
- a) Animal health and welfare 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 animal health and welfare disaster management of disasters which could have impact on animal health and welfare, and 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 food 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.

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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 food 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;

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- animal *diseases* introduced to the country or to previously free sub national regions in the last ten years;
 - *emerging diseases* in the last ten years;
 - animal *diseases* of which the prevalence has increased in the last ten years.
- b) Veterinary public health
- i) Food hygiene
- Annual national *slaughter* statistics for the past three years according to official data by species of *animals* (bovine, ovine, porcine, caprine, *poultry*, farmed game, wild game, equine, other).
 - Estimate of total annual slaughterings which occur but are not recorded under official statistics.
 - Proportion of total national *slaughter* which occurs in registered export establishments, by category of *animal*.
 - Proportion of total national *slaughter* which occurs under veterinary control, by category of *animal*.
 - Numbers of commercial *fresh meat* establishments in the country which are registered for export by the *Veterinary Authority*:
 - *slaughterhouses* (indicate species of *animals*);
 - cutting or packing plants (indicate *meat* type);
 - *meat* processing establishments (indicate *meat* type);
 - cold stores.
 - Numbers of commercial *fresh meat* establishments in the country approved by other *importing countries* which operate international assessment inspection programmes associated with approval procedures.
 - Numbers of commercial *fresh meat* establishments under direct public health control of the *Veterinary Services* (including details of category and numbers of inspection staff associated with these premises).
 - Description of the veterinary public health programme related to production and processing of animal products for human consumption (including *fresh meat*, *poultry meat*, *meat products*, game *meat*, dairy products, fish, fishery products, molluscs and crustaceans and other foods of animal origin) especially including details applying to exports of these *commodities*.
 - Descriptive summary of the roles and relationships of other official organisations in public health programmes for the products listed above if the *Veterinary Authority* does not have responsibility for those programmes which apply to national production destined to domestic consumption or exports of the *commodities* concerned.
- ii) Zoonoses
- Descriptive summary of the numbers and functions of staff of the *Veterinary Authority* involved primarily with monitoring and control of zoonotic diseases.

Annex XVIII (contd)

- 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).

Annex XVIII (contd)

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 for taking our comment into account 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 audiences.

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, and have established linkages with relevant agencies, particularly for animal health and welfare disaster management of disasters which could have impact on animal health and welfare, and for exotic disease control.
- 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 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.

Annex XIX (contd)

Crisis communication: means the process of communicating information as accurately as possible, albeit potentially incomplete, 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 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 dedicated communication unit or 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 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* with established linkages to relevant *Competent Authorities* with which *Veterinary Services* collaborate
 - v) Provide and coordinate continuous education on communication for the *Veterinary Services*.

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 organization-wide long-term communication objectives.

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 or interested parties, an entire community or the general public to make best possible decisions and be informed of 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 or acceptance of policy decisions and subsequent change of perception, attitude 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 utilizing available resources within a specific timeframe.

— 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. Some comments are inserted in the text below.

Article 12.1.1.

General provisions

For the purposes of the *Terrestrial Code*, African horse sickness (AHS) is defined as an *infection* of equids with African horse sickness virus (AHSV).

The following defines an *infection* with AHSV:

- 1) AHSV has been isolated and identified from an equid or a product derived from that equid; or
- 2) viral antigen or viral ribonucleic acid (RNA) specific to a serotype of AHSV has been identified in samples from an equid showing clinical signs consistent with AHS, or epidemiologically linked to a suspected or confirmed **case infection case**; or
- 3) serological evidence of active *infection* with AHSV by detection of seroconversion with production of antibodies against structural or nonstructural proteins of AHSV that are not a consequence of *vaccination* have been identified in an equid that either shows clinical signs consistent with AHS, or is epidemiologically linked to a suspected or confirmed **case infection case**.

EU comment

The EU suggests italicising the word “case” in points 2 and 3 above, to refer to the glossary definition of that term.

For the purposes of the *Terrestrial Code*, the *infective period* for African horse sickness virus (AHSV) shall **be is** 40 days for domestic horses. Although critical information is lacking for some species, this chapter applies to all equidae.

All countries or *zones* adjacent to a country or *zone* not having free status should determine their AHSV status from an ongoing *surveillance* programme. Throughout the chapter, *surveillance* is in all cases understood as being conducted as described in Article 12.1.4311, to 12.1.4513.

~~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.

AHS free AHSV free country or zone free from infection with AHSV

- 1) A country or *zone* may be considered free from infection with AHSV when African horse sickness (~~infection with AHSV~~) is notifiable in the whole country, systematic *vaccination* is prohibited, importation of equids and their semen, oocytes or embryos are carried out in accordance with this chapter, and either:
 - a) historical freedom as described in Chapter 1.4. has demonstrated no evidence of AHSV in the country or *zone*; or
 - b) the country or *zone* has not reported any case of AHSV infection for at least two years and is not adjacent to an infected country or *zone*; or
 - c) a *surveillance* programme has demonstrated no evidence of AHSV in the country or *zone* for at least ~~twenty-four months~~ two years; or
 - d) the country or *zone* has not reported any case of ~~case of~~ AHSV infection for at least 40 days and a *surveillance* programme has demonstrated no evidence of *Culicoides* for at least two years in the country or *zone*.
- 2) An AHS free ~~An AHS free~~ country or *zone* free from infection with AHSV ~~free from infection with AHSV~~ which is adjacent to an infected country or *infected zone* should include a *zone* in which *surveillance* is conducted in accordance with Articles 12.1.43~~11~~. to 12.1.45~~13~~, as relevant. ~~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.

EU comment

Further to its previous comment on the point above, the EU takes note of the new wording now proposed by the OIE. The EU understands that member countries will be requested to provide, in their respective “dossier”, the justification on the extent surveillance is carried out, or not carried out, as relevant.

- 3) An AHS free ~~An AHS free~~ country or *zone* free from infection with AHSV ~~free from infection with AHSV~~ will not lose its free status through the importation of ~~vaccinated or seropositive or vaccinated~~ equids and their semen, oocytes or embryos from infected countries or *infected zones*, provided these imports are carried out in accordance with this chapter.
- 4) To qualify for inclusion in the list of AHSV free countries or *zones*, a Member Country should:
 - a) have a record of regular and prompt animal disease reporting;
 - b) send a declaration to the OIE stating:
 - i) the section under point 1) on which the application is based;
 - ii) no routine *vaccination* against AHS has been carried out during the past ~~twelve months~~ year in the country or *zone*;
 - iii) equids are imported in accordance with this chapter;
 - c) supply documented evidence that:
 - i) *surveillance* in accordance with Articles 12.1.43~~11~~. to 12.1.45~~13~~. is applied, unless historically free in accordance with Article 1.4.6;
 - ii) regulatory measures for the early detection, prevention and control of infection with AHSV have been implemented.

5) The Member Country will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 4b)ii) and iii) and 4c) ii) above be re-submitted annually and changes in the epidemiological situation or other significant events be reported to the OIE according to the requirements in Chapter 1.1., and in particular, formally state that :

- a) there has been no *outbreak* of AHS during the past ~~twelve months~~ year in the country or *zone*;
- b) no evidence of *infection with* AHSV ~~infection~~ has been found during the past ~~twelve months~~ year 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*.~~
- 2) ~~AHS is notifiable in the whole country.~~
- 3) ~~For the application of Articles 12.1.8., 12.1.10. and 12.1.11., the seasonally free period is:~~
 - a) ~~taken to commence the day following the last evidence of AHSV transmission and of the cessation of activity of adult *Culicoides* as demonstrated by an ongoing *surveillance* programme, and~~
 - b) ~~taken to conclude either:~~
 - i) ~~at least 40 days before the earliest date that historical data show AHSV activity has recommenced; or~~
 - ii) ~~immediately when current climatic data or data from a *surveillance* and monitoring programme indicate an earlier resurgence of activity of adult *Culicoides* vectors.~~
- 4) ~~An AHSV seasonally free zone will not lose its free status through the importation of vaccinated or seropositive equids and their semen, oocytes or embryos from infected countries or *infected zones*, provided these imports are carried out in accordance with this chapter.~~

Article 12.1.4~~3~~.

AHSV ~~infected country or zone~~

For the purpose of this chapter, an AHSV ~~infected country or zone~~ is one that does not fulfil the requirements to qualify as either AHSV free country or *zone* AHS free from infection with AHSV or AHSV seasonally free *zone*.

Article 12.1.5~~4~~.

~~Establishment of a containment zone within an AHS free~~ AHS free ~~a AHS free country or zone~~ free from infection with AHSV

In the event of limited *outbreaks* within an AHS free ~~a AHS free country or zone~~ free from infection with AHSV, including within a ~~protection zone~~, a single *containment zone*, which includes all cases, and should be large enough to contain any potentially infected vectors, can be established for the purpose of minimising the impact on the entire country or *zone*. Such a zone should include all cases and can be established within a protection zone. For this to be achieved, the *Veterinary Authority* should provide documented evidence that:

- 1) the *outbreaks* are limited based on the following factors:
 - a) immediately on suspicion, a rapid response including notification has been made;

- b) standstill of movements of equids has been imposed, and effective controls on the movement of equids and their products specified in this chapter are in place;
 - c) epidemiological investigation (trace-back, trace-forward) has been completed;
 - d) the *infection* has been confirmed;
 - e) ~~the primary outbreak and likely source of the outbreak has been identified;~~ investigations on the likely source of the outbreak have been carried out;
 - f) all cases have been shown to be epidemiologically linked;
 - g) no new cases have been found in the *containment zone* within a minimum of two *infective periods* as defined in Article 12.1.1.;
- 2) the equids within the *containment zone* ~~should be~~ are clearly identifiable as belonging to the *containment zone*;
 - 3) increased passive and targeted *surveillance* in accordance with Articles 12.1.4311. to 12.1.4513. in the rest of the country or *zone* has not detected any evidence of *infection*;
 - 4) animal health measures are in place to ~~that~~ effectively prevent the spread of AHSV *infection* 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 12.1.4311. to 12.1.4513. is in place in the *containment zone*.

The free status of the areas outside the *containment zone* is suspended ~~pending the establishment of~~ while the *containment zone* is being established in accordance with points 1 to 5 above. The free status of the areas outside the *containment zone* ~~could~~ may be reinstated irrespective of the provisions of Article 12.1.65., once the *containment zone* is recognised by the OIE.

In the event of the recurrence of AHSV *infection* in the *containment zone*, the approval of the *containment zone* is withdrawn.

The recovery of the AHSV free status of the *containment zone* should follow the provisions of Article 12.1.65.

Article 12.1.65.

Recovery of free status

To regain the free status when an AHS *outbreak* occurs in an AHS free country or *zone* previously free from infection with AHSV, to regain the free status, the provisions of Article 12.1.2. apply, irrespective of whether emergency *vaccination* has been applied or not.

Article 12.1.76.

Recommendations for importation from AHS free AHSV free countries or zones free from infection with AHSV

For equids

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

- 1) showed no clinical sign of AHS on the day of shipment;
- 2) have not been vaccinated against AHS within the last 40 days;

- 3) were kept in an AHS free an AHSV free country(ies), or zone(s) free from infection with AHSV since birth or for at least 40 days prior to shipment;
- 4) either:
 - a) did not transit through an *infected zone* during transportation to the *place of shipment*; or
 - b) were protected from attacks from *Culicoides* at all times when transiting through an *infected zone*.

~~Article 12.1.8.~~

~~Recommendations for importation from AHSV seasonally free zones during the seasonally free period~~

For equids

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

- 1) showed no clinical signs of AHS on the day of shipment;
- 2) have not been vaccinated against AHS within the last 40 days;
- 3) and either
 - a) were kept in an AHSV seasonally free zone during the seasonally free period since birth or for at least 40 days prior to shipment; or
 - b) were held in isolation in a *vector-protected establishment* prior to shipment
 - i) for a period of at least 28 days and a serological test according to the *Terrestrial Manual* to detect antibodies to the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the *vector-protected establishment*; or
 - ii) for a period of at least 40 days and serological tests according to the *Terrestrial Manual* to detect antibodies against AHSV were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least seven days after introduction into the *vector-protected establishment*; or
 - iii) for a period of at least 14 days and an agent identification tests according to the *Terrestrial Manual* was carried out with a negative results on a blood samples collected not less than 14 days after introduction into the *vector-protected establishment*;
- 4) were protected from attacks from *Culicoides* at all times when transiting through an *infected zone*.

Article 12.1.9].

~~Recommendations for importation from AHSV infected countries or zones~~

For equids

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

- 1) showed no clinical sign of AHS on the day of shipment;
- 2) have not been vaccinated against AHS within the last 40 days;
- 3) were held in isolation in a *vector-protected establishment*

Annex XX (contd)

- a) for a period of at least 28 days and a serological test ~~according to the *Terrestrial Manual*~~ to detect antibodies ~~to~~ **against** the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the *vector-protected establishment*; or
 - b) for a period of at least 40 days and serological tests ~~according to the *Terrestrial Manual*~~ to detect antibodies against AHSV were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least seven days after introduction into the *vector-protected establishment*; or
 - c) for a period of at least 14 days and an agent identification tests ~~according to the *Terrestrial Manual*~~ was carried out with a negative results on a blood samples collected not less than 14 days after introduction into the *vector-protected establishment*; 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 12.1.44~~12~~ and 12.1.45~~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 12.1.40~~8~~.

Recommendations for the importation of equine semen

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

- 1) showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;
- 2) had not been immunised against AHS with a live attenuated vaccine within 40 days prior to the day of collection;
- 3) were either:
 - a) kept in an **AHS free** ~~n AHSV free~~ country or ~~free zone~~ **free from infection with AHSV** or from an ~~AHSV seasonally free zone (during the seasonally free period)~~ for at least 40 days before commencement of, and during collection of, the semen, or
 - b) kept in an **AHSV** free *vector-protected artificial insemination centre* throughout the collection period, and subjected to either:
 - i) a serological test ~~according to the *Terrestrial Manual*~~ to detect antibodies **against** the AHSV group, carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of semen; or
 - ii) agent identification tests ~~according to the *Terrestrial Manual*~~ carried out with negative results on blood samples collected at commencement and conclusion of, and at least every seven days, during semen collection for this consignment.

Article 12.1.41~~9~~.

Recommendations for the importation of *in vivo* derived equine embryos or oocytes

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

Annex XX (contd)

- 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 a AHS free ~~n-AHSV free~~ country or free zone ~~free from infection with AHSV~~ or from an ~~AHSV seasonally free zone (during the seasonally free period)~~ for at least 40 days before commencement of, and during collection of the embryos or oocytes, or
 - ii) kept in an AHSV free vector-protected *collection centre* throughout the collection period, and subjected to either:
 - a serological test ~~according to the *Terrestrial Manual*~~ to detect antibodies against the AHSV group carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of embryos or oocytes; or
 - agent identification tests ~~according to the *Terrestrial Manual*~~ carried out with negative results on blood samples collected at commencement and conclusion of, and at least every seven days during embryos or oocytes collection for this consignment;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7. or Chapter 4.9., as relevant;
- 3) semen used to fertilise the oocytes, complies at least with the requirements in Article 12.1.408.

Article 12.1.4210.

Protecting animals from *Culicoides* attack

1. Vector-protected establishment or facility

The *establishment* or facility should be approved by the *Veterinary Authority* and the means of protection should at least comprise the following;

- a) appropriate physical barriers at entry and exit points, for example double-door entry-exit system;
- b) openings of the building are *vector* screened with mesh of appropriate gauge impregnated regularly with an approved insecticide according to manufacturers' instruction;
- c) *vector surveillance* and control within and around the building;
- d) measures to limit or eliminate 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~~ equids to the place of *loading*.

Annex XX (contd)2. During transportation

When transporting equids through AHSV infected countries or AHSV infected zones, Veterinary Authorities should require strategies to protect animals from attacks by *Culicoides* during transport, taking into account the local ecology of the vector.

a) Transport by road:

Potential risk management strategies include a combination of:

- i) treating animals with chemical repellents prior to and during transportation, in sanitized vehicles treated with appropriate residual contact insecticide;
- ii) loading, transporting and unloading animals at times of low vector activity (i.e. bright sunshine and low temperature);
- iii) ensuring vehicles do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;
- iv) darkening the interior of the vehicle, for example by covering the roof or sides of vehicles with shade cloth;
- v) monitoring surveillance for vectors at common stopping and offloading points to gain information on seasonal variations;
- vi) using historical, ongoing or AHS modelling information on AHS to identify low risk ports and transport routes.

b) Transport by air:

Prior to loading the equids, the crates, containers or jet stalls are sprayed with an insecticide approved in the country of dispatch.

Crates, containers or jet stalls in which equids are being transported and the cargo hold of the aircraft ~~should~~ must be sprayed with an approved insecticide when the doors have been just after the doors to the aircraft are closed and prior to take-off, or immediately prior to the closing of the aircraft doors after loading. All possible insect harbourage should be treated. The spray containers should be retained for inspection on arrival.

In addition, during any stopover in countries or zones not free of from infection with AHSV, prior to, ~~or immediately after~~ the opening of any aircraft door and until all doors are closed, netting of appropriate gauge impregnated with an approved insecticide should ~~must~~ be placed over all crates, containers or jet stalls.

Article 12.1.4311.

Introduction to surveillance: introduction

Articles 12.1.4311. to 12.1.4513. define the principles and provide guidance on surveillance for AHSV infection, complementary to Chapter 1.4. and, for vectors, complementary to Chapter 1.5.

AHS is a vector-borne infection transmitted by a limited number of species of *Culicoides* insects. Unlike the related bluetongue virus, AHSV is so far geographically restricted to sub Saharan Africa with periodic excursions into North Africa, southwest Europe, the Middle East and adjacent regions of Asia. An important component of AHSV epidemiology is vectorial capacity which provides a measure of disease risk that incorporates vector competence, abundance, seasonal incidence, biting rates, survival rates and the extrinsic incubation period. However, methods and tools for measuring some of these vector factors remain to be developed, particularly in a field context.

Annex XX (contd)

According to this chapter, a Member Country demonstrating freedom from AHSV *infection* for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter. This requires the support of a *laboratory* able to undertake identification of AHSV *infection* through the virus detection and antibody tests ~~described in the *Terrestrial Manual*.~~

Susceptible *captive wild, feral and wild* equine populations should be included in the *surveillance* programme.

For the purposes of *surveillance*, a case refers to an equid infected with AHSV.

The purpose of *surveillance* is to determine if a country or *zone* is free from *infection with* AHSV or if a *zone* is ~~seasonally free from~~ AHSV. *Surveillance* deals not only with the occurrence of clinical signs caused by AHSV, but also with evidence of *infection with* AHSV in the absence of clinical signs.

Article 12.1.1412.

Surveillance: General surveillance conditions and methods for surveillance

- 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 suspected cases of AHSV *infection* 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 AHSV *infection surveillance* programme should:
 - a) In a ~~country/ zone~~ free or seasonally free country or zone, the *surveillance* programme for AHS should include ~~have~~ include an early warning system which oblige for reporting suspected cases. ~~for reporting suspicious cases.~~ ~~Pe~~Persons who have regular contact with equids, as well as diagnosticians, should ~~should~~ to report promptly any suspicion of AHSV *infection* to the *Veterinary Authority*. An effective *surveillance* system will periodically identify ~~suspicious~~ suspected 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~~ suspected cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected cases of AHSV *infection* should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment ~~are~~ be available ~~for~~ to those responsible for *surveillance*;
 - 3b) conduct In an AHS infected country or zone, random or targeted serological and virological *surveillance*, appropriate to the epidemiological situation, *infection* status of the country or zone should be conducted in accordance with Chapter 1.4.

Article 12.1.1513.

Surveillance strategies

The target population for *surveillance* aimed at identification of *disease* or *infection* should cover susceptible equids within the country or *zone*. Active and passive *surveillance* for AHSV *infection* should be ongoing. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate to the epidemiological situation ~~for the *infection* status of the country or zone.~~

Annex XX (contd)

A Member Country 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 Country 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 ~~should~~ will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing ~~should~~ 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 Country ~~must~~ should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence, in particular, ~~needs to~~ should 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~~ should 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~~ transmission, ~~need to~~ should be carefully designed to avoid producing results that are ~~either~~ insufficiently reliable to be accepted by the OIE for official recognition of status 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 mucous membranes and dyspnoea.

AHS suspects Suspected cases detected by clinical *surveillance* should always be confirmed by laboratory testing.

2. Serological surveillance

Serological *surveillance* of equine populations is an important tool to confirm absence of AHSV transmission in a country or *zone*. The species tested should reflect the local epidemiology of AHSV *infection*, and the equine species available. Management variables that may reduce the likelihood of *infection*, such as the use of insecticides and animal housing, should be taken into account when selecting equids to be included in the *surveillance* system.

Samples should be examined for antibodies against AHSV using tests prescribed in the *Terrestrial Manual*. Positive AHSV antibody tests results can have four possible causes:

- a) natural *infection* with AHSV;
- b) *vaccination* against AHSV;
- c) maternal antibodies;
- d) positive results due to the lack of specificity of the test.

It may be possible to use sera collected for other purposes may be used for AHSV *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of AHSV *infection* should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no AHSV *infection* is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the *animals* being sampled.

Serological *surveillance* in a free *zone* should target those areas that are at highest risk of AHSV transmission, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of AHSV, either random or targeted sampling is suitable to select *herds* or *animals* for testing.

Serological *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with an infected country or *infected zone*, based upon geography, climate, history of *infection* and other relevant factors. The *surveillance* should be carried out over a distance of at least a hundred kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of AHSV. An AHS free ~~n~~-AHSV free country or *zone* free from infection with AHSV 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~~ transmission in at risk populations;
- b) to confirm clinically suspected cases;
- c) to follow up positive serological results;
- d) to better characterise the genotype of circulating virus in a country or *zone*.

4. Sentinel animals

Sentinel *animals* are a form of targeted *surveillance* with a prospective study design. They comprise groups of unexposed equids that have are not been vaccinated and are managed at fixed locations and observed and tested sampled regularly to detect new AHSV *infections*.

Annex XX (contd)

The primary purpose of a sentinel equid programme is to detect AHSV *infections* occurring at a particular place, for instance sentinel groups may be located on the boundaries of *infected zones* to detect changes in distribution of AHSV. In addition, sentinel equid programmes allow the timing and dynamics of *infections* to be observed.

A sentinel equid programme should use *animals* of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of AHSV in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting AHSV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid confounding factors sentinel groups should comprise *animals* selected to be of similar age and susceptibility to AHSV *infection*. The only feature distinguishing groups of sentinels should be their geographical location. Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling should reflect the equine species used and the reason for choosing the sampling site. In endemic areas virus isolation will allow monitoring of the serotypes and genotypes of AHSV circulating during each time period. The borders between infected and non-infected areas can be defined by serological detection of *infection*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that AHSV *infections* are not occurring unobserved. Here sampling prior to and after the possible period of transmission is sufficient.

Definitive information on AHSV circulating in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required sentinels should be sampled at sufficiently frequent intervals to ensure that some samples are collected during the period of viraemia.

5. Vector surveillance

AHSV is transmitted between equine hosts by species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential *vector* species accurately although many such species are closely related and difficult to differentiate with certainty.

Vector surveillance is aimed at demonstrating the absence of *vectors* or defining high, medium and low-risk areas and local details of seasonality by determining the various species present in an area, their respective seasonal occurrence, and abundance. *Vector surveillance* has particular relevance to potential areas of spread. Long term *surveillance* can also be used to assess *vector* abatement measures, or to confirm continued absence of *vectors*.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local *vector* species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to equids.

Vector surveillance should be based on scientific sampling techniques. The choice of the number and types of traps to be used in *vector surveillance* and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of *vector surveillance* sites at the same locations as sentinel *animals* is advisable.

The use of a *vector surveillance* system to detect the presence of circulating virus^{es} is not recommended as a routine procedure as the typically low *vector infection* rates mean that such detections can be rare. ~~Other~~ Animal-based *surveillance* strategies are preferred to detect virus ~~circulation~~ transmission.

— Text deleted

CHAPTER 8.14.

INFECTION WITH *TRICHINELLA* SPP.**EU position****The EU supports the adoption of this modified chapter.**

Article 8.14.1.

General provisions

Trichinellosis is a widely distributed *zoonosis* caused by eating raw or undercooked *meat* from *Trichinella* infected food-producing *animals* or *wildlife*. Given that clinical signs of trichinellosis are not generally recognised in *animals*, the importance of trichinellosis lies exclusively in the *risk* posed to humans and costs of control in *slaughter* populations.

The adult parasite and the larval forms live in the small intestine and muscles (respectively) of many mammalian, avian and reptile host species. Within the genus *Trichinella*, twelve genotypes have been identified, eight of which have been designated as species. There is geographical variation amongst the genotypes.

Prevention of *infection* in susceptible species of domestic *animals* intended for human consumption relies on the prevention of exposure of those *animals* to the *meat* and of *Trichinella* infected *animals*. This includes consumption of food waste of domestic animal origin, rodents and *wildlife*.

Meat and *meat products* derived from *wildlife* should be considered a potential source of *infection* for humans. Therefore untested *meat* and *meat products* of *wildlife* may pose a public health *risk*.

For the purposes of the *Terrestrial Code*, *Trichinella infection* is defined as an *infection* of suids or equids by parasites of the genus *Trichinella*.

This chapter provides recommendations for on-farm prevention of *Trichinella infection* in domestic pigs (*Sus scrofa domesticus*), and safe trade of *meat* and *meat products* derived from suids and equids. This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005).

Methods for the detection of *Trichinella infection* in pigs and other animal species include direct demonstration of *Trichinella* larvae in muscle samples. Demonstration of the presence of *Trichinella*-specific circulating antibodies using a validated serological test may be useful for epidemiological purposes.

When authorising the import or transit of the *commodities* covered in this chapter, with the exception of those listed in Article 8.14.2., *Veterinary Authorities* should apply the recommendations in this chapter.

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

Article 8.14.2.

Safe commodities

When authorising the import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Trichinella* related conditions, regardless of the status of the animal population of the *exporting country* or *zone*:

- 1) hides, skins, hair and bristles;
- 2) semen, embryos and oocytes.

Annex XXI (contd)

Article 8.14.3.

Measures to prevent infection in domestic pig herds kept under controlled management conditions

- 1) Prevention of *infection* is dependent on minimising exposure to potential sources of *Trichinella*:
 - a) facilities and the surrounding environment should be managed to prevent exposure of pigs to rodents and *wildlife*;
 - b) raw food waste of animal origin should not be present at the farm level and should not be fed to pigs;
 - c) feed should comply with the requirements in Chapter 6.3. and should be stored in a manner to prevent access by rodents and *wildlife*;
 - d) a rodent control programme should be in place;
 - e) dead *animals* should be immediately removed and disposed of in accordance with provisions of Chapter 4.12.;
 - f) introduced pigs should originate from *herds* officially recognised as being under controlled management conditions as described in point 2, or from *herds* of a *compartment* with a negligible risk of *Trichinella infection*, as described in Article 8.14.5.
- 2) The *Veterinary Authority* may officially recognise pig *herds* as being under controlled management conditions if:
 - a) all management practices described in point 1 are complied with and recorded;
 - b) visits by approved auditors have been made periodically to verify compliance with good management practices described in point 1; the frequency of inspections should be *risk*-based, taking into account historical information, *slaughterhouse* monitoring results, knowledge of established farm management practices and the presence of susceptible *wildlife*;
 - c) a subsequent programme of audits is conducted, taking into account the factors described in point b.

Article 8.14.4.

Prerequisite criteria for the establishment of compartments with a negligible risk of *Trichinella* infection in domestic pigs kept under controlled management conditions

Compartments with a negligible risk of *Trichinella infection* in domestic pigs kept under controlled management conditions can only be established in countries, in which the following criteria, as applicable, are met:

- 1) *Trichinella infection* is notifiable in the whole territory and communication procedures on the occurrence of *Trichinella infection* are established between the *Veterinary Authority* and the public health authority;
- 2) the *Veterinary Authority* has knowledge of, and authority over, all domestic pigs;
- 3) the *Veterinary Authority* has **current** knowledge of the distribution of susceptible species of *wildlife*;
- 4) an *animal identification* and *animal traceability* system for domestic pigs is implemented in accordance with the provisions of Chapters 4.1. and 4.2.;

Annex XXI (contd)

- 5) *Veterinary Services* have the capability to assess the epidemiological situation, detect the presence of *Trichinella infection* (including genotype, if relevant) in domestic pigs and identify exposure pathways.

Article 8.14.5.

Compartment with a negligible risk of *Trichinella infection* in domestic pigs kept under controlled management conditions

The *Veterinary Authority* may recognise a *compartment* in accordance with Chapter 4.4. as having negligible risk of *Trichinella infection* in domestic pigs kept under controlled management conditions if the following conditions are met:

- 1) all *herds* of the *compartment* comply with the requirements in Article 8.14.3.;
- 2) Article 8.14.4. has been complied with for at least 24 months;
- 3) the absence of *Trichinella infection* in the *compartment* has been demonstrated by a *surveillance* programme which takes into account current and historical information, and *slaughterhouse* monitoring results, as appropriate, in accordance with Chapter 1.4.;
- 4) once a *compartment* is established, a subsequent programme of audits of all *herds* within the *compartment* is in place to ensure compliance with Article 8.14.3.;
- 5) if an audit identifies a lack of compliance with the criteria described in Article 8.14.3. and the *Veterinary Authority* determines this to be a significant breach of biosecurity, the *herd(s)* concerned should be removed from the *compartment* until compliance is re-established.

Article 8.14.6.

Recommendations for the importation of meat or meat products of domestic pigs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* or *meat products*:

- 1) has been produced in accordance with the Codex Code of Hygienic Practice for Meat (CAC/RCP 58-2005);

AND

- 2) either:
 - a) comes from domestic pigs originating from a *compartment* with a negligible risk for *Trichinella infection* in accordance with Article 8.14.5.;

OR

- b) comes from domestic pigs that tested negative by an approved method for the detection of *Trichinella* larvae;

OR

- c) was processed to ensure the inactivation of *Trichinella* larvae in accordance with the recommendations of the Codex Alimentarius (under study).

Annex XXI (contd)

Article 8.14.7.

Recommendations for the importation of meat or meat products of wild or feral pigs

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat or meat products*:

- 1) has been produced in accordance with the Codex Code of Hygienic Practice for Meat (CAC/RCP 58-2005);

AND

- 2) either:
 - a) comes from wild or feral pigs that tested negative by an approved method for the detection of *Trichinella* larvae;

OR

- b) was processed to ensure the inactivation of *Trichinella* larvae in accordance with the recommendations of the Codex Alimentarius (under study).

Article 8.14.8.

Recommendations for the importation of meat or meat products of domestic equids

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat or meat products*:

- 1) has been produced in accordance with the Codex Code of Hygienic Practice for Meat (CAC/RCP 58-2005);

AND

- 2) comes from domestic equids that tested negative by an approved method for the detection of *Trichinella* larvae.

Article 8.14.9.

Recommendations for the importation of meat or meat products of wild and feral equids

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat or meat products*:

- 1) has been inspected in accordance with the provisions in Chapter 6.2.;

AND

- 2) comes from wild or feral equids that tested negative by an approved method for the detection of *Trichinella* larvae.

— Text deleted

CHAPTER 8.12.

INFECTION WITH RIFT VALLEY FEVER VIRUS**EU position**

The EU does not support the adoption of this modified chapter as proposed. Comments are inserted in the text below which should be taken into account before adoption.

Article 8.12.1.

General provisions

- 1) The aim of this chapter is to mitigate the animal and public health risks posed by Rift Valley fever (RVF) and to prevent its international spread.
- 2) Humans and many animal species are susceptible to *infection*. For the purpose of the *Terrestrial Code*, RVF is defined as an *infection* of ruminants with Rift Valley fever virus (RVFV).

EU position

The EU reiterates its previous comment on the need to include camels in the definition of RVF. Indeed, camels have been shown to play a central role in certain epidemics in Africa, including as regards the zoonotic impact of RVF. For example, in a recent epizootic in Mauretania, camels played a significant epidemiological role, and many people have been infected and several have died of RVF after butchering and eating infected camels. Furthermore, removing camels from the case definition in the Code chapter would mean that RVF infections in camels would no longer be notifiable. Given that camels have been associated with the international spread of RVF in the past, this is unacceptable for the EU. An additional reference is given below:

El Mamy AB, Baba MO, Barry Y, Isselmou K, Dia ML, El Kory MO, Diop M, Lo MM, Thiongane Y, Bengoumi M, Puech L, Plee L, Claes F, de La Rocque S, and Doumbia B, 2011. Unexpected Rift Valley fever outbreak, northern Mauritania. *Emerging Infectious Diseases*, 17, 1894–1896 (see http://wwwnc.cdc.gov/eid/article/17/10/11-0397_article.htm).

- 3) The following defines the occurrence of RVFV *infection*:
 - a) RVFV, excluding vaccine strains, has been isolated and identified as such from a sample from **an animal** **a ruminant**; or

EU comment

The role of vaccine strains in case of live attenuated vaccines should be fully understood before their isolation can be excluded. Reference is made to the following paper:

A A Sall, P M de A Zanotto, O K Sene, H G Zeller, J P Digoutte, Y Thiongane, and M Bouloy, 1999. Genetic Reassortment of Rift Valley Fever Virus in Nature. *J Virol.*, 73(10), 8196–8200 (see <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC112837/>).

- b) antigen or ribonucleic acid specific to RVFV, excluding vaccine strains, has been identified in a sample from **an animal** **a ruminant** epidemiologically linked to a confirmed or suspected case of RVF, or giving cause for suspicion of association or contact with RVFV; or
- c) antibodies to RVFV antigens which are not the consequence of *vaccination*, have been identified in a sample from **an animal** **a ruminant** with either epidemiological links to a confirmed or suspected case of RVF, or giving cause for suspicion of association or contact with RVFV.

EU position

Referring to the above comment on the definition of RVF, the EU does not support the replacing of “animal” by “ruminant” proposed in point 3 above, as well as in other articles of this draft chapter.

- 4) For the purposes of the *Terrestrial Code*, the *incubative period* for ~~Rift Valley fever (RVF)~~ shall be ~~30~~ 14 days.
- 5) In areas where RVFV is present, epizootics of RVF may occur following favorable climatic, environmental conditions and availability of susceptible host and competent vector populations. Epizootics are separated by inter-epizootic periods.

- 6) For the purposes of this chapter:

“area” means a part of a country that experiences epizootics and inter-epizootic periods, but which does not correspond to the definition of zone:

“epizootic of RVF” means the occurrence of outbreaks at an incidence substantially exceeding that during an inter-epizootic period:

“inter-epizootic period” means the period of variable, often long, duration, with intermittent low level virus activity, which is often not detected.

EU comment

For clarity reasons, the EU suggests replacing the word “activity” by the word “transmission” in the above definition of “inter-epizootic period”. Indeed, it is not entirely clear what is meant by “low level virus activity”, especially as the definition of “epizootic of RVF” speaks of occurrence of outbreaks with reference to the inter-epizootic period, i.e. outbreaks do occur during an inter-epizootic period, albeit at a lower level.

For the purposes of this chapter, ruminants include camels.

EU position

Referring to the above comment on the definition of RVF, the EU reiterates its strong rejection of the deletion regarding camels proposed above.

- 7) The historical distribution of RVF has been parts of is the sub-Saharan African continent, Madagascar, some other Indian Ocean Islands and the south western Arabian Peninsula. However, vectors, environmental and climatic factors, land-use dynamics, and animal movements can may modify the temporal and spatial distribution of the infection.

~~Countries or zones within the historic distribution of RVF or adjacent to those that are historically infected should be subjected to surveillance.~~

~~Epidemics of RVF may occur in infected areas after flooding. They are separated by inter-epidemic periods that may last for several decades in arid areas and, during these periods, the prevalence of infection in humans, animals and mosquitoes can be difficult to detect.~~

~~In the absence of clinical disease, the RVF status of a country or zone within the historically infected regions of the world should be determined by a surveillance programme (carried out in accordance with Chapter 1.4.) focusing on mosquitoes and serology of susceptible mammals. The programme should concentrate on parts of the country or zone at high risk because of historical, geographic and climatic factors, ruminant and mosquito population distribution, and proximity to areas where epidemics have recently occurred.~~

- 8) When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.12.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the RVF status of the ruminant population of the *exporting country or zone*.
- 9) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Safe commodities

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

- 1) hides and skins;
- 2) wool and fibre.

Article 8.12.3.

Country or zone free from RVFV infection free country or zone

A country or a *zone* may be considered free from RVFV *infection* when the *disease* is notifiable in *animals* throughout in the whole country and either:

- 1) it meets the requirements for historical freedom in point 1 of Article 1.4.6.; or
- 2) a) an on-going pathogen-specific surveillance programme in accordance with Chapter 1.4 has demonstrated no evidence of RVFV infection in ruminants animals and humans in the country or zone; and
b) no indigenous human cases have occurred in the country or zone.

No country or zone which has experienced an epizootic of RVF can ever be considered free from RVFV infection.

- 1) the country or zone lies outside the historically infected regions, and is not adjacent to historically infected countries infections; or
- 2) a surveillance programme as described in Article 8.12.1. has demonstrated no evidence of RVF infection in humans, animals or mosquitoes in the country or zone during the past four years following a RVF epidemic.

~~The provisions of the last paragraph of Article 8.12.1. may need to be complied with on a continuous basis in order to maintain freedom from infection, depending on the geographical location of the country or zone.~~

~~A country or zone free from infection with RVFV infection free country or zone in which surveillance and monitoring has found no evidence that RVF infection is present will not lose its free status through the importation of ruminants animals that are seropositive, so long as they are which are either permanently marked identified as such or seropositive animals or those destined for immediate direct slaughter.~~

Article 8.12.4.

~~RVF infected e~~ Country or zone infected with RVFV without disease during the inter-epizootic period

A country or zone infected with RVFV, during the inter-epizootic period, is one in which virus activity is present at a low level but the factors predisposing to an epizootic are absent.

~~A RVF disease free country or zone is a country or zone that is not infection free (see Article 8.12.3.) but in which disease has not occurred in humans or animals in the past six months provided that climatic changes predisposing to outbreaks of RVF have not occurred during this time.~~

Article 8.12.5.

~~RVF infected e~~ Country or zone infected with RVFV with disease during an epizootic

A country or zone infected with RVFV, during an epizootic, is one in which outbreaks of RVF are occurring at an incidence substantially exceeding that of the inter-epizootic period.

~~A RVF infected country or zone with disease is one in which clinical disease in humans or animals has occurred within the past six months.~~

Article 8.12.5.bis

Strategies to protect from vector attacks during transport

Strategies to protect *animals* from *vector* attacks during transport should take into account the local ecology of the *vectors* and potential *risk management* measures include:

- 1) treating *animals* with insect repellents prior to and during transportation;
- 2) loading, transporting and unloading *animals* at times of low *vector* activity;
- 3) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the *animals* are held behind insect-proof netting;
- 4) using historical and current information to identify low risk ports and transport routes.

EU comment

Reference is made to Chapter 12.1. "Infection with African horse sickness virus", more specifically Article 12.1.12. "Protecting animals from *Culicoides* attacks", which provides further established practices that could be used also here.

Article 8.12.6.

~~Recommendations for importation from countries or zones free from RVFV infection free country or zones~~

For ruminants

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

- 1) ~~were kept in a RVF free country or zone free from RVFV infection since birth or for at least ~~30~~ 14 days prior to shipment; and~~
- 2) ~~if the *animals* were exported from a free zone, either~~
 - ~~Ba) they were vaccinated at least 14 days prior to leaving the free country or zone; or~~
 - ~~Ab) they did not transit through an area experiencing an epizootic ~~an *infected zone*~~ during transportation to the *place of shipment*; or~~
 - ~~Bc) they were protected from *vector* mosquito attacks at all times when transiting through an *infected zone* area experiencing an epizootic.~~

~~Article 8.12.7.~~

~~Recommendations for importation from RVF infection free countries or zones~~

For meat and meat products of domestic and wild ruminants

~~Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products are derived from *animals* which remained in the RVF infection free country/free zone since birth or for the last 30 days.~~

Article 8.12.8.

~~Recommendations for importation from RVF infected countries/zones without disease from countries or zones infected with RVFV during the inter-epizootic period~~

For ruminants

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

- 1) ~~showed no evidence sign of RVF on the day of shipment;~~

- 2) met one of the following conditions:
- a) ~~were kept in a RVF infected country/zone free of disease since birth or for the last six months providing that climatic changes predisposing to outbreaks of RVF have not occurred during this time; or~~
 - ba) were vaccinated against RVF at least 21 14 days prior to shipment with a modified live virus vaccine; or
 - eb) were held for at least 30 14 days prior to shipment in a mosquito-proof quarantine station which is located in an area of demonstrated low vector activity. During this period which the animals showed no clinical sign of RVFV infection and were protected from mosquitoes between quarantine and the place of shipment as well as at the place of shipment ;

AND

- 3) either
- a) did not transit through an area experiencing an epizootic infected zone with disease during transportation to the place of shipment; or
 - b) were protected from vector attacks when transiting through an area experiencing an epizootic.

~~Article 8.12.9.~~

~~Recommendations for importation from RVF infected countries or zones without disease~~

~~For meat and meat products of domestic and wild ruminants~~

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

- 4) ~~the products are derived from animals which:~~
- ~~a) remained in the RVF infected country or zone without disease since birth or for the last 30 days;~~
 - ~~b) were slaughtered in an approved abattoir and were subjected to ante- and post-mortem inspections for RVF with favourable results;~~
- 2) ~~the carcasses from which the products were derived were submitted to maturation at a temperature above +2°C for a minimum period of 24 hours following slaughter.~~

Article 8.12.10.

~~Recommendations for importation from RVF infected countries or zones with disease~~

~~Recommendations for importation from countries or zones infected with RVFV disease during an epizootic~~

~~For ruminants~~

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

- 1) showed no sign of RVF on the day of shipment;
- 2) did not originate in the area of the epizootic;
- 3) were vaccinated against RVF at least 14 days prior to shipment;
- 4) were held for at least 14 days prior to shipment in a quarantine station, which is located in an area of demonstrated low vector activity outside the area of the epizootic. During this period the animals showed no sign of RVF;
- 5) either:

- a) did not transit through an area experiencing an epizootic during transportation to the *place of shipment*, or
- b) were protected from vector attacks when transiting through an area experiencing an epizootic.
- 1) showed no evidence of RVF on the day of shipment;
- 2) were vaccinated against RVF at least 21 14 days prior to shipment with a modified live virus vaccine;

OR

- 3) were held in a mosquito-proof quarantine station for at least 30 days prior to shipment during which the *animals* showed no clinical sign of RVF and were protected from mosquito attacks between quarantine and the *place of shipment* as well as at the *place of shipment*.

Article 8.12.10.bis

Recommendations for importation of fresh meat and meat products from ruminants

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

- 1) showed no clinical signs of RVF within 24 hours before *slaughter*;
- 2) were slaughtered in an approved *slaughterhouse/abattoir* and were subjected to ante- and post-mortem inspections with favourable results;
- 3) the carcasses from which the products were derived were submitted to maturation at a temperature above 2°C for a minimum period of 24 hours following *slaughter*;

Article 8.12.11.

Recommendations for importation from RVF infected countries or zones with disease

For meat and meat products of domestic and wild ruminants

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

- 1) are from *animals* which have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for RVF with favourable results; and
- 2) have been fully eviscerated and submitted to maturation at a temperature above +2°C for a minimum period of 24 hours following *slaughter*.

Article 8.12.12.

Recommendations for importation from countries or zones not free from infection with RVFV

Recommendations for importation from countries or zones RVFV infected with disease

For semen and *in vivo* derived embryos of ruminants

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

- 1) showed no evidence sign of RVF within the period from ~~28~~ 14 days prior to ~~28~~ and 14 days following collection of the semen or embryos;
- 2) were vaccinated against RVF at least 24 14 days prior to collection. ~~with a modified live virus vaccine;~~ or
- 3) were demonstrated to be seropositive on the day of collection; or

- 4) testing of paired samples has demonstrated that seroconversion did not occur between semen or embryo collection and 14 days after.

were serologically tested on the day of collection and at least 14 days following collection and showed no significant rise in titre.

Article 8.12.12.bis

Recommendations for importation of fresh meat and meat products from ruminants from countries or zones not free from infection with RVFV

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

- 1) ruminants which showed no clinical sign of RVF within 24 hours before slaughter.
- 2) ruminants which were slaughtered in an approved slaughterhouse/abattoir and were subjected to ante- and post-mortem inspections with favourable results;
- 3) carcasses which were submitted to maturation at a temperature above 2°C for a minimum period of 24 hours following slaughter.

Article 8.12.13.

~~(Under study) Recommendations for importation from RVF infected countries or zones not free from infection with RVFV with disease or from RVF infected countries or zones without disease~~

For milk and milk products

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the consignment:

- 1) was subjected to pasteurisation; or
- 2) was subjected to a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Article 8.12.14.

Surveillance

Surveillance should be carried out in accordance with Chapter 1.4.

- 1) During an epizootic, surveillance should be conducted to define the extent of the affected area.
- 2) During the inter-epizootic period, surveillance and monitoring of climatic factors predisposing an epizootic should be carried out in countries or zones infected with RVFV.
- 3) Countries or zones adjacent to a country or zone in which epizootics have been reported should determine their RVFV status through an on-going surveillance programme.

To determine areas of low vector activity (see Articles 8.12.8. and 8.12.10.) surveillance for arthropod vectors should be carried out in accordance with Chapter 1.5.

Examination of vectors for the presence of RVFV is an insensitive surveillance method and is therefore not recommended.

— Text deleted.

CHAPTER 8.15.

TULAREMIA

EU position

The EU in general supports the adoption of this modified chapter. However, the chapter seems in need of a more thorough review. This should include *inter alia* a case definition and a change in the title of the chapter (to “Infection with *Francisella tularensis*”).

In general, the EU would favour an in depth review of disease specific chapters that have not been amended for some time, in line with the prioritised work programme of the Code Commission, instead of making small *ad hoc* revisions related to certain language issues.

Article 8.15.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for tularemia (in hares, genus *Lepus*) shall be 15 days.

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

Article 8.15.2.

Tularemia free country

A country may be considered free from tularemia when it has been shown that tularemia has not been present for at least the past two years and when bacteriological or serological surveys in previously *infected zones* have given negative results.

Article 8.15.3.

Tularemia infected zone

A zone ~~shall~~ **should** be considered as infected with tularemia **until**:

1) **until** at least one year has elapsed after the last case has been confirmed;

AND

2) **when** a bacteriological survey on ticks within the *infected zone* has given negative results; or

3) **when** regular serological testing of hares and rabbits from that *zone* has given negative results.

Article 8.15.4.

Trade in commodities

Veterinary Authorities of tularemia free countries may prohibit importation or transit through their territory, from countries considered infected with tularemia, of live hares.

Article 8.15.5.

Recommendations for importation from countries considered infected with tularemia**For live hares**

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

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

2) were not kept in a tularemia *infected zone*;

3) have been treated against **ecto**parasites (**ticks**); and

4) were kept in a *quarantine station* for the 15 days prior to shipment.

— Text deleted.

UNOFFICIAL VERSION

CHAPTER 8.X.

**INFECTION WITH BRUCELLA ABORTUS,
B. MELITENSIS AND B. SUIIS**

EU position

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

Article 8.X.1.

General provisions

- 1) The aim of this chapter is to mitigate the risk of spread of, and the risk to human health from, Brucella abortus, *B. melitensis* and *B. suis* in animals.
- 2) For the purpose of this chapter:
 - a) 'Brucella' means *B. abortus*, *B. melitensis* or *B. suis*, excluding vaccine strains.
 - b) For the purpose of this chapter, 'Animals' means domestic and *captive wild* animal populations of the following categories:
 - i) Bovidae bovids: this term means cattle (*Bos taurus*, *B. indicus*, *B. frontalis*, and *B. javanicus*), yak (and *B. grunniens*), bison (*Bison bison* and *B. bonasus*) and water buffalo (*Bubalus bubalis*);
 - ii) ~~Ovidae and Capridae~~ mean sheep (*Ovis aries*) and goats (*Capra aegagrus*);
 - iii) ~~pigs~~ means domestic pigs and ~~wild~~ bears (*Sus scrofa*);
 - iv) ~~Camelidae camelids: this term~~ means dromedary camel (*Camelus dromedarius*), Bactrian camel (*Camelus bactrianus*), llama (*Lama glama*), alpaca (*Lama pacos*), guanaco (*Lama guanicoe*) and vicuna (*Vicugna vicugna*);
 - v) Cervidae cervids: this term means roe deer (*Capreolus capreolus*), red deer (*Cervus elaphus elaphus*), wapiti/elk (*C. elaphus canadensis*), sika (*C. nippon*), samba (*C. unicolor unicolor*), rusa (*C. timorensis*), fallow deer (~~Dama dama dama~~), white-tailed, black-tailed, mule deer (*Odocoileus spp.*) and reindeer (caribou (*Cervus elaphus elaphus*, *C. elaphus canadensis*, *C. nippon*, *C. unicolor unicolor*, *C. timorensis*, *Dama dama dama*, *Odocoileus virginianus borealis*, *O. docoileus hemionus columbianus*, *O. docoileus hemionus hemionus* and *Rangifer tarandus*);
 - vi) European hare (*Lepus europaeus*).
- 3) For the purpose of the Terrestrial Code, a case is an animal infected with Brucella.
- 4) The chapter deals not only with the occurrence of clinical signs caused by Brucella infection with Brucella, but also with the presence of Brucella infection with Brucella in the absence of clinical signs.
A case is an animal infected with ~~Brucella~~.
- 5) The following defines a case of Brucella infection with Brucella:
 - a) Brucella has been isolated and/or identified as such from in a sample from an animal or a product derived from that animal;

OR

- b) positive results to one or more a diagnostic tests have been obtained, and there is an epidemiological link to a confirmed case evidence of *Brucella* infection.

EU comment

The points a) and b) above, as proposed now, seem a bit unclear, and even may be contradictory. On the one hand, deletion of the term “isolated” and limitation to the term “identified” in point a) implies that any agent identification method described in the Manual, including nucleic acid detection methods, would suffice to define a case, i.e. a positive PCR result without an epidemiological link would be regarded as equal to the isolation of the bacteria by culture. On the other hand, according to point b), a positive result in any diagnostic test seems to require an epidemiological link to a case. This would include not only serological tests but also nucleic acid detection methods.

As the case definition is a crucial element of this new chapter, the EU suggests clarifying the intended, either by reinstating “isolated and identified” in point a) or by limiting point b) to serological test methods.

- 6) When authorising import or transit of commodities listed in this chapter, with the exception of those listed in Article 8.X.2., Veterinary Authorities should require the conditions prescribed in this chapter relevant to the *Brucella* infection status of the animal population of the exporting country, zone, herd or flock.
- 7) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*. ~~In the absence of sufficient scientific information, the prescribed tests for bovines, except bovine specific indirect ELISAs, may be applied to *Corvidae* and *Camelidae*.~~

Article 8.X.2.

Safe commodities

When authorising import or transit of the following commodities, Veterinary Authorities should not require any *Brucella*-related conditions, regardless of the *Brucella* infection status of the animal population of the exporting country, ~~zone, herd or flock~~:

- 1) skeletal muscle *meat*, brain and spinal cord, digestive tract, thymus, thyroid and parathyroid glands and derived products, ~~provided that they are accompanied by an international veterinary certificate attesting that they are originating from animals that have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.;~~
- 2) cured hides and skins;
- 3) gelatine, collagen, tallow and *meat-and-bone meal*.

~~When authorising import or transit of other commodities listed in this chapter, Veterinary Authorities should require the conditions prescribed in this chapter relevant to the *Brucella* status of the animal population of the exporting country, zone or herd or flock.~~

Article 8.X.2. bis

Country or zone historically free from infection with *Brucella* in specified animal categories

A country or zone may be considered free from infection with *Brucella* in specified animal categories when:

- 1) infection with *Brucella* in animals is a notifiable disease in the whole country.

EU comment

The EU suggests deleting the words “in animals” in point 1 above (and in other places

with the same wording throughout this chapter) as they are superfluous and may give rise to confusion, given the general provisions and definitions of Article 8.X.1.

- 2) historical freedom in the relevant animal categories has been demonstrated as described in point 1 of Article 1.4.6.

Article 8.X.3.

Country or zone free from *Brucella* infection with *Brucella* in bovids in animals without vaccination in bovids

A country or zone can be qualified free from *Brucella* infection without vaccination either in one or several of the animal categories listed in Article 11.3.1.

- 1) To qualify as free from *Brucella* infection with *Brucella* in bovids without vaccination in bovids, a country or zone should satisfy for each relevant category of animals the following requirements:
- 1-a) *Brucella* infection with *Brucella* in animals is a notifiable disease in the whole country or zone;
- b) no case has been recorded in bovids for at least the past three years;
- c) regular testing of all herds has been in place for the past three years; and this testing has demonstrated that during this period, infection with *Brucella* was not present in at least 99.8% of the herds representing at least 99.9% of bovids in the country or zone;
- 2-bd) regulatory measures have been implemented for the early detection a programme should be in place to ensure effective reporting of all cases suggestive of *Brucella* infection with *Brucella* in bovids, particularly abortions, and including at least the regular submission of samples from abortion cases material to diagnostic laboratories for investigation, have been implemented;
- 3-be) neither domestic nor captive wild animals no bovids have been vaccinated against *Brucella* infection with *Brucella* for at least the past three years, and no bovids that are introduced into the country or zone have not been vaccinated during in the past three years;
- 4.d) no case of abortion due to *Brucella* infection and no isolation of *Brucella* has been recorded in animals bovids for at least the past three years;
- 5) except for pigs:
- ef) bovids and their genetic materials introduced into the country or zone should comply with the recommendations in Articles 8.X.13. and; 8.X.15. to 8.X.17.
- af) regular and periodic testing of all herds or flocks has been in place for the past three years; and this testing has demonstrated that *Brucella* infection was not present in at least 99.8% of the herds or flocks and representing at least 99.9% of animals bovids in the country or zone three consecutive years;
- 2) To maintain the status as free from *Brucella* infection with *Brucella* in bovids without vaccination in bovids, a country or zone should satisfy the following requirements:
- a) the requirements in points 1a), 1b) and 1d) to 1ef) above are met;

EU comment

The EU considers that referring to point 1d) in the point 2a) above would be overly burdensome in relation to maintenance of free status. Therefore, reference to point 1d) should be deleted and replaced by the following new point 2a.bis):

“a.bis) regulatory measures have been implemented for the early detection of infection with *Brucella* in bovids, including at least the regular submission of samples from abortion cases to diagnostic laboratories, unless *Brucella* can be ruled out as the cause of

abortion”.

- b) a *surveillance* programme based on regular **and periodic** testing of animals should be **bovids is** in place in the country or zone to detect ***Brucella* infection with *Brucella*** in accordance with **Article Chapter 1.4.4.**
- c) if a **the** *surveillance* programme described in **in** Points 2 and 5 a) and b) above has not detected ***Brucella* infection with *Brucella*** for the past five **two consecutive** years, *surveillance* should **may** be maintained in accordance with **Article Chapter 1.4.5.**
- 6.3) ~~vaccinated animals should not be introduced. Unvaccinated animals and genetic materials should comply with the recommendations in Articles 11.3.8. to 11.3.12. The **country or zone free status of free from infection with *Brucella* in bovids** without **vaccination of the country or zone for in bovids** a specified animal category is not affected by the occurrence of ***Brucella* infection with *Brucella*** in other animal categories or **feral and or wild animals** provided that **effective measures have been implemented to prevent transmission of *Brucella* infection with *Brucella*** to the relevant animal population **bovids** belonging to the specified animal category free from ***Brucella* infection** is effectively separated from the potential source of *infection*.~~

Article 8.X.4.

Country or zone free from ***Brucella* infection with *Brucella* in bovids** in animals with vaccination **in bovids**

A country or zone can be qualified free from *Brucella* infection with vaccination either in bovines or ovidae and capridae as listed in Article 11.3.1.

- 1) To qualify as free from ***Brucella* infection with *Brucella* in bovids** with vaccination **in bovids**, a country or zone should satisfy for each relevant category of animals the following requirements:
- 1-a) ***Brucella* infection with *Brucella*** in animals is a *notifiable disease* in the **whole** country **or zone**;
- b) **no case has been recorded in bovids for at least the past three years;**
- c) **regular testing of all herds has been in place for the past three years; and this testing has demonstrated that during this period, infection with *Brucella* was not present in at least 99.8% of the herds representing at least 99.9% of bovids in the country or zone;**
- 2-bd) ~~regulatory measures **have been implemented** for the early detection a programme should be in place to ensure effective reporting of all cases suggestive of ***Brucella* infection with *Brucella* in bovids**, particularly abortions, and **including at least** the regular submission of **samples from abortion cases material** to diagnostic *laboratories* for investigation, **have been implemented**;~~
- 3-ee) ~~vaccinated animals **bovids** should be **permanently** identified **as such with a permanent mark**;~~
- 4-d) ~~no case of abortion due to *Brucella* infection and no isolation of *Brucella* has been recorded in animals **bovids** for at least the past three years;~~
- 5ef) ~~bovids and their genetic materials introduced into the country or zone comply with the recommendations in Articles 8.X.13. and; 8.X.15. to 8.X.17.~~
- f) ~~regular and periodic testing of all *herds* or *flocks* has been in place for the past three years; and this testing has demonstrated that *Brucella* infection was not present in at least 99.8% of the *herds* or *flocks* and representing at least 99.9% of animals **bovids** in the country or zone, three consecutive years;~~
- 2) To maintain the status as free from ***Brucella* infection with *Brucella* in bovids** with vaccination **in bovids**, a country or zone should satisfy the following requirements:
- a) **the requirements in points 1a), 1b) and 1d) to 1ef) above are met;**
- 6-b) a *surveillance* programme based on regular **and periodic** testing of animals should be **bovids is** in

place in the country or zone to detect *Brucella* infection with *Brucella* in accordance with Article Chapter 1.4.4.;

- c) if a the surveillance programme described in Points 2 and 5 a) and b) above has not detected *Brucella* infection with *Brucella* for the past five two consecutive years, surveillance should may be maintained in accordance with Article Chapter 1.4.5.

7-8. animals and genetic materials introduced should comply with the recommendations in Articles 11.3.8. to 11.3.12.

- 3) The country or zone free status of free from *Brucella* infection with *Brucella* in bovids with vaccination of the country or zone for bovids a specified animal category is not affected by the occurrence of *Brucella* infection with *Brucella* in other animal categories or feral and or wild animals provided that effective measures have been implemented to prevent transmission of *Brucella* infection with *Brucella* to the relevant animal population bovids belonging to the specified animal category free from *Brucella* infection is effectively separated from the potential source of infection.
- 4) In addition, if The status of Aa country or zone free from *Brucella* infection with *Brucella* in bovids with vaccination in bovids wishes to change its status to country or zone free from *Brucella* infection without vaccination, remains unchanged for a period of three years after vaccination has ceased, provided that the requirements in points 1a), 1b) and 1d) to 1f) of Article 8.X.3. are met, the status of this country or zone remains unchanged for a period of at least three years after vaccination has ceased, at which time this status may be changed to free from infection with *Brucella* in bovids without vaccination provided that the requirements in point 1c) of Article 8.X.3. are met during that period.

Article 8.X.5.

Country or zone free from *Brucella* infection with *Brucella* in sheep and goats without vaccination in sheep and goats

- 1) To qualify as free from *Brucella* infection with *Brucella* in sheep and goats without vaccination in sheep and goats, a country or zone should satisfy the following requirements:
- a) *Brucella* infection with *Brucella* in animals is a notifiable disease in the whole country or zone;
 - b) no case has been recorded in sheep and goats for at least the past three years;
 - c) regular testing of all flocks has been in place for the past three years; and this testing has demonstrated that during this period, infection with *Brucella* was not present in at least 99.8% of the flocks representing at least 99.9% of sheep and goats in the country or zone;
 - bd) regulatory measures have been implemented for the early detection of *Brucella* infection with *Brucella* in sheep and goats, including at least the regular submission of samples from abortion cases material to diagnostic laboratories for investigation, have been implemented;
 - ee) no sheep and goats have been vaccinated against *Brucella* infection with *Brucella* for at least the past three years and no sheep and goats that are introduced into the country or zone, have not been vaccinated in during the past three years;
 - d) no case of *Brucella* infection has been recorded in sheep and goats for at least the past three years;
 - ef) sheep and goats and their genetic materials introduced into the country or zone comply with the recommendations in Articles 8.X.13. and, 8.X.15. to 8.X.17.;
 - f) regular and periodic testing of all flocks has been in place for the past three years; and this testing has demonstrated that *Brucella* infection was not present in at least 99.8% of the flocks representing at least 99.9% of sheep and goats in the country or zone.
- 2) To maintain the status as free from *Brucella* infection with *Brucella* in sheep and goats without vaccination in sheep and goats, a country or zone should satisfy the following requirements:

- a) the requirements in points 1a), 1b) and 1d) to 1ef) above are met;
 - b) a surveillance programme based on regular and periodic testing of sheep and goats is in place in the country or zone to detect *Brucella* infection with *Brucella* in accordance with Chapter 1.4. Article 1.4.4.;
 - c) if the surveillance programme described in b) above has not detected *Brucella* infection with *Brucella* for two consecutive years, surveillance may be maintained in accordance with Chapter 1.4. Article 1.4.5.
- 3) The country or zone free status of free from infection with *Brucella* in sheep and goats without vaccination of the country or zone in sheep and goats is not affected by the occurrence of *Brucella* infection with *Brucella* in other animal categories or feral or wild animals provided that effective measures have been implemented to prevent transmission of *Brucella* infection with *Brucella* to sheep and goats.

Article 8.X.6.

Country or zone free from *Brucella* infection with *Brucella* in sheep and goats with vaccination in sheep and goats

- 1) To qualify as free from *Brucella* infection with *Brucella* in sheep and goats with vaccination in sheep and goats, a country or zone should satisfy the following requirements:
 - a) *Brucella* infection with *Brucella* in animals is a notifiable disease in the whole country or zone;
 - b) no case has been recorded in sheep and goats for at least the past three years;
 - c) regular testing of all flocks has been in place for the past three years; and this testing has demonstrated that during this period, infection with *Brucella* was not present in at least 99.8% of the flocks representing at least 99.9% of sheep and goats in the country or zone;
 - bd) regulatory measures have been implemented for the early detection of *Brucella* infection with *Brucella* in sheep and goats, including at least the regular submission of samples from abortion cases material to diagnostic laboratories for investigation, have been implemented;
 - ce) vaccinated sheep and goats should be permanently identified as such with a permanent mark;
 - d) no case of *Brucella* infection has been recorded in sheep and goats for at least the past three years;
 - ef) sheep and goats and their genetic materials introduced into the country or zone comply with the recommendations in Articles 8.X.13. and 8.X.15. to 8.X.17.
 - f) regular and periodic testing of all flocks have been in place for the past three years; and this testing has demonstrated that *Brucella* infection was not present in at least 99.8% of the flocks representing at least 99.9% of sheep and goats in the country or zone.
- 2) To maintain the status as free from *Brucella* infection with *Brucella* in sheep and goats with vaccination in sheep and goats, a country or zone should satisfy the following requirements:
 - a) the requirements in points 1a), 1b) and 1d) to 1ef) above are met;
 - b) a surveillance programme based on regular and periodic testing of sheep and goats is in place in the country or zone to detect *Brucella* infection with *Brucella* in accordance with Chapter 1.4. Article 1.4.4.;
 - c) if the surveillance programme described in b) above has not detected *Brucella* infection with *Brucella* for two consecutive years, surveillance may be maintained in accordance with Chapter 1.4. Article 1.4.5.
- 3) The free country or zone status of free from infection with *Brucella* in sheep and goats with vaccination

of the country or zone in sheep and goats is not affected by the occurrence of *Brucella* infection with *Brucella* in other animal categories or feral or wild animals provided that effective measures have been implemented to prevent transmission of *Brucella* infection with *Brucella* to sheep and goats.

- 4) In addition, if a country or zone free from *Brucella* infection with *Brucella* in sheep and goats with vaccination remains unchanged for a period of three years after vaccination has ceased, in sheep and goats wishes to change its status to country or zone free from *Brucella* infection without vaccination, provided that the requirements in points 1a), 1b) and 1d) to 1f) of Article 8.X.5. are met, the status of this country or zone remains unchanged for a period of at least three years after vaccination has ceased, at which time this status may be changed to free from infection with *Brucella* in sheep and goats without vaccination provided that the requirements in point 1c) of Article 8.X.5. are met during that period.

Article 8.X.7.

Country or zone free from *Brucella* infection with *Brucella* in camelids

- 1) To qualify as free from *Brucella* infection with *Brucella* in camelids, a country or zone should satisfy the following requirements:
- a) *Brucella* infection with *Brucella* in animals is a notifiable disease in the whole country or zone;
 - b) no case has been recorded in camelids for at least the past three years;
 - c) regular testing of all herds has been in place for the past three years; and this testing has demonstrated that during this period, infection with *Brucella* was not present in at least 99.8% of the herds representing at least 99.9% of camelids in the country or zone;
 - bd) regulatory measures have been implemented for the early detection of *Brucella* infection with *Brucella* in camelids, including at least the regular submission of samples of abortion cases material to diagnostic laboratories for investigation, have been implemented;
 - ee) no camelids have been vaccinated against *Brucella* infection with *Brucella* for at least the past three years and no camelids introduced into the country or zone have been vaccinated in the past three years;
 - d) no case of *Brucella* infection has been recorded in camelids for at least the past three years;
 - ef) camelids and their genetic materials introduced into the country or zone comply with the recommendations in Articles 8.X.13. and 8.X.15. to 8.X.17.;
 - f) regular and periodic testing of all herds has been in place for the past three years; and this testing has demonstrated that *Brucella* infection was not present in at least 99.8% of the herds representing at least 99.9% of camelids in the country or zone.
- 2) To maintain the status as free from *Brucella* infection with *Brucella* in camelids, a country or zone should satisfy the following requirements:
- a) the requirements in points 1a), 1b) and 1d) to 1f) above are met;
 - b) a surveillance programme based on regular and periodic testing of camelids is in place in the country or zone to detect *Brucella* infection with *Brucella* in accordance with Chapter 1.4. Article 1.4.4.;
 - c) if the surveillance programme described in b) above has not detected *Brucella* infection with *Brucella* for two consecutive years, surveillance may be maintained in accordance with Chapter 1.4. Article 1.4.5.
- 3) The free country or zone status of free from infection with *Brucella* the country or zone in camelids is not affected by the occurrence of *Brucella* infection with *Brucella* in other animal categories or feral or wild animals provided that effective measures have been implemented to prevent transmission of *Brucella* infection with *Brucella* to camelids.

Article 8.X.8.

Country or zone free from *Brucella* infection with *Brucella* in cervids

- 1) To qualify as free from *Brucella* infection with *Brucella* in cervids, a country or zone should satisfy the following requirements:
 - a) *Brucella* infection with *Brucella* in animals is a notifiable disease in the whole country or zone;
 - b) no case has been recorded in cervids for at least the past three years;
 - c) regular testing of all herds has been in place for the past three years; and this testing has demonstrated that during this period, infection with *Brucella* was not present in at least 99.8% of the herds representing at least 99.9% of cervids in the country or zone;
 - bd) regulatory measures have been implemented for the early detection of *Brucella* infection with *Brucella* in cervids, including at least the regular submission of samples from abortion cases material to diagnostic laboratories for investigation, have been implemented;
 - ee) no cervids have been vaccinated against *Brucella* infection with *Brucella* for at least the past three years and no cervids introduced into the country or zone have been vaccinated in the past three years;
 - d) no case of *Brucella* infection has been recorded in cervids for at least the past three years;
 - ef) cervids and their genetic materials introduced into the country or zone comply with the recommendations in Articles 8.X.13. and 8.X.15. to 8.X.17.
 - f) regular and periodic testing of all herds has been in place for the past three years; and this testing has demonstrated that *Brucella* infection was not present in at least 99.8% of the herds representing at least 99.9% of cervids in the country or zone;
- 2) To maintain the status as free from *Brucella* infection with *Brucella* in cervids, a country or zone should satisfy the following requirements:
 - a) the requirements in points 1a), 1b) and 1d) to 1ef) above are met;
 - b) a surveillance programme based on regular and periodic testing of cervids is in place in the country or zone to detect *Brucella* infection with *Brucella* in accordance with Chapter 1.4. Article 1.4.4.;
 - c) if the surveillance programme described in b) above has not detected *Brucella* infection with *Brucella* for two consecutive years, surveillance may be maintained in accordance with Chapter 1.4. Article 1.4.5.
- 3) The country or zone free status of free from infection with *Brucella* the country or zone in cervids is not affected by the occurrence of *Brucella* infection with *Brucella* in other animal categories or feral or wild animals provided that effective measures have been implemented to prevent transmission of *Brucella* infection with *Brucella* to cervids.

Article 8.X.9.

Herd or flock free from *Brucella* infection with *Brucella* without vaccination in bovids, sheep and goats, camelids or cervids without vaccination

- 1) To qualify as free from *Brucella* infection with *Brucella* without vaccination, a herd or flock of the relevant animal category bovids, sheep and goats, camelids or cervids should satisfy the following requirements:
 - a) the herd or flock is in a country or zone free from *Brucella* infection with *Brucella* without vaccination in for the relevant animal category and is certified free without vaccination by the Veterinary Authority;

OR

- b) the herd or flock is in a country or zone free from Brucella infection with Brucella with vaccination ~~in for~~ the relevant animal category and is certified free without vaccination by the Veterinary Authority; and no animal of the herd or flock has been vaccinated in the past three years;

OR

- c) the herd or flock met the following conditions:

- i) Brucella infection with Brucella in animals is a notifiable disease in the whole country;
- ii) no animal of the relevant category of the herd or flock has been vaccinated during in the past three years;
- iii) ~~no case of Brucella infection~~ has been detected in the herd or flock has not shown evidence of Brucella infection for at least the past nine ~~past year~~ 12 months;
- iv) animals showing clinical signs consistent with Brucella infection with Brucella all suspect cases (such as animals which have aborted abortions) have been subjected to the necessary clinical and laboratory investigations diagnostic tests with negative results;
- v) for at least the past year 12 months, there has been no evidence of Brucella infection with Brucella in other ~~susceptible animals herds or flocks~~ of the same epidemiological unit establishment, or measures have been implemented to prevent any transmission of the Brucella infection with Brucella from these ~~other susceptible animals herds or flocks~~;
- vi) all sexually mature animals of the relevant category except castrated males were subjected to a prescribed serological tested for Brucella infection two tests have been performed with negative results ~~on two occasions on all sexually mature animals present in the herd at the time of testing, at an interval of more than 6 and less than 12 months between each test, the first test being performed not before 3 three months after the slaughter of the last case and the second test at an interval of more than six and less than 12 months.~~

- 2) To maintain the free status, the following conditions should be met:

- a) the requirements in points 1a) or 1b) or 1c) i) to v) above are met;
- ab) regular prescribed tests, at a frequency depending on the prevalence of herd or flock infection in the country or zone, demonstrate the continuing absence of Brucella infection with Brucella;
- bc) animals of the relevant category introduced into the herd or flock ~~are~~ should be accompanied by a certificate from an Official Veterinarian attesting that they come from:
 - i) a country or zone free from Brucella infection with Brucella in the relevant category without vaccination;

OR

- ii) a country or zone free from Brucella infection with Brucella with vaccination and the animals of the relevant category have not been vaccinated during in the past three years;

OR

- iii) a herd or flock free from Brucella infection with Brucella with or without vaccination, and provided that the animals have not been vaccinated in the past 3 three years and were subjected ~~negative results were shown to a prescribed tested for Brucella infection with Brucella~~ during within the 30 days prior to shipment with negative results; in the ~~case case~~ of post-parturient females which have given birth during the past 30 days, the test is should be carried out at least 30 days after giving the birth. This test is not required for sexually immature animals or vaccinated animals less than 18 months of age.

- e) There is no evidence of *infection* in other epidemiologically relevant animal species kept in the same *establishment*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other species kept in the same *establishment*.

Article 8.X.10.

Herd or flock free from *Brucella* infection with *Brucella* with vaccination in bovids, sheep and goats with vaccination

A *herd* or *flock* can be qualified free from *Brucella infection* with vaccination either in bovines or ovidae and capridae as listed in Article 11.3.1.

- 1) To qualify as free from *Brucella infection* with *Brucella* with vaccination, a *herd of bovids* or *flock of sheep and goats* the relevant animal category should satisfy the following requirements:
- a) the *herd* or *flock* is in a country or zone free from *Brucella infection* with *Brucella* with vaccination for the relevant animal category and is certified free with vaccination by the *Veterinary Authority*;
- OR
- b) the *herd* or *flock* met the following conditions:
 - i) *Brucella infection* with *Brucella* in animals is a notifiable disease in the *whole* country;
 - ii) vaccinated *animals* of the relevant categories should be are permanently identified *as such*;
 - iii) no case of *Brucella infection* has been detected in the *herd* or *flock* has not shown evidence of *Brucella infection* for at least the past nine *year 12 months*;
 - iv) *animals* of the relevant category showing clinical signs consistent with *Brucella infection* with *Brucella* all suspect cases (such as animals which have aborted *abortions*) have been subjected to the necessary clinical and laboratory investigations *diagnostic tests* with *negative results*;
 - v) for at least the past *year 12 months*, there has been no evidence of *Brucella infection* with *Brucella* in other *susceptible animals herds or flocks* of the same *epidemiological unit establishment*, or measures have been implemented to prevent any transmission of the *Brucella infection* with *Brucella* from these other *susceptible animals herds or flocks*;
 - vi) all *sexually mature animals of the relevant category except castrated males* were subjected to a prescribed serological tested for *Brucella infection* *two tests* have been performed with negative results *on two occasions on all sexually mature animals present in the herd at the time of testing*, at an interval of more than 6 and less than 12 months between each test, the first test being performed not before 3 *three* months after the *slaughter* of the last case *and the second test at an interval of more than six and less than 12 months*.

Annex XXIV (contd)

- 2) To maintain the free status, the following conditions should be met:
- a) the requirements in points 1 a) or 1b) i) to v) above are met;
 - ab) regular prescribed tests, at a frequency depending on the prevalence of *herd or flock infection* in the country or *zone*, demonstrate the continuing absence of *Brucella infection with Brucella*;
 - bc) animals of the relevant category introduced into the *herd* or *flock* should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from either:
 - i) a country or *zone* free from *Brucella infection with Brucella in the relevant category* with or without *vaccination*;
- OR
- ii) a *herd* or *flock* free from *Brucella infection with Brucella* with or without *vaccination*; and provided that the *animals* have not been vaccinated in the past 3 years and were subjected to a prescribed test for *Brucella infection with Brucella* within the 30 days prior to shipment with negative results; in the case case of post-parturient females which have given birth during the past 30 days, the test is should be carried out at least 30 days after giving the birth. This test is not required for sexually immature *animals* or vaccinated *animals* less than 18 months of age.
 - e) ~~There is no evidence of *infection* in other epidemiologically relevant animal species kept in the same *establishment*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other species kept in the same *establishment*.~~

Article 8.X.11.Herd free from *Brucella infection with Brucella* in pigs

- 1) To qualify as free from *Brucella infection with Brucella*, a herd of pigs should satisfy the following requirements:
 - a) *Brucella infection with Brucella* in animals is a notifiable disease in the whole country;
 - b) no pigs of the herd have been vaccinated;
 - cb) no case of *Brucella infection* has been detected in the herd for at least the past three years;
 - cc) animals showing clinical signs consistent with *Brucella infection with Brucella* (such as abortions or orchitis) have been subjected to the necessary diagnostic tests with negative results;
 - d) no pigs of the herd have been vaccinated for at least the past three years and no pigs introduced into the herd have been vaccinated in the past three years;
 - e) for at least the past three years, there has been no evidence of *Brucella infection with Brucella* in other susceptible animals herds or flocks of the same epidemiological unit establishment, or measures have been implemented to prevent any transmission of the *Brucella infection with Brucella* from these other susceptible animals herds or flocks.

Annex XXIV (contd)

2) To maintain the free status, the following conditions should be met:

- a) the requirements in point 1) above are met;
- b) animals introduced into the herd are accompanied by a certificate from an Official Veterinarian attesting that:
 - i) they come from a herd free from *Brucella* infection with *Brucella*;

OR

- ii) they come from a herd in which a statistically valid sample of the breeding pigs, selected in accordance with the provisions of Chapter 1.4, Article 1.4.4., was subjected to a prescribed tested within 30 days prior to shipment, demonstrating the absence of *Brucella* infection with *Brucella*;

OR

- iii) they were subjected to a prescribed tested within 30 days prior to shipment with negative results.

Article 8.X.12.

Recovery of the *Brucella* infection free status in a country or a zone

Should a case of *Brucella* infection with *Brucella* in one or more animal categories occur in a free country or zone as described in Articles 8.X.3. to 8.X.8., ~~the status is suspended the free status and may not be recovered until~~ once the following requirements are met:

- 1) all infected animals of the relevant category were are have been slaughtered or destroyed as soon as *Brucella* infection with *Brucella* is confirmed the result of the diagnostic test was known;
- 2) an epidemiological investigation has been is performed within 60 days of *Brucella* infection confirmation in the herd or flock, aiming at identifying the likely source and the distribution of the infection, and shows that the number of outbreaks is limited and all are epidemiologically linked *Brucella* infection has spread to less than 0.2% of herds or flocks;
- 3) in the index herd or flock and herds or flocks identified by the epidemiological investigation:
 - a) whole herd or flock depopulation has been is practised; or,
 - 2.b) whole herd or flock depopulation has is not been practised in animal categories other than pigs, and all remaining sexually mature animals in the herd or flocks except castrated males have been subjected to a serological prescribed tested, with negative results, on three occasions, at an interval of not less than two months, then a further fourth test six months later and a final fifth test a year later;
 - c) no animals are moved from the herds or flocks except for directly for slaughter until the processes in point a) or b) above are completed;
- 3.4) in pig herds, where cases of *Brucella* infection have occurred, all pigs were slaughtered or destroyed cleansing and disinfection procedures have been applied at the end of the slaughter process and before new animals are introduced.

If When these requirements have not been are not met, the status is not recovered and Articles 8.X.3. to 8.X.8. apply as relevant.

Article 8.X.13.

Recommendations for the importation of animals *bovids, sheep and goats, camelids or cervids* for breeding or rearing

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

1) showed no clinical signs of *Brucella* infection with *Brucella* on the day of shipment;

2) originate from:

a) a country or zone free from *Brucella* infection with *Brucella* as relevant;

OR

b) a herd or flock free from *Brucella* infection with *Brucella* and all sexually mature animals were ~~subjected to a prescribed~~ serological tested for *Brucella* infection with *Brucella* with negative results during within the 30 days prior to shipment.

This test is not required for:

- pigs;
- young bovines before the age of 12 months;
- young ovidae and capridae before the age of 6 months;
- young *Camelidae* and *Corvidae* before the age of sexual maturity;

OR

c) ~~with the exception of pigs,~~ a herd or flock not qualified free from *Brucella* infection with *Brucella*:

- i) in which no case *Brucella* infection has been reported during the nine 12-months year prior to shipment;
- ii) the animals were isolated for 30 days prior to shipment and all animals in isolation were subjected during tested for infection with Brucella within that period with negative results within that period to a prescribed serological test for Brucella infection with negative results; in the ~~ease case~~ of post-parturient females which have given birth during the past 30 days, the test was is should be carried out at least 30 days after giving the birth. This test is not required for sexually immature animals or vaccinated animals less than 18 months of age.

Article 8.X.14.

Recommendations for the importation of pigs for breeding or rearing

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

1) showed no clinical signs of *Brucella* infection with *Brucella* on the day of shipment;

Annex XXIV (contd)

2) either:

a) originate from a *herd* free from *Brucella* infection with *Brucella*;

OR

b) originate from a *herd* in which a statistically valid sample of the breeding pigs, selected in accordance with the provisions of Chapter 1.4. Article 1.4.4., was subjected to a prescribed tested within 30 days prior to shipment, demonstrating the absence of *Brucella* infection with *Brucella*;

OR

c) were isolated for 30 days prior to shipment and all pigs in isolation were subjected to a prescribed tested for *Brucella* infection with *Brucella* within that period 30 days prior to shipment with negative results.

Article 8.X.15.

Recommendations for the importation of animals for slaughter

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

- 1) showed no clinical signs of *Brucella* infection with *Brucella* on the day of shipment;
- 2) originate from a country, zone, *herd* or *flock* free from *Brucella* infection with *Brucella* with or without vaccination;

OR

- 3) are not being culled eliminated as part of an eradication programme against *Brucella* infection and in the case of sexually mature bovids, sheep and goats, camelids or cervids, were subjected to a prescribed tested for *Brucella* infection with *Brucella* with negative results during within the 30 days prior to shipment and are not being eliminated as part of an eradication programme against *Brucella* infection.

Article 11.3.10.

~~Recommendations for the importation of captive European hares (*Lepus europaeus*) for restocking~~

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

- ~~1) the animals showed no clinical signs of *Brucella* infection on the day of shipment;~~
- ~~2) a programme is in place to ensure effective investigation and reporting of all cases suggestive of *Brucella* infection in establishments keeping hares.~~

Article 8.X.16.

Recommendations for the importation of semen

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

- 1) the donor animals showed no clinical signs of *Brucella* infection with *Brucella* on the day of collection of the semen;

Annex XXIV (contd)

- 2) the donor animals were not vaccinated against Brucella infection with Brucella and either:
 - a) were kept in an *artificial insemination centre* complying with the provisions of Chapter 4.5 free from *Brucella infection*;

OR

 - b) were kept in a *herd or flock* free from Brucella infection with Brucella and are subjected tested every six months to a prescribed test for Brucella infection with Brucella with negative results, and the semen was collected, processed and stored in conformity with the provisions of Articles 4.5.3. to 4.5.5. and Articles 4.6.5. to 4.6.7.
- 3) ~~the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.~~

Article 8.X.17.

Recommendations for the importation of embryos and oocytes

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

- 1) the donor animals showed no clinical signs of Brucella infection with Brucella on the day of collection;
- 2) the donor animals were not vaccinated against Brucella infection with Brucella during in the past three years and either:
 - a) were kept in a country or *zone* free from Brucella infection with Brucella, as relevant;

OR

 - b) were kept in a *herd or flock* free from Brucella infection with Brucella and are tested subjected every six months to a prescribed test for Brucella infection with Brucella with negative results;
- 3) the embryos and oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7. to Chapter 4.9.

Article 8.X.18.

Recommendations for the importation of fresh meat and meat products other than mentioned in Article 8.X.2.

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the *meat* and *meat products* come from *animals*:

- 1) which have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.;
- 2) which:
 - a) originate from a country or zone free from Brucella infection with Brucella, as relevant;

OR

 - ab) originate from a *herd or flock* free from Brucella infection with Brucella;

OR

 - bc) have not been culled eliminated as part of an eradication programme against Brucella infection with Brucella have not tested positive to a prescribed test for Brucella infection.

Annex XXIV (contd)

Article 8.X.19.

Recommendations for the importation of milk and milk products

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the *milk* or the *milk products*:

- 1) have been derived from animals in a country, zone, herd or flock free of a herd or flock free from *Brucella* infection with *Brucella* as relevant;

OR

- 2) were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Article 8.X.20.

Recommendations for importation of wool and hair

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

- 1) have not been derived from *Brucella* infected animals culled eliminated as part of an eradication programme against *Brucella* infection with *Brucella*;

OR

- 2) have been processed to ensure the destruction of the *Brucella*.

Article 8.X.21.Procedures for the inactivation of *Brucella* in casings of bovids, sheep and goats, and pigs

For the inactivation of *Brucella* in casings of bovids, sheep and goats, and pigs, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine ($A_{w,s} < 0.80$), and kept at a temperature of greater than 20°C or above during this entire period.

 — Text deleted.

CHAPTER 10.4.

INFECTION WITH AVIAN INFLUENZA VIRUSES

EU position

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

Article 10.4.1.

General provisions

- 1) For the purposes of the *Terrestrial Code*, avian influenza is defined as an *infection of poultry* caused by any influenza A virus of the H5 or H7 subtypes or by any influenza A virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75 percent mortality) as described below. These viruses are divided into high pathogenicity avian influenza viruses and low pathogenicity avian influenza viruses:
 - a) High pathogenicity avian influenza viruses have an IVPI in six-week-old chickens greater than 1.2 or, as an alternative, cause at least 75 percent mortality in four-to eight-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75 percent mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other high pathogenicity avian influenza isolates, the isolate being tested should be considered as high pathogenicity avian influenza virus;
 - b) low pathogenicity avian influenza viruses are all influenza A viruses of H5 and H7 subtypes that are not high pathogenicity avian influenza viruses.
- 2) The following defines the occurrence of *infection* with an avian influenza virus: the virus has been isolated and identified as such or specific viral ribonucleic acid (RNA) has been detected in *poultry* or a product derived from *poultry*.
- 3) *Poultry* is defined as 'all domesticated birds, including backyard *poultry*, used for the production of *meat* or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.
- 4) For the purposes of the *Terrestrial Code*, the *incubation period* for avian influenza shall be 21 days.
- 5) This chapter deals not only with the occurrence of clinical signs caused by avian influenza, but also with the presence of *infection* with avian influenza viruses in the absence of clinical signs.
- 6) Antibodies **against** H5 or H7 subtype, which have been detected in *poultry* and are not a consequence of *vaccination*, should be immediately investigated. In the case of isolated serological positive results, *infection* with avian influenza viruses may be ruled out on the basis of a thorough epidemiological and *laboratory* investigation that does not demonstrate further evidence of such an *infection*.
- 7) For the purposes of the *Terrestrial Code*, 'avian influenza free establishment' means an *establishment* in which the *poultry* have shown no evidence of *infection* with avian influenza viruses, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.

Annex XXV (contd)

- 8) *Infection* with influenza A viruses of high pathogenicity in birds other than *poultry*, including wild birds, should be notified according to Article 1.1.3. However, a Member Country should not impose bans on the trade in *poultry commodities* in response to such a *notification*, or other information on the presence of any influenza A virus in birds other than *poultry*, including wild birds.
- 9) Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

Article 10.4.2.

Determination of the avian influenza status of a country, zone or compartment

The avian influenza status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

- 1) avian influenza is notifiable in the whole country, an ongoing avian influenza awareness programme is in place, and all notified suspect occurrences of avian influenza are subjected to field and, where applicable, *laboratory* investigations;
- 2) appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in *poultry*, and the *risk* posed by birds other than *poultry*; this may be achieved through an avian influenza *surveillance* programme in accordance with Articles 10.4.27. to 10.4.33.;
- 3) consideration of all epidemiological factors for avian influenza occurrence and their historical perspective.

Article 10.4.3.

Country, zone or compartment free from avian influenza

A country, *zone* or *compartment* may be considered free from avian influenza when it has been shown that *infection* with avian influenza viruses in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, avian influenza free status can be regained:

- 1) In the case of *infections* with high pathogenicity avian influenza viruses, three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.
- 2) In the case of *infections* with low pathogenicity avian influenza viruses, *poultry* may be kept for *slaughter* for human consumption subject to conditions specified in Article 10.4.19. or a *stamping-out policy* may be applied; in either case, three months after the *disinfection* of all affected *establishments*, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

Article 10.4.4.

Country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry

A country, *zone* or *compartment* may be considered free from *infection* with high pathogenicity avian influenza viruses in *poultry* when:

- 1) it has been shown that *infection* with high pathogenicity avian influenza viruses in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, although its status with respect to low pathogenicity avian influenza viruses may be unknown; or

Annex XXV (contd)

- 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 avian influenza but any virus detected has not been identified as high pathogenicity avian influenza virus.

The *surveillance* may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, the 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 country, zone or compartment free from avian influenzaFor 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 avian influenza on the day of shipment;
- 2) the *poultry* were kept in an avian influenza free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination ~~have been~~ should be attached to the *certificate*.

Article 10.4.6.

Recommendations for the importation of live birds other than poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) on the day of shipment, the birds showed no clinical sign of *infection* with a virus which would be considered avian influenza in *poultry*;
- 2) the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of *infection* with a virus which would be considered avian influenza in *poultry* during the isolation period;
- 3) a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.4.29., was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from *infection* with a virus which would be considered avian influenza in *poultry*;
- 4) the birds are transported in new or appropriately sanitized *containers*.

If the birds have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination ~~have been~~ should be to the *certificate*.

Annex XXV (contd)

Article 10.4.7.

Recommendations for importation from a country, zone or compartment free from avian influenzaFor day-old live poultry

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

- 1) the *poultry* were kept in an avian influenza free country, *zone* or *compartment* since they were hatched;
- 2) the *poultry* were derived from parent *flocks* which had been kept in an avian influenza free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* or the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination ~~have been~~ should be to the *certificate*.

Article 10.4.8.

Recommendations for importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultryFor day-old live poultry

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

- 1) the *poultry* were kept in a country, *zone* or *compartment* free from infection with high pathogenicity avian influenza viruses in *poultry* since they were hatched;
- 2) the *poultry* were derived from parent *flocks* which had been kept in an avian influenza free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* or the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination ~~have been~~ should be attached to the *certificate*.

Article 10.4.9.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) on the day of shipment, the birds showed no clinical sign of *infection* with a virus which would be considered avian influenza in *poultry*;
- 2) the birds were hatched and kept in isolation approved by the *Veterinary Services*;
- 3) the parent *flock* birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from *infection* with a virus which would be considered avian influenza in *poultry*;
- 4) the birds are transported in new or appropriately sanitized *containers*.

If the birds or parent flocks have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination ~~have been~~ should be attached to the *certificate*.

Article 10.4.10.

Recommendations for importation from a country, zone or compartment free from avian influenzaFor hatching eggs of poultry

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

- 1) the eggs came from an avian influenza free country, *zone* or *compartment*;
- 2) the eggs were derived from parent *flocks* which had been kept in an avian influenza free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination ~~have been~~ should be attached to the *certificate*.

Article 10.4.11.

Recommendations for importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultryFor hatching eggs of poultry

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

- 1) the eggs came from a country, *zone* or *compartment* free from infection with high pathogenicity avian influenza viruses in *poultry*;
- 2) the eggs were derived from parent *flocks* which had been kept in an avian influenza free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
- 4) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination ~~have been~~ should be attached to the *certificate*.

Article 10.4.12.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the parent *flock* birds were subjected to a diagnostic test seven days prior to and at the time of the collection of the eggs to demonstrate freedom from *infection* with a virus which would be considered avian influenza in *poultry*;
- 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.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination ~~have been~~ should be attached to the *certificate*.

Annex XXV (contd)

Article 10.4.13.

Recommendations for importation from a country, zone or compartment free from avian influenzaFor eggs for human consumption

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

- 1) the eggs were produced and packed in an avian influenza free country, *zone* or *compartment*,
- 2) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.14.

Recommendations for importation from a ~~free~~ country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultryFor eggs for human consumption

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

- 1) the eggs were produced and packed in a country, *zone* or *compartment* free from infection with high pathogenicity avian influenza viruses in *poultry*;
- 2) the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
- 3) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.15.

Recommendations for importation of egg products of poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the *commodity* is derived from eggs which meet the requirements of Articles 10.4.13. or 10.4.14.; or
- 2) the *commodity* has been processed to ensure the destruction of avian influenza virus in accordance with Article 10.4.25.;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 10.4.16.

Recommendations for importation from a country, zone or compartment free from avian influenzaFor poultry semen

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the donor *poultry*.

Annex XXV (contd)

- 1) showed no clinical sign of avian influenza on the day of semen collection;
- 2) were kept in an avian influenza free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.17.

Recommendations for the importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultryFor poultry semen

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

- 1) showed no clinical sign of *infection* with high pathogenicity avian influenza viruses in *poultry* on the day of semen collection;
- 2) were kept in a country, *zone* or *compartment* free from *infection* with high pathogenicity avian influenza viruses in *poultry* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.18.

Recommendations for the importation of semen of birds other than poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor birds:

- 1) were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to semen collection;
- 2) showed no clinical sign of *infection* with a virus which would be considered avian influenza in *poultry* during the isolation period;
- 3) were tested within 14 days prior to semen collection and shown to be free from *infection* with a virus which would be considered avian influenza in *poultry*.

Article 10.4.19.

Recommendations for importation from a country, zone or compartment free from avian influenza or free from infection with high pathogenicity avian influenza viruses in poultryFor 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 *infection* with high pathogenicity avian influenza viruses in *poultry* since they were hatched or for at least the past 21 days;
- 2) which have been slaughtered in an approved *abattoir* in a country, *zone* or *compartment* free from *infection* with high pathogenicity avian influenza viruses in *poultry* and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any signs suggestive of avian influenza.

Annex XXV (contd)

Article 10.4.20.

Recommendations for the importation of meat products of poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the *commodity* is derived from *fresh meat* which meets the requirements of Article 10.4.19.; or
- 2) the *commodity* has been processed to ensure the destruction of avian influenza virus in accordance with Article 10.4.26.;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 10.4.21.

Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* were processed in an avian influenza free country, *zone* or *compartment* from *poultry* which were kept in an avian influenza free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
- 2) these *commodities* have been processed to ensure the destruction of avian influenza virus using (~~under study~~):
 - a) pasteurisation or
 - b) moist heat treatment for 30 minutes at 56 °C;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 10.4.22.

Recommendations for the importation of feathers and down of poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* originated from *poultry* as described in Article 10.4.19. and were processed in an avian influenza free country, *zone* or *compartment*; or
- 2) these *commodities* have been processed to ensure the destruction of avian influenza virus (~~under study~~) using one of the following:
 - a) washed and steam-dried at 100°C for 30 minutes;
 - b) fumigation with formalin (10% formaldehyde) for 8 hours;

- c) irradiation with a dose of 20 kiloGray;
- d) any equivalent treatment which has been demonstrated to inactivate avian influenza virus;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 10.4.23.

Recommendations for the importation of feathers and down of birds other than poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* have been processed to ensure the destruction of any virus which would be considered avian influenza in *poultry* ~~(under study)~~ using one of the following:
 - a) washed and steam-dried at 100°C for 30 minutes;
 - b) fumigation with formalin (10% formaldehyde) for 8 hours;
 - c) irradiation with a dose of 20 kiloGray;
 - d) any equivalent treatment which has been demonstrated to inactivate avian influenza virus;

and

- 2) the necessary precautions were taken to avoid contact of the *commodity* with any source of viruses which would be considered avian influenza in *poultry*.

Article 10.4.24.

Recommendations for the importation of feather meal and poultry meal

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* were processed in an avian influenza free country, *zone* or *compartment* from *poultry* which were kept in an avian influenza free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
- 2) these *commodities* have been processed either:
 - a) with moist heat at a minimum temperature of 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 avian influenza viruses.

Annex XXV (contd)

Article 10.4.25.

Procedures for the inactivation of ~~the~~ avian influenza viruses in eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of avian influenza viruses present in eggs and egg products:

	Core temperature (°C)	Time
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	870 seconds
Liquid egg white	56.7	232 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	20 hours
Dried egg white	54.4	513 hours

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.26.

Procedures for the inactivation of ~~the~~ avian influenza viruses in meat

The following times for industry standard temperatures are suitable for the inactivation of avian influenza viruses present in *meat*.

	Core temperature (°C)	Time
Poultry meat	60.0	507 seconds
	65.0	42 seconds
	70.0	3.5 seconds
	73.9	0.51 second

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.27.

Introduction to surveillance ~~Surveillance~~ : introduction

Articles 10.4.27. to 10.4.33. define the principles and provide a guide on the *surveillance* for avian influenza complementary to Chapter 1.4., applicable to Member Countries seeking to determine their avian influenza status. This may be for the entire country, *zone* or *compartment*. Guidance for Member Countries seeking free status following an *outbreak* and for the maintenance of avian influenza status is also provided.

The presence of influenza A viruses in wild birds creates a particular problem. In essence, no Member Country can declare itself free from influenza A in wild birds. However, the definition of avian influenza in this chapter refers to the *infection in poultry* only, and Articles 10.4.27. to 10.4.33. were developed under this definition.

The impact and epidemiology of avian influenza differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from avian influenza at an acceptable level of confidence **will need to should** 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 Country to provide scientific data that explains the epidemiology of avian influenza in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that absence of *infection* with avian influenza viruses **infection** is assured at an acceptable level of confidence.

Surveillance for avian influenza should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from *infection* with avian influenza viruses.

Article 10.4.28.

General conditions and methods for surveillance 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 *infection* with avian influenza viruses should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of avian influenza to a *laboratory* for avian influenza diagnosis;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
- 2) The avian influenza *surveillance* programme should:
 - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of avian influenza to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of avian influenza should be investigated immediately. As suspicion cannot always be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a *laboratory* for appropriate tests. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in avian influenza diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;
 - b) implement, when relevant, regular and frequent clinical inspection, serological and virological testing of high-risk groups of *animals*, such as those adjacent to an avian influenza infected country, **or 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 influenza A viruses.

Annex XXV (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 influenza A viruses. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Documentation for freedom from *infection* with avian influenza viruses should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 10.4.29.

Surveillance strategies1. 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 avian influenza should be ongoing. The frequency of active *surveillance* should be at least every six months. *Surveillance* should be composed of random and targeted approaches using molecular, virological, serological and clinical methods.

The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of *infection* with avian influenza viruses at an acceptable level of confidence. Random *surveillance* is conducted using serological tests. 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 avian influenza status of high risk populations.

A Member Country should justify the *surveillance* strategy chosen as adequate to detect the presence of *infection* with avian influenza viruses in accordance with Chapter 1.4. and the prevailing epidemiological situation, including cases of high pathogenicity influenza A detected in any birds. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

If a Member Country wishes to declare freedom from *infection* with avian influenza viruses in a specific *zone* or *compartment*, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone* or *compartment*.

For random surveys, the design of the sampling strategy **will need should** to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing **will need should** 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 Country 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 should** be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination* and *infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There **needs to should** 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.

Annex XXV (contd)

The principles involved in *surveillance* for *disease* and *infection* are technically well defined. The design of *surveillance* programmes to prove the absence of *infection* with, or circulation of, avian influenza viruses ~~needs to~~ should 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 avian influenza at the *flock* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory *disease* or a drop in egg production, is important for the early detection of *infection* with avian influenza viruses. In some cases, the only indication of *infection* with low pathogenicity avian influenza virus may be a drop in feed consumption or egg production.

Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of avian influenza suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should have restrictions imposed upon it until avian influenza *infection* is ruled out.

Identification of suspect *flocks* is vital to the identification of sources of avian influenza viruses and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that avian influenza virus isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterisation.

3. Virological surveillance

Virological *surveillance* should be conducted:

- a) to monitor at risk populations;
- b) to confirm clinically suspect cases;
- c) to follow up positive serological results;
- d) to test 'normal' daily mortality, to ensure early detection of *infection* in the face of *vaccination* or in *establishments* epidemiologically linked to an *outbreak*.

4. Serological surveillance

Serological *surveillance* aims at the detection of antibodies against avian influenza virus. Positive avian influenza viruses antibody test results can have four possible causes:

- a) natural *infection* with avian influenza viruses;
- b) *vaccination* against avian influenza;
- c) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to four weeks;
- d) false positive results due to the lack of specificity of the test.

It may be possible to use serum collected for other survey purposes for avian influenza *surveillance*. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of avian influenza viruses should not be compromised.

The discovery of clusters of seropositive *flocks* may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or *infection*. As clustering may signal *infection*, the investigation of all instances should be incorporated in the survey design. Clustering of positive *flocks* is always epidemiologically significant and therefore should be investigated.

Annex XXV (contd)

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 *infection* with avian influenza viruses is present in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

5. Virological and serological surveillance in vaccinated populations

The *surveillance* strategy is dependent on the type of vaccine used. The protection against influenza A virus is haemagglutinin subtype specific. Therefore, two broad *vaccination* strategies exist: 1) inactivated whole viruses, and 2) haemagglutinin expression-based vaccines.

In the case of vaccinated populations, the *surveillance* strategy should be based on virological or serological methods and clinical *surveillance*. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, 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 freedom from avian influenza or freedom from infection with high pathogenicity avian influenza viruses in poultry

1. Additional surveillance procedures requirements for Member Countries declaring freedom of the country, zone or compartment from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry

In addition to the general conditions described in above mentioned articles, a Member Country declaring freedom of the entire country, or a *zone* or a *compartment* from avian influenza or from *infection* with high pathogenicity avian influenza viruses in *poultry* should provide evidence for the existence of an effective *surveillance* programme.

The strategy and design of the *surveillance* programme **will** depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter, to demonstrate absence of *infection* with avian influenza viruses or with high pathogenicity avian influenza viruses, during the preceding 12 months in susceptible *poultry* populations (vaccinated and non-vaccinated). This requires the support of a *laboratory* able to undertake identification of *infection* with avian influenza viruses through virus detection and antibody tests. 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 high pathogenicity avian influenza virus may be part of a *disease* control programme. The level of *flock* immunity required to prevent transmission **will** depend on the *flock* size, composition (e.g. species) and density of the susceptible *poultry* population. It is therefore impossible to be prescriptive. Based on the epidemiology of avian influenza in the country, *zone* or *compartment*, it may be that a decision is reached to vaccinate only certain species or other *poultry* subpopulations.

In all vaccinated *flocks* there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every six months or at shorter intervals according to the risk in the country, *zone* or *compartment*.

Evidence to show the effectiveness of the *vaccination* programme should also be provided.

Article 10.4.31.

Additional surveillance requirements procedures for countries, zones or compartments declaring that they have regained freedom from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry following an outbreak

In addition to the general conditions described in the above-mentioned articles, a Member Country declaring that it has regained country, *zone* or *compartment* freedom from avian influenza or from infection with high pathogenicity avian influenza viruses in *poultry* should show evidence of an active *surveillance* programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*. This will require *surveillance* incorporating virus detection and antibody tests. The use of sentinel birds may facilitate the interpretation of *surveillance* results.

A Member Country declaring freedom of country, *zone* or *compartment* after an *outbreak* of avian influenza should report the results of an active *surveillance* programme in which the susceptible *poultry* population undergoes regular clinical examination and active *surveillance* planned and implemented according to the general conditions and methods described in these recommendations. The *surveillance* should at least give the confidence that can be given by a randomised representative sample of the populations at risk.

Article 10.4.32.

Additional surveillance requirements procedures for avian influenza free establishments

The declaration of avian influenza free *establishments* requires the demonstration of absence of *infection* with avian influenza viruses. Birds in these *establishments* should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these recommendations. The frequency of testing should be based on the risk of *infection* and at a maximum interval of 21 days.

Article 10.4.33.

The use and interpretation of serological and virus detection tests

Poultry infected with avian influenza virus produce antibodies **against 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 is 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 neutralisation (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 **against 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 influenza A viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorisation of influenza A viruses.

Poultry can be vaccinated with a variety of influenza A vaccines including inactivated whole virus vaccines, and haemagglutinin expression-based vaccines. Antibodies **against 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.

Influenza A virus *infection* of unvaccinated birds including sentinels is detected by antibodies **against to** the NP/M, subtype specific HA or NA proteins, or NSP. *Poultry* vaccinated with inactivated whole virus vaccines containing a 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 **against 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 ~~against~~ 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 ~~against~~ the specific HA, but not any of the other viral proteins. *Infection* is evident by antibodies ~~against~~ the NP/M or NSP, or the specific NA protein of the field virus.

All *flocks* with seropositive results should be investigated. Epidemiological and supplementary *laboratory* investigation results should document the status of avian influenza *infection* for each positive *flock*.

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

1. 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 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 virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If *poultry* in the population have antibodies ~~against~~ NP/M and were vaccinated with inactivated whole virus vaccine, the following strategies should be applied:
 - i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating influenza A virus *infection*, specific HI tests should be performed to identify H5 or H7 virus *infection*;
 - ii) if vaccinated with inactivated whole virus vaccine containing homologous NA to field virus, the presence of antibodies ~~against~~ NSP could be indicative of *infection*. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins;
 - iii) if vaccinated with inactivated whole virus vaccine containing heterologous NA to field virus, presence of antibodies ~~against~~ the field virus NA or NSP would be indicative of *infection*. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins.
- b) Haemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect avian influenza *infection*. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of *infection*. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins.

2. Procedure in case of test results indicative of infection with avian influenza viruses

The detection of antibodies indicative of an *infection* with avian influenza virus in unvaccinated *poultry* should result in the initiation of epidemiological and virological investigations to determine if the *infections* are due to low and high pathogenicity viruses.

Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of avian influenza virus, by virus isolation and identification, or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting *infection* by avian influenza virus. All influenza A virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as high or low pathogenicity avian influenza viruses or other influenza A viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as high or low pathogenicity avian influenza viruses. The use of antigen detection systems, because of low sensitivity, should be limited to screening clinical field *cases* for *infection* by influenza A virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

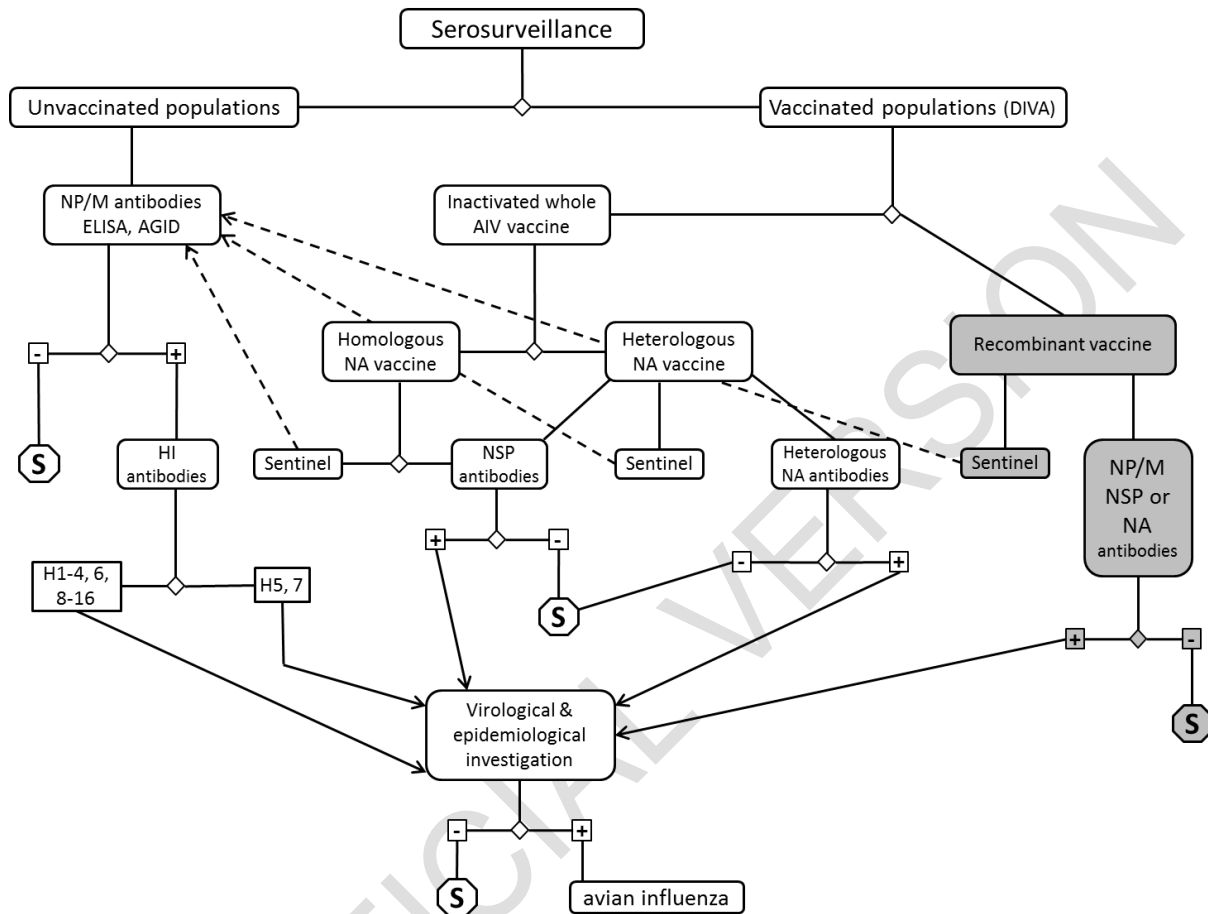
- a) characterisation of the existing production systems;
- b) results of clinical *surveillance* of the suspects and their cohorts;
- c) quantification of *vaccinations* performed on the affected sites;
- d) sanitary protocol and history of the affected *establishments*;
- e) control of *animal identification* and movements;
- f) other parameters of regional significance in historic avian influenza virus transmission.

The entire investigative process should be documented as standard operating procedure within the epidemiological *surveillance* programme.

Figures 1 and 2 indicate the tests which are recommended for use in the investigation of *poultry flocks*.

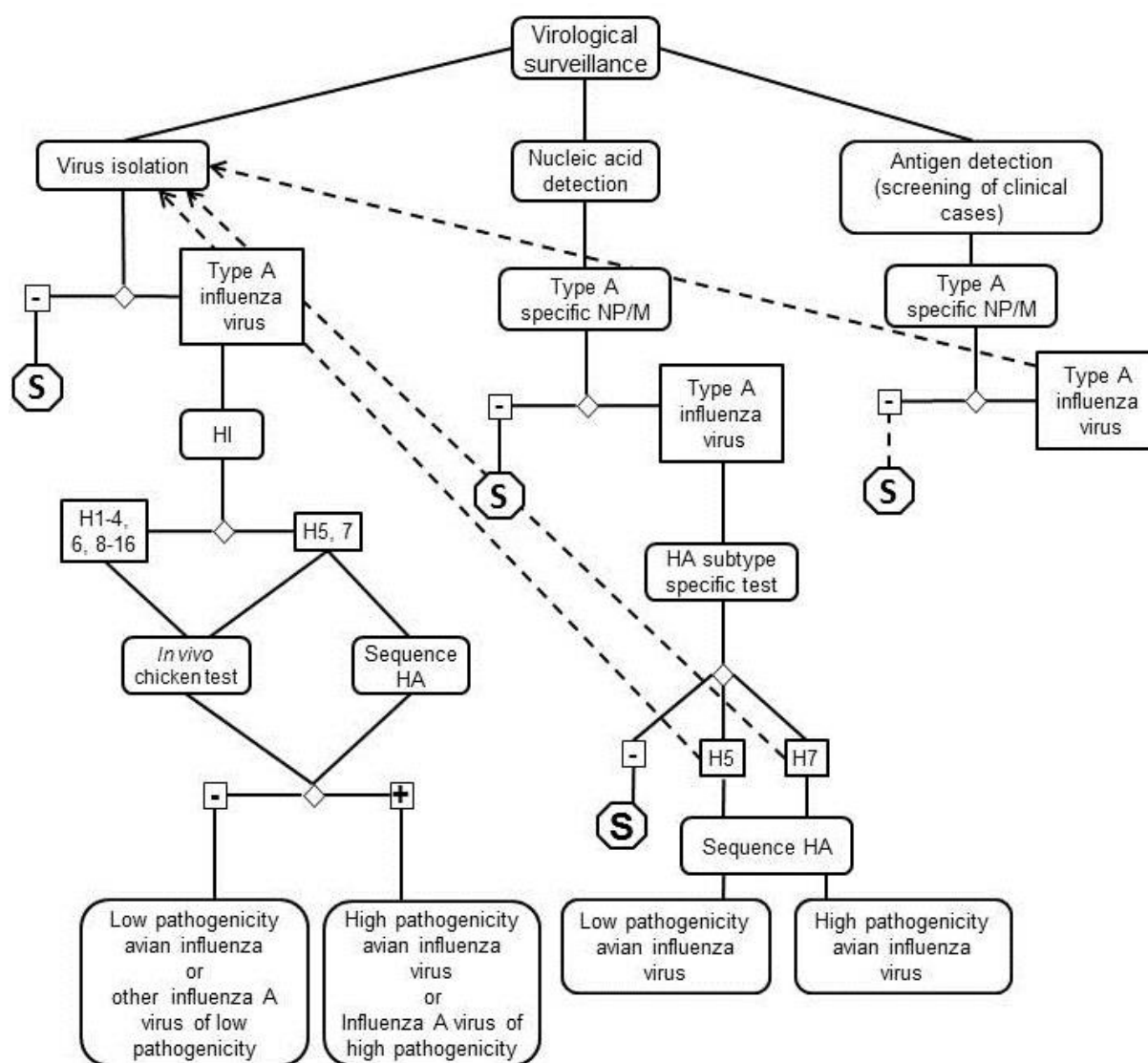
Annex XXV (contd)

Fig. 1. Schematic representation of laboratory tests for determining evidence of avian influenza infection through or following serological surveys



Key abbreviations and acronyms:	
AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbent assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence of avian influenza virus

Fig. 2. Schematic representation of laboratory tests for determining evidence of avian influenza infection using virological methods



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CHAPTER 10.9.

INFECTION WITH NEWCASTLE DISEASE VIRUS
NEW CASTLE DISEASE

EU position

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

Article 10.9.1.

General provisions

- 1) For the purposes of the *Terrestrial Code*, Newcastle disease (ND) is defined as an *infection of poultry* caused by a **Newcastle disease** virus (NDV), **which is an** avian paramyxovirus serotype 1 (APMV-1) that meets one of the following criteria for virulence:
 - a) the virus has an intracerebral pathogenicity index (ICPI) in day-old chicks (*Gallus gallus*) of 0.7 or greater; or
 - b) multiple basic amino acids have been demonstrated in the virus (either directly or by deduction) at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term 'multiple basic amino acids' refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test.

In this definition, amino acid residues are numbered from the N-terminus of the amino acid sequence deduced from the nucleotide sequence of the F0 gene, 113–116 corresponds to residues –4 to –1 from the cleavage site.'

- 2) *Poultry* is defined as 'all domesticated birds, including backyard *poultry*, used for the production of *meat* or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions, or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.

- 3) For the purposes of the *Terrestrial Code*, the *incubation period* for ND shall be 21 days.
- 4) This chapter deals with NDV *infection of poultry* as defined in Point 2 above, in the presence or absence of clinical signs.
- 5) The occurrence of *infection* with NDV is defined as the isolation and identification of NDV as such or the detection of viral RNA specific for NDV.
- 6) Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. When the use of ND vaccines is appropriate, those vaccines should comply with the standards described in the *Terrestrial Manual*.
- 7) A Member Country should not impose bans on the trade in *poultry commodities* in response to information on the presence of any APMV-1 in birds other than *poultry*, including wild birds.

Article 10.9.2.

Determination of the Newcastle disease status of a country, zone or compartment

The ND status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

- 1) ND is notifiable in the whole country, an on-going ND awareness programme is in place, and all notified suspect occurrences of ND are subjected to field and, where applicable, *laboratory* investigations;
- 2) appropriate *surveillance* is in place to demonstrate the presence of NDV *infection* in the absence of clinical signs in *poultry*, this may be achieved through an ND *surveillance* programme in accordance with Articles 10.9.22. to 10.9.26.;
- 3) consideration of all epidemiological factors for ND occurrence and their historical perspective.

Article 10.9.3.

Newcastle disease free country, zone or compartment

A country, *zone* or *compartment* may be considered free from ND when it has been shown that NDV *infection* in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.9.22. to 10.9.26.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, ND free status can be regained three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.9.22. to 10.9.26. has been carried out during that three-month period.

Article 10.9.4.

Recommendations for importation from a Newcastle disease free country, zone or compartment as defined in Article 10.9.3.

For live poultry (other than day-old poultry)

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

- 1) the *poultry* showed no clinical sign suggestive of ND on the day of shipment;
- 2) the *poultry* were kept in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* have been vaccinated against ND, the nature of the vaccine used and the date of vaccination ~~have been~~ should be attached to the *certificate*.

Article 10.9.5.

Recommendations for the importation of live birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the birds showed no clinical sign suggestive of *infection* by NDV on the day of shipment;
- 2) the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of *infection* during the isolation period;
- 3) a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.9.24., was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from *infection* with NDV;

Annex XXVI (contd)

- 4) the birds are transported in new or appropriately sanitized *containers*.

If the birds have been vaccinated against ND, the nature of the vaccine used and the date of vaccination ~~have been~~ should be attached to the *certificate*.

Article 10.9.6.

Recommendations for importation from a Newcastle disease free country, zone or compartment

For day-old live poultry

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

- 1) the *poultry* were hatched and kept in an ND free country, *zone* or *compartment* since they were hatched;
- 2) the *poultry* were derived from parent *flocks* which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* or parent *flocks* have been vaccinated against ND, the nature of the vaccine used and the date of vaccination ~~have been~~ should be attached to the *certificate*.

Article 10.9.7.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the birds showed no clinical sign suggestive of *infection* by NDV on the day of shipment;
- 2) the birds were hatched and kept in isolation approved by the *Veterinary Services*;
- 3) the parent *flock* birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from *infection* with NDV;
- 4) the birds are transported in new or appropriately sanitized *containers*.

If the birds or parent *flocks* have been vaccinated against ND, the nature of the vaccine used and the date of vaccination ~~have been~~ should be attached to the *certificate*.

Article 10.9.8.

Recommendations for importation from a Newcastle disease free country, zone or compartment

For hatching eggs of poultry

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

- 1) the eggs came from an ND free country, *zone* or *compartment*;
- 2) the eggs were derived from parent *flocks* which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against ND, the nature of the vaccine used and the date of vaccination ~~have been~~ should be attached to the *certificate*.

Article 10.9.9.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the parent *flock* birds were subjected to a diagnostic test seven days prior to and at the time of the collection of the eggs to demonstrate freedom from *infection* with NDV;
- 2) the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
- 3) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against ND, the nature of the vaccine used and the date of vaccination ~~have been~~ should be attached to the *certificate*.

Article 10.9.10.

Recommendations for importation from a Newcastle disease 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 an ND free country, *zone* or *compartment*;
- 2) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.9.11.

Recommendations for importation of egg products of poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the *commodity* is derived from eggs which meet the requirements of Article 10.9.10.; or
- 2) the *commodity* has been processed to ensure the destruction of NDV in accordance with Article 10.9.20.;

AND

- 3) the necessary precautions were taken to avoid contact of the egg products with any source of NDV.

Article 10.9.12.

Recommendations for importation from an Newcastle disease free country, zone or compartmentFor poultry semen

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

- 1) showed no clinical sign suggestive of ND on the day of semen collection;
- 2) were kept in an ND free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.9.13.

Recommendations for the importation of semen of birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor birds:

- 1) were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to and on the day of semen collection;
- 2) showed no clinical sign suggestive of *infection* with NDV during the isolation period and on the day of semen collection;
- 3) were subjected to a diagnostic test within 14 days prior to semen collection to demonstrate freedom from *infection* with NDV.

Article 10.9.14.

Recommendations for importation from a Newcastle disease free country, zone or compartment

For fresh meat of poultry

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

- 1) which have been kept in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
- 2) which have been slaughtered in an approved *abattoir* in an ND free country, *zone* or *compartment* and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any sign suggestive of ND.

Article 10.9.15.

Recommendations for importation of meat products of poultry

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

- 1) the *commodity* is derived from *fresh meat* which meet the requirements of Article 10.9.14.; or
- 2) the *commodity* has been processed to ensure the destruction of NDV in accordance with Article 10.9.21.;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.9.16.

Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* were processed in a ND free country, *zone* or *compartment* from *poultry* which were kept in a ND free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*;

OR

- 2) these *commodities* have been processed to ensure the destruction of NDV using (under study):
 - a) pasteurisation; or
 - b) moist heat treatment for 30 minutes at 56°C:

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.9.17.

Recommendations for the importation of feathers and down of poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* originated from *poultry* as described in Article 10.9.14. and were processed in a ND free country, *zone* or *compartment*; or
- 2) these *commodities* have been processed to ensure the destruction of NDV (~~under study~~) using one of the following:
 - a) washed and steam-dried at 100°C for 30 minutes;
 - b) fumigation with formalin (10% formaldehyde) for 8 hours;
 - c) irradiation with a dose of 20 kiloGray;
 - d) any equivalent treatment which has been demonstrated to inactivate NDV;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.9.18.

Recommendations for the importation of feathers and down of birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* have been processed to ensure the destruction of NDV (~~under study~~) using one of the following:
 - a) washed and steam-dried at 100°C for 30 minutes;
 - b) fumigation with formalin (10% formaldehyde) for 8 hours;
 - c) irradiation with a dose of 20 kiloGray;
 - d) any equivalent treatment which has been demonstrated to inactivate NDV;

and

- 2) the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.9.19.

Recommendations for the importation of feather meal and poultry meal

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* were processed in a ND free country, *zone* or *compartment* from *poultry* which were kept in a ND free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
- 2) these *commodities* have been processed either:

- a) with moist heat at a minimum temperature of 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 for a minimum of 280 seconds;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of ND virus.

Article 10.9.20.

Procedures for the inactivation of the Newcastle disease virus in eggs and egg products

The following times and temperatures are suitable for the inactivation of ND virus present in eggs and egg products:

	Core temperature (°C)	Time
Whole egg	55	2,521 seconds
Whole egg	57	1,596 seconds
Whole egg	59	674 seconds
Liquid egg white	55	2,278 seconds
Liquid egg white	57	986 seconds
Liquid egg white	59	301 seconds
10% salted yolk	55	176 seconds
Dried egg white	57	50.4 hours

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Annex XXVI (contd)

Article 10.9.21.

Procedures for the inactivation of ~~the~~ Newcastle disease virus in meat

The following times for industry standard temperatures are suitable for the inactivation of ND virus present in *meat*.

	Core temperature (°C)	Time
Poultry meat	65.0	39.8 seconds
	70.0	3.6 seconds
	74.0	0.5 second
	80.0	0.03 second

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.9.22.

~~Introduction to surveillance: introduction~~

Articles 10.9.22. to 10.9.26. define the principles and provide a guide on the *surveillance* for ND as defined in Article 10.9.1. and is complementary to Chapter 1.4. It is applicable to Member Countries seeking to determine their ND status. This may be for the entire country, *zone* or *compartment*. Guidance for Member Countries seeking free status following an *outbreak* and for the maintenance of ND status is also provided.

Surveillance for ND is complicated by the known occurrence of **avian paramyxovirus serotype 1 (APMV-1)** infections in many bird species, both domestic and wild, and the widespread utilisation of ND vaccines in domestic *poultry*.

The impact and epidemiology of ND differ widely in different regions of the world and therefore it is not possible to provide specific recommendations for all situations. Therefore, *surveillance* strategies employed for demonstrating freedom from ND at an acceptable level of confidence **will need to should** be adapted to the local situation. Variables such as the frequency of contacts of *poultry* with wild birds, different biosecurity levels, production systems and the commingling of different susceptible species require specific *surveillance* strategies to address each specific situation. It is incumbent upon the Member Country to provide scientific data that explains the epidemiology of ND in the region concerned and also demonstrates how all the risk factors are managed. There is, therefore, considerable latitude available to Member Countries to provide a well-reasoned argument to prove freedom from NDV *infection*.

Surveillance for ND should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from NDV *infection*.

Article 10.9.23.

~~General conditions and methods for surveillance: general conditions and methods~~

- 1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular there should be in place:
 - a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease* or NDV *infection*;
 - b) a procedure for the rapid collection and transport of samples from suspect cases of ND to a *laboratory* for ND diagnosis;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data.

2) The ND *surveillance* programme should:

- a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of ND to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of ND should be investigated immediately. As suspicion cannot be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a *laboratory* for appropriate tests. This requires that sampling kits and other equipment are available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in ND diagnosis and control;
- b) implement, when relevant, regular and frequent clinical, virological and serological *surveillance* of high risk groups of *poultry* within the target population (e.g. those adjacent to an ND infected country, *zone*, *compartment*, places where birds and *poultry* of different origins are mixed, or other sources of NDV).

An effective *surveillance* system may identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is due to NDV *infection*. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from NDV *infection* should provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 10.9.24.

Surveillance strategies

1. Introduction

Any *surveillance* programme requires inputs from professionals competent and experienced in this field and should be thoroughly documented. The design of *surveillance* programmes to prove the absence of NDV *infection* ~~or~~ circulation ~~needs to~~ **should** be carefully followed to avoid producing results that are either unreliable, or excessively costly and logistically complicated.

If a Member Country wishes to declare freedom from NDV *infection* in a country, *zone* or *compartment*, the subpopulation used for the *surveillance* for the disease ~~and~~ **infection** should be representative of all *poultry* within the country, *zone* or *compartment*. Multiple *surveillance* methods should be used concurrently to accurately define the true ND status of *poultry* populations. Active and passive *surveillance* for ND should be ongoing with the frequency of active *surveillance* being appropriate to the disease situation in the country. *Surveillance* should be composed of random ~~and~~ **or** targeted approaches, dependent on the local epidemiological situation and using clinical, virological and serological methods. If alternative tests are used they should have been validated as fit-for-purpose in accordance with OIE standards. A Member Country should justify the *surveillance* strategy chosen as adequate to detect the presence of NDV *infection* in accordance with Chapter 1.4. and the prevailing epidemiological situation.

In surveys, the sample size selected for testing should be statistically justified to detect *infection* at a predetermined target prevalence. The sample size and expected prevalence determine the level of confidence in the results of the survey. The survey design and frequency of sampling should be dependent on the historical and current local epidemiological situation. The Member Country should justify the choice of survey design and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in a population) may be an appropriate strategy.

Annex XXVI (contd)

It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. unvaccinated chickens). Similarly, virological and serological testing could target species that may not show clinical signs (Article 10.9.2.) of ND and are not routinely vaccinated (e.g. ducks). *Surveillance* may also target *poultry* populations at specific risk, for example direct or indirect contact with wild birds, multi-age *flocks*, local trade patterns including live *poultry* markets, the presence of more than one species on the holding and poor biosecurity measures in place. In situations where wild birds have been shown to play a role in the local epidemiology of ND, *surveillance* of wild birds may be of value in alerting *Veterinary Services* to the possible exposure of *poultry* and, in particular, of free ranging *poultry*.

The sensitivity and specificity of the diagnostic tests are key factors in the choice of survey design, which should anticipate the occurrence of false positive and false negative reactions. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination* ~~and~~ *infection* history and for the different species in the target population. If the characteristics of the testing system are known, the rate at which these false reactions are likely to occur can be calculated in advance. There ~~needs to~~ *should* be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *flocks* which may be epidemiologically linked to it.

The results of active and passive *surveillance* are important in providing reliable evidence that no NDV *infection* is present in a country, *zone* or *compartment*.

2. Clinical surveillance

Clinical *surveillance* aims to detect clinical signs suggestive of ND at the *flock* level and should not be underestimated as an early indication of *infection*. Monitoring of production parameters (e.g. a drop in feed or water consumption or egg production) is important for the early detection of NDV *infection* in some populations, as there may be no, or mild clinical signs, particularly if they are vaccinated. Any sampling unit within which suspicious *animals* are detected should be considered as infected until evidence to the contrary is produced. Identification of infected *flocks* is vital to the identification of sources of NDV.

A presumptive diagnosis of clinical ND in suspect infected populations should always be confirmed by virological testing in a *laboratory*. This will enable the molecular, antigenic and other biological characteristics of the virus to be determined.

It is desirable that NDV isolates are sent promptly to an OIE Reference Laboratory for archiving and further characterisation if required.

3. Virological surveillance

Virological *surveillance* should be conducted to:

- a) monitor at risk populations;
- b) confirm suspect clinical cases;
- c) follow up positive serological results in unvaccinated populations or sentinel birds;
- d) test 'normal' daily mortalities (if warranted by an increased risk e.g. *infection* in the face of *vaccination* or in establishments epidemiologically linked to an *outbreak*).

4. Serological surveillance

Where *vaccination* is carried out, serological *surveillance* is of limited value. Serological *surveillance* cannot be used to discriminate between NDV and other APMV-1. Positive NDV antibody test results can have five possible causes:

- a) natural *infection* with APMV-1;
- b) *vaccination* against ND;
- c) exposure to vaccine virus;
- d) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to four weeks;
- e) non-specific test reactions.

It may be possible to use serum collected for other survey purposes for ND *surveillance*. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of NDV should not be compromised.

Discovery of seropositive, unvaccinated *flocks* should be investigated further by conducting a thorough epidemiological investigation. Since seropositive results are not necessarily indicative of *infection*, virological methods should be used to confirm the presence of NDV in such populations. Until validated strategies and tools to differentiate vaccinated *animals* from those infected with field APMV-1 are available, serological tools should not be used to identify NDV *infection* in vaccinated populations.

5. Use of sentinel poultry

There are various applications of the use of sentinel *poultry* as a *surveillance* tool to detect virus circulation. They may be used to monitor vaccinated populations or species which are less susceptible to the development of clinical *disease* for the circulation of virus. Sentinel *poultry* should be immunologically naïve and may be used in vaccinated *flocks*. In case of the use of sentinel *poultry*, the structure and organisation of the *poultry* sector, the type of vaccine used and local epidemiological factors will determine the type of production systems where sentinels should be placed, the frequency of placement and monitoring of the sentinels.

Sentinel *poultry* should be in close contact with, but should be identified to be clearly differentiated from, the target population. Sentinel *poultry* should be observed regularly for evidence of clinical *disease* and any disease incidents investigated by prompt *laboratory* testing. The species to be used as sentinels should be proven to be highly susceptible to *infection* and ideally develop clear signs of clinical *disease*. Where the sentinel *poultry* do not necessarily develop overt clinical *disease* a programme of regular active testing by virological and serological tests should be used (the development of clinical *disease* may be dependent on the sentinel species used or use of live vaccine in the target population that may infect the sentinel *poultry*). The testing regime and the interpretation of the results will depend on the type of vaccine used in the target population. Sentinel birds should be used only if no appropriate *laboratory* procedures are available.

Article 10.9.25.

Additional surveillance requirements for declaration of freedom Documentation of Newcastle disease free status; additional surveillance procedures

The requirements for a country, *zone* or *compartment* to declare freedom from ND are given in Article 10.9.3.

A Member Country declaring freedom of a country, *zone* or *compartment* with or without *vaccination* should report the results of a *surveillance* programme in which the ND susceptible *poultry* population undergoes regular *surveillance* planned and implemented according to the general conditions and methods described in these recommendations.

Annex XXVI (contd)1. Member Countries declaring freedom from Newcastle disease for the country, zone or compartment

In addition to the general conditions described in the *Terrestrial Code*, a Member Country declaring freedom from ND for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective *surveillance* programme. The *surveillance* programme should be planned and implemented according to general conditions and methods described in this chapter to demonstrate absence of NDV *infection* in *poultry* during the preceding 12 months.

2. Additional requirements for countries, zones or compartments that practise vaccination

Vaccination against ND may be used as a component of a disease prevention and control programme. In vaccinated populations there is a need to perform *surveillance* to ensure the absence of NDV circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The *surveillance* should be repeated at least every six months or at shorter intervals according to the risk in the country, *zone* or *compartment*, or evidence to show the effectiveness of the *vaccination* programme is regularly provided.

Article 10.9.26.

~~Additional surveillance requirements for regaining freedom Countries, zones or compartments regaining freedom from Newcastle disease following an outbreak: additional surveillance procedures~~

A Member Country regaining country, *zone* or *compartment* freedom from ND should show evidence of an active *surveillance* programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*.

A Member Country declaring freedom of a country, *zone* or *compartment* after an *outbreak* of ND with or without *vaccination* should report the results of a *surveillance* programme in which the ND susceptible *poultry* population undergoes regular *surveillance* planned and implemented according to the general conditions and methods described in these recommendations.

 — Text deleted.

CHAPTER 11.8.

**INFECTION WITH *MYCOPLASMA MYCOIDES*
SUBSP. *MYCOIDES* SC
(CONTAGIOUS BOVINE PLEUROPNEUMONIA)**

EU position

The EU supports the adoption of this modified chapter.

Article 11.8.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for contagious bovine pleuropneumonia (CBPP) shall be six months.

For the purpose of this chapter, a *case* of CBPP means an *animal* infected with *Mycoplasma mycoides* subsp. *mycoides* SC (*MmmSC*), and freedom from CBPP means freedom from *MmmSC* infection.

For the purpose of this chapter, susceptible *animals* include **bovids cattle** (*Bos indicus*, *B. taurus* and *B. grunniens*) and water buffaloes (*Bubalus bubalis*).

For the purposes of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by *MmmSC*, but also with the presence of *infection* with *MmmSC* in the absence of clinical signs.

The following defines the occurrence of *MmmSC* infection:

- 1) *MmmSC* has been isolated and identified as such from an *animal*, embryos, oocytes or semen; or
- 2) antibodies to *MmmSC* antigens which are not the consequence of *vaccination*, or *MmmSC* DNA, have been identified in one or more *animals* showing pathological lesions consistent with *infection* with *MmmSC* with or without clinical signs, and epidemiological links to a confirmed *outbreak* of CBPP in susceptible *animals*.

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

When authorising import or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 11.8.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the CBPP status of the domestic **bovids cattle** and water buffalo population of the *exporting country, zone or compartment*.

Article 11.8.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any CBPP related conditions, regardless of the CBPP status of the domestic **bovids cattle** and water buffalo population of the *exporting country, zone or compartment*.

- 1) *milk* and *milk products*;
- 2) *hides* and *skins*;
- 3) *meat* and *meat products* (excluding lung).

Article 11.8.3.

CBPP free country or zone

To qualify for inclusion in the existing list of CBPP free countries and *zones*, a Member should:

- 1) have a record of regular and prompt animal *disease* reporting;
- 2) send a declaration to the OIE stating that:
 - a) there has been no *outbreak* of CBPP during the past 24 months;
 - b) no evidence of CBPP *infection* has been found during the past 24 months;
 - c) no *vaccination* against CBPP has been carried out during the past 24 months,

and supply documented evidence that *surveillance* for CBPP in accordance with this chapter is in operation and that regulatory measures for the prevention and control of CBPP have been implemented;

- 3) not have imported since the cessation of *vaccination* any *animals* vaccinated against CBPP.

The country or *zone* will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2a), 2b), 2c) and 3 above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

Article 11.8.4.

Recovery of free status

When a CBPP *outbreak* occurs in a CBPP free country or *zone*, one of the following waiting periods is required to regain the status of CBPP free country or *zone*:

- 1) 12 months after the last *case* where a *stamping-out policy* and serological *surveillance* and strict movement control are applied in accordance with this chapter;
- 2) if vaccination was used, 12 months after the *slaughter* of the last vaccinated *animal*.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply but Article 11.8.3. applies.

Article 11.8.5.

CBPP infected country or zone

When the requirements for acceptance as a CBPP free country or *zone* are not fulfilled, a country or *zone* shall be considered as infected.

Article 11.8.6.

CBPP free compartment

The bilateral recognition of a CBPP free *compartment* should follow the principles laid down in this chapter and in Chapters 4.3. and 4.4.

Article 11.8.7.

Recommendations for importation from CBPP free countries or zones, or from CBPP free compartments

For domestic **bovids cattle** and water buffaloes

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

- a) showed no clinical sign of CBPP on the day of shipment;
- b) were kept in a CBPP free country, zone or compartment since birth or for at least the past six months.

Article 11.8.8.

Recommendations for importation from CBPP infected countries or zones

For domestic ~~bovids~~ cattle and water buffaloes for slaughter

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

- 1) showed no clinical sign of CBPP on the day of shipment;
- 2) originate from an *establishment* where no case of CBPP was officially reported for the past six months, and
- 3) are transported directly to the *slaughterhouse* in sealed *vehicles*.

Article 11.8.9.

Recommendations for importation from CBPP free countries or zones, or from CBPP free compartments

For bovine semen

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

- 1) the donor *animals*:
 - a) showed no clinical sign of CBPP on the day of collection of the semen;
 - b) were kept in a CBPP free country, zone or compartment since birth or for at least the past six months;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.8.10.

Recommendations for importation from CBPP infected countries

For bovine semen

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

- 1) the donor *animals*:
 - a) showed no clinical sign of CBPP on the day of collection of the semen;
 - b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;
 - c) were isolated from other domestic ~~bovids~~ and water buffaloes from the day of the first complement fixation test until collection;
 - d) were kept since birth, or for the past six months, in an *establishment* where no case of CBPP was reported during that period, and that the *establishment* was not situated in a CBPP *infected zone*;

e) AND EITHER:

i) have not been vaccinated against CBPP;

OR

ii) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than four months prior to collection; in this case, the condition laid down in point b) above is not required;

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

Article 11.8.11.

Recommendations for importation from CBPP free countries or zones, or from CBPP free compartments

For *in vivo* derived or *in vitro* produced embryos or oocytes of domestic bovids and water buffaloes

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

1) the donor *animals*:

a) showed no clinical sign of CBPP on the day of collection of the embryos or oocytes;

b) were kept in a CBPP free country, *zone* or *compartment* since birth or for at least the past six months;

2) the oocytes were fertilised with semen meeting the conditions of Article 11.8.9.;

3) the embryos or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.8.12.

Recommendations for importation from CBPP infected countries

For *in vivo* derived or *in vitro* produced embryos or oocytes of domestic bovids and water buffaloes

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

1) the donor *animals*:

a) showed no clinical sign of CBPP on the day of collection of the embryos or oocytes;

b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;

c) were isolated from other domestic domestic bovids and water buffaloes from the day of the first complement fixation test until collection;

d) were kept since birth, or for the past six months, in an *establishment* where no case of CBPP was reported during that period, and that the *establishment* was not situated in a CBPP *infected zone*;

e) AND EITHER:

i) have not been vaccinated against CBPP;

OR

- ii) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than four months prior to collection; in this case, the condition laid down in point b) above is not required;
- 2) the oocytes were fertilised with semen meeting the conditions of Article 11.8.10.;
 - 3) the embryos or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.8.13.

Introduction to surveillance: introduction

Articles 11.8.13. to 11.8.17. define the principles and provide a guide for the *surveillance* of CBPP in accordance with Chapter 1.4. applicable to Member Countries seeking establishment of freedom from CBPP. Guidance is provided for Member Countries seeking reestablishment of freedom from CBPP for the entire country or for a *zone*, following an *outbreak* and for the maintenance of CBPP free status.

The impact and epidemiology of CBPP differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from CBPP at an acceptable level of confidence will need to should be adapted to the local situation. It is incumbent upon the applicant Member Country to submit a dossier to the OIE in support of its application that not only explains the epidemiology of CBPP in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically-based supporting data. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that the absence of CBPP *infection* is assured at an acceptable level of confidence.

Surveillance for CBPP should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from CBPP *infection*.

Article 11.8.14.

General conditions and methods for surveillance: general conditions and methods

- 1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples from suspect cases of CBPP to a *laboratory* for CBPP diagnoses.
- 2) The CBPP *surveillance* programme should:
 - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers (such as community animal health workers) who have day-to-day contact with livestock, *meat* inspectors as well as *laboratory* diagnosticians, should report promptly any suspicion of CBPP. They should be integrated directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) into the *surveillance* system. All suspect cases of CBPP should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in CBPP diagnosis and control;

Annex XXVII (contd)

- b) implement, when relevant, regular and frequent clinical inspection and testing of high-risk groups of *animals*, such as those adjacent to a CBPP infected country or *infected zone* (for example, areas of transhumant production systems);
- c) take into consideration additional factors such as animal movement, different production systems, geographical and socio-economic factors that may influence the risk of disease occurrence.

An effective *surveillance* system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is CBPP. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from CBPP *infection* should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 11.8.15.

Surveillance strategies1. Introduction

The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species (*Bos taurus*, *B. indicus*, *B. grunniens* and *Bubalus bubalis*) within the country or *zone*.

Given the limitations of the diagnostic tools available, the interpretation of *surveillance* results should be at the *herd* level rather than at the individual animal level.

Randomised *surveillance* may not be the preferred approach given the epidemiology of the *disease* (usually uneven distribution and potential for occult foci of *infection* in small populations) and the limited sensitivity and specificity of currently available tests. Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species, focusing on *slaughter* findings, and active clinical *surveillance*) may be the most appropriate strategy. The applicant Member Country should justify the *surveillance* strategy chosen as adequate to detect the presence of CBPP *infection* in accordance with Chapter 1.4. and the epidemiological situation.

Targeted *surveillance* may involve testing of the entire target subpopulation or a sample from it. In the latter case the sampling strategy ~~will need to~~ should incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing ~~will need to~~ should be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant Member Country 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~~ should be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated.

Irrespective of the *surveillance* system employed, the design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There ~~needs to~~ should be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve follow-up with supplementary tests, clinical investigation and post-mortem examination in the original sampling unit as well as *herds* which may be epidemiologically linked to it.

2. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs of CBPP in a *herd* by close physical examination of susceptible *animals*. Clinical inspection ~~will be~~ **is** an important component of CBPP *surveillance* contributing to reach the desired level of confidence of detection of *disease* if a sufficiently large number of clinically susceptible *animals* is examined.

Clinical *surveillance* and laboratory testing should always be applied in series to clarify the status of CBPP suspects detected by either of these complementary diagnostic approaches. Laboratory testing and post-mortem examination may contribute to confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced.

3. Pathological surveillance

Systematic pathological *surveillance* for CBPP is the most effective approach and should be conducted at *slaughterhouses* and other *slaughter* facilities. Suspect pathological findings should be confirmed by agent identification. Training courses for *slaughter* personnel and *meat* inspectors are recommended.

4. Serological testing

Serological *surveillance* is not the preferred strategy for CBPP. However, in the framework of epidemiologic investigations, serological testing may be used.

The limitations of available serological tests for CBPP ~~will~~ **will** make the interpretation of results difficult and useful only at the *herd* level. Positive findings should be followed-up by clinical and pathological investigations and agent identification.

Clustering of seropositive reactions should be expected in CBPP *infections* and ~~is~~ **is will be** usually accompanied by clinical signs. As clustering may signal field strain *infection*, the investigation of all instances should be incorporated in the *surveillance* strategy.

Following the identification of a CBPP infected *herd*, contact *herds* ~~need to~~ **should** be tested serologically. Repeated testing may be necessary to reach an acceptable level of confidence in *herd* classification.

5. Agent surveillance

Agent *surveillance* should be conducted to follow-up and confirm or exclude suspect cases. Isolates should be typed to confirm *MmmSC*.

Article 11.8.16.

Countries or zones applying for recognition of freedom from CBPP

In addition to the general conditions described in this chapter, a Member Country applying for recognition of CBPP freedom for the country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme ~~will~~ **will** depend on the prevailing epidemiological circumstances and ~~will~~ **will should** be planned and implemented according to general conditions and methods in this chapter, to demonstrate absence of CBPP *infection*, during the preceding 24 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of CBPP *infection*.

Annex XXVII (contd)

Article 11.8.17.

Countries or zones re-applying for recognition of freedom from CBPP following an outbreak

In addition to the general conditions described in this chapter, a Member re-applying for recognition of country or *zone* freedom from CBPP should show evidence of an active *surveillance* programme for CBPP, following the recommendations of this chapter.

Two strategies are recognised by the OIE in a programme to eradicate CBPP *infection* following an *outbreak*:

- 1) *slaughter* of all clinically affected and in-contact susceptible *animals*;
- 2) *vaccination* used without subsequent *slaughter* of vaccinated *animals*.

The time period before which an application can be made for re-instatement of freedom from CBPP depends on which of these alternatives is followed. The time periods are prescribed in Article 11.8.4.

Article 11.8.18.**OIE endorsed official control programme for CBPP**

The overall objective of an OIE endorsed *official control programme* for CBPP is for Member Countries to progressively improve **their the** situation and eventually attain CBPP free status. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined *subpopulations*.

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for CBPP when they have implemented measures in accordance with this article.

For an *official control programme* for CBPP to be endorsed by the OIE, the Member Country should:

- 1) have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;
- 2) submit documented evidence of the capacity of the *Veterinary Services* to control CBPP; this evidence can be provided by countries following the OIE PVS Pathway;
- 3) submit a detailed plan of the programme to control and eventually eradicate CBPP in the country or *zone* including:
 - a) the *timeline*;
 - b) the performance indicators for assessing the efficacy of the control measures to be implemented;
 - c) submit documentation indicating that the *official control programme* for CBPP has been implemented and is applicable to the entire territory;
- 4) submit a dossier on the epidemiology of CBPP in the country describing the following:
 - a) the general epidemiology in the country highlighting the current knowledge and gaps;
 - b) the measures to prevent introduction of *infection*, the rapid detection of, and response to, all CBPP *outbreaks* in order to reduce the incidence of CBPP *outbreaks* and to eliminate CBPP in at least one *zone* in the country;
 - c) the main livestock production systems and movement patterns of CBPP susceptible *animals* and their products within and into the country;

- 5) submit evidence that CBPP surveillance is in place,
- a) taking into account provisions in Chapter 1.4. and the provisions on surveillance of this chapter;
 - b) have diagnostic capability and procedures, including regular submission of samples to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the Terrestrial Manual including procedures to isolate and identify *M. mycoides* subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC;
- 6) where vaccination is practised as a part of the official control programme for CBPP, provide:
- a) evidence (such as copies of legislation) that vaccination of selected populations is compulsory;
 - b) detailed information on vaccination campaigns, in particular on:
 - i) target populations for vaccination;
 - ii) monitoring of vaccination coverage;
 - iii) technical specification of the vaccines used and description of the licensing procedures in place;
 - iv) the proposed timeline and strategy for the cessation of vaccination;
- 7) provide an emergency preparedness and contingency response plan to be implemented in case of CBPP outbreaks.

The Member Country's official control programme for CBPP will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the official control programme and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

The OIE may withdraw the endorsement of the official control programme if there is evidence of:

- = non-compliance with the timelines or performance indicators of the programme; or
- = significant problems with the performance of the Veterinary Services; or
- = an increase in the incidence of CBPP that cannot be addressed by the programme.

— 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.**

Article 1.6.1.

General principles

Member Countries may wish to make a self declaration as to the freedom of a country, *zone* or *compartment* from an OIE *listed disease*. The Member Country 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), contagious bovine pleuropneumonia (CBPP), African horse sickness (AHS), peste des petits ruminants (PPR) and classical swine fever (CSF).

Member Countries 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 or *zone* from CBPP;
- 4) the freedom of a country or *zone* from AHS;
- 5) the freedom of a country or *zone* from PPR;
- 6) the freedom of a country or *zone* from CSF.

The OIE does not grant official recognition for other *diseases*.

In these cases, Member Countries 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 Country should submit to the OIE Scientific and Technical Department a dossier providing the information requested (as appropriate) in Articles 1.6.4. (for BSE), 1.6.5. (for FMD), 1.6.6. (for CBPP), 1.6.7. (for AHS), 1.6.8. (for PPR) or 1.6.9. (for CSF).

The OIE framework for the official recognition and maintenance of disease status is described in Resolution N° XXX (administrative procedures) and Resolution N° XXXI (financial obligations) adopted during the 81st General Session in May 2013.

[Article 1.6.2.]

[Article 1.6.3.]

Article 1.6.3.bis**Endorsement by the OIE of an official control programme for CBPP**

Member Countries may wish to request an endorsement by the OIE of their official control programme for CBPP.

When requesting endorsement by the OIE of an official control programme for CBPP, the Member Country should submit to the OIE Scientific and Technical Department a dossier providing the information requested in Article 1.6.12.

[Article 1.6.4.]

[Article 1.6.5.]

[Article 1.6.6.]

[Article 1.6.7.]

[Article 1.6.8.]

[Article 1.6.9.]

[Article 1.6.10.]

[Article 1.6.11.]

Article 1.6.12.

COUNTRY WITH AN OIE ENDORSED OFFICIAL CONTROL PROGRAMME FOR CBPP

Report of a Member Country which applies for the OIE endorsement
of its official control programme for CBPP
under Chapter 11.8. of the Terrestrial Code

Please address concisely the following topics. National laws, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country and zones including physical, geographical and other factors that are relevant to CBPP 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 in specific parts of the country, the boundaries of the zones 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 zones.
- c) Provide a general description of the livestock industry in the country and any zones.

Annex XXVII (contd)

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to CBPP control programme.
- b) Veterinary Services. Provide documentation on the compliance of the Veterinary Services of the country with the provisions of Chapters 3.1. and 3.2. of the Terrestrial Code and 1.1.3. of the Terrestrial Manual and describe how the Veterinary Services supervise and control all CBPP related activities in the country and any zones. Provide maps and tables wherever possible.
- c) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small scale producers, community animal health workers and the role of the private veterinary profession in CBPP surveillance and control. Include a description of training and awareness programmes on CBPP.
- d) Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS Pathway.

3. CBPP control

- a) Provide a description of CBPP 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 MmmSC present.
- b) Describe the general epidemiology of CBPP in the country and the surrounding countries or zones highlighting the current knowledge and gaps.
- c) Describe how CBPP is controlled in the country or any zones.
- d) Provide a description of the legislation, organisation and implementation of the current CBPP control programme. Indicate if detailed operational guidelines exist and give a brief summary.
- e) Provide information on types of vaccines used and species vaccinated. Provide information on the licensing process for 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 vaccination coverage, population immunity, etc. Provide details on the studies carried out to determine the population immunity, including the study design.
- f) Provide a description of the methods of animal identification (at the individual or group level), herd registration and traceability and how the movements of animals and products are assessed and controlled, including movement of infected animals to slaughter. Describe the effectiveness of animal identification and movement controls. Provide information on pastoralism, transhumance and related paths of movement. Describe measures to prevent introduction of CBPP from neighbouring countries or zones and through trade.

4. CBPP surveillance

Provide documentary evidence that surveillance for CBPP in the country complies with the provisions of Articles 11.8.12. to 11.8.17. of the Terrestrial Code and Chapter 2.4.9. of the Terrestrial Manual. In particular, the following points should be addressed:

- a) Describe the criteria for suspecting a case of CBPP and the procedure for notifying (by whom and to whom) and what penalties are involved for failure to report.
- b) Provide a description of the means employed to detect the presence of any MmmSC strain in the susceptible population of the zone. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details of the methods applied for monitoring the performance of the surveillance system including indicators.

Annex XXVII (contd)

- c) Describe how clinical surveillance is conducted, including which levels of the livestock production system are included in clinical surveillance, such as farms, markets, fairs, slaughterhouse/abattoir, 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 of the methods applied for monitoring the performance of the surveillance system including indicators. Explain whether serological and slaughterhouse/abattoir surveys are conducted and, if so, how frequently and for what purpose.
- d) Slaughterhouses/abattoirs, slaughter slabs. What are the criteria for suspecting a lesion is CBPP? What is the procedure for notifying (by whom and to whom)? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for CBPP agent, species, type of sample, testing methods and results (including differential diagnosis). Provide procedural details on follow-up actions taken on suspicious and positive results.
- e) Provide details of training programmes for personnel involved in clinical and slaughterhouses/abattoirs surveillance, and the approaches used to increase community involvement in CBPP surveillance programmes.
- f) In countries where a significant proportion of animals in the country or zone are not slaughtered in controlled slaughterhouses/abattoirs, what are the alternative surveillance measures applied to detect CBPP (e.g. active clinical surveillance programme, laboratory follow-up).
- g) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many herds of each susceptible species are in the country or zone? How are they distributed (e.g. herd density, etc.)? Provide tables and maps as appropriate.
- h) Slaughterhouses/abattoirs and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country and the zone? How are the animals transported and handled during these transactions?

5. CBPP laboratory diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.4.9. of the Terrestrial Manual are applied. In particular, the following points should be addressed:

- a) Is CBPP laboratory diagnosis carried out in the country? If so, provide a list of laboratories approved by the Competent Authority to diagnose CBPP. If not, provide the names of and the arrangements with the laboratories to which samples are sent, the follow-up procedures and the time frame for obtaining results. If applicable, indicate the laboratories where samples originating from any zone are diagnosed. Is there regular submission of samples from the country or zone to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the standards and methods described in the Terrestrial Manual?
- b) Provide an overview of the laboratories approved to test for CBPP, in particular to address the following points:
 - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system.
 - ii) Give details of participation in inter-laboratory validation tests (ring tests).
 - iii) Biosecurity measures applied.
 - iv) Details of the type of tests undertaken including procedures to isolate and identify *M. mycoides* subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC.

Annex XXVII (contd)6. CBPP prevention

Describe the procedures in place to prevent the introduction of CBPP into the country. In particular provide details of:

a) Coordination with neighbouring countries, trading partners and other countries within the same region. Identify relevant factors about the adjacent countries and zones that should be taken into account such as size, distance from adjacent borders to affected herds or animals, surveillance carried 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) Import control procedures

Provide information on countries, zones or compartments 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, zones or compartments. Describe the controls applied to 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 of imports of susceptible animals and their products for at least the past two years, specifying country, zone or compartments of origin, the species and the number or volume.

i) Provide a map with the number and location of ports, airports and land border crossings. Advise whether the service responsible for import controls is part of the official services, or if it is an independent body. If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or zone or their final destination, concerning the import and follow-up of the following:

- ≡ animals.
- ≡ semen, embryos and oocytes.
- ≡ veterinary medicinal products, i.e. biologics.

iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and emergency response

a) Give details of any written guidelines, including contingency plans, available to the Veterinary Services for dealing with suspected or confirmed outbreaks of CBPP.

b) Advise whether quarantine is imposed on premises with suspected cases, pending final diagnosis? What other procedures are followed regarding suspected cases?

c) In the event of a CBPP 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 CBPP;
- iv) indicate the control or eradication procedures, such as vaccination, stamping-out policy, partial slaughter with vaccination, movement control, pastured livestock and livestock as pets, control of the livestock waste (e.g. offal, especially lungs, and carcasses), campaign to promote awareness of farmers, etc. that would be taken;
- v) describe the procedures used to confirm that an outbreak has been successfully controlled or eradicated, including any restrictions on restocking;
- vi) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for disease control or eradication purposes and their prescribed timetable.

8. Official control programme for CBPP 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 CBPP in the Member Country, including:

- a) objectives,
- b) expected status to be achieved; for zones (if applicable) and for the whole country,
- c) timelines of the control programme including cessation of vaccination,
- d) performance indicators, including methods for measurement and verification,
- e) description of the funding for the control programme and annual budgets for its duration,

9. Recovery of official endorsement of the national CBPP control programme

Member Countries applying for recovery of the official endorsement of the national CBPP control programme should provide updated information in compliance with the provisions of Article 11.8.18. of the Terrestrial Code.

 — Text deleted.

D R A F T C H A P T E R 4 . X .

H I G H H E A L T H S T A T U S H O R S E S U B P O P U L A T I O N**EU position**

The EU thanks the OIE for having taken some of its comments into account. The EU confirms its general support for the concept outlined in this chapter. Whilst recognising the importance of advancing the concept, the EU nevertheless has some continuing concerns about the situation where this conceptual chapter is proposed for early adoption without having developed and agreed the necessary chapters or guidelines that would make it understandable and thus implementable in a common and consistent way by member countries.

It is difficult for the EU to fully endorse such a new conceptual chapter in the absence of the required implementation guidelines and standards. We note that indeed, the draft chapter contains references to an international biosecurity plan developed by the industry and to OIE biosecurity guidelines concerning which we do not have any information.

However, the EU notes the importance of adopting this first chapter as a strong sign of support from the OIE World Assembly and the OIE member countries for the overall concept of the High Health Status Horse Subpopulation (HHS), and as an incentive to keep the momentum for finalising the work of the relevant *ad hoc* group.

The EU is confident that this concept, which is in line with the concept of compartmentalisation described in Chapter 4.4. of the Code, will greatly facilitate the temporary international movement of competition horses to the benefit of the horse industry and member countries alike. The EU furthermore understands that there will be opportunity to fine-tune and further improve this chapter, once adopted, as has been customary for newly adopted Terrestrial Code chapters in recent years.

Thus notwithstanding the concerns identified above, the EU supports the adoption of this new Code chapter at the OIE General Session in May 2014.

Specific comments are inserted in the text below.

Article 4.X.1.

General provisions

This chapter provides recommendations for the establishment of a *subpopulation* of horses that are moved internationally to compete in equestrian competitions, including thoroughbred races, and that have a **certified** high health status **certified by the Veterinary Authority**, in order to facilitate their safe temporary importation, onward movement and return to the country of usual residence.

EU position

The EU acknowledges that it is not the remit of the OIE to define the “high performance” sport horses, and thus accepts that the term “high performance”, initially forming an integral part of this concept (HHP or “High Health, High Performance”), has been omitted from this draft new Code chapter.

However, as stated in its previous comment, the EU is of the opinion that this scheme should be restricted to high level international competitions. Indeed, a higher level of competition reduces the number of horses participating in the subpopulation and the number of venues which require compliance with the high health requirements.

Therefore, in the paragraph above, the EU suggests inserting the words “high level” before the words “equestrian competitions”.

Furthermore, the EU suggests establishing an abbreviation for the High Health Status Horse Subpopulation, which could be “HHS”, and could be included in the paragraph above as follows:

“This chapter provides recommendations for the establishment of a *subpopulation* of horses (High Health Status Horse Subpopulation or HHS) that are moved internationally to compete in equestrian competitions, [...]”.

In line with the provisions in Chapter 4.4., the *subpopulation* is established by the application of documented health management practices and biosecurity measures to create and maintain a functional separation between horses within the defined *subpopulation* and all other equids at all times. The separation, at all times, of high health status horses from all other equids is essential to maintain their membership in the *subpopulation*.

EU position

The EU suggests mentioning the concept of compartmentalisation explicitly when referring to Chapter 4.4. in the paragraph above, so as to make the link with that concept clearer, as follows:

“In line with the provisions on compartmentalisation in Chapter 4.4., [...]”.

Horses that are moved internationally for the purpose of breeding or any other purpose not linked to competitions are not included in this *subpopulation*.

EU position

With reference to its previous comment, the EU is of the opinion that the sentence above regarding breeding is drafted in an unacceptably vague way. Rather than stating which horses are not included in this subpopulation, it should be clarified unequivocally in this point that breeding is not permitted for horses temporarily moved internationally for competition purposes under this scheme.

The following alternative wording is suggested to replace the sentence above:

“Horses that are moved internationally for the purpose of breeding or any other purpose not linked to competitions are not included in this subpopulation. To be certified into the subpopulation and to remain member of that subpopulation, horses are excluded from any reproduction activity and from any competitions not included in the definition of the high health subpopulation”.

Indeed, the exclusion of any breeding activity during the time of membership in the subpopulation reduces the list of diseases of concern, and the limitation to equestrian competitions, including racing, reduces the number of events and ties the movement of those horses to the biosecurity guidelines referred in Article 4.X.3.

Alternatively, the paragraph above could be retained as proposed by the OIE and the new sentence suggested by the EU could be included in Article 4.X.2. to become one of the criteria for inclusion of a horse in the subpopulation.

Article 4.X.2.

Criteria for the inclusion of horses in the high health status subpopulation

1. High health status

Each horse in the *subpopulation* is subjected to specific measures to establish and maintain protect its health status, and preserve minimise the probability of spreading diseases to that of the other horses in the subpopulation.

These measures comprise a specific set of *laboratory tests*, treatments and *vaccinations* appropriate to the disease status of the horse's region of origin, regions visited and the regions that it will visit. Records of all treatments and *vaccinations*, and results of tests and clinical inspections are documented in an individual passport that complies with Chapter 5.12.

EU position

The EU suggests the following alternative wording for the first sentence of the paragraph above:

“These measures comprise a specific set of laboratory tests, treatments and vaccinations appropriate to the disease status of the country or region of origin and temporary import of the horse ~~horse's region of origin, regions visited and the regions that it will visit.~~”

Indeed, while it is important to take account of diseases of regional importance, for certain diseases the region is of lesser importance than the country. Furthermore, the movement is already described in the first paragraph of Article 4.x.1., which clearly states that there is a country of usual residence from where the horse departs and that any other country can only admit the horse for a limited period of time, and that the horse eventually returns to the country of usual residence, unless it is on its way outside the subpopulation permanently imported according to national rules, preferably based on OIE requirements.

2. Identification and traceability

Consistent with the provisions of Chapters 4.1. and 4.2., horses in the *subpopulation* are individually identified as follows:

- a) Each horse bears an permanent unique identifier individual identification, preferably a microchip.
- b) Each horse is accompanied at all times by its individual passport that contains information on the horse's unique identifier.
- c) Each horse has an attachment to its passport individual document that identifies it as a member of the high health status *subpopulation* and refers to the passport and the identifier.
- d) Horses are registered in an international database that contains relevant information linked to the passport and the identifier. *Veterinary Authorities* should have access to this database.

EU position

The wording of point d) above could give rise to misunderstandings. Indeed, the EU is of the opinion that access by the Veterinary Authorities to the international database is a prerequisite for the good functioning of the HHS concept, which is not properly reflected by the wording “should have access”. Therefore, the EU suggests amending point d) as follows:

“Horses are registered in an international database ~~that contains relevant information linked to the passport and the identifier, to which~~ Veterinary Authorities should have access ~~to this database.~~”

3. Management of the subpopulation

- a) In the course of each veterinary examination of a horse, its passport is checked, its identity verified and the details of any all official tests and treatments, including *vaccinations*, are recorded and signed by the examining *veterinarian*.

For certification purposes, the passport is examined, verified and signed by an official veterinarian, in accordance with Article 5.2.2.

- b) The high health status of each horse in the *subpopulation* is maintained by ensuring compliance at all times with an *international* biosecurity plan approved by the Veterinary Authorities of the importing and exporting countries, in accordance with the relevant recommendations of the OIE. This compliance is assured and validated through continual veterinary supervision of horses at the *establishment* of usual residence, during transport and at competition venues. This supervision is provided by authorised *veterinarians*. Non-compliance results in suspension of the high health status of the horse.
- c) An appropriate qualification period is required for entry or re-entry of a horse into the *subpopulation*. The procedures for qualification should be described in the international biosecurity plan.
- d) A maximum period is set for each absence of a horse from its country of usual residence, as specified in the international biosecurity plan.

EU position

The EU is of the opinion that the newly added sentence in point a) above (“For certification purposes, [...] with Article 5.2.2.”) should be deleted, since the veterinary examination is already regulated in the first paragraph of that point a).

In addition, for consistency reasons, the following wording should be added under point d) as follows:

“A maximum period is set for each absence of a horse from its country or region of usual residence, as specified in the international biosecurity plan.”

Furthermore, a new point e) covering the certification should be added as follows:

“e) During their international movement, the horses are accompanied by a dedicated health certificate, on which the official veterinarian confirms the membership of the horse in the subpopulation and certifies compliance with the conditions set out in that certificate in accordance with the principles provided for in Article 5.2.2.”

Indeed, the passport is not a substitute for an animal health certificate, which must accompany the horse during its international movement.

Article 4.X.3.

Recommendations for the Veterinary Authorities

Veterinary Authorities are encouraged to officially recognise Organisations that will be are responsible for ensuring compliance with this chapter should be approved and supervised by the Veterinary Authorities. *Veterinary Authorities* are also encouraged to develop specific protocols for the temporary importation of horses of high health status entering the country solely for the purpose of competition at equestrian events and for their return to their country of origin.

EU position

The EU suggests amending the second sentence of the paragraph above as follows:

“*Veterinary Authorities* are also encouraged to develop specific protocols for the temporary importation of horses of high health status entering the country solely for the purpose of competition at equestrian events carried out in accordance with this Chapter and for their onward movement to other HHS equestrian competitions or return to their country of origin.”

Indeed, the option of onward movement is already described in Article 4.x.1. Furthermore, it is important that these horses, in order to maintain their high health status, compete in venues which also have a high health status, which means that the participating horses are separated from the local equine population. This separation from the local equine population represents a security for the participants in the event as well as for the local equine population.

Veterinary Authorities are encouraged to recognise the international biosecurity plan guidelines developed by ~~the OIE in collaboration with~~ the International Equestrian Federation (FEI) and the International Federation of Horseracing Authorities (IFHA) on the basis of the relevant OIE guidelines. (Under study.)

EU position

The amendments to the paragraph above seem to indicate that the international biosecurity plan, which will to a large extent form the basis of this concept, will entirely be developed by the industry. The EU queries in what way and at what stage the OIE and the World Assembly will be consulted in the elaboration of this plan.

Furthermore, it is not clear what is meant by “relevant OIE guidelines”. Perhaps this should be “relevant OIE biosecurity guidelines”, as referred to in the *ad hoc* group report.

— Text deleted.

CHAPTER 12.8.

INFECTION WITH EQUID HERPESVIRUS TYPE 1
(EQUINE RHINOPNEUMONITIS)**EU position**

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

However, the chapter seems in need of a more thorough review. In general, the EU would favour an in depth review of disease specific chapters that have not been amended for some time, in line with the prioritised work programme of the Code Commission, instead of making small *ad hoc* revisions as a follow-up to certain changes elsewhere in the Code.

Article 12.8.1.

General provisions

Equine rhinopneumonitis (ER) is a collective term for any one of several highly contagious, clinical disease entities of equids that may occur as a result of *infection* by either of two closely related herpesviruses, equid herpesvirus-1 and -4 (EHV-1 and EHV-4).

EU comment

For reasons of consistency, the EU suggests removing the hyphen from the name of the pathogen in the paragraph above, to read as follows:

“equid herpesvirus 1”.

Infection by either EHV-1 or EHV-4 is characterised by a primary respiratory tract disease of varying severity that is related to the age and immunological status of the infected animal. Infections by EHV-1 in particular are capable of progression beyond the respiratory mucosa to cause the more serious disease manifestations of abortion, perinatal foal death, or neurological dysfunction.

EU comments

Furthermore, for consistency with the title, the EU suggests replacing the words “infection by” by “infection with” in the paragraph above and throughout the whole chapter.

Finally, as the chapter is now reduced to infection with EHV-1, the paragraph above should reflect the fact that only a single causative virus is considered. Therefore, the EU suggests the following alternative wording to the second sentence:

“*Infections by with EHV-1 in particular are is* capable of progression beyond the respiratory mucosa to cause the more serious disease manifestations of abortion, perinatal foal death, or neurological dysfunction”.

For the purpose of *international trade*, recommendations are provided for EHV-1 (abortigenic and paralytic forms) only.

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

Article 12.8.2.

Recommendations for the importation of equines ~~equids~~

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

- 1) showed no clinical sign of EHV-1 equine herpes virus type 1 infection (~~abortigenic and paralytic forms~~) on the day of shipment and during the 21 days prior to shipment;
- 2) were kept for the 21 days prior to shipment in an *establishment* where no case of EHV-1 equine herpes virus type 1 infection (~~abortigenic and paralytic forms~~), was reported during that period.

— Text deleted.

CHAPTER 12.9.

INFECTION WITH EQUINE ARTERITIS VIRUS

EU position**The EU 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 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 equine arteritis virus EAV in the absence of clinical signs. For the purposes of this chapter, isolation is defined as the separation of domestic equids from those of a different EVA health status, utilising appropriate biosecurity measures, with the objective of preventing the transmission of *infection*.

The *infective period* for EVA shall be 28 days for all categories of equids except sexually mature stallions where the *infective period* may be for the life of the *animal*. Because the *infective period* may be extended in the case of virus shedding in semen, the status of seropositive stallions should be checked to ensure that they do not shed virus in their semen.

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

Article 12.9.2.

Recommendations for the importation of uncastrated male equids

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animals* showed no clinical sign of EVA on the day of shipment and during the 28 days prior to shipment and met one of the following requirements:

- 1) were isolated for the 28 days prior to shipment and were subjected to a test for EVA 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:

EITHER:

- a) with a negative result,

OR

- b) with a positive result, followed at least 14 days later by a second test showing a stable or decreasing antibody titre;

and were immediately vaccinated against EVA and regularly revaccinated according to the recommendations of the manufacturer; or

- 3) met the following requirements:

- a) were isolated; and

- b) not earlier than seven days of commencing isolation were subjected to a test for EVA on a blood sample with negative results; and
 - c) were then immediately vaccinated; and
 - d) were kept separated from other equids for 21 days following *vaccination*; and
 - e) were revaccinated regularly according to the recommendations of the manufacturer; or
- 4) have been subjected to a test for EVA carried out on a blood sample with positive results and then: either
- a) were subsequently test mated to two mares within six months prior to shipment which were subjected to two tests for EVA with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or
 - b) were subjected to a test for ~~EVA~~ ~~EAV~~ with negative results, carried out on semen collected during the six months prior to shipment; or
 - c) were subjected to a test for ~~EVA~~ ~~EAV~~ with negative results, carried out on semen collected within six months after the blood sample was tested, then immediately vaccinated, and revaccinated regularly in accordance with the recommendations of the manufacturer.

Article 12.9.3.

Recommendations for the importation of equids other than uncastrated males

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the *animals* showed no clinical sign of EVA on the day of shipment and

EITHER

- 1) were kept in an *establishment* where no *animals* have shown any signs of EVA for the 28 days prior to shipment; and
 - a) were subjected to a test for EVA carried out on blood samples collected either once within 21 days prior to shipment with negative result, or on two occasions at least 14 days apart within 28 days prior to shipment, which demonstrated stable or declining antibody titres; or
 - b) were regularly vaccinated according to the recommendations of the manufacturer;

OR

- 2) were isolated for the 28 days prior to shipment and during this period the *animals* showed no sign of EVA.

Article 12.9.4.

Recommendations for the importation of equine semen

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the donors were kept for the 28 days prior to semen collection in an *establishment* where no equid has shown any clinical sign of EVA during that period and showed no clinical sign of EVA on the day of semen collection; and

- 1) were subjected between six and nine months of age to a test for EVA:

Annex XXX (contd)

EITHER:

a) with a negative result,

OR

b) with a positive result, followed at least 14 days later by a second test showing a stable or decreasing antibody titre;

and were immediately vaccinated for EVA and regularly revaccinated according to the recommendations of the manufacturer; or

- 2) were isolated and not earlier than seven days of commencing isolation were subjected to a test for EVA on a blood sample with negative results, immediately vaccinated for EVA, kept for 21 days following *vaccination* separated from other equids and regularly revaccinated according to the recommendations of the manufacturer; or
- 3) were subjected to a test for EVA on a blood sample with negative results within 14 days prior to semen collection, and had been separated from other equids not of an equivalent EVA status for 14 days prior to blood sampling until the end of semen collection; or
- 4) have been subjected to a test for EVA 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 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 EVA ~~EAV~~ 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 EVA ~~EAV~~ with negative results, carried out on semen collected within six months after the blood sample was collected, then immediately vaccinated, and revaccinated regularly; or
- 5) for frozen semen, were subjected with negative results either:
 - a) to a test for EVA 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 EVA ~~EAV~~ carried out on an aliquot of the semen collected immediately prior to processing or on an aliquot of semen collected within 14 to 30 days after the first collection of the semen to be exported.

Article 12.9.5.

Recommendations for the importation of in vivo derived equine embryos

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the donor *animals* showed no clinical sign of EVA on the day of embryo collection; and

EITHER

- 1) were kept in an *establishment* where no *animals* have shown any signs of EVA for the 28 days prior to collection; and

Annex XXX (contd)

- a) were subjected to a test for EVA carried out on blood samples collected either once within 21 days prior to collection with negative result, or on two occasions at least 14 days apart within 28 days prior to collection, which demonstrated stable or declining antibody titres; or
- b) were regularly vaccinated according to the recommendations of the manufacturer;

OR

- 2) were isolated for the 28 days prior to collection and during this period the *animals* showed no sign of EVA_z;

AND

- 3) semen used to fertilise the oocytes complies with the requirements in Article 12.9.4.

— Text deleted.

UNOFFICIAL VERSION

CHAPTER 14.8.

**INFECTION WITH PESTE
DES PETITS RUMINANTS VIRUS**

EU position

The EU supports the adoption of this modified chapter.

Article 14.8.1.

General provisions

Peste des petits ruminants (PPR) susceptible *animals* are primarily domestic sheep and goats although cattle, camels, buffaloes and some wild ruminant species can also be infected and may act as sentinels indicating the spill over of peste des petits ruminants virus (PPRV) from domestic small ruminants. Even if some wild small ruminants can be infective, only domestic sheep and goats play a significant epidemiological role.

For the purpose of the *Terrestrial Code*, PPR is defined as an *infection* of domestic sheep and goats with PPRV.

This chapter deals not only with the occurrence of clinical signs caused by PPRV, but also with the presence of *infection* with PPRV in the absence of clinical signs.

The following defines the occurrence of PPRV *infection*:

- 1) PPRV, excluding vaccine strains, has been isolated and identified as such from a domestic sheep or goat or a product derived from it; or
- 2) viral antigen or viral ribonucleic acid (RNA) specific to PPRV, excluding vaccine strains, has been identified in samples from a domestic sheep or goat showing clinical signs consistent with PPR, or epidemiologically linked to an *outbreak* of PPR, or giving cause for suspicion of association or contact with PPR; or
- 3) antibodies to PPRV antigens which are not the consequence of *vaccination*, have been identified in a domestic sheep or goat with either epidemiological links to a confirmed or suspected *outbreak* of PPR or showing clinical signs consistent with recent *infection* of PPRV.

For the purposes of the *Terrestrial Code*, the *incubation period* for PPR shall be 21 days.

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

Article 14.8.2.

Safe commodities

When authorising import or transit through their territory of the following *commodities*, *Veterinary Authorities* should not require any PPR related conditions regardless of PPR status of the *exporting country* or *zone*: semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather, e.g. wet blue and crust leather), which have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 14.8.3.

PPR free country or zone

- 1) The PPR status of a country or zone ~~should can only~~ be determined ~~on the basis of after considering~~ the following criteria, as applicable:
- a) PPR ~~is should be~~ notifiable in the whole territory, and all clinical signs suggestive of PPR should be subjected to appropriate field or *laboratory* investigations;
 - b) an on-going awareness programme ~~is should be~~ in place to encourage reporting of all cases suggestive of PPR;
 - c) ~~systematic vaccination against PPR is prohibited; and~~
 - d) ~~importation of domestic ruminants and their semen, oocytes or embryos are is carried out in accordance with this chapter;~~
- ~~ede)~~ the *Veterinary Authority* ~~should have has~~ current knowledge of, and authority over, all domestic sheep and goats in the country or zone;
- ~~def)~~ 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 Articles 14.8.27. to 14.8.33.
- 2) To qualify for inclusion in the list of PPR free countries or zones, a Member Country should either:
- a) ~~declare~~ apply for recognition of historical freedom as described in point 1 of Article 1.4.6.; or
 - b) apply for recognition of freedom and submit to the OIE:
 - i) a record of regular and prompt animal *disease* reporting;
 - ii) a declaration stating that:
 - there has been no *outbreak* of PPR during the past 24 months;
 - no evidence of PPRV *infection* has been found during the past 24 months;
 - no *vaccination* against PPR has been carried out during the past 24 months;
 - importation of domestic ruminants and their semen, oocytes, or embryos is carried out in accordance with this chapter;
 - iii) supply documented evidence that *surveillance* in accordance with Chapter 1.4. is in operation and that regulatory measures for the prevention and control of PPR have been implemented;
 - iv) evidence that no *animals* vaccinated against PPR have been imported since the cessation of *vaccination*.

The Member Country will be included in the list only after the application and submitted evidence has been accepted by the OIE. Changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1. Retention on the list requires annual reconfirmation of point 2 above ~~that the information in points b)i) to b)iv) above be re-submitted annually.~~

Article 14.8.4.

PPR free compartment

A PPR free *compartment* can be established in either a PPR free country or *zone* or in an infected country or *infected zone*. In defining such a *compartment* the principles of Chapters 4.3. and 4.4. should be followed. Domestic sheep and goats in the PPR free *compartment* should be separated from any other susceptible *animals* by the application of an effective biosecurity management system.

A Member Country wishing to establish a PPR free *compartment* should:

- 1) have a record of regular and prompt animal *disease* reporting and if not PPR free, have an *official control programme* and a *surveillance* system for PPR in place according to Articles 14.8.27. to 14.8.33. that allows an accurate knowledge of the prevalence of PPR in the country or *zone*;
- 2) declare for the PPR free *compartment* that:
 - a) there has been no *outbreak* of PPR during the past 24 months;
 - b) no evidence of PPRV *infection* has been found during the past 24 months;
 - c) *vaccination* against PPR is prohibited;
 - d) no small ruminant in the *compartment* has been vaccinated against PPR within the past 24 months;
 - e) *animals*, semen and embryos should only enter the *compartment* in accordance with relevant articles in this chapter;
 - f) documented evidence shows that *surveillance* in accordance with Articles 14.8.27. to 14.8.33. is in place;
 - g) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;
- 3) describe in detail the animal subpopulation in the *compartment* and the biosecurity plan for PPRV *infection*.

The *compartment* should be approved by the *Veterinary Authority*.

Article 14.8.5.

Infected country or zone

A country or *zone* shall be considered as PPR infected when the requirements for acceptance as a PPR free country or *zone* are not fulfilled.

Article 14.8.6.

Establishment of a containment zone within a PPR free country or zone

In the event of limited *outbreaks* within a PPR free country or *zone*, including within a *protection zone*, a single *containment zone*, which includes all cases, can be established for the purpose of minimising the impact on the entire country or *zone*.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE that:

- 1) the *outbreaks* are limited based on the following factors:

- a) immediately on suspicion, a rapid response including *notification* has been made;
 - b) standstill of animal movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;
 - c) epidemiological investigation (trace-back, trace-forward) has been completed;
 - d) the *infection* has been confirmed;
 - e) the primary *outbreak* has been identified, and investigations on the likely source of the *outbreak* have been carried out;
 - f) all cases have been shown to be epidemiologically linked;
 - g) no new cases have been found in the *containment zone* with a minimum of two *incubation periods* as defined in Article 14.8.1. after the stamping-out of the last detected case is completed;
- 2) a *stamping-out policy* has been applied;
 - 3) the susceptible animal population within the *containment zones* is clearly identifiable as belonging to the *containment zone*;
 - 4) increased passive and targeted *surveillance* in accordance with Articles 14.8.27. to 14.8.33. in the rest of the country or *zone* has not detected any evidence of *infection*;
 - 5) animal health measures that effectively prevent the spread of the PPRV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place;
 - 6) ongoing *surveillance* is in place in the *containment zone*.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of these areas may be reinstated irrespective of the provisions of Article 14.8.7., once the *containment zone* is clearly established, by complying with points 1 to 6 above. It should be demonstrated that *commodities* for *international trade* have originated outside the *containment zone*.

The recovery of the PPR free status of the *containment zone* should follow the provisions of Article 14.8.7.

Article 14.8.7.

Recovery of free status

When a PPR *outbreak* or PPRV *infection* occurs in a PPR free country or *zone* and when a *stamping-out policy* is practised ~~with or without vaccination~~, the recovery period shall be six months after the *slaughter* of the last affected ~~animal~~ case provided that Article 14.8.32. has been complied with.

If a *stamping-out policy* is not applied, the provisions of Article 14.8.3. apply.

Article 14.8.8.

Recommendations for importation from PPR free countries or zones

For domestic sheep and goats

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

- 1) showed no clinical sign of PPR on the day of shipment;
- 2) were kept in a PPR free country or *zone* since birth or for at least the past 21 days.

Article 14.8.9.

Recommendations for importation from PPR free countries or zones

For wild ruminants

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

- 1) showed no clinical sign suggestive of PPRV *infection* on the day of shipment;
- 2) come from a PPR free country or *zone*;
- 3) if the country or *zone* of origin has a common border with a country considered infected with PPRV:
 - a) were captured at a distance from the border that precludes any contact with *animals* in an infected country, the distance should be defined according to the biology of the species exported, including home range and long distance movements;

OR

- b) were kept in a *quarantine station* for at least the 21 days prior to shipment.

Article 14.8.10.

Recommendations for importation from countries or zones considered infected with PPRV

For domestic sheep and goats

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

- 1) showed no clinical sign suggestive of PPRV *infection* for at least the 21 days prior to shipment;
- 2) either
 - a) were kept since birth, or for at least the 21 days prior to shipment, in an *establishment* where no case of PPR was reported during that period, and that the *establishment* was not situated in a PPRV *infected zone*; or
 - b) were kept in a *quarantine station* for at least the 21 days prior to shipment;
- 43) either
 - a) were not vaccinated against PPR and were submitted to a diagnostic test for PPRV *infection* with negative result no more than 21 days prior to shipment;

OR or

- b) were vaccinated against PPR with live attenuated PPRV vaccines at least 21 days prior to shipment.

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Article 14.8.11.

Recommendations for importation from countries or zones considered infected with PPRVFor wild ruminants

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

- 1) showed no clinical sign suggestive of PPRV *infection* for at least the 21 days prior to shipment;
- 2) were submitted to a diagnostic test for PPRV *infection* with negative results no more than 21 days prior to shipment;
- 3) were kept in a *quarantine station* for at least the 21 days prior to shipment.

Article 14.8.12.

Recommendations for importation from PPR free countries or zonesFor semen of domestic sheep and goats

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

- 1) showed no clinical sign of PPR on the day of the collection of the semen and during the following 21 days;
- 2) were kept in a PPR free country or *zone* for at least the 21 days prior to collection.

Article 14.8.13.

Recommendations for importation from countries considered infected with PPRVFor semen of domestic sheep and goats

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

- 1) showed no clinical sign suggestive of PPR for at least the 21 days prior to collection of the semen and during the following 21 days;
- 2) were kept, for at least the 21 days prior to collection, in an *establishment* or *artificial insemination centre* where no case of PPR was reported during that period, which was not situated in a PPRV *infected zone* and to which no *animals* had been added during the 21 days prior to collection;
- 3) were not vaccinated against PPR and were submitted to a diagnostic test for PPRV *infection* with negative results at least 21 days prior to collection of the semen;

OR

- 4) were vaccinated against PPR with live attenuated PPRV vaccines at least 21 days prior to semen collection.

Article 14.8.14.

Recommendations for importation from PPR free countries or zonesFor embryos of domestic sheep and goats and captive wild ruminants

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

- 1) the donor *animals* were kept in an *establishment* located in a PPR free country or zone at least 21 days prior to embryo collection;
- 2) the embryos were collected, processed and stored in conformity with the relevant provisions of Chapters 4.7., 4.8. and 4.9.
- 3) semen of domestic sheep and goats used to fertilise the oocytes complies at least with the requirements in Article 14.8.12. or Article 14.8.13.

Article 14.8.15.

Recommendations for importation from countries or zones considered infected with PPRVFor embryos of domestic sheep and goats

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

- 1) the donor *animals*:
 - a) and all other *animals* in the *establishment* showed no clinical sign suggestive of PPRV *infection* at the time of collection and during the following 21 days;
 - b) were kept, for at least the 21 days prior to collection, in an *establishment* where no *case* of PPR was reported during that period, and to which no susceptible *animals* had been added during the 21 days prior to collection;
 - c) were not vaccinated against PPR and were subjected to a diagnostic test for PPRV *infection* with negative results at least 21 days prior to collection;

OR

 - d) were vaccinated against PPR with live attenuated PPRV vaccines at least 21 days prior to embryo collection;
- 2) the embryos were collected, processed and stored in conformity with the relevant provisions of Chapters 4.7., 4.8. and 4.9.
- 3) semen of domestic sheep and goats used to fertilise the oocytes complies at least with the requirements in Article 14.8.12. or Article 14.8.13.

Article 14.8.16.

Recommendations for importation from countries or zones considered infected with PPRVFor embryos of captive wild ruminants

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

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- 1) the donor *animals*:
 - a) showed no clinical signs suggestive of *infection* with PPRV for at least the 21 days prior to embryo collection;
 - b) were not vaccinated against PPR and were subjected to a diagnostic test for PPRV *infection* with negative results at least 21 days prior to collection;
 - c) were kept, for at least the 21 days prior to collection, in an *establishment* where no *case* of PPR or of *infection* with PPRV was reported during that period, and to which no susceptible *animals* had been added during the 21 days prior to collection;
- 2) the embryos were collected, processed and stored in conformity with the relevant provisions of Chapters 4.7., 4.8. and 4.9.

Article 14.8.17.

Recommendation for importation of fresh meat and meat products from sheep and goats

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

- 1) showed no clinical signs of PPR within 24 hours before *slaughter*;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 14.8.18.

Recommendations for importation from PPR free countries or zonesFor milk and milk products from sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in a PPR free country or *zone* for at least the 21 days prior to milking.

Article 14.8.19.

Recommendations for importation from countries or zones considered infected with PPRVFor milk from sheep and goats

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

- 1) the *milk*:
 - a) originates from *herds* or *flocks* which were not subjected to any restrictions due to PPR at the time of *milk* collection;

OR

 - b) has been processed to ensure the destruction of the PPRV in conformity with one of the procedures referred to in Articles 8.6.38. and 8.6.39.;
- 2) the necessary precautions were taken to avoid contact of the products with any potential source of PPRV.

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Article 14.8.20.

Recommendations for importation from countries or zones considered infected with PPRVFor milk products from sheep and goats

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

- 1) these products are derived from *milk* complying with the requirements of Article 14.8.19.;
- 2) the necessary precautions were taken after processing to avoid contact of the *milk products* with any potential source of PPRV.

Article 14.8.21.

Recommendations for importation from PPR free countries or zonesFor products of sheep and goats, other than milk, fresh meat and their products

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

- 1) which have been kept in a PPR free country or *zone* since birth or for at least the past 21 days;
- 2) which have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 14.8.22.

Recommendations for importation from countries or zones considered infected with PPRVFor meal and flour from blood, meat, defatted bones, hooves, claws and horns from sheep and goats

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

- 1) the products were processed using heat treatment to a minimum internal temperature of 70°C for at least 30 minutes;
- 2) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of PPRV.

Article 14.8.23.

Recommendations for importation from countries or zones considered infected with PPRVFor hooves, claws, bones and horns, hunting trophies and preparations destined for museums from sheep and goats

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

- 1) the products were completely dried and had no trace on them of skin, flesh or tendon or were adequately disinfected; and
- 2) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of PPRV.

Annex XXXI (contd)

Article 14.8.24.

Recommendations for importation from countries or zones considered infected with PPRVFor wool, hair, raw hides and skins from sheep and goats

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

- 1) the products were adequately processed in conformity with one of the procedures referred to in Article 8.5.37. in premises controlled and approved by the *Veterinary Authority* of the *exporting country*;
- 2) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of PPRV.

Article 14.8.25.

Recommendations for importation from countries or zones considered infected with PPRVFor products of animal origin from sheep and goats intended for pharmaceutical or surgical use

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

- 1) come from *animals* which were slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results;
- 2) were processed to ensure the destruction of the PPRV in conformity with one of the procedures referred to in Article 8.6.29. or in Articles 8.6.34. to 8.6.37. as appropriate and in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.

Article 14.8.26.

Procedures for the inactivation of the PPRV in casings of sheep and goats

For the inactivation of ~~viruses present~~ PPRV in casings of sheep and goats, the following procedures should be used: treatment ~~sating~~ for at least 30 days either with dry salt (NaCl) or with saturated brine ($a_w < 0.80$), or with phosphate supplemented salt containing 86.5% percent NaCl, 10.7% percent Na_2HPO_4 and 2.8% percent Na_3PO_4 (weight/weight/weight), either dry or as a saturated brine ($a_w < 0.80$), and kept at a temperature of ~~greater than~~ 20°C or more during this entire period.

Article 14.8.27.

Introduction to surveillance: introduction

Articles 14.8.27. to 14.8.33. define the principles and provide a guide for the *surveillance* of PPR in accordance with Chapter 1.4. applicable to Member Countries seeking recognition of country or zonal freedom from PPR. Guidance is provided for Member Countries seeking reestablishment of freedom following an *outbreak* and for the maintenance of PPR free status.

Surveillance strategies employed for demonstrating freedom from PPR at an acceptable level of confidence will need to should be adapted to the local situation. *Outbreaks* of PPR may vary in severity with differing clinical presentations believed to reflect variations in host resistance and variations in the virulence of the attacking strain. Experience has shown that *surveillance* based on a predefined set of clinical signs (e.g. searching for 'pneumo-enteritis syndrome') increases the sensitivity of the system. In the case of peracute cases the presenting sign may be sudden death. In the case of sub-acute (mild) cases, clinical signs are displayed irregularly and are difficult to detect.

Where they exist, susceptible domestic species, and feral populations of these species, should be included in the design of the *surveillance* strategy.

Surveillance for PPR should be in the form of a continuing programme designed to establish that the whole country or *zone* is free from PPRV *infection*.

Article 14.8.28.

General conditions and methods for surveillance: general conditions and methods

- 1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples from suspected cases to a *laboratory* for PPR diagnosis.
- 2) The PPR *surveillance* programme should:
 - a) include an early warning system throughout the production, marketing and processing chain for reporting suspected cases. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of PPR. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All significant epidemiological events consistent with PPR, such as pneumo-enteritis syndrome, should be reported and investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment be available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in PPR diagnosis and control;
 - b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of *animals*, such as those adjacent to a PPRV infected country.

An effective *surveillance* system will periodically identify *animals* with signs suggestive of PPR that require follow-up and investigation to confirm or exclude that the cause of the condition is PPRV. The rate at which such suspected cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from PPRV *infection* should, in consequence, provide details of the occurrence of suspected cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 14.8.29.

Surveillance strategies

1. Clinical surveillance

Clinical *surveillance* aims to detect clinical signs of PPR by close physical examination. Clinical *surveillance* and epidemiological investigations are the cornerstone of all *surveillance* systems and should be supported by additional strategies such as virological and serological *surveillance*. Clinical *surveillance* may be able to provide a high level of confidence of detection of *disease* if sufficiently large numbers of clinically susceptible *animals* are examined. It is essential that clinical cases detected be followed up by the collection of appropriate samples such as ocular and nasal swabs, blood or other tissues for virus isolation or virus detection by other means. Sampling units within which suspicious *animals* are detected should be classified as infected until fully investigated.

Active search for clinical *disease* can include participatory *disease* searching, tracing backwards and forwards, and follow-up investigations. Participatory *surveillance* is a form of targeted active *surveillance* based upon methods to capture livestock owners' perceptions on the prevalence and patterns of *disease*.

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The labour requirements and the logistical difficulties involved in conducting clinical examinations should be taken into account.

PPRV isolates may be sent to an OIE Reference Laboratory for further characterisation.

2. Virological surveillance

Given that PPR is an acute *infection* with no known carrier state, virological *surveillance* should only be conducted as a follow-up to clinically suspected cases.

3. Serological surveillance

Serological *surveillance* aims to detect antibodies against PPRV. Positive antibody test results can have four possible causes:

- a) natural *infection* with PPRV;
- b) *vaccination* against PPR;
- c) maternal antibodies derived from an immune dam (maternal antibodies in small ruminants can be found only up to six months of age);
- d) heterophile (cross) and other non-specific reactions.

It may be possible to use serum collected for other survey purposes for PPR *surveillance*. However, the principles of survey design described in this chapter and the requirement for a statistically valid survey for the presence of PPRV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain *infection*. As clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the survey design.

The results of random or targeted serological surveys are important in providing reliable evidence that PPRV *infection* is not present in a country or *zone*. It is therefore essential that the survey be adequately documented.

Article 14.8.30.

Surveillance in wildlife

Where a population of a susceptible *wildlife* species may act as sentinels indicating the spill over of PPRV from domestic sheep and goats, serosurveillance data should be collected.

Obtaining meaningful data from *surveillance* in *wildlife* can be enhanced by close coordination of activities in a region. Both purposive and opportunistic samplings are used to obtain material for analysis in national or reference *laboratories*. The latter are required because many countries do not have adequate facilities to perform the full testing protocol for detecting antibodies against PPRV in *wildlife* sera.

Targeted sampling is the preferred method to provide *wildlife* data to evaluate the status of *infection* with PPRV. In reality, the capacity to perform *wildlife* sampling is minimal in most countries. However, samples can be obtained from hunted *animals*, and these may provide useful background information.

Article 14.8.31.

Additional surveillance requirements procedures for Member Countries applying for OIE recognition of PPR free status

The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances in and around the country or *zone* and should be planned and implemented according to the conditions for status recognition described in Article 14.8.3. and methods in this chapter, to demonstrate absence of PPRV *infection* during the preceding 24 months. This requires the support of a *laboratory* able to undertake identification of PPRV *infection* through virus, antigen or viral nucleic acid detection and antibody tests.

The target population for *surveillance* aimed at identifying *disease* and *infection* should cover significant populations within the country or *zone* to be recognised as free from PPRV *infection*.

The strategy employed should be based on an appropriate combination of randomised and targeted sampling requiring *surveillance* consistent with demonstrating the absence of PPRV *infection* at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Risk-based approaches (e.g. based on the increased likelihood of *infection* in particular localities or species) may be appropriate to refine the *surveillance* strategy. The Member Country should justify the *surveillance* strategy chosen as adequate to detect the presence of PPRV *infection* in accordance with Chapter 1.4. and the epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular subpopulations likely to exhibit clear clinical signs.

Consideration should be given to the risk factors for the presence of PPRV, including:

- 1) historical *disease* patterns;
- 2) critical population size, structure and density;
- 3) livestock husbandry and farming systems;
- 4) movement and contact patterns, such as market and other trade-related movements;
- 5) virulence and infectivity of the strain.

The sample size selected for testing ~~will need to~~ **should** be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and predetermined minimum *disease* prevalence determine the level of confidence in the results of the survey. The applicant Member Country should justify the choice of design, minimum prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the minimum prevalence in particular should be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained.

Irrespective of the testing system employed, *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There ~~needs to~~ **should** be an effective procedure for following-up positives to subsequently determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *herds* or *flocks* which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease* or *infection* are technically well defined in Chapter 1.4. The design of *surveillance* programmes to demonstrate the absence of PPRV *infection* ~~needs to~~ **should** be carefully followed to ensure the reliability of results. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

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Article 14.8.32.

Additional surveillance requirements procedures for recovery of free status

Following an *outbreak* of PPR in a Member Country at any time after recognition of PPR freedom, the origin of the virus strain should be thoroughly investigated. In particular it is important to determine if this is due to the re-introduction of virus or re-emergence from an undetected focus of *infection*. Ideally, the virus should be isolated and compared with historical strains from the same area as well as those representatives of other possible sources.

After elimination of the *outbreak*, a Member Country wishing to regain the free status should undertake *surveillance* according to this chapter to demonstrate the absence of PPRV *infection*.

Article 14.8.33.

The use and interpretation of serological tests for serosurveillance of PPR

Serological testing is an appropriate tool to use for PPR *surveillance* where *vaccination* has not been practised. There is only one serotype of virus and the tests will detect antibodies elicited by *infection* with all PPRV but the tests cannot discriminate between antibodies against field *infection* and those from *vaccination* with attenuated vaccines. This fact compromises serosurveillance in vaccinated populations and meaningful serosurveillance can only commence once *vaccination* has ceased for several years. Antibodies against virulent and vaccine strains of PPRV can be detected in small ruminants from about 14 days post *infection* or *vaccination* and peak around 30 to 40 days. Antibodies then persist for many years, possibly for life, although titres decline with time.

It is necessary to demonstrate that positive serological results have been adequately investigated.

Article 14.8.34.

OIE endorsed official control programme for PPR

The objective of an OIE endorsed *official control programme* for PPR is for Member Countries to progressively improve the situation in their territories and eventually attain free status for PPR.

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for PPR when they have implemented measures in accordance with this article.

For a Member Country's *official control programme* for PPR to be endorsed by the OIE, the Member Country should:

- 1) submit documented evidence on the capacity of its *Veterinary Services* to control PPR; this evidence can be provided by countries following the OIE PVS Pathway;
- 2) submit documentation indicating that the *official control programme* for PPR is applicable to the entire territory (even if it is on a zonal basis);
- 3) have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;
- 4) submit a dossier on the status of PPR in the country describing the following:
 - a) the general epidemiology of PPR in the country highlighting the current knowledge and gaps;
 - b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all PPR *outbreaks* in order to reduce the incidence of *outbreaks* and to eliminate virus circulation in domestic sheep and goats in at least one *zone* in the country;

- c) the main livestock production systems and movement patterns of sheep and goats and their products within and into the country and, where applicable, the specific *zone(s)*;
- 5) submit a detailed plan of the programme to control and eventually eradicate PPR in the country or *zone* including:
 - a) the timeline for the programme;
 - b) the performance indicators that will be used to assess the efficacy of the control measures;
 - 6) submit evidence that PPR *surveillance* is in place, taking into account the provisions in Chapter 1.4. and the provisions on *surveillance* in this chapter;
 - 7) have diagnostic capability and procedures in place, including regular submission of samples to a *laboratory*;
 - 8) where *vaccination* is practised as a part of the *official control programme* for PPR, provide evidence (such as copies of legislation) that *vaccination* of sheep and goats in the country or *zone* is compulsory;
 - 9) if applicable, provide detailed information on *vaccination* campaigns, in particular on:
 - a) the strategy that is adopted for the *vaccination* campaign;
 - b) monitoring of *vaccination* coverage, including serological monitoring of population immunity;
 - c) serosurveillance in other susceptible species, including *wildlife* to serve as sentinels for PPRV circulation in the country;
 - d) *disease surveillance* in sheep and goat populations;
 - e) the proposed timeline for the transition to the cessation of the use of *vaccination* in order to enable demonstration of absence of virus circulation;
 - 10) provide an emergency preparedness and contingency response plan to be implemented in case of PPR *outbreak(s)*.

The Member Country's *official control programme* for PPR will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

The OIE may withdraw the endorsement of the *official control programme* if there is evidence of:

- non-compliance with the timelines or performance indicators of the programme; or
- significant problems with the performance of the *Veterinary Services*; or
- an increase in the incidence of PPR that cannot be addressed by the programme.

— Text deleted.

CHAPTER 6.5.

PREVENTION, DETECTION AND CONTROL OF
SALMONELLA IN POULTRY**EU position**

The EU in general supports the adoption of this modified chapter. Some comments are inserted in the text below for consideration by the Code Commission at its next meeting.

Article 6.5.1.

Introduction

This chapter provides recommendations on the prevention, detection and control of *Salmonella* in *poultry*.

Salmonellosis is one of the most common foodborne bacterial *diseases* in the world. The great majority of *Salmonella* infections in humans are foodborne with *Salmonella* Enteritidis and *Salmonella* Typhimurium accounting for a major part of the problem. *Salmonella* serotypes and prevalence may vary considerably between localities, districts, regions and countries and therefore, *surveillance* and identification of the prevalent *Salmonella* serotypes in humans and *poultry* should be carried out in order to develop a control programme for the area.

In most food animal species, *Salmonella* can establish a clinically inapparent *infection* of variable duration, which is significant as a potential *zoonosis*. Such *animals* may be important in relation to the spread of *infection* between *flocks* and as causes of human foodborne *infection*. In the latter case, this can occur when *meat* and eggs, or their products, enter the food chain thus producing contaminated food.

Article 6.5.2.

Purpose and scope

This chapter deals with methods for on farm prevention, detection and control of *Salmonella* in *poultry*, and complements 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). A pathogen reduction strategy at the farm level is seen as the first step in a continuum that will assist in reducing the presence of foodborne pathogens in eggs and *meat*.

Hygiene and biosecurity procedures to be implemented in *poultry* farms and hatcheries are described in Chapter 6.4. on Biosecurity Procedures in Poultry Production.

The recommendations presented in this chapter are relevant to the control of all *Salmonella* with special attention to *S. Enteritidis* and *S. Typhimurium*, as these are common *Salmonella* serotypes in many countries. It should be noted that the epidemiology of animal and human salmonellosis in a particular locality, district, region or country is important for effective control of *Salmonella*.

Article 6.5.3.

Definitions

Breeders: means *poultry* destined for the production of fertile eggs for incubation for the purpose of producing *day-old birds*.

Competitive exclusion: means the administration of defined or undefined bacterial flora to *poultry* to prevent gut colonisation by enteropathogens, including *Salmonella*.

Culling: means the destruction or *slaughter* of a *flock* before the end of its normal period.

Layers: means *poultry* during the period of laying eggs for human consumption.

Article 6.5.4.

Surveillance of poultry flocks for *Salmonella*

Where justified by *risk assessment*, *surveillance* should be carried out to identify infected *flocks* in order to take measures that will reduce the prevalence in *poultry* and the risk of transmission of *Salmonella* to humans. Sampling methods, frequency and type of samples required should be determined by the *Veterinary Services* based on a *risk assessment*. Microbiological testing is preferred to serological testing because of its higher sensitivity in broiler *flocks* and higher specificity in breeder and layer *flocks*. In the framework of regulatory programmes for the control of *Salmonella* in *poultry* and salmonellosis in humans, confirmatory testing may be required to exclude false positive or negative results.

1. Available methods for sampling

Drag swabs: sampling is done by dragging swabs throughout the *poultry* house.

Boot swabs: sampling is done by walking throughout the *poultry* house with absorbent material placed over the footwear of the sampler.

Dust samples: sampling is done by collecting dust from exhaust fans, screens and other equipment in the *poultry* house.

Faecal samples: multiple fresh faecal/caecal samples collected from different areas in the *poultry* house.

Meconium, chick box liners, dead in shell and culled *day-old birds* at the hatchery.

Hatchery samples: throughout the hatchery, including inside the incubators.

2. Sample size

Refer to the *Terrestrial Manual* (under development).

3. Laboratory methods

Refer to the *Terrestrial Manual* (under development).

4. Time and frequency of testing

Time and frequency of sampling for each *poultry* type are listed below:

a) Breeders and hatcheries

i) Breeder flocks before lay

- Before the end of the first week of life when the status of the breeder *flock* or the hatchery is not known or does not comply with this chapter.
- Within the four weeks before being moved to another house, or before going into production if the birds will remain in the same house for the production period.
- One or more times during the growing period if there is a culling policy in place. The frequency would be determined on commercial considerations.

ii) Breeder flocks in lay

- At least at monthly intervals during the laying period.
- Additional testing should be determined by the *Veterinary Services*.

- iii) Hatcheries
 - Testing at hatcheries should complement on farm testing.
 - The minimal frequency should be determined by the *Veterinary Services*.
- b) Poultry for the production of eggs for human consumption
 - i) Flocks grown to be layers
 - Before the end of the first week of life when the status of the breeder *flock* or the hatchery is not known or does not comply with this chapter.
 - Within the four weeks before being moved to another house, or before going into production if the birds will remain in the same house for the production period.
 - One or more times during the growing period if there is a culling policy in place. The frequency would be determined by commercial considerations.
 - ii) Layer flocks
 - At expected peak of lay for each production cycle (the period of time in the laying cycle when the production of the *flock* is highest).
 - One or more times if there is a culling policy in place or if eggs are diverted to processing for the inactivation of the pathogen. The minimal frequency should be determined by the *Veterinary Services*.
- c) Poultry for the production of meat
 - i) *Flocks* should be sampled at least once.
 - ii) When sampling occurs on farms and when there is a long period (two weeks or more) between thinning and final depopulation, further testing should be considered.
 - iii) When sampling occurs on farms, *flocks* should be sampled as late as possible before the first birds are transported to the *slaughterhouse*. In order to allow for the implementation of control measures during processing, this should be done at a time that ensures the results are available before *slaughter*.

Whether sampling occurs on the farm which is more appropriate for consequent control measures or at the processing plant, there should be an integrated system in place which allows for investigation of the source of positive *flocks*.

d) Testing of empty poultry houses

Bacteriological monitoring of the efficacy of *disinfection* procedures is recommended when *Salmonella* have been detected in the previous *flock*.

As appropriate, sampling of equipment and surfaces as well as boot swabs or drag swabs of the empty *poultry* house after depopulation, cleaning and *disinfection*.

Results from *surveillance* may lead to the implementation of additional prevention and control measures to reduce the risk of transmission of *Salmonella* to humans:

- 1) In breeders, control measures may be implemented to reduce the transmission of *Salmonella* to the next generation, especially for trans-ovarian transmitted serotypes such as *S. Enteritidis*.
- 2) In layer *flocks*, control measures will reduce and may eliminate contamination of eggs with *Salmonella*.

- 3) In *poultry* for *meat* production, control measures may be implemented at *slaughter* or further down the food chain.

Article 6.5.5.

Prevention and control measures

Salmonella prevention and control may be achieved by adopting Good Agricultural Practices and Hazard Analysis Critical Control Point (HACCP), and general measures detailed in Chapter 6.4. on Biosecurity Procedures in Poultry Production, in combination with the following additional measures, where appropriate. No single measure used alone will achieve effective *Salmonella* control.

Additional prevention and control measures include *vaccination*, competitive exclusion, use of organic acids, culling and product diversion to processing.

Antimicrobial agents should not be used to control *infection* with *Salmonella* in *poultry* because the effectiveness of the treatment is limited, may mask the *infection* at sampling, has the potential to produce residues in *meat* and eggs and can contribute to the development of antimicrobial resistance. *Antimicrobial agents* may also reduce normal flora in the gut and increase the likelihood of colonisation with *Salmonella*. In special circumstances *antimicrobial agents* may be used to salvage birds with high genetic value.

- 1) *Day-old birds* used to stock a *poultry* house should be obtained from breeder *flocks* and hatcheries that have been monitored according to this chapter and in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected.
- 2) Layer and breeder *flocks* should be stocked from *flocks* that have been monitored according to this chapter and in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected.
- 3) Feed contamination with *Salmonella* is known to be a source of *infection* for *poultry*. Therefore, it is recommended to monitor the *Salmonella* status of *poultry* feed, and if found positive to take corrective measures. Heat treated feeds with or without the addition of other bactericidal or bacteriostatic treatments, e.g. organic acids, are recommended. Where heat treatment is not possible, the use of bacteriostatic or bactericidal treatments is recommended. Feed should be stored in clean closed containers to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents.

EU comment

From practical experience in certain countries, it is essential to handle and store heat treated feed so as to prevent recontamination e.g. via non-treated feed. This should explicitly be stated in point 3 above, by adding the following sentence:

“Treated feed should be handled and stored in such a way as to avoid recontamination, e.g. via untreated feed”.

- 4) Competitive exclusion may be used in *day-old birds* to reduce colonisation by *Salmonella*.

When used, competitive exclusion should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the *Veterinary Services*.

- 5) Vaccines are used against *Salmonella* infections caused by different serotypes in various *poultry* species, including single or combined vaccines. Vaccines produced according to the *Terrestrial Manual* should be used.

If live vaccines are used, it is important that field and vaccine strains be easily differentiated in the laboratory. If serology is used as the *surveillance* method, it may not be possible to distinguish between *vaccination* and *infection* with a field strain.

Vaccination can be used as part of an overall *Salmonella* control programme. It is recommended that *vaccination* not be used as the sole control measure.

When the status of the breeder *flock* or the hatchery from which the *flock* originates is not known or does not comply with this chapter, *vaccination* of *flocks*, starting with *day-old birds*, against the *Salmonella* serotypes known to be significant should be considered.

Vaccination against the *Salmonella* serotypes known to be significant should be considered when moving *day-old birds* to a previously contaminated shed so as to minimise the risk of the birds contracting *Salmonella* infection.

When used, vaccines should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the *Veterinary Services*.

Vaccination against *S. Enteritidis* can cause cross-reactions in *Salmonella* Pullorum/*S. Gallinarum* serological tests and needs to be considered when implementing measures for these pathogens.

- 6) Depending on animal health, *risk assessment*, and public health policies, culling is an option to manage infected breeder and layer *flocks*. Infected *flocks* should be destroyed or slaughtered and processed to minimise human exposure to *Salmonella*.

If culling is not applied, eggs for human consumption should be diverted for processing for inactivation of *Salmonella*.

- 7) *S. Enteritidis* is characterised by its ovarian transmission pattern. Countries should set targets for eradicating (or significantly reducing) *S. Enteritidis* from egg-producing *flocks* through a guided policy for eradication from the top of the production pyramid, i.e. from grandparent *flocks* through breeder *flocks* to layer *flocks*.
- 8) The responsible *veterinarian* should evaluate the results of *surveillance* testing for *Salmonella* and supervise the implementation of appropriate control measures. These results should be available to the *veterinarian* before marketing if a veterinary certificate for *flock Salmonella* status is required. When required by the *Competent Authority*, the *veterinarian* or other person responsible for notification should notify the *Competent Authority* if the presence of *Salmonella* of the relevant serotype is confirmed.

Article 6.5.6.

Prevention of *Salmonella* spread from infected flocks

If a *flock* is found infected with specific *Salmonella* serotypes of concern, the following actions should be taken in addition to general measures detailed in Chapter 6.4. on Biosecurity Procedures in Poultry Production:

- 1) According to the epidemiological situation, investigations should be carried out to determine the origin of the *infection*.
- 2) Movement of *poultry flocks* at the end of the production cycle should only be allowed for *slaughter* or destruction.

Special precautions should be taken in the transport, *slaughter* and processing of the birds, e.g. they could be sent to a separate *slaughterhouse* or processed at the end of a shift before cleaning and *disinfection* of the equipment.

- 3) Litter should not be reused as such. Used *poultry* litter, carcasses and other potentially contaminated farm waste should be disposed of in a safe manner to prevent the direct or indirect exposure of humans, livestock and *wildlife* to *Salmonella*. Particular care needs to be taken when utilising used *poultry* litter to fertilise plants intended for human consumption. If litter is not removed, it should be treated in a manner to inactivate infectious agents, to prevent the spread from one *flock* to the next.
- 4) Particular care should be taken in cleaning and *disinfection* of the *poultry* house and equipment.
- 5) Before restocking the facility, a bacteriological examination should be carried out as detailed in this chapter and the *Terrestrial Manual*.

Article 6.5.7.

Recommendations for ~~introduction importation~~ of live poultry (other than day-old birds)

~~Introduced live poultry (other than day-old birds) should. Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:~~

- 1) ~~the poultry~~ originated ~~ed~~ from a flock that participates in a *Salmonella* surveillance programme in accordance with the recommendations in Article 6.5.4.;
- 2) ~~the poultry~~ originated ~~ed~~ from a flock in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected prior to ~~movement shipment~~ and have had no contact with birds or other material from flocks that do not comply with this chapter;
- 3) ~~the poultry~~ originated ~~ed~~ from a flock that complies with the recommendations ~~in of~~ Chapter 6.4.

Article 6.5.8.

Recommendations for ~~introduction importation~~ of day-old birds

~~Introduced day-old birds should. Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:~~

- 1) ~~the day-old birds~~ showed ~~ed~~ no clinical signs ~~of salmonellosis on the day of movement shipment;~~
- 2) ~~the day-old birds~~ originated ~~ed~~ from a breeder flock and a hatchery that participate in a *Salmonella* surveillance programme in accordance with the recommendations in Article 6.5.4.;
- 3) ~~the day-old birds~~ originated ~~ed~~ from a breeder flock and a hatchery in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected and have had no contact during setting, incubation or hatching with *hatching eggs* or other material from *establishments* that do not comply with this chapter;
- 4) ~~the day-old birds~~ originated ~~ed~~ from a breeder flock and a hatchery that comply with the recommendations ~~in of~~ Chapter 6.4.;
- 5) ~~the day-old birds were shipped~~ ~~be transported~~ in new and clean *containers*.

EU comment

As the article above has been aligned with the purpose and scope of the chapter and only concerns introduction of day-old birds within a given country, the systems in place in certain countries whereby containers may be re-used if properly cleaned, which provide appropriate safety at national level while being more cost effective, should be taken into account. Thus, the EU suggests amending point 5) above as follows:

“5) be transported in new and or clean *containers*”.

Article 6.5.9.

Recommendations for ~~introduction importation~~ of hatching eggs

~~Introduced hatching eggs should. Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:~~

- 1) ~~the hatching eggs~~ originated ~~ed~~ from a breeder flock that participates in a *Salmonella* surveillance programme in accordance with the recommendations in Article 6.5.4.;

- 2) ~~the hatching eggs~~ originated from a breeder *flock* in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected and have had no contact with *poultry* or other material from *establishments* that do not comply with this chapter;
- 3) ~~the hatching eggs~~ originated from a breeder *flock* that complies with the recommendations in of Chapter 6.4.;
- 4) ~~the hatching eggs were shipped~~ be transported in new and clean packaging materials.

— Text deleted

CHAPTER 4.13.

**GENERAL RECOMMENDATIONS ON DISINFECTION
AND ~~DISINSECTISATION~~ DISINSECTION**

EU position

The EU supports the adoption of this modified chapter.

Article 4.13.1.

General provisions

Veterinary Authorities are requested to draw up regulations in their respective countries concerning the use of disinfectants and insecticides on the basis of the principles described below:

- 1) The choice of disinfectants and of procedures for *disinfection* should be made taking into account the causal agents of *infection* and the nature of the premises, *vehicles* and objects which are to be treated.
- 2) Disinfectants and insecticides should be authorised only after thorough tests have been carried out under field condition.
- 3) The following should be considered:
 - a) few universal disinfectants exist;
 - b) whereas hypochlorite, which is very often used, may be regarded as a universal disinfectant, its effectiveness is diminished by prolonged storage and it is therefore necessary to check its activity before use; a concentration of 0.5 percent active chlorine appears necessary for satisfactory *disinfection*;
 - c) no matter what substances are used, *disinfection* techniques should comprise the following:
 - i) thorough soaking of bedding and litter as well as faecal matter with the disinfectant;
 - ii) washing and cleaning by careful brushing and scrubbing of the ground, floors and walls;
 - iii) then further washing with the disinfectant;
 - iv) washing and disinfecting the outside of *vehicles*; these procedures will be carried out, if possible, with liquids applied under pressure and the washing, disinfecting or destroying of articles used for tying up the *animals* (ropes, reins, etc.) should not be omitted.

Article 4.13.2.

Pathogen-specific disinfection

- 1) Foot and mouth disease virus is easily destroyed by a high or low pH but the disinfectants used may be caustic or corrosive in concentrated form.
- 2) Mycobacteria are very resistant to disinfectants and a high concentration is required to destroy the organisms, as well as prolonged action.
- 3) *Bacillus anthracis*

- a) In situations in which manure, dung or bedding may be contaminated with *Bacillus anthracis* (*B. anthracis*) spores, the following are recommended:
- i) small volumes by incineration; or
 - ii) chemothermal treatment by composting as follows:
 - mix with one of the following at a rate of 1–1.5 litre/m³;
 - 10 percent formaldehyde (approximately 30 percent formalin), or
 - 4 percent glutaraldehyde (pH 8.0–8.5);
 - turn the material after five weeks;
 - leave for a further five weeks.

[Note: Spontaneous combustion of the composting pile is possible. Also note: Formalin is a dangerous chemical and as such the appropriate personal protective equipment should be used and safety training on the handling of this chemical should be provided.]

- b) In situations in which liquid manure (slurry) may be contaminated with *B. anthracis* spores, *disinfection* with formalin (35 percent aqueous solution of formaldehyde) with stirring for one hour daily is recommended:
- i) for slurry up to 5 percent dry matter, 50 kg formalin per m³ for 4 days;
 - ii) for slurry >5 percent and <10 percent dry matter, 100 kg formalin per m³ for 4 days.

[Note: Formalin is a dangerous chemical and as such the appropriate personal protective equipment should be used and safety training on the handling of this chemical should be provided.]

- c) In situations in which surfaces in animal houses, stables, *vehicles*, etc. may be contaminated with *B. anthracis* spores, the following three-step approach is recommended:
- i) a preliminary *disinfection* should be carried out using one of the following disinfectants at a rate of 1–1.5 litres/m³ for 2 hours;
 - 10 percent formaldehyde (approximately 30 percent formalin); or
 - 4 percent glutaraldehyde (pH 8.0–8.5);
 - ii) all surfaces should be washed and scrubbed using ample hot water and, when cleaned and waste water is free from dirt particles, dried;
 - iii) a final *disinfection* step should be carried out using one of the following disinfectants applied at a rate of 0.4 litre/m³ for 2 hours;
 - 10 percent formaldehyde (approximately 30 percent formalin), repeated after one hour; or
 - 4 percent glutaraldehyde (pH 8.0–8.5), repeated after one hour; or
 - 3 percent hydrogen peroxide; or
 - 1 percent peracetic acid, repeated after one hour; or
 - 5–10 percent sodium hypochloride solution.

[Note: Formaldehyde and glutaraldehyde should not be used at temperatures below 10°C. Hydrogen peroxide and peracetic acid are not suitable in the presence of blood. As with all chemicals the appropriate personal protective equipment should be worn and appropriate safety training should be provided to staff handling dangerous chemicals.]

- d) Contaminated rooms which cannot be cleared before cleaning and *disinfection* can be fumigated to eliminate *B. anthracis* spores. The following procedure is recommended:

- i) all windows, doors and vents to the outside should be sealed with heavy adhesive tape; and
- ii) for rooms up to 30 m³, 4 litres of water containing 400 ml of concentrated formalin (37 percent w/v formaldehyde) in an electric kettle (with a timing switch to turn it off) should be boiled away and the room left overnight. Room temperature should be >15°C.

[Note: Formaldehyde fumigation is hazardous and proper respirators should be on hand for operator safety. The effectiveness of the fumigation process should be verified by exposing dried discs of filter paper which have been dipped in a suspension of spores of B. subtilis var. globigii or B. cereus or Sterne vaccine strain of B. anthracis and placed in the room before fumigation is started. At the end of fumigation, the discs should be placed on nutrient agar plates containing 0.1 percent histidine and incubated overnight at 37°C. If fumigation has been effective, there will be no bacterial growth.]

— Text deleted.

**FUTURE WORK PROGRAMME FOR THE
TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

EU comment

The EU thanks the OIE Code Commission for providing its detailed revised work programme for member country comments, which it supports, and thanks the Code Commission for having taken into account some suggestions previously made by the EU.

As mentioned in the general EU comment on the cycle of standard development in the introduction of the TAHSC report, and while not wishing to create delays implementing important changes in the OIE Code, the EU would appreciate if the normal two year cycle of standard development outlined in the “procedures” document on the OIE website would be respected as a general rule. Therefore, when agreeing to embark on new work, it would be important for the Code Commission to prioritise its work well, and to coordinate its work programme closely with that of the Scientific Commission. This implies also the need to provide the Code Commission with adequate time and resources in order to allow it to complete its tasks while adhering to the transparency principles proper to the OIE.

Furthermore, with reference to the general EU comment on safe commodities in the introduction of the TAHSC report, the EU suggests defining the term “safe commodity” in the glossary, as that term is used in several disease specific chapters of the Code.

As regards the Chapter 14.9 of the Code related to scrapie, the EU would like to suggest making this Chapter more consistent with Chapter 11.5 on BSE as the diseases share some epidemiological characteristics. In particular, the EU would like to note the merit of reducing the required level of surveillance once the scrapie freedom status is recognised for a Member country and of replacing the concept of scrapie freedom with that of negligible scrapie risk.

While recently revising its import requirements for meat and meat products, the EU has noted significant differences in the OIE recommendations for heat treatment in several disease specific chapters of the Code (re. structure and level of detail, and re. specific temperature requirements). To some extent these differences are not easily comprehensible and make the elaboration of import requirements based on OIE standards for a given commodity (e.g. pork meat) challenging. Therefore, the EU would like to suggest revising these recommendations for individual commodities in a horizontal way, i.e. chapter by chapter, in order to allow for more coherence for individual commodities, where possible. An appendix is included at the end of this Annex to better illustrate this problem.

The EU wishes to reiterate its previous comment regarding the Code Chapter 6.9. on “Responsible and Prudent use of Antimicrobial Agents in Veterinary Medicine”. While supporting the adoption of that amended chapter at the General Session in May 2014, the EU kindly suggests that work in this regard be continued in order to further address the ever increasingly important issue of antimicrobial resistance. In line with the recommendations of the March 2013 OIE Global Conference on the Prudent Use of Antimicrobial Agents for Animals, the EU encourages policy discussions be continued within the OIE in order to seek options to address this complex issue at a global level in an effective way while taking into account the different practices currently in place

across the world. Furthermore, the EU invites the OIE to confirm its continued efforts in this area and in the context of One Health in order to improve the global situation as regards AMR including to work closely together with the Codex Alimentarius Commission.

As regards the section of the work programme regarding animal welfare, although being in favour of reviewing the welfare of animals in disaster areas, the EU would greatly welcome if the OIE could commence work on a standard concerning the welfare of equine and bovine working animals. The latter would potentially contribute to improving the welfare of many animals on a daily basis. Time permitting we would also ask the OIE to consider the possibility of drafting a standard concerning the welfare of rabbits kept for the purpose of meat and/or fur production.

Finally, the EU notes that the OIE list of diseases is included in chapter 1.2. “Criteria for the inclusion of diseases, infections and infestations on the OIE list”. As the title of that chapter refers solely to the criteria for listing, and not to the list of diseases itself, there is room for confusion. Since the OIE list of diseases is of such crucial importance for the overall OIE standards and for international trade, the EU would suggest having a separate Terrestrial Code chapter with the actual list of diseases, entitled “Diseases listed by the OIE”, as is already the case in the OIE Aquatic Code.

Topic		
Action	How to be managed	Status (Feb 2014)
Restructuring of the <i>Terrestrial Code</i>, including Harmonisation of the <i>Terrestrial</i> and <i>Aquatic Codes</i>		
1. Work with AAHSC towards harmonisation, as appropriate, of the Codes 2. CH rename by disease agents 3. Revision and formatting of Section 7 4. Revision of the Users' guide 5. OIE policy on wildlife	TAHSC & ITD 3.TAHSC & AWWG 4. TAHSC & SCAD 5. TAHSC with WG on Wildlife & SCAD	1. revised CH 1.1. for adoption 2. Ongoing 3. ongoing 4. Revised User's Guide for adoption 5. Ongoing
Notification of 'emerging disease'		
Clarification of definition, criteria for notification, etc.	SCAD & TAHSC	Revised texts for adoption
Listed diseases		
1. Criteria for listing 2. List of diseases	TAHSC & SCAD	1. Revised CH 1.2. for adoption 2. done
Evaluation of VS and OIE PVS pathway		
Veterinary education aspect	TAHSC & AHG & ITD	Ongoing
Veterinary products (AMR)		
1. Updating CH 6.9. 2. Updating CH 6.10. 3. Updating CH 6.6. 4. Updating CH 6.7.	TAHSC & SCAD & AHG	1. Revised CH 6.9. for adoption 2. Revised CH 6.10. for adoption 3. Revised CH 6.6. for adoption 4. Ongoing
FMD		
Revise chapter including wildlife	SCAD & TAHSC	Ongoing
AHS		
Official recognition – zones	SCAD & TAHSC	Revised CH 12.1. for adoption

PPR		
Update CH on PPR	SCAD & TAHSC	Revised CH 14.8. adoption
CSF		
Official recognition CSF	SCAD/AHG & TAHSC	Ongoing
Horse diseases		
1. International movement of competition horses 2. Update Dourine chapter 3. Update Glanders chapter	1. AHG/SCAD & TAHSC 2. SCAD/TAHSC 3. AHG/SCAD/TAHSC	1. Draft new CH for adoption 2. Pending expert advice 3. Ongoing
CWD		
Decision on listing (new CH)	TAHSC & SCAD & AHG	AHG to be convened
PRRS		
New CH	SCAD/AHG	Draft new CH for MC
Other Terrestrial Code texts on diseases in need of revision		
Review chapter on BSE	SCAD/TAHSC	September 2014
Update BT and EHD in line with AHS	SCAD & AHG	Ongoing
Update CH on brucellosis	AHG/SCAD & TAHSC	Revised CH for adoption
Update CH on tuberculosis	AHG/SCAD & TAHSC	AHG to be convened
Update CH on avian mycoplasmosis	SCAD and TAHSC	Seek expert opinion
Update CH on ASF	SCAD	AHG to be convened
Pet food certificate CH	TAHSC	On hold
Update CH on Scrapie	TAHSC	Ongoing
Animal production food safety		
1. Collaboration with Codex 2. Zoonotic parasitic diseases a. <i>Trichinella</i> spp. b. <i>Taenia solium</i> (Porcine cysticercosis)	1. TAHSC and ITD 2. AHG & TAHSC	1. Ongoing 2. a. Revised CH 8.14. for adoption b. Draft new CH for MC
Animal welfare		
New texts: 1. Broiler production systems 2. Dairy cattle production systems 3. CH 7.5., 7.6. 4. Disaster management	AWWG & AHGs &TAHSC	1. Revised CH 7.10. for adoption 2. Draft new CH for MC 3. Ongoing 4. AHG to be convened

Note: MC; Member comments, CH: chapter, Q: questionnaire, SURV: surveillance, ITD: International Trade Department, S&T Dept: Scientific & Technical Department

ITEM, ANNEX, CHAPTER NUMBERS AND CURRENT STATUS

Item	Annex	Chapter	Title	Provided for comments	GS82
1			General comments		
2	IV		User's Guide	Feb. 13	A
2	V	5.1.	General obligations related to certification		A
3	VI		Glossary	Sep.13	A
4	VII	1.1.	Notification of diseases and epidemiological information	Sep.13	A
5	VIII	1.2.	Criteria for listing diseases	Sep.13	A
		8.15.	Vesicular stomatitis		
		15.4.	Swine vesicular disease		
6	IX	2.1.	Import risk analysis	Sep.13	A
8		4.6.	Collection and processing of bovine, small ruminant and porcine semen		E
	X	4.7.	Collection and processing of <i>in vivo</i> derived embryos from livestock and equids		A
9	XI	5.2.	Certification procedures		A
	XII	5.4.	Animal health measures applicable before and at departure		A
10	XIII	6.6.	Introduction to the recommendations for controlling antimicrobial resistance	Sep. 12	A
		6.7.	Harmonisation of national antimicrobial resistance surveillance and monitoring programmes	Sep. 12	E
	XIV	6.9.	Responsible and prudent use of antimicrobial	Sep.13	A
	XV	6.10	Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals	Feb. 12	A
11	XXXIV	7.X.	Animal welfare and dairy cattle production systems	Feb. 13	C
	XXXV		Report of <i>ad hoc</i> Group on Animal welfare and dairy cattle production systems		I
		7.5.	Slaughter of animals	Feb. 13	E
		7.6.	Killing of animals for disease control purposes	Feb. 13	E
	XVI	7.10.	Animal welfare and broiler chicken production systems	Sep. 13	A
	XVII	3.1.	Veterinary Services	Sep.13	A
	XVIII	3.2.	Evaluation of Veterinary Services		A
XIX	3.3.	Communication	A		
12	XX	12.1	Infection with African horse sickness virus	Sep. 12	A
		8.3.	Infection with bluetongue virus		E
		8.X.	Infection with epizootic hemorrhagic virus	Sep. 12	E
13	XXI	8.14.	Infection with <i>Trichinella</i> spp	Sep. 13	A
	XXXVI	New	Infection with <i>Taenia solium</i>		C
	XXXVII		Report of <i>ad hoc</i> Group on <i>Taenia solium</i>		I

Annex XL (contd)

Item	Annex	Chapter	Title	Provided for comments	GS82
14		8.6.	Foot and mouth disease	Feb. 13	D
		1.6.	Procedure for self declaration and for official recognition by the OIE		
15	XXII	8.12.	Infection with Rift Valley fever virus	Sep. 13	A
16	XXIII	8.15.	Tularemia		A
17	XXIV	8.X.	Infection with <i>Brucella abortus</i> , <i>B. melitensis</i> and <i>B. suis</i>	Sep. 11	A
18	XXV	10.4.	Infection with avian influenza viruses	Sep. 13	A
19	XXVI	10.9.	Newcastle disease	Sep. 13	A
20	XXVII	11.8.	CBPP	Sep. 13	A
		1.6.	Procedure for self declaration and for official recognition by the OIE		
21	XXVIII	4.X.	High health status horse subpopulation	Sep. 13	A
	XXIX	12.8.	Infection with Equid herpesvirus type 1 (Equine rhinopneumonitis)	Sep. 13	A
	XXX	12.9.	Infection with equine arteritis virus	Sep. 13	A
		12.10	Glanders		D
22	XXXI	14.8.	Infection with peste des petits ruminants virus	Sep. 13	A
23		15.2.	Infection with classical swine fever virus		D
24	XXXVIII	New	Porcine reproductive and respiratory syndrome		C
26	XL		Work programme		C
28	XXXII	6.5.	Prevention, detection and control of <i>Salmonella</i> in poultry		A
	XXXIII	4.13	General recommendation on disinfection and disinsectisation		A

A: proposed for adoption at 82nd General Session, C: For Member comments, E: under expert consultation (*ad hoc* Groups, Specialist Commissions etc.), D: deferred to Sep 2014 meeting, I: For Member Country 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

Appendix to EU comments on the work programme of the OIE TAHSC

OIE Terrestrial Code – Prescribed heat treatment for meat (2013)

1 – CSF

Meat: 3 procedures for the inactivation of the CSF virus in meat (Article 15.2.23.)

1 Heat treatment

Meat shall be subjected to one of the following treatments:

heat treatment in a hermetically sealed container with a Fo value of 3.00 or more;

heat treatment at a minimum temperature of 70°C, which should be reached throughout the meat.

2 Natural fermentation and maturation

The meat should be subjected to a treatment consisting of natural fermentation and maturation having the following characteristics:

an aw value of not more than 0.93, or

a pH value of not more than 6.0.

Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.

3 Dry cured pork meat

Italian style hams with bone-in should be cured with salt and dried for a minimum of 313 days.

Spanish style pork meat with bone-in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.

(Chapter 15.2. http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.15.2.htm)

2 – ASF

Meat products for animal feed: No specific treatment mentioned:

"have been processed in an establishment approved by the Veterinary Authority for export purposes so as to ensure the destruction of the ASF virus, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASF virus."

(Chapter 15.1. http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.15.1.htm)

3 – FMD

Meat: 3 treatments recommended for inactivation of FMDV in meat (Article 8.6.34)

Canning

Meat is subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate the FMD virus.

Thorough cooking

Meat, previously deboned and defatted, shall be subjected to heating so that an internal temperature of 70°C or greater is maintained for a minimum of 30 minutes.

After cooking, it shall be packed and handled in such a way that it cannot be exposed to a source of virus.

Drying after salting

When rigor mortis is complete, the meat must be deboned, salted with cooking salt (NaCl) and completely dried. It must not deteriorate at ambient temperature.

Appendix to EU comments on the work programme of the OIE TAHSC

'Drying' is defined in terms of the ratio between water and protein which must not be greater than 2.25:1.

(Chapter 8.6. http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.8.6.htm)

4. Rift Valley Fever

Meat and meat products of domestic and wild ruminants: No specific treatment except maturation and, depending on status of country/zone of origin, evisceration (Articles 8.12.9. and 8.12.11.)

"the carcasses from which the products were derived were submitted to maturation at a temperature above +2°C for a minimum period of 24 hours following slaughter." or

"have been fully eviscerated and submitted to maturation at a temperature above +2°C for a minimum period of 24 hours following slaughter."

(Chapter 8.12. http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.8.12.htm)

5 – AI

Procedures for the inactivation of the AI virus in Poultry meat (Article 10.4.26.)

Core temperature (°C)	Time
60.0	507 seconds
65.0	42 seconds
70.0	3.5 seconds
73.9	0.51 second

(Chapter 10.4. http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.10.4.htm)

6 – ND

Procedures for the inactivation of the ND virus in Poultry meat (Article 10.9.21.)

Core temperature (°C)	Time
65.0	39.8 seconds
70.0	3.6 seconds
74.0	0.5 second
80.0	0.03 second

(Chapter 10.9. http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.10.9.htm)

7 – SVD

Meat products: No specific recommendations (Article 15.4.13.)

"the meat products have been processed to ensure the destruction of the SVD virus;"

(Chapter 14.4. http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.15.4.htm)

8 – Rinderpest (Article 8.13.5)

(Refers to Articles 8.12.5. to 8.12.9. of the *Terrestrial Animal Health Code* 2010 Edition)

Meat products: refers to FMD chapter Article 8.6.34 - see above

Blood and meat meals: minimum internal temperature of 70°C for at least 30 minutes

(Chapter 8.13. http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.8.13.htm)

9 – Sheep & Goat pox

No prescribed treatment

(Chapter 14.10 http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.14.10.htm)

Appendix to EU comments on the work programme of the OIE TAHSC

10 – Peste des Petits Ruminants

No prescribed treatment

(Chapter 14.8. http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.14.8.htm)