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**Subject:** **86th General Session of the OIE - May 2018**

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 (Annexes 1 and 2, respectively) to be raised and drafts proposed for adoption at the 86th General Session of the World Assembly of National Delegates of the OIE in May 2018 in Paris.

Furthermore, we take this opportunity to inform you that the EU supports the adoption of the draft revised chapters and the updated glossary of the OIE *Terrestrial Manual* to be proposed for adoption in May 2018, with the exception of draft revised Chapter 2.1.17. on rabies. The intended EU position on that OIE *Terrestrial Manual* chapter is at Annex 3.

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

Yours sincerely,

| Dr Damyan Iliev<br>CVO and OIE Delegate<br>Bulgaria | Dr Bernard Van Goethem<br>Director for Crisis Management in Food, Animals and Plants<br>European Commission, DG Health and Food Safety |
|---|---|
| | |

Dr. M. Eloit
Director General
World Organisation for Animal Health (OIE)
12, rue de Prony
75017 Paris
France

Annexes: 3

Copy: All Directors / Chief Veterinary Officers of the EU 28 and Iceland, Liechtenstein, Norway, Switzerland, and Albania, the former Yugoslav Republic of Macedonia, Montenegro, Serbia and Turkey

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 2 299 11 11
Office F101 3/086- Tel. direct line +32 2 295 10 16 - Fax +32 2 295 31 44

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

# Annex 1

Original: English

February 2018

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

**Paris, 12–23 February 2018**

**EU comment**

**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 2018 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 86th OIE General Session are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report.**

**Please note that the EU positions re. Annexes 4 to 32 (part A) as well as the EU comments on Annexes 36, 41 and 42 (part B) are appended to this document, while the EU comments on Annexes 33 to 35 and 37 to 40 (part B) will be provided to the OIE separately by 12 July 2017.**

**The EU would like to stress once 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 OIE Headquarters in Paris from 12 – 23 February 2018. The list of participants is attached as **Annex 1**.

The Code Commission thanked the following Member Countries for providing comments: Argentina, Australia, Brazil, Canada, Chile, China, Colombia, Costa Rica, Fiji, Guatemala, Japan, Korea, Malaysia, Mexico, New Caledonia, New Zealand, Norway, Singapore, South Africa, Switzerland, Chinese Taipei, Thailand, USA, OIE Members of the Region of the Americas, the Member States of European Union (EU) and the African Union Interafrican Bureau for Animal Resources (AU-IBAR) on behalf of African Member Countries of the OIE. Comments were also received from the European Serum Product Association (ESPA), Global Alliance of Pet Food Associations (GAPFA) the International Coalition for Animal Welfare (ICFAW) and International Egg Commission (IEC). The Code Commission referred comments regarding translation to the OIE Headquarters.

The Code Commission reviewed Member Country comments, which were submitted on time and supported by a rationale, and amended relevant chapters of the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) where appropriate. The amendments are presented in the usual manner by 'double underline' and '~~strikethrough~~' and the chapters are annexed to this report. In Annexes 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21 23, 33, 34, 37 and 38, amendments proposed at this meeting are highlighted with a coloured background to distinguish them from those proposed previously.

The Code Commission considered all Member Country comments supported by a rationale and documented its responses. However, because of the large volume of work, the Code Commission was not able to draft a detailed explanation of the reasons for accepting or not each of the comments received and focused its explanations on the major ones.

The Code Commission encourages Member Countries to refer to previous reports when preparing comments on longstanding issues. The Code Commission also draws the attention of Member Countries to those instances where the Scientific Commission for Animal Diseases (the Scientific Commission), the Biological Standards Commission, a Working Group or an *ad hoc* Group has addressed specific Member Countries comments or questions and proposed answers or amendments. In such cases the rationale is described in the Scientific Commission's, Biological Standards Commission's, Working Group's or *ad hoc* Group's reports and Member Countries are encouraged to review its report together with those of the Scientific Commission, Biological Standards Commission, Working Groups and *ad hoc* Groups. These reports are readily available on the OIE website.



Member Countries should note that texts (including the questionnaires related to official recognition of disease status) in **Part A** of this report are proposed for adoption at the 86th General Session in May 2018. Texts in **Part B** are submitted for comments. Comments on **Part B** of the report must reach OIE Headquarters **by 12 July 2018** for them to be considered at the September 2018 meeting of the Code Commission. Comments received after the due date will not be submitted to the Code Commission for its consideration. The reports of meetings of *ad hoc* Groups and other related documents are attached for information in **Part C**. Member Countries are invited to submit comments on the suggestions of the *ad hoc* Group on Avian Influenza, in particular the definition of *poultry* and the proposals relating to the structure of Chapter 10.4. These comments must reach OIE Headquarters by **10 May 2018.**

All comments and related documents should be sent by email to the OIE Standards Department at: standards.dept@oie.int.

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 Word files rather than pdf files because pdf files are difficult to incorporate into the working documents of the Code Commission. Comments should be submitted as specific proposed text changes, supported by a structured rationale or by published scientific references. Proposed deletions should be shown using '~~strikethrough~~' and additions using '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 Code Commission's working documents. Member Countries are also requested **not** to reproduce the full text of a chapter as this makes it easy to miss comments while preparing the working documents.

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**1. Meeting with the Director General**

The Code Commission met with Dr Monique Eloit, Director General, on 15 February 2018. Dr Eloit welcomed the Code Commission members and thanked them for their support and commitment to achieving OIE objectives.

The Director General noted the Council would consider the report of the Evaluation Committee on the assessment of applications for nomination for election to the OIE Specialist Commissions at the end of February 2018. The report contains the list of candidates found suitable for nomination for election to a Specialist Commission and the final list will be provided to OIE Delegates 60 days before the General Session. The Director General also noted the ongoing objective of the OIE to continue to improve the transparency of the standards setting process, in particular the technical item on 'Implementation of standards; state of play and capacity building' which would inform the ongoing development of the Observatory that would be discussed at the OIE General Session in May 2018. The Director General also noted that there would only be one technical item at the General Session to allow sufficient time for discussion on the Commissions and the elections.

**2. Adoption of the agenda**

The Agenda was adopted, with the addition of the item on veterinary paraprofessionals and also noting that the draft chapter on animal welfare and laying hen production systems (Chapter 7.Z.) had not been included, as due to the unavailability of several key members of the *ad hoc* Group, the meeting to consider Member Country comments could not be held until March 2018. The report of the *ad hoc* Group will be considered by the Code Commission in September 2018. The adopted agenda of the meeting is attached as **Annex 2**.

**3. Cooperation with other Specialist Commissions**

**a) Meeting with the President of the Aquatic Animal Health Standards Commission**

The President of the Code Commission met with the President of the Aquatic Animal Health Standards Commission (Aquatic Animals Commission). The Presidents discussed issues of mutual interest in the *Terrestrial* and *Aquatic Codes* to facilitate harmonisation of relevant chapters in the two *Codes* when under review by the respective Commissions. Notably: alignment of relevant revised text in the User's Guide and Chapter 5.3. of the *Aquatic Code* and the equivalent *Terrestrial Code* chapters and the development of a guidance document on the application of the criteria used by OIE for listing of diseases by the Aquatic Animals Commission.

The Code Commission agreed that these meetings are important to facilitate harmonisation of relevant horizontal chapters in the two *Codes*.

**EU comment**

**The EU commends the OIE for these coordination efforts between the Code and Aquatic Animals Commissions, as indeed harmonisation of these key texts in both OIE Codes are crucial.**

**b) Consultation with the President of the Biological Standards Commission and Scientific Commission**

The meeting schedule did not allow for a meeting with the President of the Biological Standards Commissions. However, there was consultation on several key items of work that was coordinated through the Secretariats.

The Biological Standards Commission provided advice to the Code Commission in response to Member Country comments and in response to specific questions.

The Code Commission and the Scientific Commission met on 16 February 2018 to discuss issues of mutual interest. The Scientific Commission also provided advice to the Code Commission in response to Member Country comments on several chapters under consideration at this meeting, including both horizontal and listed disease-specific chapters. It also provided suggestions for proposed amendments on its own initiative.

The report of the Joint Meeting with the Scientific Commission is attached as **Annex 3.**

## 4. Texts proposed for adoption at the General Session in May 2018

### 4.1. User's Guide

Comments were received from Costa Rica, Guatemala, New Caledonia, Switzerland, USA, EU and AU-IBAR.

The Code Commission noted several comments in support of the proposed amendments were appreciated.

In response to Member Countries comments, the Code Commission made minor editorial changes to include 'reptiles' in the list of animals included in point 2 of Section A, Introduction and to point 4 of Section C, for consistency by replacing 'pathogen' with 'pathogenic agent'.

In response to a Member Country comment concerning an apparent inconsistency between the *Terrestrial* and *Aquatic* Codes (Section B, point 4), the Code Commission considered that the term 'should' was appropriate when used in the context of this point, which is about guidance on conducting import risk analysis. An importing country conducting a risk analysis to justify measures that are more stringent than OIE standards should use the guidance in Section 2 to justify these measures i.e. the import risk analysis should be based on the guidance in Section 2. The Member Country made the same comment to the Aquatic Animals Commission which agreed with the Code Commission that the appropriate term is 'should' and not 'may' and it would amend its User's Guide accordingly.

In response to other Member Countries comments on Section B, point 8, the Code Commission noted that the chapters in Section 6 specifically relate to preventive measures in animal production systems, which are not for trade *per se*. The second sentence of the paragraph is clear that the chapters in this section are intended to assist Member Countries in meeting their veterinary public health objectives. Furthermore, the Code Commission considered that the proposed amendments in Section C, relating to Chapter 6.4. adequately address the concern regarding the use of standards for trade. In response to a Member Country proposal to include an additional sentence in 6.4. to highlight that the chapters in this section are not intended as trade restrictive impediments the Code Commission considered this unnecessary. It understood the concerns being expressed but considered this was already adequately addressed.

Section C Specific Issues. Several Member Countries commented on the use of the word 'disease' in the User's Guide, and the relationship with the proposal to delete it from the Glossary. The Code Commission again reiterated its previous statements that the deletion of the definition of the term disease from the Glossary would not mean it would not be used elsewhere in the *Code*. It would only be a change in formatting, the term no longer appearing in italics throughout the *Code* except within the definitions of 'listed disease' and 'emerging disease'.

The revised User's Guide is attached as **Annex 4** and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

**The EU thanks the OIE and supports the adoption of this modified User's guide.**

### 4.2. Glossary Part A

Comments were received from Argentina, Brazil, Australia, China, Guatemala, New Zealand, Switzerland, Thailand, EU and AU-IBAR.

The Code Commission noted comments in support of the revised definitions in the Glossary and made editorial changes in response to Member Country comments and to address consistency and clarity.

In response to a Member Country proposal to include definitions for 'embryo collection', 'oocyte collection' and 'semen collection', the Code Commission thanked the Member Country for raising

this point and noted it would consider the need when revising both Chapters 4.6. and 4.7. and that this would be included in its work programme.

***ANIMAL WELFARE***

Comments were received from Australia, USA and EU.

The Code Commission noted Member Countries comments in support of the proposed definition.

The Code Commission recalled that the purpose of modifying the definition of animal welfare is to provide a more concise definition in the Glossary and to leave the technical and descriptive text in Chapter 7.1., precisely in Article 7.1.1. General principles.

For purposes of consistency with the modifications made in Article 7.1.1. General principles, the Code Commission agreed with the proposal of some Member Countries to replace the word 'psychological' with 'mental', referring to the state of the animal in the definition of animal welfare.

***COMPARTMENTS***

In response to a Member Country comment proposing the inclusion of text referring to epidemiological separation, the Code Commission considered that the proposal was too detailed and could in fact lead to confusion, as the purpose of a compartment is to exclude a disease. In order to address the Member Country comment the Code Commission inserted the words 'separated from other populations by' to avoid confusion.

In response to another Member Country proposal to change 'control measures' to 'sanitary measures', the Code Commission noted the definitions of 'sanitary measure' and 'biosecurity' were both in the Glossary. The term 'sanitary measures' is more used in the context of the WTO SPS Agreement, and of countries and zones, and 'control measures' is more appropriate to be applied in the context of compartments.

***CONTAINMENT ZONE***

A Member Country highlighted an inconsistency between Article 4.3.7 and the definition proposed in the Code Commission's September 2017 report. The Code Commission agreed with the Member Country and proposed to include new text after 'that are epidemiologically linked' recalling that it may not always be possible to identify the definitive epidemiological link and that it should be the main criterion in defining the number of containment zones. It also reiterated its explanation (September 2017) that the design of the containment zone or zones depends on the Veterinary Services' strategy to manage outbreaks while facilitating safe trade. Furthermore, containment zones for diseases with OIE official status must be recognised by the Scientific Commission, and countries should provide the OIE with evidence to justify the establishment and the maintenance of the zone. For other diseases, countries should provide evidence to their trading partners.

In response to a Member Country proposal to include 'infested' in the definition, the Code Commission disagreed, as an 'infected zone' by definition includes 'infested' animals.

***DISEASE***

The Code Commission reiterated its explanation about the removal of the definition of 'disease' from the Glossary. Member Countries are reminded that they should consider the explanations and rationale included in the Code Commissions reports when preparing their comments. The dictionary definition is more appropriate and allows the continued use of the word 'disease' but without italics and there is no need for a specific OIE definition. The word 'disease' would only remain in the Glossary where it was part of another definition for example, 'emerging disease' and 'listed disease'. In response to other Member Countries comments, the Code Commission also noted that it will use the word more consistently and will amend other chapters as relevant, specifically Chapter 1.3. once the proposal has been adopted.

***FREE ZONE***

The Code Commission noted comments received in support of the proposed definition.

***INFECTED ZONE***

In response to several Member Countries comments, the Code Commission recalled it had previously discussed, with the Scientific Commission, the need for an additional definition for 'infested zone' but did not agree with the addition. The Code Commission reminded Member Countries that the current definition of 'infected zone' adequately covers both, infected or infested. In this regard, it clarified, for example, a country free from varroa; varroa is found in the country; a zone where bees are infested is established and it is the infected zone; the Code Commission would continue to use the term 'infected zone' for simplicity. It further noted that consequential amendments to listed disease-specific chapters would be considered on a case-by-case basis and as chapters are revised.

***PROTECTION ZONE***

The Code Commission noted that the replacement of 'adjacent' with 'neighbouring' is being systematically applied as chapters are revised.

***TRANSPARENCY***

The Code Commission noted comments received in support of the proposed deletion of the definition.

***VACCINATION***

Some Member Countries proposed to add the word 'appropriate' before 'vaccine' as the notion of the appropriateness of the vaccine with a view to the pathogenic agent against which an immune response is to be elicited seems to be missing from the definition. The Code Commission noted that in the definition of vaccination, the term 'vaccine' is used as defined in the *Terrestrial Manual* and as such covers the appropriateness to pathogenic agents.

***ZONE~~/REGION~~***

In response to a Member Country proposal to retain the wording 'for the purpose of international trade…' the Code Commission clarified that the word 'zone' when used in the Code is more generic than 'free zone'; for example Article 4.3.1. clearly states that zoning is used either for international trade or disease control. For clarity the Code Commission reinstated the wording 'for the purpose of international trade' and added 'or disease prevention and control'.

The revised definitions are attached in **Annex 5** and are proposed for adoption at the 86th General Session in May 2018.

**EU position**

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

**Comments are inserted in the text of Annex 5.**

NB: With respect to new or revised definitions being proposed because of a new or revised chapter, these definitions will be included with the chapter in the relevant annex. This will assist Member Countries in their review of the chapters and preparation of their comments.

### 4.3. Import Risk Analysis (Articles 2.1.1. and 2.1.3.)

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

The Code Commission noted comments from Member Countries in support of the proposed amendments.

**Article 2.1.1**

In response to a Member Country comment regarding the need to include a sentence defining transparency at the point in the article where the word first appears, the Code Commission agreed in

principle and moved the wording from Article 2.1.3. point 4, to the second paragraph of this article, as it considered it was more appropriate.

In relation to another Member Country proposal to delete the last sentence of the second paragraph of the article, the Code Commission did not agree, as a risk analysis may lead to an importing country setting import conditions. Furthermore, it considered that the inclusion of the sentence on transparency addressed the Member Country's concern. However, to clarify that communication is not only with trading partners, it added 'and all interested parties' to the last sentence of the paragraph. In response to other Member Countries comments on the same sentence it included 'communication' for further clarity.

The revised Articles 2.1.1. and 2.1.3. are attached in **Annex 6** and are proposed for adoption at the 86th General Session in May 2018.

**EU position**

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

**4.4. Criteria applied by the OIE for assessing the safety of commodities (Chapter 2.2.)**

Comments were received from Singapore, Switzerland and EU.

The Code Commission noted comments of several Member Countries in support of the proposed amendments.

In response to a comment from a Member Country, the Code Commission explained the current text 'is not present in the tissue … in an amount able to cause infection' means that either the pathogenic agent is not present at all or if present, it is not in an amount able to cause infection. Thus, the Code Commission considered that the proposal to include 'or is in' did not improve the clarity of the sentence.

The revised Chapter 2.2. is attached as **Annex 7** and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

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

**4.5. Zoning and compartmentalisation (Chapter 4.3.)**

Comments were received from Argentina, Brazil, Australia, Canada, Chile, Chinese Taipei, Costa Rica, Guatemala, Japan, New Caledonia, New Zealand, Switzerland, Thailand, USA, OIE Members of the Region of the Americas, EU and AU-IBAR.

The Code Commission noted comments in support of the proposed revised chapter.

In response to the general comments from Member Countries, the Code Commission noted that international trade was adequately covered in the introduction and it was unnecessary to repeat this throughout the document. It also noted that the chapter is primarily for disease control and not just for trade. Concerning a proposal to include diagrams to illustrate the differences between the concepts of zoning and compartmentalisation the Scientific Commission and the Code Commission recalled that the decision had been made to remove all diagrams from the *Code*, as they may not be correctly interpreted.

In respect to other Member Countries suggesting that the chapter should refer to 'legal or administrative boundaries' as well, the Code Commission agreed with the Scientific Commission that zones should be controlled at all times, but this may not necessarily need to be based on legal boundaries. It further noted the concept was covered in point 1 of Article 4.3.3.

**Article 4.3.1.**

The Code Commission made editorial amendments to improve the clarity of the article in response to Member Countries comments. In responding to comments related to 'epidemiologically linked' the Code Commission explained in relation to compartmentalisation that even if animals are in different locations and they have the same epidemiological situation, they are epidemiologically linked and share the same status. Moreover, if they are under the same biosecurity management, this allows the definition of a subpopulation and that is not always possible on a geographical basis.

In response to a question concerning compartmentalisation in relation to wild animals, the Code Commission noted that 'under common practices for biosecurity' would mean the animals are under permanent human supervision. This is incompatible with the definition of feral and wild animals. However, captive wild animals can be kept in a compartment.

**Article 4.3.2.**

The Code Commission made minor editorial amendments in response to Member Countries comments to improve the clarity of the article.

The Code Commission disagreed with the proposal of a Member Country to include 'where applicable' after 'animal traceability' and the example given of bluetongue virus. If an unvaccinated animal comes into a free zone from an infected zone, there is a need to have animal identification in place, which is always dependent on national priorities and available resources.

The Code Commission thanked Member Countries for bringing to its attention that it had proposed to add 'movement control' in the first paragraph. On reflection, the Code Commission noted that movement control is not related to defining a compartment and that it was more appropriate to add it in paragraph 2.

In response to Member Countries comments about replacing 'disease' with 'epidemiology of the infection', the Code Commission disagreed because in this case 'disease' was used in its generic meaning, while 'infection' was a defined term and that in the *Code* it would not use 'epidemiology of infection'.

The Code Commission disagreed with the same Member Countries proposal to define a minimum size for a zone. The size of a zone depends on a number of factors: the presence of a vector; environmental factors; human factors; livestock density etc. For this reason, zones are not all defined the same way; it is up to the Veterinary Services to define the best size according to these factors.

In response to a Member Country proposal for alternate wording for the 4$^{th}$ paragraph specifically, to delete the reference to Chapter 3.2.*,* the Code Commission explained that Chapter 3.1. is very general and Chapter 3.2. gives further important detail on the quality of Veterinary Services and the reference should be kept. The Code Commission amended the first sentence for clarity, noting that laboratories are sometimes not under the responsibility of the Veterinary Services.

In response to Member Countries comments that there are some difficulties in the understanding of, and translation of, the word 'industry' the Code Commission agreed and proposed to use the term 'production sector' which includes all those responsible for all or part of the animal and food chain, production of live animals and animal products as well as farmers etc. The Code Commission noted that this would need to be considered in other chapters as they were revised and asked the OIE Headquarters to consider this in future.

**Article 4.3.3.**

In regard to Member Countries requests for clarification of what is meant by 'epidemiological separation' in point 3, the Code Commission and the Scientific Commission clarified that the concept of 'epidemiological separation' should be understood as the contrary to 'epidemiologically linked'. On the second part of their question on the partnership between Veterinary Services and production sectors (industry), the Code Commission proposed to amend the sentence to avoid any confusion that the Veterinary Services should document everything.

In point 4, in response to several Member Countries comments, the Code Commission disagreed that animal identification was not valid for all species and clarified that an animal identification system did not imply 'individual animal identification'. This was further clarified by the first sentence of this point and the terms that are clearly defined in the Glossary.

> ***ANIMAL IDENTIFICATION*** means the combination of the identification and registration of an animal individually, with a unique identifier, or collectively by its epidemiological unit or group, with a unique group identifier.
>
> ***ANIMAL IDENTIFICATION SYSTEM*** means the inclusion and linking of components such as identification of establishments or owners, the persons responsible for the animals, movements and other records with animal identification.

In response to another Member Country opposed to the replacement of 'animal' with 'commodities,' the Code Commission recalled that the Glossary definition of 'commodity' includes animals.

The Code Commission partially accepted the proposals of a Member Country and proposed amendments to point 7 for clarity. It did not accept the same Member Country proposal to include 'with appropriate rectification as necessary and how the measures will be….' but agreed with the inclusion of text to highlight the need for risks 'to be adequately managed'.

In response to Member Countries proposal to include a new sentence, 'The Veterinary Services should carry out documented periodic inspections and verification audits of facilities…' the Code Commission considered this adequately covered in Article 4.3.2. General Considerations and it was unnecessary to repeat it.

**Article 4.3.4.**

In response to Member Countries comments regarding the need for surveillance to cover the demographics of the animal population, the Code Commission agreed with the Scientific Commission that this is included in the concept of the epidemiological situation. The Code Commission further agreed with the proposal of the Scientific Commission to replace 'pathogen-specific surveillance' with 'specific surveillance' as the Glossary definition of 'specific surveillance' includes pathogen specific surveillance. It did not agree with the proposal of another Member Country to delete reference to 'and vector'.

In response to another Member Country proposal to reword the third paragraph, the Code Commission disagreed with the proposal noting that 'one or more' may include all susceptible species.

**Article 4.3.5.**

In response to Member Countries proposal to refer to both 'infected and infested zone', the Code Commission reiterated the term is adequately defined in the Glossary.

The Code Commission noted in regard to Member Countries comments proposing to include reference to 'disease-specific chapters' to clarify the proposed changes it had made in September 2017, that it is clear that the definition of 'infected zone' would be included in the disease-specific chapters and this is why it had included 'relevant'.

**Article 4.3.6.**

The Code Commission noted the number of comments opposed to the proposal to include new text on the concept of 'temporary protection zone', at the end of the article. The Member Country comments were discussed during the meeting with the Scientific Commission and both Commissions agreed that the concept of 'temporary protection zone' should not preclude this chapter from being presented for adoption.

The paragraphs relating to the concept were deleted from Article 4.3.6. for the time being, and the Specialist Commissions, together with relevant experts, will further discuss the issue in order to clarify how to manage this type of zone that had been proposed to address specific problems for specific parts of the world.

In respect of the first paragraph, the Code Commission disagreed with the proposal of a Member Country to add a new sentence to provide clarity on the role of the protection zone noting this was covered in the first sentence and repeating the wording did not add clarity. It further clarified that a protection zone is to prevent the spread of disease not to reduce the probability of the pathogenic agent entering the country.

In response to the proposal of a Member Country to delete the reference to 'and vehicles' and replace 'animal products' with 'commodities' the Code Commission drew the attention of the Member Country to the rationale provided in its September 2017 report for these changes. The full report is available on the OIE website.

Extract September 2017 TAHSC report

> 'The Code Commission considered the comments of Member Countries and clarified that because of an oversight there were two proposals of definition included in the Glossary in its February 2017 report and that the first proposal for the definition should not have been included. It disagreed with a comment stating that the establishment of a protection zone does not guarantee that the introduction of the pathogenic agent is prevented. In response to a request to delete the second 'vehicles' before 'for transportation' in point 4), the Code Commission noted that the definition of *vehicles/vessels* contained in the Glossary specifically referenced live animals and did not include commodities, and it amended the point to read 'used for transport' to clarify the intent of this point. The Code Commission further noted that any time the status of the protection zone changes, the status should be determined in accordance with the relevant listed disease-specific chapters.'

In point 4, the Code Commission and the Scientific Commission agreed with the proposal of Member Countries to insert 'and disinsection' as this would be relevant to vector-borne diseases.

In regard to the paragraph after point 6, the Code Commission disagreed with the amendments proposed by Member Countries as it considered the proposal changed the intent of the sentence however in order to address these concerns the sentence was reworded for clarity.

**Article 4.3.7.**

In response to a Member Country proposal to delete 'all' before 'outbreaks' in the first paragraph, the Code Commission proposed to retain 'all epidemiologically linked outbreaks' as it is evident that in some very rare cases a country could have cases not epidemiologically linked and would have more than one containment zone. Furthermore, it was not possible to cover all field circumstances in the *Code*.

In response to Member Countries comments on the second sentence of the article, on the need to specify the objectives in the definition of containment zone, the Code Commission did not accept the proposal to include additional wording as it did not add clarity and was covered in the following points.

In point 1, the Code Commission disagreed with Member Countries proposal to add 'within the containment zone' as it considered that this part of the article is about what should be included in the contingency plan, and related to the suspicion of the specified disease before the establishment of the zone. In response to other Member Countries comments on the same point, the Code Commission considered that the word 'appropriate' addressed their concerns.

In point 2, the Code Commission did not accept a Member Country proposal to include 'zones' to allow for multiple containment zones as it did not add clarity to the point.

Point 3, the Code Commission did not accept Member Countries proposals to include additional wording to highlight that the emergency control measures were applied within the containment zone as it did not consider it improved the clarity.

Point 6, in response to Member Countries proposal to include 'other' as biosecurity is also a sanitary measure, the Code Commission disagreed and recalled the definition of 'biosecurity' contained in the

Glossary. It modified the point to include 'fomites' to address a Member Country proposal to include 'feed and fodder' in the list.

Point 6, in response to Member Countries comments that the point was unclear, the Code Commission amended the point to address this concern noting that a containment zone is considered effectively established when the conditions in either point a) or point b) are met.

Point 6, in response to a general comment from Member Countries that this same provision may not be consistent in individual listed disease-specific chapters of the *Code*, the Code Commission requested that the OIE Headquarters look at this in order to harmonise the provisions as much as possible.

Point 6 b), in response to a Member Country's proposals to include reference to 'appropriate surveillance' outside the protection zone, the Code Commission disagreed as this was implicit.

The Code Commission and the Scientific Commission agreed with Member Countries proposals to include an additional sentence in order to state that should a case occur in the protection zone the whole country will lose its status and proposed the inclusion of a new sentence at the end of the article. The Scientific Commission further reiterated that should a case occur in an approved containment zone of option a) or in the protection zone of option b) of the draft article, the rest of the country should lose its status and would be considered infected.

In response to another Member Country proposal, on point b) of the same paragraph, the Code Commission disagreed, as the proposal did not add clarity.

In response to Member Countries proposals to mention the difference between disease with an official status granted by the OIE and other listed disease as regards recognition of containment zones in the second last paragraph, the Code Commission clarified, that it should not be explicitly mentioned in this paragraph but in the listed disease-specific chapters.

**Article 4.3.8.**

In response to a Member Country proposal to align the text in the second paragraph with the WTO SPS Agreement, the Code Commission reiterated that it was not necessary to repeat the text of the SPS Agreement in the *Code*. The meaning of the paragraph is the same and it is clear as written.

The Code Commission disagreed with a Member Country proposal to include reference to being able to meet the importing country's requirements, as the article is only about bilateral recognition of country or zone status and is to encourage Member Countries to recognise zones. Other chapters cover conditions for trade. To clarify this, the Code Commission proposed to change the subtitle of the article to 'Bilateral recognition of country or zone status by trading countries'.

The revised draft Chapter 4.3. is attached as **Annex 8** and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

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

**4.6. Collection and processing of in vitro produced embryos from livestock and horses (Chapter 4.8.)**

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

Several member countries supported the proposed changes to this chapter.

In response to a Member Country comment that there was an issue of consistency between Article 4.8.4. and Chapter 4.6., as there are no listed diseases that donor animals must be tested for, the Code Commission agreed and reiterated the need for scientific advice. As soon as advice on specific testing regimes is provided new recommendations could be proposed for inclusion in the chapter.

**Article 4.8.1.**

The Code Commission reworded the article for improved clarity, in response to a Member Country comment, noting that morula or blastocysts are a stage and it is the 'morula' or 'blastocysts stage' that makes them ready for transfer, not the time.

**Article 4.8.2.**

The Code Commission clarified that the use of 'inspection' is correct in this context, the team has to be inspected not assessed, and regarding the responsibility of the Veterinary Authority or the Veterinary Services, it recognised that this was not always clear in countries but in the *Code,* it is necessary to distinguish between them and their roles and responsibilities.

**Article 4.8.3.**

The Code Commission proposed amendments for clarity and syntax including correcting the name of the IETS. It also agreed with the comment of a Member Country that a team can use more than one laboratory site however, it considered this was already covered in the first paragraph of the article.

**Article 4.8.4.**

In response to a Member Country comment requesting the inclusion of text to indicate that new sterile needles should be used for aspiration of oocytes for each donor, the Code Commission noted that this was not exactly what was recommended in the IETS Manual. As the paragraph already referenced the recommendations of the IETS Manual it is not necessary to include this as a recommendation.

The Code Commission agreed with a Member Country that the need to trace the embryos back to the donor was not clear and proposed to amend the paragraph for clarity.

In order to address the concerns of Member Countries regarding clarity in point 4, the Code Commission proposed an amendment to clarify that the slaughterhouse/abattoir should be officially approved and under the supervision of a veterinarian.

In response to a Member Country comments on points 1 to 4 and point 7, the Code Commission agreed with some of the proposed editorial changes for clarity. However, others were not considered necessary or even a possible source of confusion.

**Article 4.8.5.**

The Code Commission agreed with the proposal of a Member Country to delete 'optional' from the subheading of the article for clarity. It did not agree with the proposal of another Member Country to include a cross-reference to Chapter 4.6. Collection and processing of bovine, small ruminant and porcine semen, as there is no specific chapter for semen from equids. The Code Commission added 'relevant to listed disease-specific chapters' as these chapters have specific requirements.

**Article 4.8.6.**

Despite the fact that the *Code* already references the IETS Manual, the Code Commission agreed with a proposal of a Member Country to insert a new point a), specifically referencing the need for oocytes and embryos to be washed between each stage of production (IETS Manual 4$^{th}$ Edition, pp 63), as it considered it was an important risk mitigation measure, as there were no tests available to be included in the chapter.

**Article 4.8.7.**

In response to a Member Country comments on points 2c) and 3c) the Code Commission agreed that sealing of the containers should be done prior to shipment from the exporting country and proposed to amend the text and the title of the article for clarity.

The revised draft Chapter 4.8. is attached as **Annex 9** and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

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

**4.7. New chapter on vaccination (Chapter 4.X.)**

Comments were received from Argentina, Australia, Brazil, Canada, Chile, China, Chinese Taipei, Costa Rica, Guatemala, Japan, New Caledonia, New Zealand, Singapore, Switzerland, USA, OIE Members of the Region of the Americas and EU.

The Code Commission noted several Member Countries comments in support of the draft chapter.

In response to one Member Country comment in relation to the term 'disease', it noted that the word 'disease' would not disappear from the *Code*. References to 'disease-specific chapters' would be replaced with 'listed disease-specific chapters' and the definitions of 'notifiable disease' and 'emerging disease' will remain. In response to proposals to include the term 'infestation' within the definition of 'infection', the Code Commission did not agree with the rationale provided as there are *Code* chapters that refer only to 'infestation with', and the distinction is still relevant.

It further thanked a Member Country for the advice that it was conducting a project in relation to vaccination against ticks in cattle and noted it would ask the OIE Headquarters to provide this information to the Biological Standards Commission.

The Code Commission agreed with the proposal of Member Countries to replace 'marketing authorisation' with 'relevant regulatory approvals' throughout the chapter. The Code Commission recommended that the OIE Headquarters consider the use of the term 'relevant regulatory approvals' throughout the *Code* and the *Manual*.

**Article 4.X.1.**

The Code Commission disagreed with the proposal to narrow the scope of the chapter. While the primary objective of the recommendations is to guide Veterinary Services, they may be used by all concerned sectors as appropriate. Member Countries are invited to refer to the Code Commission's September 2017 report. The Code Commission agreed with the Scientific Commission to replace the term 'Veterinary Authority' with 'Veterinary Services' as it was the more appropriate term given the objective of the guidance.

In response to a proposal of several Member Countries to delete 'successful', the Code Commission agreed as it was implicit that guidance is provided to assist with successful implementation. The Code Commission disagreed with a proposal from the same Member Countries to add to point 4) 'if applicable for the Member Country concerned'. However, the Code Commission clarified the point relates to vaccine-producing countries only.

**Article 4.X.2.**

In response to the proposal of two Member Countries to include a definition of 'strategic vaccination,' the Code Commission agreed with the Scientific Commission that the term 'strategic vaccination' is not used in the current chapter and vaccination strategies can be adapted to specific situations.

**Article 4.X.3**

In response to a Member Country comment regarding the proposed deletion of the word ‘disease’ and its replacement with ‘infection’, the Code Commission agreed that in this case, the use of ‘disease’ was more appropriate than ‘infection’ as it was in the general context of the disease. This amendment also addressed a comment of another Member Country requesting the inclusion of ‘infestation’.

In response to Member Countries comments regarding the liaison between the veterinary and public health authorities, the Code Commission added ‘implementation’ and ‘as relevant’ to highlight that cooperation between the two should not only be during the development phase of the campaign but may occur at different stages. Two Member Countries proposed the deletion of reference to ‘prevent the introduction of a pathogenic agent from an infected neighbouring country or zone’. The Code Commission agreed that vaccination does not prevent the entry of the pathogenic agent. In order to address this, it proposed to replace ‘pathogenic agent’ with ‘disease’ as in fact, some vaccination can actually prevent the transmission of infection and thus prevent the introduction of the disease.

**Article 4.X.4.**

In response to a request from Member Countries for the addition of a point regarding the existence of a vaccine, the Code Commission noted this was covered in point 8) the availability of vaccine.

Point 1, in response to a Member Country proposal to include ‘incidence and reproductive number’ when calculating the proportion of a population that needs to be vaccinated, the Code Commission agreed with the Scientific Commission that the inclusion was unnecessary as these concepts are included in the broad definition of epidemiology.

Point 2, the Code Commission disagreed with a Member Country proposal to delete this point. While point 1 relates to the general epidemiology and characteristics of the disease as can be found, for example, in OIE technical disease cards, point 2 relates to the epidemiological situation in the country. The Code Commission made minor modifications to clarify this.

Point 5, the Code Commission agreed to a Member Country proposal to add two new points on the health status of the animals and the possibility of differentiating vaccinated animals from infected animals. However, the Code Commission was of the view that these were already addressed in Articles 4.X.7. point 2, target population and 4.X.6 biological characteristics. The Code Commission made minor amends to both Articles 4.X.6. point 2 b) and 4.X.7. point 2, to clarify this point.

Point 7, the Code Commission agreed with the comments of several Member Countries that animal identification was not feasible in wild animals, and clarified that this section was in relation to the considerations when launching a vaccine programme. Furthermore, it was not considered necessary to amend the text but was taken into account in point 5 of Article 4.X.8. which deals with animal identification. The Code Commission further noted, in response to Member Countries comments on the same point, on the possible interference of a vaccination programme with disease surveillance and the existence of a tool for post-vaccination monitoring, that all these issues were covered in Article 4.X.6. 2b) biological characteristics.

Point 9, the Code Commission agreed with a Member Country that the cost-benefit analysis should also consider the impact of the vaccination programme on public health and amended the point accordingly.

**Article 4.X.5.**

In response to a comment from a Member Country regarding the possible challenges of translating the word ‘blanket’ and proposing to use ‘mass’, the Code Commission asked the OIE Headquarters to ensure that the translation was appropriate to convey the meaning of this point and proposed no change to the English version.

**Article 4.X.6.**

In response to Member Countries proposals to include an additional sentence in this article on the need to balance the benefit with the risk posed by vaccination, when only one vaccine is available, the

Code Commission considered it was a valid point and included a new sentence linking this to the factors in the previous article.

Point 1, in response to two Member Countries comments, the Code Commission made an editorial amendment for consistency by replacing 'including marketing authorisation' with 'relevant regulatory approvals' throughout the rest of the Chapter.

Point 2 b), for consistency with the *Manual* the Code Commission replaced 'thermostability' with 'thermotolerance' and for clarity added 'unintentional' to point c) transmission of live vaccine strains.

**Article 4.X.7.**

Point 1, in response to Member Countries comments, the Code Commission reworded this point to make it clearer that compensation is not always compulsory. In response to a question regarding the need to have a legal basis in the country to compensate animal owners for adverse reactions, the Code Commission noted that this would indeed be an incentive to animal owners to vaccinate when there are known possible adverse reactions.

Point 2, the Code Commission agreed with a Member Country proposal to delete reference to the efficacy of the vaccine in the last sentence because it will be part of the design of the vaccination coverage and effective immunity is adequately covered in Article 4.X.6. 2 b).

Point 3, the Code Commission confirmed that the vaccination programme is carried out under the responsibility of the Veterinary Services.

**Article 4.X.8.**

The Code Commission made editorial amendments in response to Member Countries comments for clarity and consistency including where appropriate changing 'Veterinary Authority' to 'Veterinary Services'. In regards to point 5 on animal identification, it agreed to include 'domestic' before animals, as this addressed several Member Countries comments including those made on Article 4.X.4. point 7. In response to Member Countries comments on point 7, 'biosecurity' was included as it may be useful to consider when preparing to cease vaccination.

**Article 4.X.9.**

The Code Commission agreed with the Scientific Commission that, in response to a Member Country comment, the age of the animals should be considered as part of the evaluation and monitoring programme, but disagreed with the inclusion of vaccination strategy. The point was amended accordingly.

**Article 4.X.10.**

In response to Member Countries comments, the Code Commission considered that the problem of vaccine availability is covered in point 4.

**Article 4.X.11.**

In response to Member Countries comments noting that the first paragraph may not encourage countries to implement vaccination, the Code Commission amended the second paragraph to highlight that the *Code* provides additional recommendations on the management and trade of vaccinated animals and their products. In response to a Member Country comment that the last paragraph of the article contained information too specific for a general chapter, the Code Commission proposed amendments to the third paragraph.

A Member Country commented on the type of measures an importing country might take when an exporting country implements systematic vaccination or emergency vaccination. The Code Commission understood the concerns, clarified that the paragraph relates to a potential increased risk of introduction of a disease in a free country or zone, and proposed to replace 'occurrence' with 'introduction'.

The revised draft Chapter 4.X. is attached as **Annex 10** and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

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

**A comment is inserted in the text of Annex 10.**

**4.8. The role of Veterinary Services in food safety systems (Chapter 6.1.)**

Comments from Argentina, Australia, Brazil, Canada, China, Malaysia, New Caledonia, Singapore, Switzerland, Thailand, OIE Members of the Region of the Americas and EU, AU-IBAR.

The Code Commission noted comments in support of the proposed changes to this chapter.

In relation to Member Countries comments on the need to explain the context in which Veterinary Services contribute to food safety systems, the Code Commission clarified that this is not explained in this chapter but rather in Articles 3.2.9. and 3.4.12. It also mentioned that each country has its own administrative organisational structure, which means they may not always have the same entities dealing with food safety, which is why it is more appropriate to use 'Competent Authority'. The Code Commission explained that this chapter is intended to assist Members Countries to understand the role of Veterinary Services in food safety.

**Article 6.1.1.**

The Code Commission did not agree with Member Countries comments and reiterated the explanation given in its previous report that food safety encompasses foodborne zoonosis and food hygiene, the latter being related to food products. Veterinarians are trained in animal health, including foodborne zoonosis and food hygiene, which supports their role in food safety.

The Code Commission agreed with the proposal of a Member Country to delete the unnecessary wording at the beginning of the first sentence to improve the readability and clarity.

**Article 6.1.3.**

1. Food chain approach

The Code Commission did not agree with a Member Country suggestion to replace 'hazards' with 'risk' in the first paragraph, as a hazard is a factor to be detected on the food chain in order to reduce the risk.

The Code Commission did not agree with a Member Country suggestion to change 'adverse' to 'unwanted'. The Code Commission explained that the difference between an 'adverse' and an 'unwanted' health effect was discussed over several meetings. A hazard may not have an adverse health effect but may still be unwanted. As 'hazard' is defined in the Glossary, as having the potential to cause an adverse health effect, the Code Commission considered the concern is already covered.

2. Risk-based food safety systems

The Code Commission did not agree with Member Countries proposal to change the example on the importance of monitoring food safety outcomes […] system, to include a reference to 'prevalence or occurrence of infections in the zone', as this was covered in other chapters, for example, Article 6.12.4. Objectives of prevention and control measures.

The Code Commission did not agree with another Member Country proposal to delete the examples provided on monitoring food safety outcomes […] system. Firstly, the Code Commission clarified that the OIE mandate includes animal production food safety. Furthermore, it noted the majority of foodborne zoonotic diseases are linked to the status of the herd rather than the zone of origin of the animals. The Code Commission further clarified that because of the OIE's mandate it is relevant for

the *Code,* rather than the FAO/WHO Codex Alimentarius, to address the status of animals before the slaughterhouse.

4. Responsibilities of the relevant Competent Authorities

In regard to a Member Country suggestion to delete 'other responsible agencies,' the Code Commission agreed that Competent Authorities are inclusive of 'other responsible agencies' and amended the sentence for clarity.

The Code Commission agreed with a Member Country proposal to delete 'reassess' in the point on 'assessment of third party', considering that where the Competent Authority delegates some control responsibilities to a third party, it should assess the third party regularly. This amendment also addressed the concerns of another Member Country.

**Article 6.1.4.**

1. Roles and responsibilities Veterinary Services in a food safety system

The Code Commission agreed with a proposal of a Member Country to re-order the sentence as it could be misinterpreted as currently written. In response to a Member Country comment that the notion of 'a flexible approach' was not clear, the Code Commission clarified that it means that Veterinary Services should be able to adapt to the situation depending on the risks and the type of production etc. Such adaptability is needed for the Veterinary Services to be effective and efficient.

The Code Commission agreed in part with the proposal of a Member Country to amend the paragraph describing the contribution of Veterinary Services to other food safety activities. However, the Code Commission did not agree to include 'active role' as it considered this was already covered in education and training in the OIE Guidelines for Core Veterinary Curriculum.

2. Activities of Veterinary Services throughout the food chain

The Code Commission noted that a variety of terms are used to describe the activities of Veterinary Services throughout the food chain (i.e. from farm to harvest, farm to transformation, farm to fork etc.).

Regarding a Member Country proposal to reword the paragraph on primary production, the Code Commission did not agree as it changed the meaning of the sentence. Here the intended meaning is that Veterinary Services play a key role in biosecurity and in early detection, surveillance etc.

The Code Commission agreed with the comment of a Member Country to include 'healthy' in item a), as Veterinary Services play a key role in ensuring that animals are healthy, through their presence on farm and in collaboration with farmers. Some Member Countries did not appear to understand the text, so the Code Commission amended it to clearly state that biosecurity and early detection and surveillance are key roles of the Veterinary Services, replacing 'and' with 'as well as'.

The Code Commission disagreed with a Member Country proposal to include 'and/or additives' and referred to the definition of 'feed' in the Glossary, which includes all feed ingredients, and additives are feed ingredients. The Code Commission deleted the word 'animal' as it was unnecessary considering the definition in the Glossary.

The Code Commission agreed with Member Countries proposals to delete the words 'In regard to food safety', as the chapter is about food safety, so it is implicit.

In response to a Member Country comment in relation to the role of the Veterinary Services in control and guidance, the Code Commission clarified that their role involves both. According to the dictionary definition, 'guidance' can be advice, or information or direction on how to do something. For clarity, the Code Commission changed the word 'guidance' to 'direction'.

The Code Commission disagreed with a Member Country proposal to add 'in particular', as the Member Country considered the role of Veterinary Services could also extend to plant products. In

general Veterinary Services are not involved in the investigation or response to foodborne illness outbreaks in humans that are not linked to animal products i.e. vegetables or other plant products.

The revised draft Chapter 6.1. is attached as Annex 11 and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

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

**Comments are inserted in the text of Annex 11.**

**4.9. Harmonisation of national antimicrobial resistance surveillance and monitoring programmes (Chapter 6.7.) including consideration of the report of the ad hoc Group on Antimicrobial Resistance (January 2018)**

Comments were received from Argentina, Australia, Brazil, China, Japan, New Caledonia, New Zealand, Singapore, Switzerland, Thailand, USA, OIE Members of the Region of the Americas, EU and AU-IBAR.

The Code Commission thanked the *ad hoc* Group for its work and noted that it had made proposals to harmonise text throughout Chapter 6.7., and to address Member Country comments. The Code Commission considered the revised draft chapter article by article taking into consideration the suggestions of the *ad hoc* Group and Member Country comments. Given the volume of comments on this chapter, Member Countries are requested to read the *ad hoc* Group report where more detailed rationales are provided.

The Code Commission and the *ad hoc* Group noted conflicting comments received from Member Countries on the importance of the environment and animal feed in surveillance of antimicrobial resistance and monitoring of the prevalence of resistance. It was noted in response to these comments that monitoring and surveillance will always be according to national priorities, and it was unnecessary to repeat this throughout the text. Furthermore, the *ad hoc* Group recognised that in addition to human, animal and food, the environment is also important for surveillance of AMR and should be identified as such in the chapter. Nevertheless, as some Member Countries have currently limited surveillance measures in place, it was of the opinion that environment should be part of the surveillance of AMR when it is possible and part of the national priorities. For example, some countries sample the animal-immediate-environment or wider environment as part of national priorities; the Code Commission agreed with the *ad hoc* Group on this point.

**Article 6.7.2.**

Points 3 and 4, the Code Commission disagreed with a Member Country proposal to replace 'human' with 'public', noting that the chapter is about monitoring and surveillance for both animal and human health, whereas veterinary public health is a broader term.

**Article 6.7.3.**

In response to Member Countries comments, the Code Commission proposed to replace 'animal feed' with 'feed' as feed is always linked to the feeding of animals and is defined in the Glossary.

The Code Commission agreed with the *ad hoc* Group, not to accept a Member Country proposal to replace 'should' with 'may' in respect of considering feed and the environment and to add 'dependent on scientific advice' as it was unnecessary, since national priorities allow for risk assessment and new scientific inputs and a monitoring program should be science-based anyway.

**Article 6.7.4.**

Point 1 a), the Code Commission did not accept a proposal of a Member Country to include 'as outlined in the study design' and to add a new bullet point on representativeness and appropriateness

of the sample. The Code Commission agreed with the proposal of the *ad hoc* Group to amend bullet a) to include 'and meets the objectives of surveillance' to address the Member Country concerns.

Point 2, a Member Country proposed to add a new sentence to the third paragraph to clarify samples from which bacteria were not isolated cannot be used in the calculation of prevalence of the resistance phenotype, while agreeing with the Member Country's rationale, the Code Commission disagreed with the proposed amendment. This is because the 2nd paragraph clarifies that both the expected prevalence of the bacteria in the sample type and the expected prevalence of the resistance phenotype are taken into account in deciding the sample size for the prevalence of the resistance phenotype.

Table 1, the *ad hoc* Group at first agreed with a proposal to update Table 1 for lower prevalence, ensuring consistency with the rest of the Table. However, the *ad hoc* Group noted that the figures in this table had been generated using a widely used software (Epi Info TM Version 7.2.2.6., freely available at https://www.cdc.gov/epiinfo/index.html). Furthermore, it noted that at low levels of expected prevalence, exact methods of sample size calculation would be preferred to the approximate methods used here; that the sample size estimates in the table should be considered as indicative only; and that a statistician should be consulted during the design of the surveillance programme to ensure the sample size, in particular for rare occurrences, is suitable for the national situation. In view of this comment from the *ad hoc* Group, the Code Commission proposed that Table 1 be deleted from the chapter and requested the OIE Headquarters to provide this information on the OIE website for Member Countries.

Point 3 a), the Code Commission disagreed with Member Countries proposals to replace 'animal' with 'livestock', noting the article is about food producing animals and the term livestock encompasses all food producing animals and its meaning is broader.

The Code Commission agreed with the proposal of Member Countries to add 'criteria such as' to allow a more flexible approach to resource allocation in relation to categories of food producing animals.

Point 3 b), the Code Commission agreed with the *ad hoc* Group not to accept a Member Country proposal to include 'taking a risk-based approach' and 'although the extent of this is still unknown'. The *ad hoc* Group noted that there is currently insufficient information available on risk-based approaches to AMR and that inclusion of this would be considered when more information becomes available. The Code Commission also disagreed with the second part of the proposal, as it did not add value to the paragraph.

Point 3 c), the Code Commission agreed with a Member Country, that monitoring programmes on animal feed should be based on available resources, species and national priorities. However, as reference to national priorities is covered in Article 6.7.3. General aspects, there is no need to repeat it throughout the chapter.

Point 3 d), in response to Member Countries proposals to include the environment, the Code Commission agreed with the proposal of the *ad hoc* Group to include a new point noting that national priorities are already covered.

Point 4, Member Countries proposed to delete 'and should be linked to pathogen specific', the Code Commission agreed that many countries do not routinely conduct pathogen surveillance of feedstuffs and amended the sentence for clarity.

The Code Commission agreed with the *ad hoc* Group and proposed to re-order the paragraphs for consistency but did not accept the editorial amendments as proposed by a Member Country, as it did not add to the clarity of the sentence.

Regarding Table 2, in response to Member Countries comments the Code Commission agreed with the *ad hoc* Group proposal to include a new line to cover sampling of the animal-immediate or the wider environment (see also point 3, d) above) in the chapter.

The Code Commission and the *ad hoc* Group did not accept a Member Country proposal to insert 'prior to any anti-microbial interventions' as it considered this too detailed, given the more general nature of the other examples.

**Article 6.7.5.**

Point 1 b), in response to a proposal of a Member Country to add 'animal health concern', the Code Commission disagreed as clinically ill animals recover and can still enter the food chain and emerging resistance would always be considered an animal health concern.

The Code Commission disagreed with the proposal of a Member Country to replace 'should' with 'may' but agreed with the proposal to add 'one or more', to indicate the importance of surveillance of animal bacterial pathogens and at the same time maintaining flexibility.

**Table 3**

The Code Commission noted a Member Country proposal to include 'meat' with respect to where samples are collected for commensal *E.coli* and that the table should be expanded to include other categories including zoonotic bacteria and commensal bacteria. The *ad hoc* Group did not accept the proposal as it related to text already agreed during this round of revision to the chapter, but it will be considered in a future revision of the chapter. The Code Commission further noted that commensal bacteria are covered in Article 6.7.5.3. and as Table 3 focuses on animal bacterial pathogens it is not appropriate to include commensals and zoonotic bacteria.

In response to Member Countries suggestions to include 'aquatic animals,' the Code Commission noted that this was within the mandate of the Aquatic Animals Commission and was covered in Section 6 of the Aquatic Code. The President raised this issue with the President of the Aquatic Animals Commission during their meeting on 14 February 2018. The Member Countries are encouraged to address these comments to the Aquatic Animals Commission.

**Point 2**

The Code Commission disagreed with the proposal of the *ad hoc* Group and a Member Country to amend the text to allow flexibility for the design of epidemiology studies according to national priorities, as national priorities are already covered in the chapter and it would be unnecessarily repetitive. The Code Commission agreed with other editorial amendments that improved the clarity of this point.

The Code Commission rejected the proposal of the *ad hoc* Group to insert a new point to address sampling of the environment and amended the paragraph as proposed by the Member Countries.

In response to a Member Country proposal to include 'phage-typed or genetic methods,' the Code Commission recalled that the rationale for phage-typed methods being deleted was because they are not considered reliable by experts.

The Code Commission disagreed with the proposal of the *ad hoc* Group to insert 'based on national priorities' at the beginning of article 6.7.5. in points b) and c) as it is included in Article 6.7.3. General aspects. However, the Code Commission proposed to change 'and' to 'or' to clarify that campylobacter should be isolated from food-producing animals or associated food products rather than always both.

Point 3, the Code Commission disagreed with the *ad hoc* Group decision not to consider a Member Country proposal to include 'meat' in the second paragraph. The Code Commission recalled the discussion from its last meeting, that it was more appropriate to take the samples from feed at the feed mill; it does not mean you cannot take them at other points. The Code Commission proposed to amend the sentence to indicate that samples should preferably be taken from healthy animals and to improve syntax and readability.

**Article 6.7.7.**

The *ad hoc* Group disagreed with a Member Country proposal to delete text in the second paragraph, explaining that not all surveillance systems can provide quantitative data at this point in time; not all audiences can correctly interpret qualitative data; and the quantitative data can be misinterpreted as being a completely accurate representation of what would happen in the body, therefore it was necessary to maintain the emphasis on both qualitative and quantitative data. The Code Commission also recalled that 'qualitative' and 'quantitative' had been added previously to enhance Member Countries capabilities and to consider those countries that could not do quantitative analysis. It further noted that the technique has been included in the *Code* for a long time. In response to the second part of the same Member Countries proposal to delete 'inhibition zone diameters', the Code Commission agreed that there is a better technique but the *Code* has to be practical in order for all Member Countries to be able to implement it.

**Article 6.7.8.**

In response to a Member Country proposal to include reference to 'clinical breakpoints,' the Code Commission noted the opinion of the *ad hoc* Group (see below) and agreed with its proposals for amending the text.

> "The Group noted that there are not always clinical breakpoints available for all antimicrobial/bacterial species combinations and that clinical breakpoints might differ between countries. The Group noted that the microbiological breakpoints do not differ between the countries. Human AMR surveillance is based on the microbiological breakpoint and hence if a desire for the surveillance program is to compare with human AMR, then the microbiological breakpoint would be preferable. The Group agreed that both types of breakpoints could provide useful information.
>
> As a result of this discussion, the Group agreed to maintain the original text and add the concept of clinical breakpoints as a new sentence to maintain the original intent of the paragraph, yet add the new information. The new sentence at the end was added as follows: 'Clinical breakpoints (where available) should also be reported.' The group did not delete the last sentence of the paragraph because no rationale was provided by the Member Country for the deletion. The Group did not accept the change to 'microbiological cut off' because the standard terminology is 'microbiological breakpoint' or 'epidemiological cut-off value' based on EUCAST1 and CLSI2."

A Member Country proposed to modify point 10, which addresses collecting data at the individual isolate level and including data on uses of antimicrobials. The Code Commission disagreed with the proposal to replace 'along with' with 'may' and proposed to add 'where available' which would allow for greater flexibility in reporting, as not all countries will be able to collect data on antimicrobial use or management practices.

The Code Commission noted that if the revised chapter was adopted by the General Session in 2018, it would not be included in its work programme for further revision until there is robust data from experts and discussion in other fora is complete (i.e. Codex).

The revised draft Chapter 6.7. is attached as **Annex 12** and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

**The EU thanks the OIE for having taken into account some of its previous comments.**

**However, we cannot support the adoption of this modified chapter unless the important comments inserted in the text of Annex 12 have been addressed.**

**A further comment is inserted in Annex 12.**

**4.10. Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals (Articles 6.8.1. and 6.8.1 bis) including consideration of the report of the ad hoc Group on Antimicrobial Resistance (January 2018)**

Comments were received from Argentina, Australia, Brazil, Japan, Malaysia, Singapore, Switzerland, USA, EU and AU-IBAR.

**Article 6.8.1.**

In response to Member Countries proposals to replace 'therapeutic' with 'infectious disease related' the *ad hoc* Group proposed the inclusion of 'infection or disease'. The Code Commission partly disagreed with the rationale provided by the *ad hoc* Group i.e. therapeutic is related to disease and nontherapeutic is related to production, but proposed to include 'infectious disease' for consistency with the *Code*.

The Code Commission disagreed with the proposed addition of 'production' in relation to nontherapeutic use, as there are other uses that are not related to production i.e. colouring of bones, research etc. and it is unnecessary to include a list of examples. However, the Code Commission agreed it was appropriate to leave 'including growth promotion' as this was the major percentage of nontherapeutic use.

A Member Country proposed adding 'according to a country's resources and priorities' to the second paragraph about 'evaluating antimicrobial exposure in food-producing animals.' The Code Commission agreed with the rationale of the *ad hoc* Group not accepting the addition as the implementation of OIE standards is always in accordance with a country's resources and priorities.

**Article 6.8.1. bis**

The Code Commission agreed with the suggestion of the *ad hoc* Group not to accept Member Countries proposals to amend the text to harmonise the G7 CVO Forum definitions and the OIE definitions. The rationale is provided below:

'The Group noted that the G7 and the OIE processes are different and that the representation of the two groups is very different. As part of the review of the two sets of definitions, the Group recalled that at their previous meeting (and documented in the meeting report), that 'control' had the same meaning as 'metaphylaxis' and that 'preventive' had the same meaning as 'prophylaxis'. The Code Commission took note of the Group's meeting report and decided to adopt the most well understood terms of 'control' and 'preventive use' for inclusion in the Chapter. The Group also noted that in human medicine, 'metaphylaxis' is not well understood worldwide and hence 'metaphylaxis' is not the preferred word for the OIE. With all this in mind, the Group recommended keeping the OIE definitions.'

Furthermore, the *ad hoc* Group considered that the question of whether the OIE guidelines would need to be amended to guide interpretation of the WHO guidelines on use of medically important antimicrobials in food-producing animals was outside its mandate and Terms of Reference. The Code Commission also noted that the prudent use of antimicrobials is covered in Chapter 6.9., whereas this chapter is meant to help members in monitoring the use.

Taking into consideration the proposals and rationale of the *ad hoc* Group and the discussion above, the Code Commission proposed the following amendments to the definitions.

**Therapeutic Use**

The Code Commission included 'infectious disease', see rationale provided above.

The Code Commission disagreed with Member Countries proposals to include 'dose and duration' in the sub-points on both 'treatment' and 'control'. The Code Commission proposed instead to delete the reference in the sub point 'prevent', as this also addressed other Member Country comments proposing its deletion, because dose and duration relates to the prudent use of antimicrobials, covered in Chapter 6.9. The Code Commission also agreed with the proposed deletion of 'Using an appropriate dose and for a limited, defined duration', because its policy is to

have short descriptive, explanatory definitions and not to include recommendations within definitions.

Further in the proposed definition of 'to prevent' the Code Commission agreed with Member Countries proposals to replace 'developing' with 'acquire'. The Code Commission clarified 'infection' is defined as the entry and development of a pathogenic agent, the ultimate goal being to prevent infectious disease.

**Nontherapeutic Use**

The Code Commission proposed to replace 'infection or disease' with 'infectious disease' for consistency with the rest of the chapter, especially Article 6.8.1.

**Growth promotion**

The Code Commission accepted a Member Country proposal to delete 'in their feed or water', as the inclusion of the route of administration within the growth promotion definition is irrelevant and is confusing, as it can also apply to the definitions underneath therapeutic use.

The Code Commission disagreed to completely align the definition with that of the Codex Alimentarius, which dates years back, by adding *'The term does NOT apply to the use of antimicrobials for the specific purpose of treating, controlling, or preventing infectious diseases, even when an incidental growth response may be obtained'*. The Code Commission considered there is no need to specify what is not growth promotion, since the other uses of antimicrobials are already defined above. However, for clarity, and to answer the concerns of the *ad hoc* Group of possible growth response side effect of therapeutic use, it added the word 'only' before 'to increase their weight gain'.

In response to a Member Country comment that exclusions of some products within the definition should be considered, the Code Commission disagreed as the definition of 'antimicrobial agents' contained in the Glossary is clear.

The draft revised Article 6.8.1. and new Article 6.8.1.bis (including the definitions) are attached at **Annex 13** and are proposed for adoption at the 86th General Session in May 2018.

**EU position**

**The EU thanks the OIE for having taken into account some of its previous comments.**

**However, we cannot support the adoption of this modified chapter unless the important comments inserted in the text of Annex 13 have been addressed.**

**A further comment is inserted in Annex 13.**

**4.11. Prevention and control of *Salmonella* in commercial pig production systems (Articles 6.13.2., 6.13.3. and 6.13.16.)**

Comments were received from Switzerland, EU and AU-IBAR.

The Code Commission noted Member Countries support for the proposed amendments to the chapter and that it had responded to Member Countries comments regarding the purpose of this chapter under Agenda Item 2 User's Guide.

In examining Member Countries comments on Article 6.13.2. the Code Commission noted its previous discussions on the definition of 'commercial pig production systems' and that the differences in countries understanding of trade as only being international trade, and others that did not distinguish between international and domestic trade. It further noted that 'commercially placing on the market' was also not clear and did not add clarity to the definition. The definition was amended to clarify that the chapter is applicable 'for the production and sale of pigs or pig meat'.

**Article 6.13.3**.

In response to Member Countries comments relating to outdoor pig production systems being by default commercial, the Code Commission noted that outdoor pig production systems are becoming more common so they should be mentioned.

**Article 6.13.16.**

The Code Commission partially agreed with a Member Country proposal to include 'wild animals' as well as 'wild birds' and replaced 'wild birds' with 'wildlife'.

The revised Chapter 6.13. is attached as **Annex 14** and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

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

**4.12. New chapter on introduction to recommendations for veterinary public health (Chapter 6.X.)**

Comments were received from Australia, Malaysia, Singapore, Switzerland and EU.

The Code Commission noted comments in support of the proposed new chapter.

**Article 6.X.1.**

The Code Commission agreed with the proposal of a Member Country to replace 'eating habits and their consequences such as' with 'changing food consumption patterns' but kept 'and their consequences such as' to keep the link between the two.

The Code Commission disagreed with Member Countries proposals to include 'zoonotic' before 'emerging disease' as the paragraph was about the factors that influence the emergence of disease, only some of which are zoonotic. However, for clarity, it proposed amending the wording to include 'some of which are zoonotic' after 'emerging diseases'.

The Code Commission disagreed with the proposal of a Member Country to include 'unregulated' before 'use', because any use, including misuse, can contribute to problems.

The Code Commission partially agreed with a Member Country proposal to amend the paragraph to include Veterinary Services role in the 'management of health risks…' but considering the rest of the paragraph was clear and needed no additional clarification.

The revised draft Chapter 6.X. is attached as **Annex 15** and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

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

**A comment is inserted in the text of Annex 15.**

**4.13. Introduction to the recommendations for animal welfare (Article 7.1.1.)**

Comments were received from Australia, Canada, Costa Rica, Guatemala, Malaysia, New Zealand, Switzerland, Thailand, USA, OIE Members of the Region of the Americas, EU, AU-IBAR, and ICFAW.

The Code Commission took note of the general comments of Member Countries and an organisation and reiterated the objective of the proposed modification to the OIE definition of

animal welfare was to develop a concise text, harmonised with the approach taken in the Glossary of the *Code* while the details remain in the chapter.

The Code Commission agreed with Member Countries proposals to replace the word ‘psychological' with ‘mental' when referring to the state of the animal in relation to the condition in which it lives, as the term ‘mental' is more commonly used for animals and easily understood and accepted by all Member Countries. This modification was also applied in the second paragraph of this article.

In response to a Member Country proposal to amend the last part of the first paragraph of the article, to replace the word ‘dies' with ‘death', the Code Commission did not agree with the suggestion as it did not add clarity to the text.

The Code Commission accepted a Member Country proposal to replace the word ‘enjoy' with ‘experience'. The Code Commission agreed that, although the intention was to use ‘enjoy' in its legal sense, the term could easily be interpreted in its common meaning that is to ‘feel pleasure'. The Code Commission noted and thanked some Member Countries for their comments on the third paragraph and reassured them that the OIE would continue promoting the basic concepts and guidelines mentioned throughout Chapter 7.1.

In response to a Member Country proposal to delete the third paragraph of the article, as it considered it was repetitive, the Code Commission did not agree as the first part refers to the condition of the animal's environment and the second part relates to the users, and how they should treat the animals.

The Code Commission agreed with the proposal of a Member Country to add the word ‘safe' as a condition of the need for a stimulating environment to achieve good animal welfare. In the same paragraph, the Code Commission did not agree with the suggestion of an organisation to include the word ‘secure' as another necessary condition, because it considered the previous modification covered it, and the two words have similar meanings.

The Code Commission did not agree with the suggestions of some Member Countries to modify the last sentence of the third paragraph of the article. Nevertheless, it made some modifications to improve readability.

The revised definition of animal welfare proposed for adoption at the 86th General Session in May 2018 under Agenda Item 2 Glossary Part A.

The revised Article 7.1.1. is attached as **Annex 16** and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

**The EU thanks the OIE for its work on the revision of Article 7.1.1. and for taking some of the EU comments into account. The EU can agree with the proposed changes and support the adoption of this revised article.**

**4.14. New article on guiding principles for the use of measures to assess animal welfare (Article 7.1.X.)**

Comments were received from Canada, New Zealand, Switzerland, Thailand, USA, EU and AU-IBAR.

The Code Commission took note of the general comments of Member Countries regarding the suggestion to review the chapter to ensure that newer production system practices are well covered in the *Code*. The Code Commission indicated that for recently developed chapters and ones under development, Article 7.1.2. guiding principles for animal welfare and Article 7.1.3. scientific basis for recommendations are also applicable.

In examining Member Country comments on point 1, the Code Commission agreed to replace the word ‘enjoyment' with ‘experience', for consistency with Article 7.1.1.

The Code Commission did not agree with a Member Country proposal to delete the last part of the first sentence of point 1, as OIE animal welfare standards are applicable globally and some specific conditions should be considered, as is the case with outdoor systems.

Some Member Countries commented on a preference to use the concept of the 'five domains' instead of 'five freedoms' referring to favourable outcomes for animal welfare. The Code Commission noted that the latter is still part of the guiding principles for animal welfare and are mentioned in Article 7.1.2. but agreed this could be considered in a future revision of the chapter.

The Code Commission agreed with the proposal of some Member Countries on point 3, to replace the word 'standards' with 'recommendations'. Nevertheless, the Code Commission agreed to keep the word 'standard' in point 1 of this article, as in this case, it refers to the general concept of animal welfare and not to a specific recommendation in the chapter.

On the same point, the Code Commission agreed with the suggestion of a Member Country to delete the reference to 'other relevant bodies' participation in the collection of data. The Code Commission modified the text to emphasise that data used to establish relevant target values could have different origins.

The Code Commission agreed with a Member Country comment on point 4 to reword the sentence to clarify that resource-based measures and management-based measures could also be used if they are linked to an animal welfare outcome.

Regarding the same point, the Code Commission agreed with a Member Country comment on the need to clarify the concepts of animal-based measures, resource-based measures, and management-based measures. Therefore, the Code Commission recommend that the OIE Headquarters include a brief explanation of these concepts on the animal welfare portal on its website.

The Code Commission agreed with a Member Country proposal to delete the words 'or conditions', referring to the selection of appropriate animal-based measures, as its meaning is not well understood. However, the Code Commission added the word 'environment', to highlight the need to consider this aspect as its relationship could be fundamental to the animal welfare outcomes expected.

The Code Commission proposed to place this new article after Article 7.1.3. scientific basis for recommendations, as these are the basis for developing animal welfare recommendations and will apply to other chapters on animal welfare in the *Code*.

The new Article 7.1.X. is attached as **Annex 17** and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

**The EU thanks the OIE for its work on the revision of draft Article 7.1.3bis. The EU can agree with the proposed changes and in general supports the adoption of this draft article. The EU would also like to present two additional comments. These are inserted in the text of Annex 17.**

**4.15. Animal Welfare and Pig Production Systems (Chapter 7.X.) including consideration of the *ad hoc* Group report (January 2018)**

Comments were received from Argentina, Australia, Canada, China, Japan, Malaysia, New Caledonia, New Zealand, Singapore, Switzerland, Thailand, USA, OIE Members of the Region of the Americas, EU, AU-IBAR and ICFAW.

The Code Commission thanked the *ad hoc* Group for its work and noted that it had made proposals to harmonise text throughout the chapter and to address Member Country comments. The Code Commission considered the revised draft chapter article by article taking into consideration the suggestions of the *ad hoc* Group and Member Country comments. However, given the volume of comments on this chapter, only the comments and amendments made by the Code Commission that differ from the suggestions of the *ad hoc* Group are included in this report. Member Countries are requested to read this report jointly with the report of the *ad hoc* Group.

The Code Commission took into consideration the proposed modifications to Chapter 7.1. in reviewing this chapter.

**Article 7.X.1.**

The Code Commission aligned the definition of 'commercial pig production systems' with Chapter 6.13. Prevention and control of salmonella.

**Article 7.X.3.**

Point 2, the Code Commission considered it more appropriate to use ‘kept' in paddocks instead of ‘housed’ and agreed to use the word ‘mantenidos' in the Spanish version of the *Code*.

**Article 7.X.4.**

In the first paragraph regarding the examples of indicators based on criteria (or measurables) for the welfare of pigs, the Code Commission changed ‘hybrid' to ‘crossbreed', as hybrid could refer to an interspecies crossing.

The Code Commission recommended harmonising the terminology in all the animal welfare chapters such as the use of the expression ’animal-based criteria’ after the adoption of Articles 7.1. and 7.1.3 bis to improve consistency among chapters.

Point 1, the Code Commission partially agreed with the amendment proposed by the *ad hoc* Group in response to a Member Country proposal to add a new paragraph on behaviours as indicators of good animal welfare and health in pigs. However, it did not consider it was relevant to include examples related to vocalisation.

Point 1, the Code Commission replaced ‘freezing' with ‘sudden immobility' to improve clarity and facilitate translation.

Point 9, the Code Commission proposed new wording in response to Member Countries comments, which proposed the use of ‘on' rather than ‘in' when referring to painful or potentially painful procedures performed on pigs.

**Article 7.X.7.**

The Code Commission amended the paragraph proposed by the *ad hoc* Group, for clarity and consistency.

The Code Commission did not agree with the modifications proposed by the *ad hoc* Group on the fourth paragraph regarding the timely manner in which to provide treatment for sick or injured pigs. The Code Commission considered it more appropriated to use ‘as soon as possible’ rather than ‘without delay’.

**Article 7.X.8.**

The Code Commission disagreed with the proposal of the *ad hoc* Group as it considered that the Member County proposal gave greater clarity and amended the paragraph accordingly.

The Code Commission did not agree with the proposal of the *ad hoc* Group to add ‘or both’ when referring to the use of ‘analgesia or anaesthesia', as in English ‘or' is not exclusive unless preceded by ‘either’.

The Code Commission did not agree with the suggestion of the *ad hoc* Group to remove the reference to the quality of the water (drinkable) to be offered to the pigs and retained the original wording for consistency with other chapters of the *Code*.

**Article 7.X.10.**

The Code Commission amended the examples proposed by the *ad hoc* Group ‘of fostered normal behaviours’ with ‘environmental enrichment’ for clarity.

**Article 7.X.16.**

The Code Commission reworded the sentence proposed by the *ad hoc* Group taking into account a Member Country comment about the effect of the temperature in relation to the weight of pigs.

**Article 7.X.20.**

The Code Commission disagreed with the comment of the *ad hoc* Group not to accept a Member Country proposal on monitoring newly weaned pigs. The Code Commission proposed to add ‘carefully' to highlight the need to monitor newly weaned pigs for any signs of ill health or abnormal stress.

**Article 7.X.22.**

The Code Commission disagreed with the modifications to the second paragraph proposed by the *ad hoc* Group and reformulated the sentence according to the suggestion of a Member Country.

**Article 7.X.26.**

A Member Country proposed to include reference to the Livestock Emergency Guidelines and Standards (LEGS) of FAO. The Code Commission did not agree as links to the LEGS website and the LEGS guidelines are included in the OIE webpage (Developments in animal welfare.)

The Draft Chapter 7.X. is attached as **Annex 18** and is proposed for adoption at the 86th General Session in May 2018. The report of the *ad hoc* Group is attached as **Annex 43** for Member Countries information.

**EU position**

**The EU thanks the OIE for its work on the revision of the draft chapter and for taking some of the EU comments into account. The EU can agree with the proposed changes and support the adoption of this draft chapter.**

**Nevertheless given the importance of this chapter, the EU asks the OIE to reconsider the EU comments reiterated in the text of Annex 18, in particular as regards group housing of sows, for future revisions of the chapter following adoption. The EU will provide additional scientific information as soon as it becomes available.**

**Furthermore, the EU would like to present some additional comments for further fine-tuning of the chapter following its adoption. These are inserted in the text of Annex 18.**

### 4.16. Infection with bluetongue virus (Chapter 8.3.)

Comments were received from Australia, China, Chinese Taipei, New Zealand, Switzerland, USA, EU and AU-IBAR.

In response to a general comment of a Member Country regarding consistency in Article 8.3.6. to Article 8.3.10. and proposing to align them with other chapters such as Chapter 8.8. foot and mouth disease, the Code Commission noted that this chapter was currently under revision and recalled it had explained in its February 2016 report the approach it would be taking to naming of diseases in the *Code* in the future.

**TAHSC 2016 February Report**

**'c) Convention for naming diseases in the Code**

In response to a Member Country's comment, the Code Commission clarified that the new convention for naming a disease is to use the wording 'infection with [pathogenic agent]'. It noted that if the vernacular disease name differs from this format, the Code Commission will decide whether to include the vernacular name in brackets in the title only, e.g. Infection with *Chlamydophila abortus* (Enzootic abortion of ewes, ovine chlamydiosis). The Code Commission noted that this convention will be implemented with all new chapters and for existing chapters as they come up for review.

The Code Commission also noted that for describing the disease status of a country or zone, if the disease is named after the pathogenic agent name, then the country or zone status will be described as 'free from infection with [pathogenic agent]', e.g. free from infection with Chlamydophila abortus, or free from infection with Brucella spp. However, if the pathogenic agent is named after the vernacular name of the disease, the country or zone status will be described as 'free from [disease]', e.g. free from foot and mouth disease or free from rabies.

The Code Commission noted that it will continue to discuss this naming convention with the Biological Standards Commission to ensure appropriate harmonisation of disease chapter titles in the *Code* and the *Manual*.'

**EU comment**

**The EU supports the Code Commission's approach to naming of diseases in the Code, as described in its February 2016 meeting report.**

Responding to a proposal from a Member Country, the Code Commission noted that there was a need for expert opinion on timeframes and durations for the collection of semen and embryos. The Code Commission has requested OIE Headquarters to obtain this advice. With respect to the proposal to define 'embryo collection ', 'oocyte collection' and 'semen collection', the Code Commission included this in its earlier discussion on the Glossary.

**Article 8.3.4.**

Member Countries comments on seasonally free status were forwarded to OIE Headquarters for expert advice.

In response to a Member Country proposal the Code Commission did not agree to include reference to Articles 8..3.14 to 8.3.17 because the reference to 'the surveillance' in accordance with these articles is covered in point 1) of this article.

**Article 8.3.6.**

Some Member Countries consider there is a contradiction between different options in this article. The Code Commission amended point 5 a) for clarity.

**Article 8.3.7.**

In response to a Member Country proposal on points 3 and 4 for consistency and clarity, the Code Commission simplified the two points by deleting 'in the zone' rather than adding extra words.

**Article 8.3.8.**

The Code Commission agreed with a proposal of a Member Country to replace 'dispatch' with 'shipment' to add clarity to the article.

**Article 8.3.9.**

The Code Commission did not accept the rationale, which a Member Country provided in support of its proposal to make a major change to add a waiting period after the collection of the embryos. Indeed the incubation period should not be considered because there is only a risk when the animal shows clinical signs of the disease during collection.

**Article 8.3.11.**

The Code Commission agreed with the proposal of a Member Country to include 'the semen used to fertilise the oocytes complied with Article 8.3.9. or Article 8.3.10' as semen can be used from a country or zone different from the one where the embryos are produced.

**Article 8.3.16.**

The Code Commission agreed with the proposal of a Member Country to replace 'types' with 'serotypes' for clarity.

The revised draft Chapter 8.3. is attached as **Annex 19** and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

**The EU in general supports the adoption of this modified chapter.**

**A comments is inserted in the text of Annex 19.**

**4.17. Infection with *Brucella abortus, B. melitensis* and *B. suis* (Article 8.4.10.)**

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

The Code Commission noted several Member Countries comments in support of the revised article.

The Code Commission recalled that the changes to this article had been proposed to address the concerns of a Member Country.

The Code Commission disagreed with the proposal of a Member Country to insert 'intact' and delete 'except castrated males' as it did not consider 'intact' added clarity, it inserted 'and spayed females' as it should be explicit these animals should not be tested. The Code Commission disagreed with the proposal of the same Member Country to change the interval of more than '6' to '9' months as this was not supported by a rationale and no value was added by including 'after the first test'.

The Code Commission agreed with the proposal of a Member Country to include 'castrated males or spayed females' in order to be consistent with the change proposed above.

The Code Commission further explained that the rationale for the proposed changes to this article was to clarify that castrated males and spayed females are not considered sexually mature.

The revised draft Article 8.4.10. is attached as **Annex 20** and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

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

**4.18. Infection with rinderpest virus (Article 8.16.2.)**

Comments were received from Switzerland and EU.

In answer to comments of several Member Countries, and from the Biological Standards Commission and the Scientific Commission and after having thoroughly discussed with the OIE Headquarters, the Code Commission proposed to delete the word 'pathological' and reinsert the words 'from animals known or suspected to be infected' since the definition of 'pathological material' in the Glossary seemed to be confusing in the context of the chapter. However, the Code Commission noted that the definition of RPV containing material only applies to material already stored, and is used for the annual reporting of Member Countries that may still be holding such material in their laboratories (national, academia or other facilities). It is linked to Article 8.16.9. only (2017 edition of the Code online) and does not apply to the case definition of Rinderpest in Article 8.16.5. Contrary to the Member Countries comments, it will not have an effect on notification. In that respect, any suspected case should be investigated and eventually confirmed or not, thus there will be no remaining material of 'suspected case'. Furthermore, limiting the definition of RPV containing material to pathological material only from proven infected animals might lead either to the keeping of material that could be containing RPV, or to laboratories doing confirmation tests where they have no capacity to do so and eventually to unnecessary risk.

In response to a question from the OIE Headquarters, the Code Commission clarified that 'laboratory generated material' would include diagnostic kits produced by pharmaceutical companies.

The revised draft Article 8.16.2. is attached as **Annex 21** and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

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

**4.19. Infection with lumpy skin disease virus (Articles 11.9.4., 11.9.5., 11.9.6. and 11.9.15.)**

Comments were received from New Zealand, Switzerland and EU.

The Code Commission noted a number of Member Countries comments in support of the revised chapter. One Member Country proposed the inclusion of lactose as a safe commodity. The Code Commission requested the OIE Headquarters review previous scientific advice on the safety of lactose in relation to this disease and provide it for the September 2018 meeting of the Code Commission.

The revised Articles 11.9.4., 11.9.5., 11.9.6. and 11.9.15. are attached as **Annex 22** are proposed for adoption at the 86th General Session in May 2018.

**EU position**

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

**4.20. Infection with *Burkolderia mallei* (Glanders) (Chapter 12.10.)**

Comments were received from Argentina, Australia, Brazil, Chile, China, Mexico, New Caledonia, New Zealand, Switzerland, USA, OIE Members of the Region of the Americas and EU.

A Member Country urged the OIE to harmonise diagnostic tests, especially given that the specificity of complement fixation testing has been questioned. The Code Commission and the Scientific Commission agreed with the Member Country and requested the OIE, Member Countries and other stakeholders to improve efforts to produce more data to support surveillance recommendations[1]. However, the Code Commission considered that this should not preclude the adoption of the revised *Code* chapter as the revised Chapter 2.5.11 of the *Terrestrial Manual* was adopted in May 2015.

**Article 12.10.1.**

In response to the comment of a Member Country on whether glanders is a rare or significant disease, the Code Commission proposed to amend the wording to read 'glanders, in humans, is a rare but potentially fatal disease'.

In response to Member Countries comments concerning the Glossary definition of 'outbreak', which refers to 'epidemiological unit' (i.e. a group of animals), the Code Commission agreed with the rationale and amended the article as proposed using the term 'case' instead of 'outbreak' in points 2 and 3. Further in regards to the proposal of the same Member Countries on the need to update the Glossary definition of 'epidemiological unit' to include the possibility that it can consist of just one animal, the Code Commission agreed and noted that it would work with the Scientific Commission to amend the definition and would include this in its work programme.

For editorial consistency, the Code Commission replaced 'glanders' with 'infection with *B.mallei'* in points 2 and 3.

**Article 12.10.2.**

[1] Further validation of new diagnostic assays is the subject of research developed under the collaboration between the OIE and the International Horse Sports Confederation, and by other researchers. Dossiers are in preparation for submission to the Biological Standards Commission.

In response to a Member Country proposal to include 'which is not historically free according' in the first paragraph for consistency, the Code Commission noted this was not consistent with other chapters and did not add clarity as point 1 a) of Article 1.4.6. only refers to historical freedom.

In response to several Member Countries comments, the Code Commission clarified that glanders could potentially be missed in surveillance, supporting the requirements for 3 years without a case and 12 months of active surveillance. Furthermore, the Code Commission verified that the *Manual* chapter includes a table, which lists complement fixation as a suitable method for active serological surveillance in support of free status.

**Article 12.10.3.**

The Code Commission agreed with Member Countries that tracing is only one element of any epidemiological investigation and to improve the clarity of the point added 'including' and removed the parenthesis around trace-back and trace-forward.

In response to a Member Country proposal to include 'cleansing' with 'and disinfection', the Code Commission recalled that the Glossary definition of disinfection includes cleansing and for this reason when the word '*disinfection'* is used in the *Code* it is taken to include cleansing.

***Disinfection*** means the application, **after thorough cleansing**, of procedures intended to destroy the infectious or parasitic agents of animal *diseases*, including zoonoses; this applies to premises, *vehicles* and different objects that may have been directly or indirectly contaminated.

**Article 12.10.5.**

The Code Commission modified the text in point 3, taking into account Member Countries comments in respect of the problems of taking samples within 10 days of shipment and to clarify that it was only necessary to ensure that the two samples should be taken within the imposed isolation period and at a minimum interval. The text was modified to read 'were isolated for at least 30 days prior to shipment, and during that time was subjected to test for *infection* with *B. mallei*~~,~~ with negative results carried out on two samples taken 21 to 30 days apart'. This takes into account the fact that the animals are isolated until the time of shipment and that in some regions it is not possible to obtain the results of tests within such a short period.

**Articles 12.10.6. and 12.10.7.**

A Member Country reiterated its previous comments requesting the Code Commission to reinstate the requirements for testing of semen, the Code Commission disagreed noting it had explained in previous reports how this risk was managed through the inclusion of the measures in both points 1 and 2.

The Code Commission agreed with a Member Country comment on the need to include lesions on the rest of the horse's body, noting that the risk of contamination of the semen is from lesions in the sexual organs of the animal. However, it is possible that lesions on the body could also indicate lesions elsewhere that could be missed during an inspection of the horse. The Code Commission expanded the point to include the need to examine the body as well.

In response to comments from two Member Countries with regards to the deletion of points i) and ii), the Code Commission recalled that it had provided the rationale in its report in September 2015, including scientific references. It again reminded Member Countries when preparing their written comments, it was important to look at the history of the development of the chapter, to avoid revisiting arguments that had previously been addressed, unless of course there was new scientific evidence to support their position.

**TAHSC September 2015 Report**

> 'The Code Commission reviewed the literature on the risk of transmission of B. *mallei* via semen and embryos and concluded that most of the sanitary measures proposed for Articles 12.10.6. and 12.10.7. should be deleted based on the following rationale:
>
> Most of the sanitary measures recommended in Article 12.10.6., and Article 12.10.7., should be deleted, as there is insufficient scientific basis to require such restrictions on either embryos or semen. The *ad hoc* Group report that supports the inclusion of these articles in the *Code* cites a single publication to justify the application of these measures, namely Khan et al. (2013) Glanders in animals: A review on epidemiology, clinical presentation, diagnosis, and countermeasures. Transboundary and Emerging Diseases, 60, 204-221. The *ad hoc* Group report summarises this review as stating that a large percentage of infected equines had orchitis and therefore concluded that "it cannot be stated with any certainty that semen cannot transmit B. *mallei* infection", and this same argument (orchitis) is used to justify the imposition of measures for the international trade in equine embryos.
>
> The epidemiology section of the Khan et al. review paper cited makes no reference to the transmission of B. mallei through equine germplasm although it does cite Saqib (2009) as describing 31/69 horses with glanders as having orchitis. Saqib (2009) is a Ph.D. thesis from the University of Faisalabad, Pakistan. The literature review of that thesis describes the transmission of B. mallei by ingestion or inhalation but makes no reference to venereal transmission (pp 20-21). Although the thesis does describe orchitis in a number of horses with glanders, the section of the thesis (pp 93-94) suggests that this is actually the cutaneous form of glanders and is associated with contaminated bedding.'

**Article 12.10.8.**

In response to a Member Country proposal that all susceptible species relevant to the epidemiology should be considered in surveillance, the Code Commission disagreed with the proposal as the significantly relevant species are equids as defined in Article 12.10.1.

In response to several proposals from Member Countries, the Code Commission made editorial amendments to the Article to ensure consistency and correct syntax, and improve clarity and readability.

In response to a proposal from Member Countries to delete the last paragraph related to surveillance, the Code Commission did not agree that it was redundant and moved it to the beginning of the article to improve clarity.

**Article 12.10.9.**

In response to a Member Country proposal to replace 'equids' with 'susceptible species,' the Code Commission disagreed as the only species relevant to the epidemiology are equids.

In response to the same Member Country comment regarding the prevalence of the disease being taken into account when designing sampling strategies, the Code Commission agreed with the Scientific Commission and modified the sentence for clarity.

In response to Member Countries comments in relation to prescribing testing for agent identification, the Code Commission noted that if the animal shows both clinical signs and serological positive results there is no need for further testing, as it is considered a case as defined in Article 12.10.1. However, it modified the sentence for clarity.

Member Countries proposed to add 'where possible' at the beginning of the second sentence, as agent identification may not be possible in all countries. The Code Commission noted that there are

other options to prove freedom or confirm a case, including sending samples to laboratories in other countries.

After its last meeting, the Code Commission had requested the OIE Headquarters to ask the Biological Standards Commission to consider recommending a single antigen only in the *Manual*, as this would assist Member Countries to avoid trade disputes over test results. In response, the Biological Standards Commission noted it supported the proposal in principle, but could not recommend any currently available commercial antigens as their performance varies from laboratory to laboratory.

The revised Chapter 12.10. attached as **Annex 23** and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

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

**4.21. Procedures for self-declaration and for official recognition by the OIE (Chapter 1.6.) including questionnaires.**

The OIE Headquarters advised the Code Commission that the revision of the questionnaires had been completed with the assistance of Professor MacDiarmid. Separate chapters had been prepared for each disease as requested. The text of the proposed new chapters had been aligned, where relevant and the readability had been significantly improved.

Chapter 1.6. had also been revised to include reference to the proposed new chapters and was presented for consideration of the Code Commission.

The Code Commission thanked the OIE Headquarters for its work and noted that this was a significant task that had taken a lot of resources. The result of this work was that, in its view, the proposed new chapters (questionnaires) were now, easier to read, much better aligned, consistent with terminology used throughout the *Code,* and this would greatly assist Member Countries in compiling their dossiers. The Code Commission also noted that the proposed new chapters took into account Member Countries comments provided after the February 2017 meeting, as well as input from the Scientific Commission.

**EU comment**

**The EU thanks the OIE for the significant work done to revise the questionnaires, especially for having provided them as separate chapters and with changes highlighted by the usual double underline and strikethrough that makes the reviewing procedure much easier.**

The Code Commission considered that in the future, these questionnaires could be taken out of the *Code* to facilitate their revision. The Code Commission recalled that in the report of its September 2017 meeting it had foreshadowed that it would circulate the proposed new chapters after its February 2018 meeting in anticipation of proposing them for adoption in May 2018.

**EU comment**

**As to whether the questionnaires should be taken out of the Code or not, the EU refers to its previous comments (available here https://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_position_tahsc-report_201705.pdf, cf. p. 40), which remain valid.**

The Code Commission noted the revised Chapter 1.6. contained editorial amendments and had been prepared with a view to the adoption of the proposed new chapters (questionnaires), this revision shows the deletion of the references to Articles 1.6.5. to 1.6.13. replaced by references to the proposed draft new Chapters 1.7. to 1.12.

The new chapters will be referenced as follows:

a) Application for official recognition by the OIE of free status for African horse sickness (Chapter 1.7.)
b) Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy (Chapter 1.8.)
c) Application for official recognition by the OIE of free status for classical swine fever (Chapter 1.9.)
d) Application for official recognition by the OIE of free status for contagious bovine pleuropneumonia (Chapter 1.10.)
e) Application for official recognition by the OIE of free status for foot and mouth disease (Chapter 1.11.)
f) Application for official recognition by the OIE of free status for peste des petits ruminants (Chapter 1.12.)

The Code Commission also noted that a more detailed revision of Chapter 1.6. was being undertaken by the OIE Headquarters (**see Agenda Item 6.1.**).

The revised Chapter 1.6., and proposed new chapters 1.7., 1.8., 1.9., 1.10., 1.11. and 1.12. are attached as **Annexes 24 to 30** and are proposed for adoption at the 86th General Session in May 2018.

**EU position**

**The EU in general supports the adoption of the modified Chapter 1.6. and the new Chapters 1.7. to 1.12. Indeed, we welcome OIE's work on the revision of Chapter 1.6. and on the questionnaires, and appreciate the fact that the individual questionnaires will in the future be provided as separate chapters. We note that work to revise Chapter 1.6. is ongoing (see also EU comments on Annex 39 b) and would encourage the OIE to also continue the revision of draft Chapters 1.7. to 1.12., taking into account the numerous specific EU comments that are inserted in the text of Annexes 24 to 30.**

**4.22. Diseases, infections and infestations listed by the OIE (Articles 1.3.1., 1.3.2. and 1.3.5.)**

Comments were received from EU.

The Code Commission noted with the adoption of new and revised chapters of the *Code* and the naming disease–specific chapters as 'infection with ...' there was inconsistency between these chapters and Chapter 1.3. The Code Commission proposed editorial amendments to the relevant articles to address this inconsistency.

The revised Articles 1.3.1., 1.3.2. and 1.3.5. are attached as **Annex 31** and are proposed for adoption at the 86th General Session in May 2018.

**EU position**

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

**A specific comment is inserted in the text of Annex 31.**

**Furthermore, in order to avoid this type of inconsistency between Chapter 1.3. and the disease-specific chapters in the future, it would be preferable to make this type of editorial amendment in Chapter 1.3. whenever a disease-specific chapter with a modified title is adopted. For example this may well be the case for the glanders chapter in May 2018, resulting in the need to amend the relevant entry in Article 1.3.4.**

**5. Texts circulated for Member Country comments at the September 2017 Code Commission meeting**

**5.1. Animal health surveillance (Chapter 1.4.)**

Comments were received from Australia, Canada, Japan, New Caledonia, New Zealand, Switzerland, USA and EU.

The Code Commission considered general comments of Member Countries including a proposal to restructure the chapter.

**Article 1.4.1.**

In response to a Member Country comment the use of the terms 'infection and infestation' and 'disease', the Code Commission explained that when the Code uses either of these terms 'infection' or 'infestation' are more specific, but as noted previously , while 'disease' appears in the *Code* in a more general sense. The *Code* recommendations are about the absence, presence or distribution of an infection; and about the control, emergence, epidemiology or impact of a disease. The Code Commission amended the article to reflect this more clearly. The Code Commission and the OIE Headquarters will work on reflecting this more accurately in the User's Guide to assist Member Countries in the interpretation of the *Code*. The Code Commission considered the addition of a reference to Chapter 3.4. in point 3 to include the components of organisation, staff, communication and legislation.

**Article 1.4.2.**

The Code Commission disagreed with Member Countries proposals to include 'or infested' and 'or uninfested' in the definitions for 'sensitivity' and 'specificity'. It considered the addition would result in the unnecessary repetition of words and drew the attention of Member Countries to the definition of 'infected zone' that includes both infection and infestation.

The Code Commission did not accept the proposal of a Member Country to amend the definition of 'test' as it did not consider it required further clarity and was consistent with terms used in the Glossary of the *Manual.*

After reviewing the Member Country comments and reviewing the report of the 2017 *ad hoc* Group the Code Commission identified some confusion arising from the use of the word 'random'. The *ad hoc* Group discussed the following terminology: 'random sampling' versus 'probability sampling' and 'non-random sampling' versus 'non-probability sampling'. The *ad hoc* Group concluded that they were synonyms and for the sake of consistency with the definitions provided in Article 1.4.2., as well as for consistency throughout the chapter, the Group proposed to adopt the terminology 'probability sampling' and 'non-probability sampling'. For consistency with the view of the *ad hoc* Group the Code Commission modified the definitions for 'probability sampling' and 'sampling unit' to for clarity.

**Article 1.4.3.**

Point 1 a), the Code Commission replaced 'infection and infestation' with 'disease' for consistency as noted above. The Code Commission agreed with the proposal of a Member Country to include reference to the subpopulation and target population at the end of the point, for clarity.

The Code Commission did not agree to Member Countries proposal to include 'listed disease-specific' before 'chapters' in the second paragraph and in point c), because the word 'relevant' is sufficient here and there is no need to include specific references.

In response to a Member Country proposal to move point 2 a) i) diagnostic tests, to the section on design as a new point 1, b), the Code Commission agreed that these elements should be considered during the design of the surveillance system. However, it considered it more logical to insert it as a new point e) and amended the text for clarity, accepting only some of the Member Countries proposed wording changes.

In response to a proposal to add 'and biology' after 'epidemiology' in the second dash of point b), the Code Commission agreed with the Member Countries noting that it should read 'epidemiology and biology'. A Member Country proposed several additions to the list in this point, the Scientific Commission and the Code Commission agreed that the additions were valid, but did not add them, as the list is not meant to be exhaustive. The Code Commission proposed the inclusion of 'pathogenesis' in the examples of epidemiology and a new point 'risk of introduction and spread' as it considered this phrase useful.

Point f), the Code Commission agreed with the proposal of a Member Country to indicate that sophisticated mathematical or statistical analysis 'may be' justified. However, the President of the Code Commission informed the members that the *ad hoc* Group had specifically included the phrase 'should only be carried out when justified…' as sophisticated mathematical or statistical analysis can be misused and the intent was indeed to discourage the use of these types of methods if not backed by solid data and capacities.

The Code Commission agreed with the Scientific Commission not to accept the proposal of Member Country to include a new point j), resources (e.g. personnel, time, funding, laboratory capacity etc.), as these resources are already considered as part of the quality Veterinary Services in the first paragraph of the article.

Point 2 a), the Code Commission agreed with the proposal of Member Countries to avoid incorrect references in the future by deleting the reference to the specific chapter of the *Manual*.

Point 3, in response to a proposal of a Member Country to amend the title of the sub-section, the Code Commission disagreed as the alternate proposal does not accurately reflect the meaning of the paragraph and the rationale given was not persuasive.

**Article 1.4.4.**

The Code Commission disagreed with the proposal of a Member Country to change the title of this section to 'Surveillance activities and methodology' as the article describes different methods, which includes various activities.

Point 1, paragraph 2, the Code Commission disagreed with the proposal of a Member Country to replace 'reporting' with 'notification' as notification has a specific meaning in the *Code* and would always be within the mandate of the Veterinary Authority. The Code Commission did not accept the proposal of the same Member Country to add 'ensuring reporting of animal health related events to the Veterinary Authority', as it considered this is adequately covered by effective communication and data sharing. Furthermore, it is implicit that effective communication is needed to ensure these links are established. The Code Commission made a minor modification for clarity on this point.

Point 2, the Member Country that proposed restructuring this section did not provide any rationale for deleting text, therefore the Code Commission agreed only to move the existing text without making any changes.

Point 3, in response to a Member Country proposal to include the concept of risk-based surveillance as described by Hoinville et al. 2013[i], the Code Commission agreed with the comment but was not prepared, at this time, to make substantial modifications proposed. It did, however, modify the text to add clarity to the point.

Point 4 c), the Code Commission agreed with a Member Country comment that the point did not take into account the different systems for oversight of inspection procedures, which influence the quality of surveillance information collected at slaughterhouses and abattoirs. It proposed to amend the point to emphasise the different situations and the extent to which the Competent Authority is involved in the supervision of ante-mortem and post-mortem inspection, including reporting systems.

The Code Commission disagreed with the same Member Country proposal to delete point e) independence of the inspection staff, as it is not ambiguous. Furthermore this point is very important for some other regions and countries.

The Code Commission did not accept the comment of Member Countries to reference a variety of other systems in this paragraph. While the Code Commission understood the intent, no text was proposed for inclusion and so it was difficult to address the comment.

Points 5 and 6, the Code Commission accepted the proposal of a Member Country to move the points to point 10 'Other data sources'.

Point 7, the Code Commission accepted the proposal of a Member Country to amend the title of this point to 'Surveillance of sentinel units'.

Point 8, the Code Commission disagreed with the proposal of a Member Country to move to point 10 Other data sources, as clinical observations relate to clinical surveillance and the collection of clinical data.

Point 9, the Code Commission accepted the proposal of a Member Country to amend the title to 'Syndromic surveillance'.

Point 10, Other data sources - in response to a Member Country proposal to restructure the chapter, the point is now point 7 and appears as follows:

New point 7 a (former point 2) data generated by control programmes and health schemes

New point 7 b (former point 5) laboratory investigation records

New point 7 c (former point 6) biological specimen banks.

The Code Commission agreed there was logic in the proposal of a Member Country to move Article 1.4.9. and include it at the end of this article 1.4.4. as a new point 8, Combination and interpretation of surveillance results.

The Code Commission disagreed with a Member Country proposal to add a reference to 'expert opinion elicitation data' to the list under d) in Point 10, as it is not sufficiently important or relevant to be included in the current chapter.

**Article 1.4.5. (new point 2 under Article 1.4.4.)**

Point 1, a Member Country commented that probability-based sampling had been introduced previously in the document and should be offered as an option in the sampling section and that disease freedom fits under Article 1.4.6. point 1. The Code Commission agreed documenting freedom from infection or infestation is not the sole reason for carrying out surveys. However, because there was also some inconsistency, as point 1 is about the types of surveys. The Code Commission proposed deleting the second paragraph as it would not cause any deficiency in the chapter. The Code Commission did, however, retain the second part of the paragraph and inserted it as point 2, b) i).

Point 3 a), the Code Commission did not accept the proposal of a Member Country to include 'sub-populations' after 'population' as it was unnecessary. However, it accepted the same Member Country's editorial proposal to include 'should be' for clarity in the second paragraph.

In response to a Member Country proposal to include 'risk-based sampling', the Code Commission reiterated the comment it made on Article 1.4.2. However, it agreed in principle with the rationale provided and proposed the inclusion of text to address the concerns expressed by the Member Country.

Point 3 b), the Code Commission disagreed with a Member Country proposal to include 'clustering, (multi vs, single stage sampling). However, it proposed to include 'possible clustering' after 'expected prevalence', for clarity.

Point 3 c) i), the Code Commission did not agree with the comment of a Member Country, that risk-based sampling is not considered as a probability-based sampling method. It noted that a surveillance system can be designed based on risk and when conducting risk-based surveillance either probability or non-probability based sampling can be used. The Code Commission explained that cluster-based sampling would be probability-based and is included in the risk-based methods. It further noted that the term 'risk-based surveillance' is not used in the chapter. The Code Commission noted the above rationale and addressed the proposal of another Member Country to insert 'risk-based sampling' in the list at this point.

The Code Commission agreed to the proposal to move this article to become a new point 2 under Article 1.4.4.

**Article 1.4.6.**

The Code Commission disagreed with the proposal of a Member Country to merge articles 1.4.6., 1.4.7. and 1.4.8. as this would not improve the consistency with Chapter 4.3. and would lead to significant challenges when cross-referencing this chapter. The Code Commission amended the title of the article for clarity and proposed to delete the chapeau as it considered it to be unnecessary.

Point 1, In response to Member Countries comments that the second paragraph was unclear, the Code Commission proposed to delete 'the pathogenic agent' and replace it with 'infection or infestation in an animal population', in order to address the concerns. In response to another Member Country comment that the paragraph did not allow for historical freedom, the Code Commission and the Scientific Commission agreed and proposed to amend the second sentence for clarity.

The Code Commission disagreed with a Member Country proposal to delete 'however' at the beginning of the third paragraph, as this would change the intent of the paragraph.

In response to the proposal of a Member Country to include the recommendations regarding early warning system (Article 1.4.8.) in this article, the Code Commission noted that in fact, it should be placed earlier in the chapter, before Article 1.4.6. (See below.)

The Code Commission proposed amendments to the fourth paragraph as the former wording lacked clarity and did not accept a proposal to include 'all relevant species' as this would narrow the scope.

Point 2, the Code Commission disagreed with a Member Country proposal to add, to point iv), text regarding the possibility of distinguishing vaccinated animals. However, the Code Commission noted that the current text forbidding vaccination was inconsistent with the proposed draft Chapter 4.X. on vaccination, especially article 4.X.11. The Code Commission thus proposed to delete that condition as a prerequisite for freedom. In response to the same Member Country proposal to delete point v), the Code Commission did not agree, as the rationale did not support its deletion. Concerning the same Member Country proposal to include a new point vi), the Code Commission considered this should be included in the article on the early warning system.

Point 2, the Code Commission disagreed with the proposal of another Member Country to add two new points vi) and vii). On the first point, it considered the competence and effectiveness of Veterinary Services were covered in point 1. On the second point, the Code Commission considered that it was not related to the prerequisite, but to the situation of the disease, which is covered in points b and c of the same article.

The Code Commission accepted other editorial proposals from a Member Country to improve the clarity of point b iii). It did not accept a proposal of a Member Country to replace '25' with '10' in the same point. The Code Commission clarified that where a list does not specify 'or', all the points should be complied with. This longstanding convention is used throughout the *Code*.

Point c), the Code Commission agreed to a proposal from Member Countries to replace 'achieved' with 'demonstrated', for accuracy.

Point c i), the Code Commission did not agree with the proposal of Member Countries to include a time requirement of 10 years as a default, as the situation would be different depending on the disease and the specific country situation and no fit-for-all prescriptive time period could be defined. In response to another Member Country proposal on this point, the Code Commission agreed to add the phrase 'for at least as long as the surveillance has been in place'. It considered that this addition also addressed the concerns of other Member Countries.

Point c ii), the Code Commission did not agree with the proposal of Member Countries to include a default time period that surveillance has been applied as this was already described in Article 1.4.3. point 1 b).

Point 3 a), the Code Commission agreed with the proposal of a Member Country to include text to clarify a starting point and duration for this point. In response to the same Member Country comment on point b), proposing to delete 'ongoing', the Code Commission noted that, by default there should always be some level of surveillance in order to maintain the compartment and surveillance should be ongoing and adapted to the level of risk. It also referred to Chapter 4.4. application of compartmentalisation, especially Article 4.4.5.

Point 4, the Code Commission agreed with a Member Country proposal to include 'or compartment' for clarity and consistency with the definition in the Glossary.

Point 4 e), the Code Commission disagreed with the proposal of a Member Country to add a new point to clarify that naturally infected animals can be distinguished diagnostically from vaccinated animals. It noted that vaccination does sometimes allow for shedding of viable organisms.

Point 4 f), in response to a Member Country proposal to include recommendations for the maintenance of compartment freedom from infection or infestation, the Code Commission and the Scientific Commission disagreed, because point 3 already describes the need for 'ongoing' surveillance in compartments, and maintenance of compartments is already described in detail in Chapter 4.4. The same rationale applies to the proposal of another Member Country to include 'for countries or zones'.

In response to a Member Country comment relating to self-declaration and official recognition, the Code Commission noted that these are part of the procedures described in Chapter 1.6., which is also under revision.

**Article 1.4.8.**

In response to a Member Country concern on the inclusion of the defined components of an early warning system in the chapter rather than in the Glossary, the Code Commission noted that it did not consider it appropriate to include such detail in the Glossary. The Glossary should only contain short and clear definitions of terms used with a specific meaning in the *Code*.

The Code Commission agreed with the proposal of a Member Country to include 'under the control of the Veterinary Authority' in the first paragraph, as it agreed it is a fundamental component of a country's surveillance system.

In response to various Member Country comments on this article, the Code Commission proposed to include new text under point 5 and a new point 5bis. The new text proposed is text deleted from Chapter 4.Y.4. on disease control programmes, as it more logically fits in this chapter on surveillance.

The Code Commission did not consider it necessary to add 'private veterinarians' to 'relevant stakeholders' as it considers there could be a broad range of stakeholders which would include private veterinarian, private laboratories, village leaders etc.

In line with its agreement to a Member Country proposal to restructure the chapter, the Code Commission moved this article to become Article 1.4.5.

**Glossary definition of Early Warning System**

The Code Commission considered Member Countries comments on the proposed definition. It noted that 'characterisation' is included in 'identification', and that the definition is not about the identification of a pathogenic agent. For clarity, it proposed to delete the word 'identification' and to add 'communication'. It finally noted that the use of the word 'disease' in the definition was appropriate.

The Code Commission noted the large number of Member Country comments received on this chapter and agreed with the OIE Headquarters that the next round of comments on the chapter could be reviewed by experts before the Commission September meeting.

The draft revised Chapter 1.4. and draft revised definition of 'early warning system' are attached as **Annex 33** in clean and tracked versions and are proposed for Member Country comments.

**EU comment**

**[To be provided in July 2018]**

**5.2. New chapter on official control of listed and emerging diseases (previous title - Management of outbreaks of listed diseases) (Chapter 4.Y.)**

Comments were received from Argentina, Australia, Canada, Costa Rica, Guatemala, New Caledonia, New Zealand, Switzerland, Thailand, USA and EU.

The Code Commission noted the general comments of Member Countries would be addressed in the specific articles and thanked those that supported the proposed draft chapter.

**Title**

The Code Commission proposed to amend the title to read 'Official control of listed and emerging disease' in response to a Member Country comment. However, it did not agree with the proposal to include 'programme' as it was covered in the chapter.

For consistency within the chapter, the Code Commission amended 'emerging and listed disease' to 'listed and emerging disease' throughout.

The Code Commission took note of Member Countries comments and the apparent misunderstanding of the purpose and scope of the draft chapter and clarified that the purpose of the chapter is to provide recommendations to Member Countries on the development of control programmes in response to outbreaks of animal diseases, to avoid their spread or achieve their eradication.

**Article 4.Y.1.**

The Code Commission agreed with a Member Country proposal to include the words 'including a zoonosis' in the first line of the article but did not consider it was necessary to repeat this throughout the chapter. Furthermore, it proposed amending the same phrase in the second paragraph and replace it with 'for listed and emerging disease, including zoonosis'. In response to the same Member Country proposal relating to the use of 'disease' or 'infection', the Code Commission noted this should not be done systematically but should be assessed on a case by case basis depending on the context of the sentence. In this particular context, the word 'disease' was appropriate.

The Code Commission proposed to delete 'hazard' and replace it with 'disease' for clarity and accuracy.

The Code Commission agreed with a Member Country proposal to include 'where possible' after 'cost-benefit analysis' as it agreed that such analysis might not always be possible.

Paragraph 5, the Code Commission disagreed with the proposal of a Member Country to replace 'infection or infestation' with 'disease' as it is the infection or infestation that is eradicated.

Paragraph 6, was amended for consistency to clarify the purpose of the chapter and the phrase 'management of outbreaks' was deleted. In response to a Member Country proposal to include 'methods' and adapting 'new technologies' the Code Commission partially accepted the rationale provided and proposed other amendments for clarity.

In response to other Member Countries comments that an exit strategy may not always be necessary or appropriate to have beforehand, and to consider mentioning the experience of other Veterinary Services in cross-border simulation exercises for transboundary animal diseases, the Code Commission noted that no proposal for text was provided. Nevertheless, the Code Commission proposed amendments to the paragraph to take this comment into account, noting that cross-border simulation exercises are covered elsewhere in the chapter.

**Article 4.Y.2.**

The Code Commission made editorial amendments for consistency. It did not accept Member Countries proposals to include 'products of animal origin' before 'property' as it considers 'property' would include the products. However, it agreed to include 'or losses incurred due to movement restrictions' in the sub-bullet on sources of finance and compensation as it agreed this was an important consideration.

Point 3, the Code Commission did not accept the proposal of a Member Country to delete reference to 'risk analysis to identify and prioritise potential disease risks' as risk analysis is an essential part of the decision-making process. In response to another Member Country proposal to include a new bullet point to separate definitions and procedures for listed disease and emerging disease, the Code Commission disagreed, as it did not add clarity. In response to another Member Country proposal to include two additional bullet points on procedures for delimiting surveillance, and for tracking and tracing animals, the Code Commission partially disagreed as it considered animal identification and surveillance were already covered in the existing bullets. However, even though it considered the tracking and tracing of animals from infected properties could be managed under the *animal identification system,* to capture this more clearly it proposed to add a new point on procedures for epidemiological investigations of cases including tracing of animals and animal products.

In response to other Member Countries comments that restrictions on movements should include equipment and vehicles, the Code Commission proposed to include fomites, to address this comment. In response to the same Member Countries proposal to include a new bullet to cover procedures for the destruction of products and materials (animal feed, farm equipment, vehicles etc.), the Code Commission agreed that feed and bedding were missing from this point and the others being covered in the point on disinfection and disinsection. In order to address this gap, the Code Commission proposed to separate the procedures for destruction or slaughter from the procedures for the destruction and safe disposal or processing, including materials such as fodder and bedding.

Finally, the Code Commission and the Scientific Commission partially agreed with a Member Country proposal to include three new bullet points to address procedures for: collection, recording, storage and analysis of data; surveillance to map the prevalence and distribution of the incursion and for proof of freedom; and recovery of affected industries and communities. The Code Commission proposed to include a new bullet to address this comment. However, it noted that the recovery of affected industries and communities was beyond the scope of the *Code* and may not be under the responsibility of the Veterinary Authority.

**Article 4.Y.3.**

Point 1, the Code Commission amended this point to clarify that the risk analysis to identify and prioritise should determine a list of notifiable diseases that require preparedness planning.

The Code Commission examined Member Countries comments on this article and accepted a number of editorial amendments. In response to a Member Country proposal to add a new paragraph on communication of risks, the Code Commission disagreed and noted there is a specific article on communication, Article 4.Y.11.

Point 2, in response to a Member Country proposal to include a fifth type of plan, i.e. 'prevention plan', the Code Commission noted that the chapter was about 'control' and the article is about 'preparedness' not about prevention or mitigation. Many countries do not consider prevention or mitigation as part of preparedness that is dealt with in other parts of the *Code.* In response to the same Member Country proposal to replace 'notifiable disease' with 'listed disease', the Code Commission disagreed as the use of 'notifiable disease' was intentional to take into account the need for a risk analysis as described in Point 1.

In response to another Member Country proposal to add 'standard operating procedures' and 'critical' to point c), the Code Commission disagreed as this did not significantly improve the point.

The Code Commission considered a proposal of the Scientific Commission addressing the concerns of a Member Country on Article 4.Y.7. and included 'food supply' in point d) of this point.

Point 3, in response to Member Countries comments on Article 4.Y.1., the Code Commission proposed to insert a new sentence on simulation exercises between neighbouring countries.

**Article 4.Y.4.**

In response to Member Countries proposals to replace 'or' with 'and' in the first sentence, the Code Commission agreed, as Chapter 1.4. always applies.

In answer to a Member Country requesting reinstatement of points 2 to 6 in this article, the Code Commission noted that this text was included in the new draft of revised Chapter 1.4. It further noted that it decided to keep in this article the part of point 5 relating to the management of outbreaks rather than surveillance.

**Article 4.Y.5.**

The Code Commission agreed with an editorial amendment proposed by a Member Country and noted it had previously responded to the point on 'listed disease'. The Code Commission did not agree to a Member Country proposal to include in a new point 1, reference to measures described in the publication 'Good Emergency Management Practice: The essentials (GEMP)' Manual published by the FAO in 2011. The Code Commission pointed out that this was already covered in Article 4.Y.4.

Point 1, the Code Commission agreed to a Member Country proposal to include 'as appropriate' because current text is too prescriptive and because it suggests that killing and slaughter must always be used in all outbreak management.

Point 2, the Code Commission considered a comment from Member Countries highlighting that the objective of the control strategy (e.g. complete eradication or not) was not covered in this point. Noting that no text was proposed to address this concern, the Code Commission proposed to modify the paragraph and include a new sentence 'The strategies chosen will, in turn, influence the final objective of the control programme.'

The Code Commission agreed in principle with a Member Country proposal to include reference to the legal framework for compensation and proposed to amend the second last paragraph using language consistent with the chapter.

**Article 4.Y.6.**

The Code Commission noted the request of Member Countries to give a definition of animal products. The Code Commission invited those Member Countries to propose a suitable definition, consistent with other *Code* terminology for its consideration.

In response to Member Countries comments on the title of this article, the Code Commission proposed to delete 'killing' because in English, culling means both killing and slaughter.

The Code Commission disagreed with the proposal of a Member Country to include a new sentence taken directly from the GEMP Manual, as it did not improve the clarity of the paragraph. In response to other Member Countries proposal to include 'as well as vaccination,' the Code Commission disagreed, as this was not relevant to this article.

In response to a Member Country proposal to replace the last sentence of the paragraph 'Killing should preferably be performed on site…', the Code Commission disagreed, as the sentence proposed would change the meaning of the paragraph. The current sentence addresses the risk of spread by moving live infected animals to another site for killing. In response to other Member Countries comments on the same paragraph, the Code Commission considered that the method of disposal was covered in Chapter 4.12. and proposed a minor editorial amendment so that the order of the methods of disposal did not reflect any hierarchy.

The Code Commission did not accept a Member Country comment on the separation of animals, as the text is clear as written. The Code Commission did not agree with another comment from the same Member Country regarding processing and inactivation, as the proposal did not improve clarity.

The Code Commission noted a comment from Member Countries on the need to harmonise the timing of the different elements of the stamping-out policy (killing - disposal - cleaning) and the opinion of the Scientific Commission that this should be addressed in the listed disease-specific chapters.

**Article 4.Y.7.**

The Code Commission disagreed with a Member Country proposal to include a reference to Development of Secure Food Supply Plans, considering it too detailed and not relevant to all Member Countries. It also noted that 'food supply' had been added to Article 4.Y.3. to address this point.

The Code Commission proposed amendments to the last paragraph in response to Member Countries and to improve the clarity, noting that 'communication media' would likely not be a 'relevant authority' and further noted that it was incumbent on Veterinary Authorities to share information on disease outbreaks, especially when they occur close to national borders.

**Article 4.Y.8.**

The Code Commission made minor editorial amendments to improve the clarity of this article. In response to Member Countries comments, it noted that birds are included in the defined term 'wildlife'.

**Article 4.Y.9**

In response to Member Countries comment noting an inconsistency between the title of the article that included treatment while the text of the article dealt with vaccination only, the Code Commission agreed and deleted 'treatment' from the title. It also noted that it would work further on this article and invited the Member Countries to propose specific text regarding treatment. the Code Commission disagreed with editorial comments from the same Member Countries, as the word 'produced' was appropriate in both instances.

In response to a Member Country proposal on the last paragraph, the Code Commission agreed with the rationale and proposed amendments for improved clarity and consistency with the *Code* and to address the proposal.

**Article 4.Y.10.**

The Code Commission agreed with a proposal of Member Countries to include 'eradication' and agreed with a proposal to reorder 'containment zone and protection zone' for clarity and consistency with the *Code*. Regarding a further comment of Member Countries that it was important to mention that the zoning used for outbreak control and eradication needs to be adapted and updated periodically, the Code Commission agreed with the Scientific Commission that this was already covered and there was no need for additional text.

**Article 4.Y.11**

The Code Commission agreed with the proposal of Member Countries to include reference to the media in this article. It further noted, in response to a comment from a Member Country under Article 4.Y.3 on the need for the chapter to mention risk communication strategies in the framework of risk analysis, that Chapter 3.3. deals with communication.

The revised new Chapter 4.Y. is attached as **Annex 34** for Member Country comments**.**

**EU comment**

**[To be provided in July 2018]**

### 5.3. New introductory chapter for Section 4: Chapter 4.Z. Introduction to recommendations for disease prevention and control

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

In response to Member Countries proposals to replace 'contagious with 'infectious' the Code Commission agreed and proposed similar amendments to other paragraphs for consistency with this proposed change.

In response to Member Countries proposals on paragraph 3, the Code Commission clarified the text to align it with the User's Guide and noted that the chapters in this section contain recommendations that should be implemented for disease prevention and control.

In response to Member Countries comments on paragraph 4, the Code Commission proposed editorial amendments to improve readability and consistency. It did not agree with the proposal of another Member Country to change 'impact' to 'effects' as impact is more appropriate in this context. The Code Commission agreed with a Member Country proposal to include 'animal welfare' as this was also an important consideration in the context of disease control.

In response to a Member Country proposal to include 'economic impact on economy' in addition to trade, public health, animal welfare and environment, the Code Commission did not accept the proposal noting this is not an exhaustive list.

In response to Member Country proposals to amend paragraph 5, the Code Commission made only minor amendments, as many of the proposals did not improve the clarity of the text or were already implicit in the paragraph as presented.

The Code Commission noted, on the one hand, a Member Country comment suggesting deleting paragraph 6 as it was not appropriate to include this prescriptive and limiting text in the *Code*, and on the other hand other Member Countries strong support for its inclusion as it provided important guidance to allow flexible adaptation at the national level. The Code Commission explained that the sentence was to encourage Member Countries to consider their national context and ensure that any prevention and control programmes are proportionate to the risk, and are based on risk analysis.

In response to Member Countries comments proposing the inclusion in the User's Guide of clarification that these recommendations are not necessarily relevant or applicable to international trade, the Code Commission noted that once the chapter is adopted, the User's Guide may be revised.

The Code Commission noted, in respect to another Member Country proposal to include 'science-based' in this paragraph, that risk analysis is science-based, and the *Code* should be science-based so it was not necessary to add the proposed words.

The Code Commission disagreed with the Member Countries proposal to include 'one health approach' to the prerequisites, as it was too specific for a general chapter. It agreed to expand the point on 'effective awareness of private stakeholders' to include 'and active cooperation with'. The Code Commission also disagreed with a proposal to include 'clear objectives and measurable targets', as these are an essential part of the programme. It disagreed with a proposal to include 'adequate and committed funding' as a separate bullet but proposed to add it to the point on quality veterinary services.

The draft new Chapter 4.Z. is attached at **Annex 35** for Member Country comments.

**EU comment**

**[To be provided in July 2018]**

**5.4. New chapter on the killing of reptiles for their skins, meat and other products (Chapter 7.Y.) including consideration of the report of the *ad hoc* Group (January 2018)**

Comments were received from Australia, Canada, New Zealand, Norway, Singapore, Switzerland, USA and ICFAW.

The Code Commission commended the work of the *ad hoc* Group. Noting that the *ad hoc* Group had given robust justifications for the amendments proposed, for this reason, this report gives only the proposals made by the Code Commission that differed from the proposals of the *ad hoc* Group. Consequently, the Code Commission strongly recommends reading this report jointly with the report of the *ad hoc* Group.

The Code Commission agreed with the *ad hoc* Group proposal to include new text throughout the chapter to highlight the anatomical and physiological difference between reptiles and other animals covered by the OIE Glossary definition.

**Article 7.Y.3.**

Point 1, the Code Commission partially agreed with the proposal of the *ad hoc* Group in response to an organisation comment, to add a sentence connecting the animal welfare plan in the killing establishment to the recommendations of this chapter. The Code Commission reworded the sentence proposed by the *ad hoc* Group to improve clarity.

Point 2, the Code Commission agreed with the changes proposed by the *ad hoc* Group in answering a Member Country suggestion to highlight the importance of the competencies of the animal handlers in monitoring the effectiveness of the stunning and killing process.

Pont 3, a Member Country proposed adding a reference to the relevant chapters covering transport. The Code Commission agreed with the opinion of the *ad hoc* Group not to accept the proposal, as the scope of the chapters on transport by land, sea and air do not include reptiles. The Code Commission modified the wording for clarity.

On the same point, the Code Commission did not agree with the *ad hoc* Group in respect to a Member Country suggestion to add 'biosecurity' as a factor to be considered when the reptiles are captured in the wild and transported to a slaughterhouse. 'Biosecurity' as defined in the *Code* is not relevant in the context of the paragraph.

Point 4, in response to a Member Country proposal to improve the readability, the Code Commission partially agreed with the proposal of the *ad hoc* Group and reworded the paragraph to improve clarity.

**Article 7.Y.4**.

The Code Commission agreed with the opinion of the *ad hoc* Group, on a suggestion of a Member Country not to add a new bullet point in this article to highlight the importance of shortening the time between the stunning of the reptile and the killing process. Nevertheless, the *ad hoc* Group and the Code Commission reworded the sentence for consistency with the terminology used in this chapter.

**Article 7.Y.6.**

The Code Commission agreed with the *ad hoc* Group's response to a Member Country proposal to add a phrase emphasising that some methods of restraint must not be used and reworded the sentences to improve its readability.

The Code Commission did not agree with the *ad hoc* Group's proposal to add 'includes' throughout the chapter when referring to the examples of animal-based criteria (or measurables) because the lists are not exhaustive and for consistency with other animal welfare chapters.

**Article 7.Y.7.**

The Code Commission did not agree with the *ad hoc* Group suggestion to use of the word 'immediately' in relation to the interval between the stunning and killing of reptiles, because 'immediately' is not precise and because the death of the animal should occur while the animal is unconscious.

The Code Commission edited the references in the penultimate paragraph of the article to improve its readability, and for consistency with other chapters.

An organisation proposed to replace 'type' of an animal with 'species' throughout the chapter when referring to the selection of equipment to be used. The Code Commission recommended adding the word 'species' while keeping 'type', as they do not mean the same thing and should be both used for clarity. The Code Commission recommended this change be repeated throughout the chapter.

**Article 7.Y.10.**

The Code Commission did not agree with the *ad hoc* Group suggestion to replace 'should' with 'must' as proposed by a Member Country, as except in Chapter 1.1. on Member Countries obligations to notify, and in very rare other occasions, the word 'must' is not used in the *Code* recommendations.

**Article 7.Y.13.**

The Code Commission agreed partially with the proposal of an organisation on the need to include the objective of the method, to harmonise with other articles in this chapter. The Code Commission did not agree with the amendment proposed by the *ad hoc* Group in response to a Member Country suggestion on the appropriate use of the rod or probe in the pithing of the brain. The Code Commission changed the wording of the sentence to a 'minimum of four times' to better clarify the procedure.

**Article 7.Y.14.**

The Code Commission modified the text proposed by the *ad hoc* Group to improve its clarity. The Code Commission deleted the word 'method', as decapitation is not an appropriate method of killing reptiles because it does not produce unconsciousness or death within an acceptable period.

**Article 7.Y.15.**

The Code Commission agreed with the *ad hoc* Group suggestion on the comment of a Member Country, in that the effect of chemical agents on reptiles could be affected by the animal's temperature variations. However, the Code Commission reworded the sentence proposed by the *ad hoc* Group to improve readability.

**Article 7.Y.16.**

Based on the suggestion of the *ad hoc* Group, the Code Commission modified the text on methods that are unacceptable for the stunning and killing of reptiles to improve its clarity.

The new Chapter 7.Y. is attached as **Annex 36** for Member Country comments. The report of the *ad hoc* Group is attached as **Annex 44** for Member Countries information.

**EU comment**

**The EU thanks the OIE for its work on the revision of the draft chapter and for taking some of the EU comments into account.**

**The EU can agree with the proposed changes. In addition the EU would like to reiterate some previous comments. These are inserted in the text of Annex 36.**

**5.5. New chapter on animal welfare and laying hen production systems (Chapter 7.X)**

Comments were received from Australia, Canada, China, Costa Rica, Guatemala, Japan, New Caledonia, New Zealand, Norway, Singapore, Switzerland, Thailand, USA, EU, AU-BAR, ICFAW and IEC.

The OIE Headquarters reminded the Code Commission that, at its February 2017 meeting, it had reviewed the report of the *ad hoc* Group that met in Paris in November 2016. The Code Commission had requested that the draft chapter proposed by the *ad hoc* Group be restructured specifically to arrange the articles and bullets in a logical order for consistency with the *Code*. The OIE Headquarters had undertaken the restructuring of the document and conducted further electronic consultations with members of the *ad hoc* Group and the Code Commission to refine the text. At its September 2017 meeting, the Code Commission reviewed the restructured draft chapter and modified it accordingly for accuracy, clarity, and consistency and circulated it for Member Country comments. OIE Headquarters advised the Code Commission that due to time constraints and the lack of availability of the members of the *ad hoc* Group it had not been possible to arrange a meeting of the *ad hoc* Group in time to

prepare a new draft for the Code Commission's February 2018 meeting. The *ad hoc* Group will meet in March 2018 to review the Member Country comments received in January 2018. The report of the *ad hoc* Group and the revised chapter will be considered by the Code Commission in September 2018.

**5.6. New Chapter on infection with Trypanosoma evansi (non-equine surra) (Chapter 8.X.) and Draft revised Chapter on infection with Trypanozoon in equids (Chapter 12.3.)**

Comments were received from Australia, China, New Caledonia, New Zealand, Singapore, South Africa, Switzerland, Thailand, USA, EU and AU-BAR.

The Code Commission recalled that the draft new and revised chapters had been sent for Member Country comments in September 2017. After discussion with the Scientific Commission, it was agreed to put these two chapters on hold until after the *ad hoc* Group on animal African trypanosomoses meets in March 2018. The draft chapters and Member Country comments will be reconsidered in September 2018 together with the report of the *ad hoc* Group.

**5.7. Draft revised Chapter on Infection with Theileria annulata, T. orientalis and T. parva (bovidae) (Chapter 11.12.) and New Chapter 14.X. Infection with Theileria lestoquardi, T. luwenshuni and T. uilenbergi (small ruminants)**

Comments were received from Australia, Canada, China, New Caledonia, New Zealand, South Africa, Switzerland, Thailand, EU and AU-IBAR.

Member Countries rationale for proposing that the two chapters be merged was not accepted by the Code Commission as it considers that, after careful consideration of the host specificity of the different Theileria species, separate chapters would make their management, including surveillance easier for Member Countries.

The general comments of two Member Countries opposed to the ongoing development of these two chapters were discussed by the Presidents of the Code Commission and the Scientific Commission. It was noted that the comments of these two Member Countries added to the original scientific evidence provided by one of them to support the original request for an *ad hoc* Group to revise the current chapter to consider the inclusion of *T. orientalis*. The *ad hoc* Group considered the scientific literature available and their own experience to assess the *Theileria spp.* against the listing criteria of Chapter 1.2. It concluded that *T. annulata, T. parva, T. orientalis* ikeda and *T. orientalis* Chitose met the listing criteria and proposed including them in the *Terrestrial Code*. This decision was supported by the Code Commission and the Scientific Commission.

However, the Code Commission requested the OIE Headquarters to seek further expert advice about the listing of these diseases (**see Item 7.3. Other Business**) and agreed with the Scientific Commission to put these two chapters on hold pending the expert advice. The specific questions to be answered by the experts are as follows:

a) Review all the pathogenic agent species listed in the chapters and assess their compliance with the criteria in Chapter 1.2.;

b) Assess their host-specificity and provide guidance to the OIE on whether these can be included in a single multi-species chapter including all causative agents, or whether there is a need for separate chapters for bovines and for small ruminants.

**5.8 Infection with African swine fever virus (Articles 15.1.1 bis - 15.1.2., 15.1.3. and 15.1.22.)**

Comments were received from China, Japan, Korea, Switzerland, Thailand and EU.

The Code Commission recalled that at the General Session in 2017 two Member Countries voted against the adoption of the chapter and that during its September 2017 meeting it had proposed the deletion of the general statement on the importation of commodities and proposed the introduction of a new article on safe commodities to address their concerns. The proposals were circulated for Member Country comments in September 2017.

In response to concerns raised by several Member Countries to include canned meat and gelatine as safe commodities in the proposed new article, the Code Commission amended the article for clarity (meat in a hermetically sealed container with Fo value of 3.00 or more) to make it clear, the intention was to include 'sterilised canned meat', as defined in the Codex Recommended Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods (CAC/RCP 23-1979).

In regard to the inclusion of gelatine as a safe commodity, the Code Commission, after reviewing the literature relating to the normal industrial manufacturing processes, reconfirmed that regardless of the raw material used, it is subjected to extremes of pH and high temperatures sufficient to inactivate all known viruses and bacteria. Thus, gelatine meets the provisions of Article 2.2.1 and can be considered a safe commodity with respect to ASF.

References http://www.gelatine.org/gelatine/manufacturing.html; Prions in Humans and Animals Beat Hörnlimann, Hans A. Kretzschmar and Detlev Reisner ISBN:9783110200171 3110200171

In response to a request of several Member Countries to reinstate the deleted text in Article 15.1.2., the Code Commission agreed in principle with the need to add clarity to assist Member Countries in the implementation and correct application of the provisions of this chapter but did not agree to leave this sentence in Article 15.1.2. It proposed to insert in Article 15.1.1 bis, text relating to the import or transit of other commodities from pigs, which includes reference to the relevant articles of the chapter and is consistent with other listed disease chapters.

In addition, the Code Commission proposed a sentence at the end of Article 15.1.3. Country or zone free from ASF, to address issues related to bans on trade in commodities from countries that are free from ASF in domestic and captive wild pigs while notifying infection in wild or feral pigs.

The Code Commission agreed with the comments of Member Countries that there was an inconsistency in Article 15.1.3. and amended point 1 (historical freedom) to align it with points 2 and 3 and clarify that 'pigs and pig commodities are imported in accordance with Articles 15.1.7. to 15.1.20.'.

In response to several Member Countries comments proposing the inclusion of a new article on 'A country or zone infected with ASFV', the Code Commission did not agree, because, for this disease that has always been absent from many regions, it could indirectly lead to underreporting and to unjustified barriers to trade.

Because of the possible misinterpretation of the chapter, the Code Commission modified points 1 to 3 of Article 15.1.3. to clarify that all commodities of domestic and wild pigs should be imported from those countries in accordance with the same articles.

The same Member Countries requested the inclusion of several additional cross-references in Article 15.1.3. to add clarity and assist with interpretation of the chapter. The Code Commission did not consider it was necessary to add a large number of additional cross-references.

**Article 15.1.18.**

A Member Country requested further detailed information on inactivation of ASFV in swill feed, the Code Commission recalled that this article was built upon long-standing practice and field experience that showed the inactivation of virus in swill, and was used to successfully control the disease. It further noted that point 3 allows for use of alternative treatments that can be demonstrated to inactivate ASFV.

**Article 15.1.22.**

In response to a Member Country comment on the need for the requirement for treatment of dry-cured pig meat to be described more specifically (e.g. as it is in Chapter 8.8.31.), the Code Commission noted that this article also was related to historical experience with manufacturing and processing and had been simplified to make it useable for veterinary certification. However, the point was noted and was referred to OIE Headquarters to gather more detailed information on the different processes used to dry and cure meat.

The Code Commission considered, as there had been several significant changes to Article 15.1.1 bis and 15.1.2., as well as new proposals for Article 15.1.3. that these should be circulated for further consideration by the Member Countries and did not propose them for adoption in May 2018.

The revised Articles 15.1.1 bis., 15.1.2., 15.1.3. and 15.1.22. are attached as **Annex 37** for Member Country comments.

**EU comment**

**[To be provided in July 2018]**

### 5.9. Glossary Part B

Comments were received from New Caledonia, New Zealand and EU.

***EARLY WARNING SYSTEM***

The Code Commission considered Member Countries comments on the proposed definition, it noted that characterisation is included in identification, the definition is not talking about the identification of a pathogenic agent, for clarity it proposed to delete the word 'identification' and added 'communication' for clarity. It also noted that the use of the word 'disease' in the definition was appropriate.

***SANITARY MEASURE***

In commenting on the definition of compartment, some Member Countries proposed replacing 'control' with 'sanitary' for consistency with the definition of containment zone. The Code Commission noted that the two words were used appropriately in the respective definitions. The Code Commission did however propose a minor amendment to the definition of sanitary measure for clarity.

The revised definitions are attached as **Annex 38** for Member Country comments.

**EU comment**

**[To be provided in July 2018]**

## 6. Amendments or draft new chapters proposed to the Terrestrial Code

### 6.1. Procedures for self-declaration and for official recognition by the OIE (Articles 1.6.1. to 1.6.4.)

The Code Commission considered draft revised articles proposed by the OIE Headquarters to include references to the procedures for the publication of a self-declaration of disease freedom by the OIE. The proposed revisions included a change to the title of the chapter for clarity and amendments to the articles to outline the procedures to be followed by Member Countries in applying for publication of a self-declaration of disease freedom, recognition of official disease status, or endorsement of official control programmes by the OIE.

The Code Commission and the Scientific Commission reviewed the revised articles and thanked the OIE Headquarters for its work, agreeing that the structure and text would provide much better guidance to Member Countries.

The revised Chapter 6.1. is attached as **Annex 39 a) and 39 b) in clean and tracked versions** for Member Country comments.

**EU comment**

**[To be provided in July 2018]**

### 6.2. Welfare of working equids (Article 7.12.7. and Article 7.12.12.)

Comments were received from the EU.

The Code Commission agreed with Member Countries proposal to add 'excessive sweating' as a new example of behaviour which indicates heat stress, in Article 7.12.7.

Regarding concerns expressed by Member Countries, at the 85th OIE General Session, on Article 7.12.12. 'Appropriate workloads' and the recommendation for a maximum of working hours to which working equids should be subject, the Code Commission noted that the Region concerned had not provided the supporting information promised, despite OIE Headquarters follow-up.

The revised article 7.12.7. Welfare of working equids is attached **Annex 32** and is proposed for adoption at the 86th General Session in May 2018.

**EU position**

**The EU thanks the OIE for its work on the revision of Article 7.12.7 and for taking into account a previous EU comment. The EU can agree with the proposed change and in general support the adoption of this revised article. The EU would also like to present a specific comment that could be taken into account either at adoption or during a future revision of the article, once adopted. That comment is inserted in the text of Annex 32.**

**6.3. Infection with rabies virus (Chapter 8.14.) including consideration of the ad hoc group report (November 2017)**

The Code Commission reviewed the report of an *ad hoc* Group on rabies that met at the OIE Headquarters in Paris from 21 to 23 November 2017. It congratulated the *ad hoc* Group on its work and for the report that provided clear and detailed rationales for its suggestions.

The Code Commission requested the OIE Headquarters ensure new or revised chapters prepared by *ad hoc* Group use the definitions listed in the Glossary, are aligned with other similar chapters, are drafted in a way that is consistent with *Code* conventions, and avoid the use of ambiguous terminology.

The Code Commission reviewed the revised chapter and modified it for consistency with the *Code,* for clarity and to improve grammar and readability.

The revised draft Chapter is attached is attached as **Annex 40** for Member Country comments.

**EU comment**

**[To be provided in July 2018]**

**6.4. Infection with avian influenza viruses (Chapter 10.4.) including review of the report of the *ad hoc* Group on Avian Influenza (December 2017)**

The Code Commission highlighted the usefulness of the preparatory work of the OIE Headquarters that included a discussion paper, defining the issues and questions to be addressed by the *ad hoc* Group. The membership of the group was well balanced and included experts with a broad range of expertise. The President of the Code Commission advised the members that the report would be used to guide it in its discussion on the revision of the chapter.

**Definition of avian influenza**

The Code Commission supported the suggestion of the *ad hoc* Group that the third option of making a clear distinction between HPAI and LPAI in the same chapter and creating separate articles was the most practical and suitable option and that it could assist in better addressing the problems associated with the current definition of avian influenza. This should be included in the Terms of Reference of the next *ad hoc* Group to revise Article 10.4.1. and the relevant articles on status, trade, and surveillance.

**Definition of poultry**

The Code Commission considered the *ad hoc* Group proposed a revised definition of *poultry*. It noted that the definition had been revised to take into account those categories of birds that could have a significant epidemiological role in the spread of the disease. It further noted the difficulty of understanding the term 'backyard', which might cover different production systems and could not be uniformly applied to all situations. The Code Commission had some difficulty in understanding the meaning of the term 'self-consumption' but agreed with the definition proposed by the *ad hoc* Group.

**Safe commodities**

In respect to the recommendations on transmission pathways and safe commodities, the Code Commission noted the results of these recommendations were very important for resolving the issues in international trade.

**Vaccination**

The Code Commission noted the suggestions of the *ad hoc* Group and agreed that these issues would be considered further during the revision of the chapter. The Code Commission noted that any future *ad hoc* Group should include specific expertise in vaccination to better inform the revision of the chapter and that there is a need to gather more information on the possible positive or negative impacts of vaccination. The Code Commission agreed with the *ad hoc* Group that the revised chapter should include risk management measures for trade in commodities from vaccinated poultry, surveillance requirements when vaccination is used etc.

**Surveillance**

The Code Commission noted the *ad hoc* Group suggestion to revise Article 10.4.1. addressing the need to provide an incentive for Member Countries to carry out intense surveillance for AI viruses and that detection of low pathogenicity viruses and AI in wild birds would not lead to unjustified barriers to trade. The *ad hoc* Group suggested this was already partially addressed by point 8 but additional amendments should be proposed to clearly articulate the differences in managing risks and making notifications. The Code Commission noted this should be included in the Terms of Reference of the next *ad hoc* Group and relevant expertise should be included in the membership.

**Communication**

The Code Commission noted the actions proposed under Part B of the Terms of Reference and welcomed the initiative of the *ad hoc* Group to prepare technical papers and to enhance other communication activities associated with improving Member Countries understanding of the disease.

The Code Commission agreed with the *ad hoc* Groups suggestions and proposed that the following proposals be circulated for Member Country comments:

a) Option 3) recommended by the *ad hoc* Group, making a clear distinction between HPAI and LPAI in the same chapter. Defining AI as HPAI in Article 10.4.1 and having a separate article or articles highlighting the need for LPAI surveillance, the possibility of mutation to HPAI, potential public health consequences, inclusion in six-monthly and annual reports and the application of appropriate sanitary measures in order to manage the risk while avoiding unjustified barriers to trade.

b) Proposed definition of poultry

c) Invite Member Countries to provide scientific data or references to assist in the revision of the chapter or in resolving the issues highlighted in the *ad hoc* Group report.

The Code Commission invited Member Countries to react to these proposals before the General Session **(10 May 2018)** to inform the OIE Headquarters and assist them in drafting Terms of Reference of the next *ad hoc* Group, which was planned to be held in June or July 2018, so that the outcomes would be available for the September meeting of the Code Commission.

The Code Commission will consider the Member Countries comments and the outputs of the *ad hoc* Group (if there is a need) at its September 2018 meeting.

The proposals of the *ad hoc* Group are attached at **Annex 41** for Member Country comments. The report of the *ad hoc* Group is attached for Member Country information.

**EU comment**

**The EU in general supports the proposals of the *ad hoc* group on avian influenza on Chapter 10.4.**

**Comments are inserted in the text of Annex 41.**

**7. Other Issues**

**7.1. General comments of Member Countries on the texts circulated after the Code Commission's September 2017 meeting**

Member Country comments were received from Fiji and EU.

The Code Commission noted the comments of Member Countries on the absence of Annex 1 and *ad hoc* Group reports from its September 2017 Report. The Code Commission noted that OIE Headquarters had informed it that these were on the website, and the *ad hoc* Group reports were contained in Part C. The Code Commission further invited Member Countries to contact the OIE Headquarters if they found that documents appeared to be missing from its reports.

On the same Member Countries comments regarding the Code Commission's practice of only including modified articles in the annex to its reports when a whole chapter was not for revision, the Code Commission noted that this had been done for clarity and to improve the level of response from Member Countries. Indeed, the size of the reports and lengthy annexes could make them difficult to analyse and created difficulties for OIE Headquarters in preparing working documents for the Code Commission's meetings.

**EU comment**

**The EU thanks the OIE for this clarification and can accept this rationale. We note however that sometimes, changes in one article of a chapter (especially the first articles of a disease specific chapter) can make consequential changes necessary in other articles of the chapter. This is the case e.g. in Chapter 6.8. which is currently under review, and where only Articles 6.8.1. and 6.8.1.bis are included in Annex 13 of this report. The EU will thus if necessary continue to make comments on other articles of a chapter, even if not included in the respective annex, as is the case in Annex 13.**

**As regards the availability of the report after the meeting of the Code Commission, the EU would like to make a general suggestion. Indeed, given the large number of annexes and the overall volume of the report, the unofficial version usually becomes available on the Delegate's website only several weeks after the end of the meeting. As it is necessary to then get individual subject matter experts in member countries ready to examine the report on very short notice once the report does become available, it would be very helpful if the adopted agenda of the meeting (i.e. Annex 2) could be made available to member countries as soon as possible after the meeting. This would allow identifying the subject matters that will be contained in the report at an earlier stage and giving the relevant experts advance notice, thus greatly facilitating the overall planning of the input of member countries in the OIE standard setting.**

**7.2. Update of the Code Commission's work programme**

Comments were received from Australia, China, EU, European Serum Product Association (ESPA) and Global Alliance of Pet Food Associations (GAPFA).

The OIE Headquarters noted that some comments of one Member Country regarding the adverse impact on its own ongoing work and the difficulty to keep up with the pace of standards development did not relate specifically to the work programme of the Code Commission and these would be addressed by the OIE Headquarters rather than the Code Commission.

In response to additional comments and questions from Member Countries pertaining to the Code Commission's work programme, the Code Commission offered the following responses:

Listing of Porcine epidemic diarrhoea virus (PEDV) - the Code Commission noted this would be included in its work programme and the disease would be assessed against the criteria by experts, the comments of the Member Country would be provided to the experts. (See Agenda Item 7.3.)

Member Countries proposals concerning the need to update Chapter 1.3. was taken into consideration (see Agenda Item 4.22.)

The Code Commission noted the update provided by the Scientific Commission and the OIE Headquarters on the progress of the review of Chapter 11.4. bovine spongiform encephalopathy and welcomed the confirmation that plans for the *ad hoc* Group meetings are underway and are dependent on the resources and capacity of the OIE Headquarters.

In response to Member Countries comments in relation to the volume of the work programme of the Code Commission and noted that work should stop on disease-specific chapters on pathogenic agents that are not OIE listed, the Code Commission noted this comment was taken into account.

Some Member Countries requested the Code Commission clarify if their comments on the PRRS chapter, more specifically regarding the recommendations on semen, submitted in writing prior to and referred to orally during the OIE General Session of May 2017 will be addressed. The Code Commission noted that the chapter had only recently been adopted (May 2017) and its revision should be supported by new scientific evidence or trade problems. However, it would place the revision of the chapter on its work programme but with a relatively low priority.

Other comments from the same Member Countries on the work programme were addressed in other parts of this report under the specific agenda items. The Code Commission further noted the comment regarding Chapter 5.8. had been referred to the Biological Standards Commission for its consideration.

In response to Member Countries proposals to include a definition of 'animal products' in the Glossary, the Code Commission considered that the appropriate way to address this question would be to identify where the term appears in the *Code* and identify if there is any ambiguity with regards to its meaning. It will continue to identify and clarify any ambiguous terms such as 'animal products' and solve the problem by using already defined terms or dictionary terms.

**Chapter 3.4. veterinary legislation**

The OIE Headquarters advised the Code Commission that an *ad hoc* Group on Veterinary Legislation met at the OIE Headquarters from 23 to 25 January 2018. The OIE Headquarters noted that the *ad hoc* Group had undertaken a broad review of Chapter 3.4. Veterinary legislation and due to the timing of the meeting and the already heavy work programme of the Code Commission the report would be forwarded for its consideration in September 2018.

**Chapter 8.8. Infection with foot and mouth disease virus**

At its September 2017 meeting, the Code Commission noted that the comments from Member Countries had been reviewed by the Scientific Commission. However, considering the proposed changes to Chapter 4.3. zoning and compartmentalisation and specifically with regards to the concept

of a temporary protection zone, the Code Commission decided it would wait until its February 2018 meeting to review this chapter, with the possibility of including the concept of temporary protection zone to address problems in maintaining FMD free status, and its implications for international trade. In view of the lack of consensus on the inclusion of this new concept in Chapter 4.3. the Code Commission agreed with the Scientific Commission to put this chapter on hold pending further discussion of this and other issues.

**Chapter 15.2. Infection with classical swine fever virus**

The Code Commission agreed with the Scientific Commission to await their further advice about the revision of the procedures for recognition of official status before proceeding with any further review of this chapter.

**Request for international trade standards for animal serum products used in cell culture media**

The OIE Headquarters informed the Code Commission it had received a request from the European Serum Product Association (ESPA) requesting the OIE consider developing specific international trade standards for a new category of products 'animal serum used in culture media'. The Code Commission noted it was on the agenda Biological Standards Commission and would discuss it with that Commission in September 2018. The Code Commission requests Member Countries to inform it of any problems in the trade of these products.

**Update on request to restart work on a standard for pet food – proposal from Global Alliance of Pet Food Associations (GAPFA)**

At its September 2018 meeting, the Code Commission considered a request from GAPFA, to restart work on the development of an international standard for pet food. The organisation expressed its continued interest in facilitating the development of consensus-based guidance for the global pet food industry, to better support the health and welfare of pets and to help the elimination of disease from foodborne pathogens.

The OIE Headquarters informed the Code Commission that GAPFA had responded positively to the proposal to develop a model certificate and confirmed its commitment to supporting the development of such a certificate, including by providing scientific evidence on pathogenic inactivation. The Code Commission reiterated that while the work was on its work programme it remained a relatively low priority until such scientific evidence and draft certificate is provided.

**Work Programme specific amendments**

The Code Commission noted the following:

a) that revision of the User's Guide was ongoing in light of Member Country comments and the development of new chapters; specifically in response to a Member Country comment relating to the need to address 'precedence of chapters', the Code Commission disagreed as it considers that all the chapters have the same level of importance, if a difference in scope;

b) that revision to the Glossary are consequential to work on the chapters of the *Code* and can be considered as an ongoing part of its work programme.

The Code Commission updated its work programme, revising priorities considering the advice from OIE Headquarters, the work of other Specialist Commissions and Member Country comments.

The updated work programme is attached as **Annex 42** for Member Countries information and comments.

**EU comment**

**The EU thanks the Code Commission for having taken its previous comments into consideration, and in general supports the proposed revised work programme.**

**Specific comments are inserted in Annex 42.**

### 7.3. Diseases, infections and infestations listed by the OIE (Chapter 1.3.)

The Code Commission noted that there were several diseases that required assessment against the criteria for listing in Chapter 1.2. It requested the OIE Headquarters to consider convening an *ad hoc* Group (with specific terms of reference) to review the following diseases or pathogenic agents against the criteria for listing:

- Porcine epidemic diarrhoea;
- West Nile fever;
- Chronic wasting disease;
- *Theileria* spp.;
- *Mycobacterium tuberculosis*; and
- *Mycobacterium paratuberculosis*.

The Code Commission and the Scientific Commission noted that the experts chosen to do this work need not be specialists in the specific diseases but rather epidemiology specialists and should be capable of conducting critical literature reviews in preparation for the assessment. See also Agenda Item 5.7.

### 7.4. Infection with Trichinella spp. (chapter 8.17.)

Comments were received from the USA.

The Code Commission considered a Member Country proposal that 'negligible risk' should be consistently defined between the OIE and Codex documents on *Trichinella*. For negligible risk, the Codex Guidance (CAC/GL 86-2015) clearly sets the prevalence of infection as not exceeding 1 infected carcass per 1,000,000 pigs slaughtered with at least 95% confidence. The Code Commission recalled the progression of the OIE chapter and the Codex guidelines, which were not developed in parallel and had not the same scope, and that the prevalence level in Codex is based on monitoring of country slaughtered pigs only. The Code Commission did not accept the proposal to engage in a revision of the current Chapter 8.17., as no new scientific evidence or trade issue was raised by the Member Country and, because, realistically, it would be extremely difficult for Member Countries to produce a statistically valid estimate of less than 1/1,000,000 with 95% confidence for such a parasitic infection, and negligible risk should be applied to compartments under appropriate biosecurity and with historical data of absence.

### 7.5. Proposed list of main focus areas and specialities for OIE Collaborating Centres

The Code Commission noted the work undertaken by the OIE and the Biological Standards Commission on the proposed list of main focus areas and specialties for OIE Collaborating Centres. It noted that the Biological Standards Commission would finalise the list and the guidelines for applicants, consider designation and maintenance procedures, performance criteria and networks, and propose them for consideration of the General Session in May 2018.

### 7.6. Veterinary Paraprofessionals

Comments were received from Australia, Japan, Singapore and EU.

The OIE *ad hoc* Group on Veterinary Paraprofessionals met from 12 to 14 February 2018 at the OIE Headquarters in Paris, France.

OIE Headquarters described the progress of the work of the *ad hoc* Group, as well as relevant events since the last Code Commission meeting in September 2017, including the OIE Regional Conference on Veterinary paraprofessionals (VPPs) held in Asia in December 2017. The role of the *ad hoc* Group was to consider comments and feedback from Member Countries and other relevant experts, and the relevant recommendations from the Regional Conference concerning the draft Competency Document that had been circulated as an annex to the September 2017 report of the Code Commission.

OIE Headquarters explained that while the number of replying Member Counties was limited, they covered the OIE regions well, except the Middle East, and that all replies expressed appreciation of the work as useful even if it may not directly help improve some national Veterinary Services due to the absence of relevant VPPs in certain countries. OIE Headquarters provided a revised version of the Competency Document, which it aims to publish as OIE guidelines in the near future, and noted that changes were made in general for clarifications, addition of missing elements and facilitating the use.

OIE Headquarters also reported that ambiguities in the *Code* definition of *veterinary statutory body* had been noted, by members of the *ad hoc* Group as well as by participants in the OIE Regional Conference on Veterinary paraprofessionals in Asia. Feedback suggested that it was not clear from the current wording if the intention was for a single *veterinary statutory body* to be responsible for regulation of both veterinarians and veterinary paraprofessionals.

The Code Commission thanked the OIE for the update and expressed appreciation for the *ad hoc* Group's work, which it considers will assist many Member Countries to improve Veterinary Services where VPPs play an important role. The Code Commission also expressed its expectation for the on-going work of the *ad hoc* Group to develop the core curricula guidelines based on the Competency Document.

The report of the *ad hoc* Group and the revised Competency Document are attached as **Annex 46** for Member Countries information.

### 7.7. Date of next meetings

The Code Commission was informed that the dates for the next meetings would be decided by the OIE Headquarters pending the election of new members of the four Specialist Commissions. Members elected to the Specialist Commissions in May 2018, will be advised in writing of the dates once they are confirmed. However, tentative dates being considered for the Code Commission are **11 to 20 September 2018**, noting this would only allow for an 8-day meeting, but facilitate orientation for new members of the four Specialist Commissions and a specific training for the Presidents to be held on **8 September 2018**.

_____

…/Annexes

[i] Citation: Hoinville.L, Alban, L., Gibbens, J., Gustafson, L., Hasler, B., Saegerman, C., Salman, M., Stark K. 2013. Proposed terms and concepts for describing and evaluating animal-health surveillance systems. Preventive Veterinary Medicine 112, 1-12.

Annex 4

# USER'S GUIDE

**EU position**

**The EU thanks the OIE and supports the adoption of this modified User's guide.**



## A. Introduction

1) The OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) establishes 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* to set up measures providing for early detection, internal reporting, notification, ~~and~~ control or eradication of pathogenic agents, including zoonotic ones, in terrestrial animals (mammals, birds, reptiles 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. Correctly applied, they protect animal health and welfare and veterinary public health during production and trade in animals and animal products, and in the use of animals.

4) The absence of chapters, articles or recommendations on particular aetiological agents or commodities does not preclude the application of appropriate sanitary measures by the Veterinary Authorities, provided they are based on risk analyses conducted in accordance with the *Terrestrial Code*.

5) The year that a chapter was first adopted and the year of its last revision are noted at the end of each chapter.

6~~5~~) The complete text of the *Terrestrial Code* is available on the OIE Web site and individual chapters may be downloaded from: http://www.oie.int.

~~6) The year that a chapter was first adopted and the year of its last revision are noted at the end of each chapter.~~

## B. *Terrestrial Code* content

1) Key terms and expressions used in more than one chapter in the *Terrestrial Code* are defined in the Glossary, in the case where common dictionary definitions are not deemed to be adequate. The reader should be aware of the definitions given in the Glossary when reading and using the *Terrestrial Code*. 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 been adopted by the World Assembly of OIE Delegates and the particular provisions are thus not 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, zone or compartment.

4) The standards in Section 2 are designed to guide the importing country in conducting import risk analysis in the absence of OIE recommendations on particular aetiological agents or commodities. The importing country should also use these standards to justify import measures which are more stringent than existing OIE standards.

5) The standards in the chapters of Section 3 are designed for the establishment, maintenance and evaluation of 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 animal identification, traceability, zoning, compartmentalisation, disposal of dead animals, disinfection, disinsection 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. They address veterinary certification and the measures applicable by the exporting, transit and importing countries. A range of model veterinary certificates is provided to facilitate consistent documentation in 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. They include 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 production, transport, and slaughter or killing, as well as 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 take 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 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 OIE Organic Statutes. 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 events of epidemiological significance.

Chapter 1.2. describes the criteria for the inclusion of ~~a disease,~~ an infection or infestation in the OIE List and Chapter 1.3. gives the current list. Diseases are divided into nine categories based on the host species of the aetiological agents.

2. Diagnostic tests and vaccines

It is recommended that specified diagnostic tests and vaccines in *Terrestrial Code* chapters be used 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*). Experts responsible for facilities used for disease diagnosis and vaccine production should be fully conversant with the standards in the *Terrestrial Manual*.

3. Freedom from a disease, infection or infestation

Article 1.4.6. provides general principles for declaring a country or zone free from a disease, infection or infestation. This article applies when there are no specific requirements in the listed disease-specific chapter.

4 Prevention and control

Chapters 4.3. and 4.4. describe the measures that should be implemented to establish zones and compartments. Zoning and compartmentalisation should be considered as tools to control diseases and to facilitate safe trade.

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 the measures relate principally to OIE listed diseases or infections, general standards apply to all infectious disease risks. Moreover, in Chapter 4.7. diseases that are not listed are marked as such but are included for the information of Member Countries.

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. Chapters 6.5., 6.12. and 6.13. ~~is an example of a~~ provide recommendations for some specific on-farm prevention and control plans for the ~~non-~~unlisted food-borne pathogenic agent *Salmonella* ~~in poultry~~ as part of the Veterinary Services mission to ~~avoid~~ prevent, eliminate or control food safety hazards in animal production.

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 for these animals.

5. Trade requirements

Animal health measures related to international trade should be based on OIE standards. A Member Country may authorise the importation of animals or animal products into its territory under conditions different from those recommended by the *Terrestrial Code*. To scientifically justify more stringent measures, the importing country should conduct a risk analysis in accordance with OIE standards, as described in Chapter 2.1. Members of the WTO should refer to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

Chapters 5.1. to 5.3. describe the obligations and ethical responsibilities of importing and exporting countries in international trade. Veterinary Authorities and all veterinarians directly involved in international trade should be familiar with these chapters. Chapter 5.3. also describes the OIE informal procedure for dispute mediation.

The OIE aims to include an article listing the commodities that are considered safe for trade without the need for risk mitigation measures specifically directed against a particular listed disease, infection or infestation, regardless of the status of the country or zone of origin for the agent in question, at the beginning of each listed disease-specific chapter in Sections 8 to 15. This is work in progress and some chapters do not yet contain articles listing safe commodities. When a list of safe commodities is present in a chapter, importing countries should not apply trade restrictions to such commodities with respect to the agent in question.

6. International veterinary certificates

An international veterinary certificate is an official document that the Veterinary Authority of an exporting country issues in accordance with Chapters 5.1. and 5.2. It lists 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.

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 zones or compartments within them, and be based upon the standards in the *Terrestrial Code*.

Annex 4 (contd)

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

*a)* identify the diseases, infections or infestations from which the importing country is justified in seeking protection because of its own health status. Importing countries should not impose measures in regards to diseases that occur in their own territory but are not subject to official control programmes;

*b)* for commodities capable of transmitting these diseases, infections or infestations through international trade, the importing country should apply the relevant articles in the listed disease-specific chapters. The application of the articles should be adapted to the disease status of the country, zone or compartment of origin. Such status should be established according to Article 1.4.6. except when articles of the relevant listed disease chapter specify otherwise;

*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. 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 5.13. provide, as further guidance to Member Countries, model certificates that should be used as a baseline.

7. Guidance notes for importers and exporters

It is recommended that Veterinary Authorities prepare 'guidance notes' to assist importers and exporters understand trade requirements. These notes should identify and explain the trade conditions, including the measures to be applied before and after export and during transport and unloading, and the 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.

Annex 5

# GLOSSARY PART A

**EU position**

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

**Comments are inserted in the text below.**

***ANIMAL WELFARE***

means the physical and ~~psychological~~ mental state ~~of well-being~~ of ~~how~~ an *animal* ~~is coping with~~ in relation to the conditions in which it lives and dies. ~~An *animal* is in a good state of *welfare* if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear and distress. Good *animal welfare* requires *disease* prevention and veterinary treatment, appropriate shelter, management, nutrition, humane handling and humane *slaughter/killing*. *Animal welfare* refers to the state of the *animal*; the treatment that an *animal* receives is covered by other terms such as animal care, animal husbandry, and humane treatment.~~

**EU comment**

**The EU thanks the OIE for its work on the revision of the animal welfare definition and for taking the EU comment into account. The EU can agree with the proposed changes and support the adoption of the revised definition.**

***COMPARTMENT***

means an animal *subpopulation* contained in one or more *establishments*, separated from other populations by ~~under~~ a common *biosecurity* management system, and with a ~~distinct~~ specific *animal health status* with respect to ~~a~~ ~~specific~~ one ~~disease~~ or more ~~specific~~ ~~diseases~~ *infections* or *infestations* for which ~~required~~ the necessary *surveillance*, ~~control and~~ *biosecurity* and control measures have been applied for the purpose of *international trade* or disease prevention and control in a country or *zone* ~~*international trade*~~.

**EU comment**

**The EU can support the insertion of "separated from other populations" in the definition of compartment above, however this should be specified further, as separation needs to be ensured only as regards animal species that are susceptible to the relevant infection / infestation. We thus suggest inserting the word "susceptible" before "population".**

***CONTAINMENT ZONE***

means an *infected* ~~defined~~ *zone* ~~around and~~ defined within a previously free country or *zone*, which includes ~~including~~ all suspected or confirmed *cases* that are epidemiologically linked ~~infected *establishments*, taking into account the epidemiological factors and results of investigations,~~ and where movement control, *biosecurity* and *sanitary measures* are applied to prevent the spread of, and to eradicate, the ~~*infection*~~ *infection* or *infestation* ~~are applied~~.

~~***DISEASE***~~

~~means the clinical or pathological manifestation of *infection* or *infestation*.~~

***FREE ZONE***

means a *zone* in which the absence of a specific ~~the~~ ~~disease,~~ *infection* or *infestation* ~~under consideration~~ in an animal *population* has been demonstrated ~~by~~ in accordance with the relevant requirements ~~specified~~

~~in~~ of the *Terrestrial Code* ~~for free status being met~~. ~~Within the *zone* and at its borders, appropriate *official veterinary control* is effectively applied for *animals* and animal products, and their transportation.~~

***INFECTED ZONE***

means a *zone* either in which an *infection* or *infestation* has been confirmed, or one that ~~does not meet the provisions for freedom of~~ is defined as such in the relevant chapters of the *Terrestrial Code.*

***PROTECTION ZONE***

means a *zone* where specific *biosecurity* and *sanitary measures* are implemented to prevent the entry of a pathogenic agent into a free country or *zone* from a~~n adjacent~~ neighbouring country or *zone* of a different *animal health status*.

~~***TRANSPARENCY***~~

~~means the comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the *risk analysis*. Conclusions should be supported by an objective and logical discussion and the document should be fully referenced.~~

***VACCINATION***

means the ~~successful immunisation~~ administration of a vaccine, ~~susceptible *animals* through the administration~~ in accordance with the manufacturer's instructions and the *Terrestrial Manual*, ~~where~~ when relevant, ~~of a vaccine comprising antigens appropriate to the~~ with the intention of inducing immunity in an *animal* or group of *animals* against one or ~~several~~ more pathogenic agents ~~disease to be controlled~~.

***ZONE~~/REGION~~***

means a ~~clearly defined~~ part of a ~~territory~~ country defined by the *Veterinary Authority*, containing an animal *population* or *subpopulation* with a ~~distinct~~ specific *animal health status* with respect to an ~~specific disease, *infection* or *infestation* for which required *surveillance*, control and *biosecurity* measures have been applied~~ for the purposes of *international trade* or disease prevention or control.

Annex 6

# CHAPTER 2.1.

# IMPORT RISK ANALYSIS

**EU position**

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



## Article 2.1.1.

**Introduction**

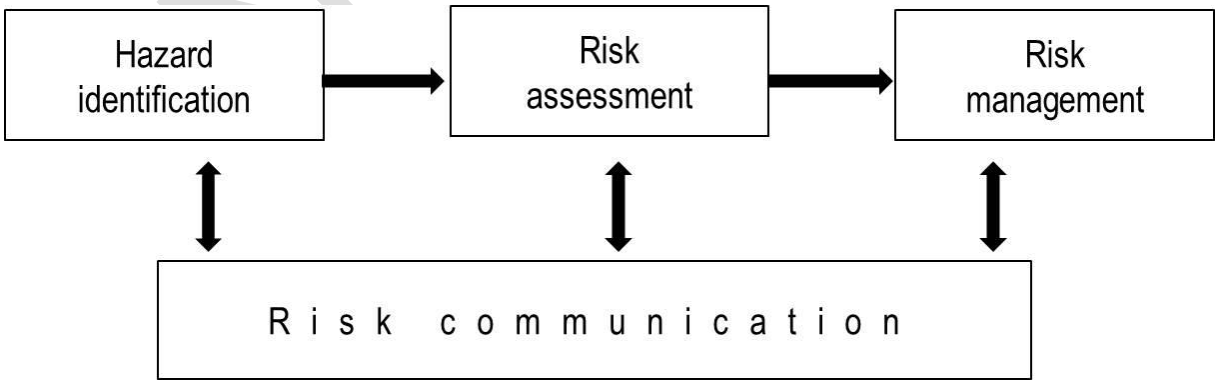
The importation of *animals* and animal products involves a degree of *disease risk* to the *importing country*. This *risk* may be represented by one or several *diseases* or *infections*.

The principal aim of import *risk analysis* is to provide *importing countries* with an objective and defensible method of assessing the *disease risks* associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, biological products and *pathological material*. The analysis should be transparent. Transparency means the comprehensive documentation and communication of all data, information, assumptions, methods, results, discussion and conclusions used in the *risk analysis*. This is necessary so that the *exporting country* ~~is~~ and all interested parties are 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 provides recommendations and principles for conducting transparent, objective and defensible *risk analyses* for *international trade*. The components of *risk analysis* 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.

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.]

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. ~~Transparency means the comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the *risk analysis*.~~

*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.

[…]

Annex 7

CHAPTER 2.2.

# CRITERIA APPLIED BY THE OIE FOR ASSESSING THE SAFETY OF COMMODITIES

**EU position**

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

Article 2.2.1.

**General provisions**

For the purposes of this chapter the word 'safety' is applied only to animal and human health considerations for *listed diseases*.

In many disease-specific chapters, the second article lists *commodities* that can be traded from a country or *zone* regardless of its status with respect to the specific *listed disease*. The criteria for their inclusion in the list of *safe commodities* are based on the absence of the pathogenic agent in the traded *commodity*, either due to its absence in the tissues from which the *commodity* is derived or to its inactivation by the processing or treatment that the *animal* products have undergone.

The assessment of the safety of the *commodities* using the criteria relating to processing or treatment can only be undertaken when processing or treatments are well defined. It may not be necessary to take into account the entire process or treatment, so long as the steps critical for the inactivation of the pathogenic agent of concern are considered.

For the criteria in Article 2.2.2. to be applied, ~~It~~ it is expected that processing or treatment (i) uses standardised protocols, which include the steps considered critical in the inactivation of the pathogenic agent of concern; (ii) is conducted in accordance with Good Manufacturing Practices; and (iii) that any other steps in the treatment, processing and subsequent handling of the *animal* product do not jeopardise its safety.

Article 2.2.2.

**Criteria**

For an *animal* product to be considered a *safe commodity* for *international trade*~~,~~ as described in the User's guide and Article 2.2.1., it should comply with the following criteria:

1) There is strong evidence that the pathogenic agent is not present in the tissues from which the *animal* product is derived in an amount able to cause *infection* in a human or *animal* by a natural exposure route. This evidence is based on the known distribution of the pathogenic agent in an infected *animal*, whether or not it shows clinical signs of disease.

OR

2) If the pathogenic agent may be present in, or may contaminate, the tissues from which the *animal* product is derived, the standard processing or treatment applied to produce the *commodity* to be traded, while not being specifically directed at this pathogenic agent, inactivates it to the extent that possible *infection* of a human or *animal* is prevented through its action, which is:

Annex 7 (contd)

*a)* physical (e.g. temperature, drying, irradiation);

or

*b)* chemical (e.g. iodine, pH, salt, smoke);

or

*c)* biological (e.g. fermentation);

or

*d)* a combination of *a)* to *c)* above.

Annex 8

CHAPTER 4.3.

# ZONING AND COMPARTMENTALISATION

**EU position**

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

Article 4.3.1.

**Introduction**

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

The purpose of this chapter is to provide recommendations on the principles of zoning and compartmentalisation to Member Countries wishing to establish and maintain different *subpopulations* with specific health status within their territory. These principles should be applied in accordance with the relevant chapters of the *Terrestrial Code*. This chapter also outlines a process by which trading partners may recognise such *subpopulations*.

Establishing and maintaining a disease-free status throughout the country should be the final goal for Member Countries. However, given the difficulty of achieving this goal ~~of establishing and maintaining a disease free status for an entire territory, especially for diseases the entry of which is difficult to control through measures at national boundaries~~, there may be benefits to a Member Country in establishing and maintaining a *subpopulation* with a ~~distinct~~ specific health status within its territory for the purposes of *international trade* or disease prevention or control. *Subpopulations* may be separated by natural or artificial geographical barriers or~~, in certain situations,~~ by the application of appropriate *biosecurity* management.

~~Zoning and compartmentalisation are procedures implemented by a Member Country under the provisions of this chapter with a view to defining *subpopulations* of distinct health status within its territory for the purpose of disease control and/or *international trade*.~~

While zoning applies to an animal *subpopulation* defined primarily on a geographical basis ~~(using natural, artificial or legal boundaries)~~, compartmentalisation applies to an animal *subpopulation* defined primarily by management and husbandry practices related to *biosecurity*. In practice, spatial considerations and ~~good~~ appropriate management, including *biosecurity plans*, play important roles in the application of both concepts.

~~A particular application of the concept of zoning is the establishment of a *containment zone*. In the event of limited *outbreaks* of a specified disease within an otherwise free country or *zone*, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*.~~

~~This chapter is to assist Member Countries wishing to establish and maintain different *subpopulations* within their territory using the principles of compartmentalisation and zoning. These principles should be applied in accordance with the measures recommended in the relevant disease chapter(s). This chapter also outlines a process through which trading partners may recognise such *subpopulations*. This process is best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to *outbreaks* of disease.~~

~~Before trade in *animals* or their products may occur, an *importing country* needs to be satisfied that its *animal health status* will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its borders and within its territory.~~

~~As well as contributing to the safety of *international trade*, zoning and compartmentalisation may assist disease control or eradication within a Member Country's territory.~~

Annex 8 (contd)

Zoning may encourage the more efficient use of resources within certain parts of a country. ~~and~~ C~~c~~ompartmentalisation may allow the functional separation of a *subpopulation* from other domestic ~~*animals*~~ or *wild animals* through *biosecurity* ~~measures~~, which ~~a *zone* (through geographical separation)~~ would not be achieved through geographical separation. In a country where a disease is endemic, establishment of *free zones* may assist in the progressive control and eradication of the disease. To facilitate disease control and the continuation of trade following a disease *outbreak* in a previously free country or *zone*, zoning may allow a Member Country to limit the extension of the disease to a defined restricted area, while preserving the status of the remaining territory. ~~the~~ For the same reasons, the use of compartmentalisation may allow a Member Country to take advantage of epidemiological links among *subpopulations* or common practices relating to *biosecurity*, despite diverse geographical locations~~, to facilitate disease control and/or the continuation of trade~~.

A Member Country may thus have more than one *zone* or *compartment* within its territory.

~~Zoning and compartmentalisation cannot be applied to all diseases but separate requirements will be developed for each disease for which the application of zoning or compartmentalisation is considered appropriate.~~

~~To regain free status following a disease *outbreak* in a *zone* or *compartment*, Member Countries should follow the recommendations in the relevant disease chapter in the *Terrestrial Code*.~~

Article 4.3.2.

**General considerations**

The *Veterinary Services* of ~~an *exporting*~~ a Member ~~country~~ Country ~~which~~ that is establishing a *zone* or *compartment* within its territory ~~for *international trade* purposes~~ should clearly define the *subpopulation* in accordance with the recommendations in the relevant chapters ~~in~~ of the *Terrestrial Code*, including those on *surveillance*, on ~~and~~ ~~the~~ *animal identification* and *animal traceability* and on *official control programmes* ~~of live *animals*~~. ~~The *Veterinary Services* of an *exporting country* should be able to explain to the *Veterinary Services* of an *importing country* the basis for claiming a distinct *animal health status* for the given *zone* or *compartment* under consideration.~~

The procedures used to establish and maintain the ~~distinct~~ specific *animal health status* of a *zone* or *compartment* ~~will~~ depend on the epidemiology of the disease, including ~~in particular~~ the presence and role of *vectors* and susceptible *wildlife* ~~species,~~ and environmental factors, on the animal production systems as well as on the application of *biosecurity* and *sanitary measures*, including movement control.

*Biosecurity* and *surveillance* are essential components of zoning and compartmentalisation, and should be developed through active cooperation between industry and *Veterinary Services*.

The ~~authority, organisation and infrastructure of the~~ *Veterinary Services*, including *laboratories*, should be ~~clearly documented~~ established and should operate in accordance with ~~the~~ Chapters 3.1. and 3.2. ~~on the evaluation of *Veterinary Services* of the *Terrestrial Code*~~, to provide confidence in the integrity of the *zone* or *compartment*. The final authority ~~of~~ over the *zone* or *compartment*, for the purposes of domestic and *international trade*, lies with the *Veterinary Authority*. The *Veterinary Authority* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment*. These include the human and financial resources and the technical capability of the *Veterinary Services* and of the relevant industry and production system (especially in the case of a *compartment*), including for *surveillance*, diagnosis and, when appropriate, *vaccination*, treatment and protection against *vectors*.

In the context of maintaining the *animal health status* of a *population* or *subpopulation* of a country, *zone* or *compartment*, ~~references to 'import', 'importation' and 'imported animals/ products' found in the *Terrestrial Code* apply both to~~ importations into ~~a~~ the country as well as ~~and to the~~ movements of *animals* and their products, and fomites, into the *zones* ~~and~~ or *compartments*~~. Such movements~~ should be the subject of appropriate *sanitary measures* and *biosecurity* ~~to preserve the *animal health status* of the country, *zone*/ or *compartment*~~.

The *Veterinary Services* should provide movement certification, when necessary, and carry out documented periodic inspections of facilities, *biosecurity*, records and *surveillance* procedures. *Veterinary Services* should conduct or audit *surveillance*, reporting, ~~*vaccination* and~~ *laboratory* diagnostic examinations and, when relevant, *vaccination*.

~~The *exporting country* should be able to demonstrate, through detailed documentation provided to the *importing country*, that it has implemented the recommendations in the *Terrestrial Code* for establishing and maintaining such a *zone* or *compartment*.~~

~~An *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Terrestrial Code* are applied and the *Veterinary Authority* of the *exporting country* certifies that this is the case.~~

~~The *exporting country* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment* for *international trade* purposes. These include the human and financial resources, and the technical capability of the *Veterinary Services* (and of the relevant industry and production system, in the case of a *compartment*) including disease *surveillance* and diagnosis.~~

~~*Biosecurity* and *surveillance* are essential components of zoning and compartmentalisation, and the arrangements should be developed through cooperation of industry and *Veterinary Services*.~~

~~Industry's responsibilities include the application of *biosecurity* measures, documenting and recording movements of *animals* and personnel, quality assurance schemes, monitoring the efficacy of the measures, documenting corrective actions, conducting *surveillance*, rapid reporting and maintenance of records in a readily accessible form.~~

~~Industry's~~ The production sector's responsibilities include, in consultation with the *Veterinary Services* if appropriate, the application of *biosecurity*, documenting and recording movements of *commodities* and personnel, managing quality assurance schemes, documenting the implementation of corrective actions, conducting *surveillance*, rapid reporting and maintenance of records in a readily accessible form.

~~The *Veterinary Services* should provide movement certification, and carry out documented periodic inspections of facilities, *biosecurity* measures, records and *surveillance* procedures. *Veterinary Services* should conduct or audit *surveillance*, reporting and *laboratory* diagnostic examinations.~~

Article 4.3.3.

**Principles for defining and establishing a zone or compartment~~, including protection and containment zones~~**

~~In conjunction with the above considerations, the~~ The following principles ~~should~~ apply when Member Countries define a *zone* or a *compartment*.

1) The extent of a *zone* and its geographical limits should be established by the *Veterinary Authority* on the basis of natural, artificial ~~and/~~or legal boundaries, and made public through official channels.

~~2) A *protection zone* may be established to preserve the health status of *animals* in a free country or *zone*, from adjacent countries or *zones* of different *animal health status*. Measures should be implemented based on the epidemiology of the disease under consideration to prevent introduction of the pathogenic agent and to ensure early detection.~~

~~These measures should include intensified movement control and *surveillance* and may include:~~

~~*a)* *animal identification* and *animal traceability* to ensure that *animals* in the *protection zone* are clearly distinguishable from other populations;~~

~~*b)* *vaccination* of all or at risk susceptible *animals*;~~

~~*c)* testing and/or *vaccination* of *animals* moved;~~

~~*d)* specific procedures for sample handling, sending and testing;~~

~~*e)* enhanced *biosecurity* including cleansing – *disinfection* procedures for transport means, and possible compulsory routes;~~

~~f) specific *surveillance* of susceptible *wildlife* species and relevant *vectors*;~~

~~g) awareness campaigns to the public or targeted at breeders, traders, hunters, *veterinarians*.~~

~~The application of these measures can be in the entire free *zone* or in a defined area within and/or outside the free *zone*.~~

~~3) In the event of limited *outbreaks* in a country or *zone* previously free of a disease, a *containment zone* may be established for the purposes of trade. Establishment of a *containment zone* should be based on a rapid response including:~~

~~a) Appropriate standstill of movement of *animals* and other *commodities* upon notification of suspicion of the specified disease and the demonstration that the *outbreaks* are contained within this zone through epidemiological investigation (trace-back, trace-forward) after confirmation of *infection*. The primary *outbreak* has been identified and investigations on the likely source of the *outbreak* have been carried out and all *cases* shown to be epidemiologically linked.~~

~~b) A *stamping-out policy* or another effective control strategy aimed at eradicating the disease should be applied and the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*. Increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* should be carried out and has not detected any evidence of *infection*.~~

~~c) Measures consistent with the disease-specific chapter should be in place to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*, including ongoing *surveillance* in the *containment zone*.~~

~~d) For the effective establishment of a *containment zone*, it is necessary to demonstrate that there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the last detected *case*.~~

~~e) The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The free status of these areas could be reinstated, once the *containment zone* is clearly established, irrespective of the provisions of the disease-specific chapter.~~

~~f) The *containment zone* should be managed in such a way that it can be demonstrated that *commodities* for *international trade* can be shown to have originated outside the *containment zone*.~~

~~g) The recovery of the free status of the *containment zone* should follow the provisions of the disease-specific chapter.~~

2~~4~~) The factors defining a *compartment* should be established by the *Veterinary Authority* on the basis of relevant criteria such as management and husbandry practices related to *biosecurity*, and ~~made public~~ communicated to the relevant operators through official channels.

3~~5~~) *Animals* and *herds*~~/~~ or *flocks* belonging to ~~such~~ *subpopulations* of *zones* or *compartments* ~~need to~~ should be recognisable as such through a clear epidemiological separation from other *animals* and all ~~things~~ factors presenting a ~~disease~~ *risk*. ~~For a *zone* or *compartment*, the~~ The ~~*Veterinary Authority* should document in detail~~ T~~t~~he measures taken to ensure the identification of the *subpopulation* and to ~~the~~ establish~~ment~~ and ~~maintenance of~~ maintain its health status through a *biosecurity plan* should be documented in detail. These measures ~~used to establish and maintain the distinct~~ specific ~~*animal health status* of a *zone* or *compartment*~~ should be appropriate to the particular circumstances, and ~~will~~ depend on the epidemiology of the disease, environmental factors, the health status of *animals* in adjacent areas, applicable *biosecurity* ~~measures~~ (including movement controls, use of natural~~,~~ ~~and~~ artificial or legal boundaries, ~~the~~ spatial separation of *animals*, control of fomites, and commercial management and husbandry practices), and *surveillance*.

4~~6~~) Relevant ~~*animals*~~ *commodities* within the *zone* or *compartment* should be identified in such a way that their movements are traceable. Depending on the system of production, identification may be done at the *herd*~~,~~ or *flock* ~~lot~~ or individual animal level. Relevant ~~animal~~ movements of *commodities* into and out of the *zone* or *compartment* should be well documented and controlled. The existence of ~~a valid~~ an *animal identification system* is a prerequisite to assess the integrity of the *zone* or *compartment*.

5~~7~~) For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant industry and the *Veterinary Authority*, and their respective responsibilities. It should also describe the ~~routine~~ standard operating procedures to provide clear evidence that the *surveillance* conducted, the ~~live~~ *animal identification* and *traceability* system, and the management and husbandry practices are adequate to meet the definition of the *compartment*. In addition to information on controls of movements of relevant *commodities* ~~animal movement controls~~, the plan should include *herd* or *flock* production records, *feed*, water and bedding sources, *surveillance* results, birth and *death* records, visitor logbook, morbidity and mortality history and investigations, medications, *vaccinations*, documentation of training of relevant personnel and any other criteria necessary for evaluation of *risk management*. The information required may vary in accordance with the species and diseases under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the *risks* are being managed and regularly ~~re-assessed~~ reassessed, and the measures adjusted accordingly.

Articles 4.3.4. to 4.3.7. describe different types of *zones* that can be established by Member Countries. However, other types of *zones* may be established for the purposes of disease control or trade.

Article 4.3.4.

**Free zone**

A *free zone* is one in which the absence of a specific *infection* or *infestation* in an animal population has been demonstrated in accordance with the relevant requirements of the *Terrestrial Code*.

In conjunction with Articles 4.3.2. and 4.3.3., and depending on the prevailing epidemiological situation, the attainment or maintenance of free status may require past or ongoing *specific surveillance* and *vector surveillance*, as well as appropriate *biosecurity* and *sanitary measures*, within the *zone* and at its borders. The *surveillance* should be conducted in accordance with Chapter 1.4. and the relevant chapters of the *Terrestrial Code*.

The free status can apply to one or more susceptible animal species populations, domestic or *wild*.

So long as an ongoing *surveillance* demonstrates there is no occurrence of the specific *infection* or *infestation*, and principles determined for its definition and establishment are respected, the *zone* maintains its free status.

Article 4.3.5.

**Infected zone**

An *infected zone* is one either in which an *infection* or *infestation* has been confirmed, or that is defined as such in the relevant chapters of the *Terrestrial Code*.

An *infected zone* in which an *infection* or *infestation* has been confirmed may be:

1) a *zone* of a country where the *infection* or *infestation* is present and has not yet been eradicated, while other *zones* of the country may be free; or

2) a *zone* of a previously free country or *zone*, in which the *infection* or *infestation* has been introduced or reintroduced, while the rest of the country or *zone* remains unaffected.

To gain free status in an *infected zone*, or regain free status following an *outbreak* in a previously *free zone*, Member Countries should follow the recommendations in the relevant chapters of the *Terrestrial Code*.

Article 4.3.6.

**Protection zone**

A *protection zone* may be established to preserve the *animal health status* of an *animal population* in a free country or a *free zone* by preventing the introduction of a pathogenic agent of a specific *infection* or *infestation* from neighbouring countries or *zones* of different *animal health status* to that animal *population*. A *protection zone* can be established within or outside the *free zone* or within the free country.

Annex 8 (contd)

*Biosecurity* and *sanitary measures* should be implemented in the *protection zone* based on the animal management systems, the epidemiology of the disease under consideration and the epidemiological situation prevailing in the neighbouring infected countries or *zones*.

These measures should include intensified movement control and *surveillance* and specific *animal identification* and *animal traceability* to ensure that *animals* in the *protection zone* are clearly distinguishable from other populations, and may also include:

1) *vaccination* of all or at risk susceptible *animals*;

2) testing or *vaccination* of *animals* moved;

3) specific procedures for sample handling, dispatching and testing;

4) enhanced *biosecurity* including *disinfection* and disinsection procedures for *vehicles*/*vessels* and vehicles used for transportation of animal products, feed or fodder, and possible compulsory routes for their movements within, to or from the *zone*;

5) specific *surveillance* of susceptible *wildlife* and relevant *vectors*;

6) awareness campaigns aimed at the public or targeted at breeders, traders, hunters or *veterinarians*.

Anytime the status of the *protection zone* changes, the status of the country or *zone* in which it was established should be redetermined in accordance with the relevant *listed disease*-specific chapters.

~~In the event of an emergency, such as a sudden increased *risk* to a free country or *zone*, a temporary *protection zone* may be established in a free country or *zone*. In such a situation, Mmeasures, such as *vaccination*, implemented in that a *protection zone* established in a free country or *zone* will not affect the status of the rest of the free country or *zone*. However, even if some of such the measures, such as *vaccination*, may make it necessary to distinguish the status of the *protection zone* from the rest of the country or *zone*.~~

~~A temporary *protection zone* should be established for a defined period at the end of which either it is permanently distinguished from the rest of the country or *zone* or it is disestablished.~~

~~In the event of an occurrence, in a temporary *protection zone*, of a *case* of an *infection* or *infestation* for which it was established, this will not affect the status of the rest of the country or *zone*, provided that the *zone* was established at least two incubation periods before the occurrence.~~

Article 4.3.7.

**Containment zone**

In the event of *outbreaks* in a country or *zone* previously free from a disease, a *containment zone*, which includes all epidemiologically linked *outbreaks* may be established to minimise the impact on the rest of the country or *zone*.

A *containment zone* is an *infected zone* that should be managed in such a way that *commodities* for *international trade* can be shown to have originated either from inside or outside the *containment zone*.

Establishment of a *containment zone* should be based on a rapid response, prepared in a contingency plan, and that includes:

1) appropriate control of movement of *animals* and other *commodities* upon declaration of suspicion of the specified disease;

2) epidemiological investigation (trace-back, trace-forward) after confirmation of *infection* or *infestation*, demonstrating that the *outbreaks* are epidemiologically related and all contained within the defined boundaries of the *containment zone*;

3) a *stamping-out policy* or another effective emergency control strategy aimed at eradicating the disease;

4) *animal identification* of the susceptible population within the *containment zone* enabling its recognition as belonging to the *containment zone*;

5) increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* demonstrating no occurrence of *infection* or *infestation*;

6) *biosecurity* and *sanitary measures*, including ongoing *surveillance* and control of the movement of *animals*, ~~and~~ other *commodities* and fomites within and from the *containment zone*, consistent with the *listed disease*-specific chapter, when there is one, to prevent spread of the *infection* or *infestation* from the *containment zone* to the rest of the country or *zone*.

~~For the effective establishment of a *containment zone*, it is necessary to demonstrate that either:~~

A *containment zone* is considered as effectively established when the following is demonstrated:

EITHER

*a)* there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the disposal of the last detected *case*.

OR

*b)* the *containment zone* comprises an *infected zone* where *cases* may continue to occur and a *protection zone*, where no *outbreaks* have occurred for at least two *incubation periods* after the control measures above are in place, and that separates the *infected zone* from the rest of the country or *zone*.

The free status of the areas outside the *containment zone* is suspended pending the effective establishment of the *containment zone*. Once the *containment zone* has been established, the areas outside the *containment zone* regain free status.

The free status of the *containment zone* should be regained in accordance with the relevant *listed disease*-specific chapters or, if there are none, with Article 1.4.6.

In the event of an occurrence of a *case* of the *infection* or *infestation* for which the *containment zone* was established, either in the *containment zone* defined in point *a)* or in the *protection zone* defined in point *b)*, the rest of the country or *zone* is considered infected.

Article 4.3.8.

**Bilateral recognition of country or zone status by trading countries**

While the OIE has procedures for official recognition of status for a number of *infections* (refer to Chapter 1.6.), for other *infections* or *infestations*, countries may recognise each other's status through a bilateral process. Trading partners should exchange information allowing the recognition of different *subpopulations* within their respective territories. This recognition process is best implemented through establishing parameters and gaining agreement on the necessary measures prior to *outbreaks* of disease.

The *Veterinary Services* of an *exporting country* should be able to explain to the *Veterinary Services* of an *importing country* the basis for claiming a specific *animal health status* for a given *zone* or *compartment* under consideration.

Annex 8 (contd)

The *exporting country* should be able to demonstrate, through detailed documentation provided to the *importing country*, that it has implemented the recommendations in the *Terrestrial Code* for establishing and maintaining such a *zone* or *compartment*.

In accordance with Chapter 5.3., an *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Terrestrial Code* are applied and the *Veterinary Authority* of the *exporting country* is able to demonstrate that this is the case.

Annex 9

CHAPTER 4.8.

# COLLECTION AND PROCESSING OF OOCYTES AND *IN VITRO* PRODUCED EMBRYOS ~~/OOCYTES~~ FROM LIVESTOCK AND HORSES

**EU position**

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

Article 4.8.1.

**Aims of control**

Production of embryos *in vitro* involves the collection of oocytes from the ovaries of donors, *in vitro* maturation and fertilisation of the oocytes, then *in vitro* culture to the morula~~/~~ or blastocyst stage. At ~~at~~ this stage, ~~which~~ they are ready for transfer into recipients. The purpose of official sanitary control of *in vitro* produced embryos intended for movement internationally is to ensure that specific pathogenic organisms, which could be associated with such embryos, are controlled and transmission of *infection* to recipient animals and progeny is avoided. The conditions outlined in this chapter are also applicable where the movement of *in vitro* maturing (IVM) oocytes is intended.

Article 4.8.2.

**Conditions applicable to the embryo production team**

The embryo production team is a group of competent technicians, including at least one *veterinarian*, to perform the collection and processing of ovaries~~/~~ and oocytes and the production and storage of *in vitro* produced 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 the hygienic collection of ovaries and oocytes and all other procedures involved in the production of embryos intended for international movement.

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

5) The production team should have adequate facilities and equipment for:

   *a)* collecting ovaries ~~and/~~or oocytes;

   *b)* processing of oocytes and production of embryos at a permanent or mobile laboratory;

   *c)* storing oocytes ~~and/~~or embryos.

   These facilities need not necessarily be at the same location.

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

7) The embryo production 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 and processing of oocytes and the production and storage of embryos.

Article 4.8.3.

**Conditions applicable to the processing laboratories**

A processing laboratory used by the embryo production team may be mobile or permanent. It may be contiguous with the oocyte recovery area or at a separate location. It is a facility ~~in which~~ where oocytes ~~which that have been~~ recovered from ovaries are then matured and fertilised, and where the resulting embryos are further cultured *in vitro*.

Embryos may also be subjected to any required treatments such as washing and storage and quarantine in this laboratory.

Additionally:

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

2) While embryos for export are being produced prior to their storage in ampoules, vials or straws, no oocyte~~/~~ or embryo of a lesser health status should be recovered or processed in the same laboratory.

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

4) The processing laboratory should be constructed with materials which permit its effective cleansing and *disinfection*. This should be done frequently and always before and after each occasion when embryos for export are processed.

5) The processing laboratory should have and use appropriate facilities to handle and process embryos for export, in accordance with the recommendations in the Manual of the International Embryo ~~Transfer~~ Technology Society (IETS).

Article 4.8.4.

**Conditions applicable to donor animals**

Oocytes for the *in vitro* production of embryos are obtained from donors basically in two different ways: individual collection or batch collection. The recommended conditions for these differ.

Individual collection usually involves the aspiration of oocytes from the ovaries of individual live animals on the farm where the animal resides, or at the laboratory. Occasionally oocytes may also be recovered from individual live donors by aspiration from surgically excised ovaries. When oocytes are recovered from individual live animals, the conditions for these donors should resemble those set out in Article 4.7.4.

In these cases the cleaning and sterilisation of equipment (e.g. ultrasound guided probes) is especially important and should be carried out between each donor in accordance with the recommendations in the Manual of the ~~International Embryo Transfer Society (~~IETS~~)~~[1].

Batch collection involves the removal of ovaries from batches of donors slaughtered at a *slaughterhouse*/*abattoir* ~~(hereafter '*abattoir*')~~; these ovaries are then transported to the processing laboratory where the oocytes are recovered from the ovarian follicles by aspiration or slicing techniques. Batch collection has the disadvantage that it is usually impractical to ~~relate~~ trace the ovaries ~~which are~~ transported to the laboratory back to the donors ~~which were~~ slaughtered at the *slaughterhouse*/*abattoir*. Nevertheless, it is critical to ensure that only healthy tissues are obtained and that they are removed from the donors and transported to the laboratory in a hygienic manner.

Additionally:

1) The *Veterinary ~~Authority~~ Services* should have knowledge of the *herd~~(s)~~* or *flock~~(s)~~* from which the donor animals ~~have been~~ were sourced.

2) The donor animals should not originate from *herds* or *flocks* that are subject to veterinary restrictions for foot and mouth disease~~, rinderpest and~~ or peste des petits ruminants, and neither should the removal of any tissue or aspiration of oocytes take place in an *infected zone*, or one that is subject to veterinary restrictions for those diseases.

3) In the case of oocyte recovery from live donors, post-collection surveillance of the donors and donor *herd~~(s)~~* or *flock~~(s)~~* should be conducted based on the recognised *incubation periods* of the diseases of concern to determine retrospectively the health status of donors.

4) In the case of oocyte recovery from batches of ovaries collected from a~~n~~ *slaughterhouse/abattoir*, the *slaughterhouse/abattoir* ~~it~~ should be officially approved and under the supervision of a *veterinarian* ~~whose responsibility is to ensure~~ responsible for ensuring that ante-~~mortem~~ and post-mortem inspections of potential donor animals are carried out, and ~~to certify~~ for certifying them ~~to be~~ free from ~~of~~ clinical or pathological signs of the diseases listed in point 2.

5) Donor animals slaughtered at a~~n~~ *slaughterhouse/abattoir* should not ~~have been~~ be animals designated for compulsory *slaughter* for a *notifiable disease* ~~and~~ or ~~should not~~ be slaughtered at the same time as such animals ~~donors from which ovaries and other tissues will be removed~~.

6) Batches of ovaries and other tissues collected from a~~n~~ *slaughterhouse/abattoir* should not be transported to the processing laboratory before confirmation has been obtained that ante- and post-mortem inspection of donors has been ~~satisfactorily completed~~ carried out with favourable results.

7) Equipment for the removal and transport of ovaries and other tissues should be cleaned and sterilised before use and used exclusively ~~used~~ for these purposes.

8) Records of the identities and origins of all donors should be maintained for inspection by the *Veterinary ~~Authority~~ Services* for a period of at least two years after the embryos have been exported. While this may be difficult to achieve in the case of batch collection, it is to be expected that the identities of the *herds* or *flocks* from which the donors originated will be maintained.

Article 4.8.5.

**~~Optional~~ ~~t~~Tests and treatments**

A supplementary approach for ensuring that *in vitro* produced embryos do not transmit disease is ~~by~~ testing various materials to confirm the absence of pathogenic ~~organisms~~ agents listed in point 2 of Article 4.8.4.

Tests may also be used to assess whether quality control procedures being applied in the processing laboratory are of an acceptable standard.

Tests may also be carried out on the following materials:

1) non-viable oocytes~~/~~ or embryos from any stage of the *in vitro* production line from batches intended for export;

2) samples of *in vitro* maturation medium taken prior to mixing the oocytes with semen for the fertilisation process;

3) samples of embryo culture medium taken immediately prior to embryo storage~~.~~;

4) a pool of the last three washes from the 10 washes performed on the embryos.

Annex 9 (contd)

These samples should be stored at 4°C and tested within 24 hours. If this is not possible, then the samples should be stored frozen at minus 70°C or lower.

Additionally:

1) Semen used to fertilise oocytes *in vitro* should have been collected and processed in accordance with Chapter 4.5. and meet the health requirements ~~and standards set out~~ in Chapter 4.6. as appropriate to the species and in relevant *listed* disease-specific chapters.

   When the donor of the semen used to fertilise the oocytes 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 on the spare embryos may be required to verify that these infectious diseases were not transmitted.

   An alternative may be to test an aliquot of semen from the same collection date.

2) Any biological product of animal origin, including co-culture cells and media constituents, used in oocyte recovery, maturation, fertilisation, culture, washing and storage should be free ~~of~~ from ~~living pathogens~~ pathogenic agents. Media should be sterilised prior to use by approved methods in accordance with the ~~IETS~~ Manual[1] of the IETS and handled appropriately ~~in such a manner as~~ to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the ~~IETS~~ Manual of the IETS[1].

3) All equipment used to recover, handle, culture, wash, freeze and store oocytes~~/~~ or embryos should be new or cleaned and sterilised prior to use as recommended in the ~~IETS~~ Manual of the IETS[1].

Article 4.8.6.

**Risk management**

With regard to disease transmission, transfer of *in vitro* produced embryos is a low risk method for moving animal genetic material although the *risk* is not quite as low as for *in vivo* derived embryos. It should be noted that categorisation of diseases~~/~~ and ~~disease~~ pathogenic agents by the IETS, as described for *in vivo* derived embryos in Article 4.7.14., does not apply in the case of *in vitro* produced embryos. Irrespective of the animal species, there are three phases in the embryo production and transfer process that determine the final level of *risk*. These are as follows:

1) the first phase comprises the risk potential for ovary~~,~~ ~~/~~ oocyte~~/~~ or embryo contamination and depends on:

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

   *b)* the health status of the *herds* or *flocks* and the donors from which the ovaries~~,~~ ~~/~~ oocytes~~,~~ ~~/~~ ~~or~~ embryos or semen for fertilisation of oocytes are collected;

   *c)* the ~~pathogenic~~ characteristics of the ~~specified disease~~ pathogenic agents listed in point 2 of Article 4.8.4.;

2) the second phase covers risk mitigation by the use of internationally accepted procedures for the processing of embryos which are set out in the ~~IETS~~ Manual of the IETS[1]. These include the following:

   *a)* oocytes and embryos should be washed between each stage of production;

   b) after the *in vitro* culture period is finished the embryos should be washed at least ~~ten~~ 10 times with at least 100–fold dilutions between each wash, and a fresh pipette should be used for transferring the embryos through each wash;

*cb)* only embryos from the same donor (in the case of individual collection) or from the same batch (in the case of batch collection) should be washed together, and no more than ten embryos should be washed at any one time;

*dc)* sometimes, for example when inactivation or removal of certain viruses (e.g. bovine herpesvirus-1, or 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 of the IETS[1];

*ed)* 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 from adherent material;

3) the third phase, which is applicable to diseases listed in point 2 of Article 4.8.4. encompasses the *risk* reductions resulting from:

*a)* post-collection surveillance of the donors and donor *herds* or *flocks* based on the recognised incubation periods of the diseases of concern to determine retrospectively the health status of the donors whilst the embryos are stored (in species where effective storage by cryopreservation is possible) in the *exporting country*. Post-collection *surveillance* of donors is not, of course, possible in the case of batch collection from an *slaughterhouse*/*abattoir*, although surveillance of the *herds* or *flocks* of origin may be possible;

*b)* testing of oocytes, embryos, co-culture cells, media and other samples (e.g. blood) (as referred to in Article 4.8.5.) in a *laboratory* for presence of disease pathogenic agents.

Article 4.8.7.

**Conditions applicable to the storage, and transport and export of oocytes and embryos**

Oocytes and *in vitro* produced embryos can be stored and transported fresh, chilled or frozen.

Fresh embryos may undergo culture in portable incubators during transportation and should arrive at the recipient animal within five days, in time for transfer of the mature blastocysts. Chilled embryos should be transferred within 10 days of chilling.

The *Veterinary Services* should have knowledge of the variety of oocyte and embryo storage systems available and should have procedures in place for the safe and timely inspection and certification of these oocytes and embryos to ensure their viability.

1) Only embryos from the same individual donor or from the same batch collection should be stored together in the same ampoule, vial or straw.

2) For frozen oocytes and embryos

*a)* Sterile ampoules, vials or straws should be sealed prior to freezing or after vitrification and should be labelled according to the Manual of the IETS[1].

*b)* The frozen oocytes and embryos should if possible, depending on the species, be frozen in fresh liquid nitrogen that has not been used previously or other cryoprotectant and then stored in fresh cryoprotectant liquid phase nitrogen that has not been used previously or in the vapour phase of liquid nitrogen cleaned disinfected containers under strict hygienic conditions at a storage place.

*c)* Liquid nitrogen containers should be sealed prior to shipment from the *exporting country*.

3) For fresh or chilled oocytes and embryos

*a)* Sterile Ampoules ampoules, vials or straws should be sealed prior to storing in portable incubators at the time of freezing and should be labelled in accordance with the IETS Manual of the IETS[1].

Annex 9 (contd)

*b)* The fresh or chilled oocytes and embryos should be stored under strict hygienic conditions in portable incubators disinfected in accordance with the ~~IETS~~ Manual of the IETS and manufacturer's instructions.

*c)* Portable incubators should be sealed prior to shipment from the *exporting country*.

~~4) Liquid nitrogen containers should be sealed prior to shipment from the *exporting* country.~~

4~~5~~) Oocytes and embryos ~~Embryos~~ should not be exported until the appropriate veterinary certificates are completed.

Article 4.8.8.

**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 4.8.6. and conducted in accordance with Chapter 4.9.

Annex 10

# CHAPTER 4.X.

# VACCINATION

**EU position**

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

**A comment is inserted in the text below.**



## Article 4.X.1.

**Introduction and objectives**

~~In general,~~ *Vaccination* is intended to prevent and control ~~and prevent~~ the occurrence of a disease and reduce the transmission of the pathogenic agent. ~~For the purpose of disease control~~ Ideally, vaccines should induce immunity that~~, ideally,~~ prevents *infection*. However, some vaccines may only prevent clinical signs, or reduce multiplication and shedding of the pathogenic agent.

*Vaccination* may contribute to improvement of *animal* and human health, *animal welfare*, agricultural sustainability and to reduction of the use of *antimicrobial agents* in *animals*.

The objective of this chapter is to provide guidance to *Veterinary Services* ~~*Authorities*~~ for the ~~successful~~ use of *vaccination* in support of disease prevention and control programmes. The recommendations in this chapter may be refined by the specific approaches described in the *listed disease*-specific chapters of the *Terrestrial Code*. Furthermore, the recommendations in this chapter may also be used for any diseases for which a vaccine exists.

The *vaccination* strategy applied depends on biological, technical and policy considerations, available resources and the feasibility of implementation. ~~The recommendations in this chapter are intended for all diseases for which a vaccine exists.~~

~~In addition to other disease control measures, *vaccination* may be a component of a disease control programme.~~ The prerequisites to enable a Member Country to successfully implement *vaccination* include compliance with:

1) the recommendations on *surveillance* in Chapter 1.4.;

2) the relevant provisions in Chapters 3.1. and 3.4.;

3) the recommendations on *vaccination* in the *listed disease*-specific chapters of the *Terrestrial Code*;

4) in vaccine-producing countries, the relevant general and specific recommendations for ~~principles of~~ veterinary vaccine production and quality control in ~~Chapter 1.1.8. of~~ the *Terrestrial Manual.*

~~The objective of this chapter is to provide guidance to Member Countries for successful implementation of *vaccination* in support of disease control programmes. The recommendations in this chapter may be refined by the specific approaches described in the disease-specific chapters of the *Terrestrial Code*.~~

~~Standards for vaccines are described in the *Terrestrial Manual*.~~

## Article 4.X.2.

**Definitions**

For the purposes of this chapter:

**Vaccination programme:** means a plan to apply *vaccination* to an epidemiologically appropriate proportion of the susceptible animal population for the purpose of disease prevention or control.

**Emergency vaccination:** means a *vaccination* programme applied in immediate response to an *outbreak* or increased *risk* of introduction or emergence of a disease.

**Systematic vaccination:** means an ongoing routine *vaccination* programme.

**Vaccination coverage:** means the proportion of the target population to which vaccine was administered during a specified timeframe.

**Population immunity:** means the proportion of the target population effectively immunised at a specific time.

**EU comment**

**The EU would suggest amending the definition of population immunity above, as it does not seem to be correct. Indeed, it is not entirely clear what is meant by "effectively immunised", which could be misunderstood as being the same as "vaccine was indeed administered" i.e. the definition of "vaccination coverage".**

**However, herd or population immunity in fact means that if a certain percentage of a population is fully protected against infection, an introduction of the pathogenic agent will not result in extensive spread and only in a minor outbreak (i.e. basic reproduction number R0 will be smaller than 1). Furthermore, the infection will not spread to another population, as this does not occur if R0 < 1. Population immunity therefore applies to spread of the agent in the population. We therefore suggest amending the definition as follows:**

**"Population immunity: means the ~~proportion of the target population effectively immunised at a specific time~~ prevention of the spread of a pathogenic agent in a population as a result of the vaccination of a sufficiently high proportion of the target population."**

Article 4.X.3.

**Vaccination programmes**

The objectives and strategy of a *vaccination* programme should be defined by the *Veterinary Authority* before the implementation of ~~the~~ *vaccination*, taking into account the epidemiology of the disease ~~disease *infection*~~, its impact and zoonotic potential, the species affected and their distribution.

If these factors indicate that the programme should be expanded beyond national boundaries, the *Veterinary Authority* should liaise with the *Veterinary Authorities* of neighbouring countries. When appropriate, a regional approach to harmonise *vaccination* programmes is recommended.

*Veterinary Authorities* should liaise, as relevant, with public health authorities when developing and implementing *vaccination* programmes against zoonoses.

*Vaccination* programmes may include systematic *vaccination* and emergency *vaccination*.

1) Systematic *vaccination* in infected countries aims to reduce the incidence, prevalence or impact of a disease with the objective of prevention, control and possible eradication. In ~~disease~~ free countries or *zones*, the objective of systematic *vaccination* is to prevent the introduction of a ~~pathogenic agent~~ disease from an infected neighbouring country or *zone*, or to limit the impact in the case of ~~an~~ the introduction of that disease ~~pathogenic agent~~ ~~disease~~.

2) Emergency *vaccination* provides an adjunct to the application of other essential *biosecurity* and disease control measures and may be applied to control *outbreaks*. Emergency *vaccination* may be used in response to:

   *a)* an *outbreak* in a free country or *zone*;

*b)* an *outbreak* in a country or *zone* that applies systematic *vaccination*, but when ~~vaccines are~~ revaccination is applied to boost existing immunity;

*c)* an *outbreak* in a country or *zone* that applies systematic *vaccination*, but when the vaccine employed does not provide protection against the strain of the pathogenic agent involved in the *outbreak;*

*d)* a change in the *risk* of introduction of a pathogenic agent or emergence of a disease in a free country or *zone*.

*Vaccination* programmes should ~~consider other~~ be integrated with other ongoing animal health related activities involving the target population. This can improve the efficiency of the programme and reduce the cost by ~~sharing~~ optimisation of resources.

Article 4.X.4.

**Launching a vaccination programme**

When deciding whether to initiate a *vaccination* programme the *Veterinary Authority* should consider, among others, the following:

1) the epidemiology of the disease ~~disease *infection*~~;

1bis) the probability that the disease cannot be rapidly contained by means other than *vaccination*;

2) the ~~an increased~~ *incidence* and *prevalence* of ~~an existing~~ the disease, if present;

3) the ~~an increased~~ likelihood of introduction of a pathogenic agent or emergence of a disease;

3bis) the zoonotic potential of the disease;

4) the density of the exposed susceptible animals ~~*population*~~;

5) the ~~an insufficient~~ level of population immunity;

6) the *risk* of exposure of specific *subpopulations* of susceptible animals;

7) the suitability of a *vaccination* programme as an alternative to or an adjunct to other disease control measures such as a *stamping-out policy;*

7bis) the existence of an *animal identification system* to differentiate vaccinated from unvaccinated *subpopulations*;

8) the availability of a safe and effective vaccine ~~resources~~;

8bis) the availability of human, financial, and material resources;

9) the cost-benefit analysis ~~considerations~~ of the *vaccination* programme, including ~~the~~ its impact on trade and public health.

Article 4.X.5.

**Vaccination strategies**

Different *vaccination* strategies may be applied alone or in combination, taking into account the epidemiological and geographical characteristics of occurrence of the disease. The following strategies may be applied:

1) **Blanket vaccination:** *vaccination* of all susceptible animals in an area or an entire country or *zone*.

2) **Ring vaccination:** *vaccination* ~~primarily~~ of all susceptible animals in a delineated area surrounding the location ~~*establishments*~~ where an *outbreak* has occurred. ~~To prevent outward spread of disease, *vaccination* should be applied from the outer boundary of the area inwards.~~

3) **Barrier vaccination:** *vaccination* in an area along the border of an infected country or *zone* to prevent the spread of ~~disease~~ *infection* into or from a neighbouring country or *zone*.

4) **Targeted vaccination:** v*accination* of a *subpopulation* of susceptible animals ~~defined by a greater likelihood of exposure or severity of the consequences~~.

Article 4.X.6~~7~~.

**Choice of vaccine**

Depending on the disease, several vaccines may be available. To achieve the objectives of the *vaccination* programme, the choice of a vaccine is a critical element that depends on ~~different~~ several factors including:

1. Availability and cost

   *a)* availability of the vaccine including ~~marketing authorisation~~ relevant regulatory approvals and ~~in~~ adequate quantities at the time required;

   *b)* capacity of the providers to supply the vaccine for the duration of the *vaccination* campaign and to respond to increased needs;

   *c)* flexibility in the number of doses per vial to match the structure of the target population;

   *d)* a comparison of the costs of vaccines that meet the technical specifications established in the *vaccination* programme.

2. Vaccine characteristics

   *a)* Physical characteristics

   – route and ease of administration;

   – volume of dose;

   – type of adjuvant and other components.

   *b)* Biological characteristics

   – immunity against circulating strains;

   – live, inactivated or biotechnology-derived vaccines;

   – number of strains and pathogens included in the vaccine;

   – potency of the vaccine;

   – onset of immunity;

   – shelf-life and expiry date;

   – ~~thermostability~~ thermotolerance;

   – duration of the effective immunity;

   – number of doses required to achieve effective immunity;

   = ability to be monitored for vaccine-induced immunity;

   – ~~effect on the~~ ability for vaccinated animals to be differentiated from infected ~~from vaccinated~~ animals, at the individual or group level;

   – suitability of vaccine formulation for species and age of animals in the target population;

– safety for the users, the consumers and the environment.

*c)* Side effects

– adverse reactions;

– unintentional transmission of live vaccine strains~~.~~;

– reversion of attenuated strains to virulence.

When a single vaccine only is available, the same factors listed above should be considered in deciding whether or not to launch a *vaccination* programme.

Article 4.X.7~~6~~.

**Other critical elements of a vaccination programme**

In addition to the choice of vaccine, the *vaccination* programme should include the following other critical elements. ~~and~~ The *vaccination* programme should be communicated to all stakeholders.

1. Legal basis

There should be a legal basis for the *vaccination* programme, including for possible compulsory compliance and for possible compensation of animal owners for ~~possible~~ adverse reactions in their animals.

2. Target population

The *vaccination* programme should define the animal population to be vaccinated and the geographical area where the target population is located.

The target population may include the entire susceptible population or an epidemiological relevant *subpopulation* depending on the likelihood of exposure, the consequences of the disease, the role of the different *subpopulations* in the epidemiology of the ~~disease~~ *infection* and the resources available. The target population may include *wildlife*.

Factors to consider in determining the target population may include species, age, health status, maternal immunity, sex, production types, geographical distribution as well as the number of *animals* and *herds*. These factors should be reviewed and updated regularly.

3~~2~~. Vaccination coverage

~~In practical terms, it~~ It may be difficult to immunise the entire target population. The *vaccination* programme should define the minimum *vaccination* coverage necessary to achieve ~~for the minimum~~ a sufficient population immunity ~~required to achieve~~ to fulfil the objectives of the programme. The minimum *population* immunity required will vary according to the epidemiology of the disease, density of susceptible animals, ~~efficacy of the vaccine~~ and geographical factors.

Measuring population immunity during the monitoring of the *vaccination* programme may assist ~~to~~ in identifying subsets of the target *population* that have not been adequately immunised.

4~~3~~. Stakeholder involvement

*Veterinary Services* ~~The *vaccination* programme~~ should demonstrate good governance of the *vaccination* programme by ~~the *Veterinary Services* and by~~ clearly identifying the involvement of different stakeholders including other ~~government agencies~~ governmental organisations, ~~farmers~~ animal owners, farmer organisations, private sector veterinarians, non-governmental organisations, *veterinary paraprofessionals*, local government authorities and vaccine suppliers. Stakeholder acceptance of *vaccination* is crucial for the success of the *vaccination* programme. Different stakeholders should preferably be involved in the planning and implementation of *vaccination*, the awareness campaigns, the monitoring of *vaccination*, the production and delivery of vaccines and the financing of the *vaccination* programme.

5~~4~~. Resources

*Vaccination* programmes may often span several years. To achieve the desired objective, human, financial and material resources should be available throughout the estimated duration of the *vaccination* programme.

6~~5~~. Actions and timeline

The *vaccination* programme should describe the responsibilities, expected deliverables and timeline for each activity.

7~~6~~. Timing of vaccination campaigns

The *vaccination* programme should describe the periodicity of ~~the~~ any *vaccination* campaigns. Depending on the disease and type of vaccine, animals may be vaccinated once or several times during their lifetime.

The objective of ~~the~~ a *vaccination* campaign ~~is~~ should be to achieve the ~~necessary~~ *vaccination* coverage necessary to attain or maintain ~~and~~ the minimum population immunity in the target *population* within a defined timeframe. The *vaccination* campaign should be implemented in such a manner as to ensure that the majority of the target *population* is immunised within as short a time as possible. The *vaccination* programme should include a detailed description of the implementation of ~~the~~ *vaccination* campaigns, including frequency and starting and ending dates of each campaign.

The frequency, timing and duration of ~~the~~ *vaccination* campaigns should be determined taking into consideration the following factors:

*a)* vaccine characteristics and manufacturer's directions for use;

a*bis*) vaccine storage facilities and delivery systems;

*b)* accessibility of the target population;

*c)* animal handling facilities;

*d)* animal body condition and physiological state;

*e)* geographical factors;

*f)* climate conditions;

*fbis*) *vector* activity;

*g)* awareness, acceptance and engagement of stakeholders;

*h)* types of production systems and animal movement patterns;

*i)* timing of agricultural, social or cultural activities;

*j)* availability of resources.

8~~7~~. Auditing of ~~the~~ vaccination campaigns

The *vaccination* programme should include periodic auditing of all the participants in ~~the~~ any *vaccination* campaigns. Auditing ensures that all components of the system function and provide verifiable documentation of procedures. Auditing may detect deviations of procedures from those documented in the programme.

Indicators related to auditing of ~~the~~ a *vaccination* campaign may include:

*a)* proportion of the targeted *population* of *animals* and *herds* vaccinated within the defined timeframe;

*b)* number of vaccine doses used compared with number of animals vaccinated;

*bbis)* number of animals vaccinated compared to census figures for the relevant animal *population*;

*c)* number of reports of breaches of the cold chain;

*d)* performance of vaccinator teams ~~in respect of~~ in complying with the standard operating procedures;

*e)* timing and ~~length~~ duration of the campaign;

*f)* overall cost and cost per individual animal vaccinated.

To enable auditing of the *vaccination* programme, a recording system should be in place to measure the indicators above.

Article 4.X.8.

**Logistics of vaccination**

*Vaccination* campaigns should be planned in detail and well in advance considering the following elements:

1. Procurement of vaccine

The vaccine selected for use in a *vaccination* programme should have been ~~be~~ subjected to the ~~registration~~ relevant regulatory approval procedure of the country, which is congruent with the recommendation of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary ~~Medical~~ Medicinal Products (VICH).

For systematic *vaccination* campaigns, the process of procurement of the selected vaccine should be initiated in advance to ensure timely delivery to meet the timeframe of the *vaccination* campaign.

National disease contingency plans should provide for emergency *vaccination*. These provisions may allow for simplified procedures to procure vaccine and grant authorisation for temporary use. If *vaccination* is to be used systematically, definitive relevant regulatory approval ~~registration~~ should be obtained.

Vaccine banks, established in accordance with Chapter 1.1.10. of the *Terrestrial Manual*, facilitate the timely procurement of vaccines.

1~~bis~~. Procurement of equipment and consumables

In addition to the vaccine itself, the planning of the *vaccination* campaigns should include the procurement of all necessary equipment and consumables.

2. Implementation of the vaccination programme

~~In addition to the vaccine itself, the planning of the *vaccination* campaigns should include the procurement of all necessary equipment and consumables as well as~~ Sstandard operating procedures should be established to:

*a)* implement the communication plan;

*b)* establish, maintain and monitor the fixed and mobile components of the cold chain;

*c)* store, transport and administer the vaccine;

*d)* clean and disinfect equipment and *vehicles,* including heat sterilisation of reusable equipment;

*e)* dispose of waste;

~~*e*~~*bis)* determine the disposition of partially used or unused containers of vaccine, ~~(~~such as ampoules, vials~~,~~ and bottles~~, etc.) of vaccine~~;

~~*e*~~*ter)* implement *biosecurity* to ensure *vaccination* teams do not transmit the pathogenic agent between *establishments*;

*f)* identify vaccinated animals;

*g)* ensure the safety and welfare of animals ~~and *vaccination* teams~~;

*gbis)* ensure the safety of *vaccination* teams*;*

*h)* record activities of vaccination teams;

*i)* document *vaccinations*.

The availability of appropriate animal handling facilities ~~at the *vaccination* site~~ is essential to ensure effective *vaccination* as well as safety and welfare of *animals* and *vaccination* teams.

3. Human resources

*Vaccination* should be conducted by appropriately trained and authorised personnel under the supervision of the *Veterinary* *Services* ~~*Authority*~~. The *vaccination* programme should provide for periodic training sessions including updated written standard operating procedures for field use.

The number of *vaccination* teams should be sufficient to implement the *vaccination* campaign within the defined timeframe. The *vaccination* teams should be adequately equipped and have means of transport to reach the places where *vaccination* is carried out ~~sites~~.

4. Public awareness and communication

The *Veterinary* *Services* ~~*Authority*~~ should develop a communication strategy in accordance with Chapter 3.3.*,* which should be directed at all stakeholders and the public to ensure awareness and acceptability of the *vaccination* programme, its objectives and potential benefits.

The communication plan may include details on the timing and location of the *vaccination*, target *population* and other technical aspects that may be relevant for the public to know.

5. Animal identification

*Animal identification* allows for the differentiation of vaccinated from ~~non-~~unvaccinated domestic animals and is required for the monitoring and certification of *vaccination*.

Identification can range from temporary to permanent identifiers and can be individual or group-based. *Animal identification* should be ~~carried out~~ implemented in accordance with Chapters 4.1. and 4.2.

6. Record keeping and vaccination certificates

*Vaccination* programmes under the *Veterinary* *Service's* ~~*Authority's*~~ responsibility should provide for maintenance of detailed records of the vaccinated population.

Whenever needed, the *Veterinary Services* should consider issuing official certificates of the *vaccination* status of animals or groups of animals.

7. Additional animal health related activities

In addition to *vaccination* against a specific pathogenic agent, *vaccination* programmes may include other animal health-related activities such as *vaccination* against other pathogenic agents, treatments, *biosecurity*, *surveillance*, *animal identification* and communication.

Including additional animal health-related activities may enhance the acceptability of the *vaccination* programme. These activities should not negatively affect the primary objective of the *vaccination* programme.

Simultaneous *vaccination* against multiple pathogenic agents may be conducted, provided that compatibility has been demonstrated and the efficacy of the immune response against each of the pathogenic agents is not compromised.

Article 4.X.9.

**Evaluation and monitoring of a vaccination programme**

~~The~~ A *vaccination* programme should provide for outcome-based evaluation and monitoring to assess ~~the~~ its achievements ~~of the *vaccination* programme~~. Evaluation and monitoring should be carried out periodically during the campaign to enable the timely application of corrective measures and to enhance the sustainability of the *vaccination* programme.

Based on the objectives and targets of the *vaccination* programme, the following outcomes should be assessed:

1) *vaccination* coverage stratified by species, age, geographical location and type of production system;

2) population immunity measured by testing, stratified by species, geographical location and type of production system;

3) frequency and severity of ~~adverse reactions~~ side effects;

4) reduction of *incidence*, ~~or~~ *prevalence* or impact of the disease.

If the objectives and targets of the *vaccination* programme are not achieved, the reasons for this should be identified and addressed.

Article 4.X.10.

**Exit strategy of a vaccination programme**

The *vaccination* programme may provide for an exit strategy to cease *vaccination*. The cessation of *vaccination* may apply to the entire target population or to a subset of it, as defined by the *risk* of exposure and as determined by the *Veterinary Authority*.

Criteria to cease *vaccination* may include:

1) eradication of the disease in a country or *zone* has been achieved;

2) *risk analysis* demonstrates sufficient reduction of likelihood of introduction of the pathogenic agent or emergence of the disease;

3) reduction of the incidence, ~~or~~ prevalence or impact of the disease to a level where alternative measures such as a *stamping-out policy* may be ~~sufficient~~ more appropriate to achieve disease control;

4) inability of the programme to meet the desired objectives;

5) adverse public reaction to the *vaccination* programme~~.~~;

6) a revised cost-benefit analysis leads to decision to cease the *vaccination* programme.

When the achievement of ~~disease~~ free status requires the cessation of *vaccination*, the *Veterinary Authority* should prohibit *vaccination* and take appropriate measures to control remaining vaccine stocks as well as vaccine importation.

The cessation of *vaccination* may require the revision of the contingency plan and enhanced *biosecurity, sanitary measures* and *surveillance* for early detection of disease.

Annex 10 (contd)

Article 4.X.11.

**Impact on disease status and management of vaccinated animals**

*Vaccination* has proved its capacity to help prevent, control and eradicate several diseases in addition to or as alternative to *stamping-out* policy. However, depending on the disease and type of vaccine used, *vaccination* may mask underlying *infections*, affect disease *surveillance* and have implications for the movement of vaccinated animals and their products.

When appropriate, *vaccination* programmes should include provisions for the management of vaccinated animals such as '*vaccination* to live' or 'suppressive *vaccination*' policies. *Listed* ~~D~~*disease*-specific chapters of the *Terrestrial Code* provide additional recommendations on the management and trade of vaccinated animals and their products.

~~Disease f~~Free countries or *zones* applying systematic or emergency *vaccination* in response to an ~~change in the~~ increased *risk* of ~~occurrence~~ introduction of a disease should inform trading partners and the OIE of their *vaccination* programme, as appropriate. Unless otherwise specified in the relevant *listed disease*-specific chapter, ~~I~~in the absence of *cases* ~~and unless otherwise specified in the relevant *listed disease* specific chapters~~, *vaccination* of animals does not affect the ~~disease~~ status of the country or *zone*~~,~~ and should not disrupt trade.

Annex 11

CHAPTER 6.1.

# THE ROLE OF ~~THE~~ VETERINARY SERVICES IN FOOD SAFETY SYSTEMS

**EU position**

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

**Comments are inserted in the text below.**

Article 6.1.1.

**Introduction**

*Veterinarians* are trained in both animal health (including foodborne zoonoses) and food ~~safety~~ hygiene, which makes them uniquely equipped to play a central role in ensuring food safety, especially the safety of food of animal origin.

Close cooperation and effective communication between all participants in a food safety system, including *veterinarians*, other relevant professionals and stakeholders, is critical for the effective operation of the system. ~~Food safety systems are now considerably different from those of earlier years and this provides a wider role for the *Veterinary Services*. The characteristics of these systems are global,~~ Indeed, ~~the global, regional, national and local implications of food safety systems, in reach, especially in relation to~~ the globalisation of the food supply~~, which requires a greater~~ demands a high level of engagement and collaboration between *Competent Authorities* responsible for animal health, food safety and public health, in line with the One Health approach. This provides a wider role and greater responsibilities for *Veterinary Services*. ~~There is a particular emphasis on risk-based food safety systems where implementation is a responsibility shared with a wide range of actors along with assurance of non-food safety requirements that are of high importance to consumers.~~

Food safety activities performed by *Veterinary Services* should be integrated to the greatest extent possible with the activities of all other responsible agencies throughout the food chain.

~~The education and training of *veterinarians*, which includes both *animal* health (including *zoonoses*) and food safety components, makes them uniquely equipped to play a central role in ensuring food safety, especially the safety of foods of *animal* origin. In addition to *veterinarians*, other professionals are involved in ensuring an integrated food safety system throughout the food chain.~~

Article 6.1.2.

**Purpose and scope**

The purpose of this chapter is to provide guidance to Member Countries on the role and responsibilities of ~~the~~ *Veterinary Services* in food safety systems.

This chapter should be read in conjunction with Chapter~~s~~ 4.1., Chapter 4.2., and relevant chapters of Sections 6 and 7.

~~The OIE and Codex Alimentarius Commission, through the development and implementation of standards and guidelines, contribute to improving food safety and human health by reducing risks that may arise at the farm and any subsequent stages in the food production continuum.~~

~~Therefore, this~~This chapter should also be read in conjunction with the Codex Alimentarius Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013), General Principles of Food Hygiene (CAC/RCP

1-1969), Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009), and other relevant Codex texts ~~on hygienic practices, food import and export certification systems and antimicrobial resistance~~.

Article 6.1.3.

**Characteristics of a food safety system**

1. ~~Farm to plate approach~~ Food chain approach

Food safety is best assured by an integrated, multidisciplinary approach~~, considering~~ that considers the ~~whole~~ entire food chain. ~~Everyone in the food chain, such as food business operators, the *Veterinary Services* and consumers, has a responsibility to ensure that food is safe.~~ A ~~modern~~ food safety system should take into account the complexity of food production and the ~~increased~~ globalisation of the food supply, and should be risk-based. ~~The application of traceability systems and sharing of food chain information will enhance the effectiveness of a food safety system. The food safety system~~ It should ~~include consideration of~~ consider *hazards* and potential ~~risks~~ associated *risks* at ~~with~~ each ~~component~~ stage of the food chain, ~~namely~~ i.e. primary production, transport, processing, storage and distribution, and integrate *risk management* responses to such *risks* at the most appropriate points along ~~these throughout~~ the food chain ~~continuum~~.

The prevention, detection, and control of foodborne *hazards* throughout the food chain is generally more effective in reducing or eliminating the *risk* of unwanted health effects than relying on controls of the final product.The application of traceability systems and sharing food chain information enhance the effectiveness of a food safety system. Everyone involved in the food chain, including food business operators, *Veterinary Services* and consumers, has a responsibility to ensure that food is safe.

2. Risk-based food safety systems

Risk-based food safety systems include measures based on good practices (such as good agricultural practice ~~Good Agricultural Practice~~, good hygienic practice ~~Good Hygienic Practice~~), hazard analysis and critical control points (HACCP) principles and *risk analysis* ~~assessment~~. The design and application of a risk-based food safety system depends ~~this risk-based approach depend~~ on the availability of adequate scientific information and effective utilisation of the technical resources of food business operators and *Competent Authorities*. ~~and technical resources of the *Competent Authority*. Monitoring and review are essential to evaluate the performance of a risk-based food safety system.~~

Monitoring food safety outcomes and reviewing control measures are essential to ensure the effective performance of a risk-based food safety system. For example, providing information on the occurrence of *infections* on the farm prior to dispatch of animals for *slaughter* may allow more targeted, risk-based inspection at the *slaughterhouse/abattoir*.

~~For international trade, a risk-based approach to food safety systems contributes to the determination of equivalence between trading partners.~~

3. ~~Primary r~~Responsibilities of food business operators for food safety

Food business operators, including feed producers, farmers, processors, wholesalers, distributors, importers, exporters and retailers, have primary responsibility for ensuring the safety of their products and should be able to demonstrate that they comply with relevant food safety regulatory requirements. ~~The food~~ Food business operators have a responsibility to inform the *Competent Authority* in their country of any non-compliance associated with their product and take action to manage the *risk* e.g. the withdrawal of the product.

4. Responsibilities of the relevant Competent Authority~~ies~~

~~Each Member Country should establish its objectives for *animal* health and public health protection, through consultation with stakeholders (especially livestock producers, processors and consumers) in accordance with the social, economic, cultural, religious and political contexts of the country. Based on these objectives and the analysis of scientific information, the *Competent* *Authorities* *Authority* has~~ are responsible for developing ~~the responsibility to develop national legislation and~~ policies, legislation and regulations relevant to food safety. ~~The *Competent Authority*~~ They should also take steps to ~~raise awareness of these both~~ communicate these within ~~the~~ their country and ~~to~~ with trading partners.

*Competent Authorities* should ~~collaborate with other responsible agencies to~~ ensure that roles and responsibilities for food safety systems, including responses to foodborne disease *outbreaks*, are addressed in a coordinated manner.

~~The *Competent Authority* should ensure~~ The relevant *Competent Authorities* should verify that the control systems used by food business operators are appropriate, validated and effective, and operated in such a way that the regulatory requirements ~~standards~~ are met. This ~~should be verified~~ can be achieved through activities such as inspection and audit. In the event of noncompliance, appropriate corrective actions and sanctions should be applied.

~~When~~ If the *Competent Authority* delegates some control responsibilites to a third party, it should assess ~~and~~ regularly ~~reassess~~ that third party's competency.

**EU comment**

**The EU suggests inverting the sentence above as follows (style):**

**"[…], it should regularly assess ~~regularly~~ […]".**

~~5. Animal and public health roles of the Veterinary Services~~

~~At the national level the activities of the *Competent Authority* serve both public and *animal* health objectives. In the case of food safety, this duality of roles provides an opportunity for the *Veterinary Services* to perform complementary activities throughout the food chain in coordination with other relevant agencies. It is important that this duality of functions is recognised, and relevant public health and *animal* health activities are integrated.~~

Article 6.1.4.

**~~The role R~~roles and responsibilities of ~~the~~ Veterinary Services in a food safety system**

1. Roles and responsibilities ~~Responsibilities~~ of ~~the~~ Veterinary Services

~~The~~ *Veterinary Authorities* ~~*Authority*~~ or other *Competent Authorities* ~~*Authority*~~ should provide an appropriate institutional environment to allow ~~the~~ *Veterinary Services* to implement the necessary policies and standards, and ensure adequate resources for them to carry out their tasks in a sustainable manner. ~~Within the *Veterinary Services* there~~ should ~~be~~ have a clear chain of command and ~~well documented assignment of~~ respective roles and responsibilities should be clearly defined and well documented. ~~and chain of command. In developing policies and national standards for food safety, the *Veterinary Authority* or other *Competent Authority* should collaborate with other responsible agencies to ensure that food safety risks are addressed in a coordinated manner.~~

~~In order for *Veterinary Services* to make the best possible contribution to food safety, it is important that the education and training of *veterinarians* and *veterinary para-professionals* meet appropriate levels of competence and that there are national programmes for ongoing professional development.~~

~~The~~ *Veterinary Services* should ~~be responsible for, or involved in,~~ be fully involved, in accordance with their mandate and organisational structure at the national level, in the design and implementation of ~~national control programmes of~~ a risk-based food safety system ~~appropriate to their mandate and organisational structure at the national level~~. ~~Implementation includes verification, audit, assurance and certification.~~ In the implementation of food safety systems for foods of animal origin, ~~the~~ *Veterinary Services* should retain responsibility for verification and audit and facilitate a flexible approach to operational activities.

~~Where food safety activities are delegated outside of the *Veterinary Services*, the~~ *Veterinary Services* should retain overall responsibility for the delivery and performance of any activities delegated to third party providers. ~~competency standards and performance of the delegated activities.~~

~~In addition to *veterinarians*, several other professional groups are involved in ensuring food safety throughout the food chain, including analysts, epidemiologists, food technologists, human and environmental health professionals, microbiologists and toxicologists. Irrespective of the roles assigned to the different~~

~~professional groups and stakeholders by the administrative system in the country, close cooperation and effective communication between all involved is imperative to achieve the best results from the combined resources.~~

~~In view of the competencies within the *Veterinary Services*, they~~ Where relevant, ~~the~~ *Veterinary Services* should ~~contribute to~~ have an active role in other food safety related activities, such as investigations of foodborne disease *outbreaks*, food ~~defence~~ defense, disaster management, and identifying emerging *risks*. In addition, *Veterinary Services* should ~~contribute to~~ have an active role in the development and management of coordinated *surveillance* and control programmes for foodborne pathogens of public health importance.

In order for *Veterinary Services* to make the best possible contribution to ensuring food safety, the education and training of *veterinarians* and *veterinary paraprofessionals* should include appropriate training in food safety systems and ongoing professional development.

2. Activities of Veterinary Services throughout the food chain

~~The *Veterinary Services* have a significant role to play throughout the food safety system.~~ Depending on the ~~role and~~ responsibilities of the *Competent Authority*, the responsibilities of the *Veterinary Services* may be limited to the first part of the food chain, ~~(from farm to *slaughterhouse/abattoir* and associated premises for further processing)~~ while in other cases the *Veterinary Services* may be responsible for the whole food chain.

**EU comment**

**The EU does not agree with the deletion of the parenthesis above, as otherwise it is not clear what is meant by "the first part of the food chain".**

*a)* Primary production

Through their presence on farms and ~~appropriate~~ collaboration with farmers, *Veterinary Services* play a key role in ensuring that *animals* are healthy and kept under good sanitary and hygienic conditions, ~~and~~ as well as in *biosecurity* and ~~in the~~ early detection, *surveillance* and treatment of animal diseases, including conditions of public health significance. ~~The *Veterinary Services* advise on animal husbandry practices, *biosecurity* and interventions that limit the transmission of animal diseases, including foodborne *zoonoses*.~~

**EU comment**

**The EU reiterates its previous comment that the sentence above is overly long and complex and thus unintelligible. It should preferably be split in two.**

~~Because of the importance of traceability throughout the food chain, the verification by the *Veterinary Services* of *animal identification* is an important function.~~

~~In regard to food safety, The~~ *Veterinary Services* ~~assist~~ provide ~~guidance~~ direction to farmers on practices that ~~how to~~ prevent or minimise physical and chemical hazards (~~e.g.~~ for example, mycotoxins, environmental contaminants ~~drug~~ and pesticide residues~~, mycotoxins and environmental contaminants~~) in primary production, including ~~through~~ ~~animal~~ *feed*.

~~Producers' organisations, particularly those with veterinary advisers, are in a good position to provide awareness and training as they are regularly in contact with farmers and are well placed to understand their priorities. Technical support from the *Veterinary Services* is important and both private *veterinarians* and employees of the *Veterinary Authority* can assist. The~~ *Veterinary Services* play a central role in ensuring the responsible and prudent use of ~~biological products and~~ *veterinary medicinal products* ~~drugs~~, including *antimicrobial agents* in accordance with Chapter 6.9. in animal husbandry. This helps to minimise the ~~*risk*~~ likelihood of noncompliant levels of veterinary drug residues ~~developing antimicrobial resistance and unsafe levels of veterinary drug residues~~ in food~~s~~ of animal origin and the development of antimicrobial resistance.

*Veterinary Services* also play an important role in ensuring traceability throughout the food chain by verifying *animal identification* in accordance with Chapters 4.1. and 4.2.

*b)* ~~Processing~~ Slaughter, processing and distribution

Activities at the *slaughterhouse/abattoir* should be designed and implemented according to an integrated, risk-based approach in accordance with Chapter 6.2. ~~The~~ *Veterinary Services* have an essential role in ensuring that these activities, including meat inspection, minimise ~~processing (including meat inspection) and distribution minimises~~ foodborne *risks* to public health. This may be provided by supervision and verification of process control and direct involvement in operational activities such as ante-~~mortem~~ and post-mortem inspection. *Slaughterhouse/abattoir* inspection of live

*animals* ~~(ante-mortem)~~ and their carcasses ~~(post-mortem)~~ plays a key role both in ~~both~~ the *surveillance* network for animal diseases and zoonoses, and in ensuring the safety and suitability of *meat* and by-products for their intended uses. Control or reduction of biological *hazards* of public health and animal health importance by ante- and post-mortem meat inspection is a core responsibility of ~~the~~ *Veterinary Services*. ~~and they should have primary responsibility for the development and effective implementation of relevant inspection programmes. Chapter 6.2. provides recommendations for the control of biological hazards of *animal* health and public health importance through ante- and post-mortem meat inspection.~~

~~The~~ *Veterinary Services* may be responsible for overseeing the control measures during processing and distribution of food of animal origin. ~~The *Veterinary Services* also~~ They also play an important role in raising the awareness of food producers, processors and distributors regarding ~~other stakeholders of the~~ measures required to assure food safety.

~~*Veterinarians* provide essential inputs in terms of scientific information, risk assessment, validation of control measures, and monitoring and review of public health outcomes, in the design and implementation of a risk-based food safety system.~~

~~*Veterinarians* have an important role in ensuring food safety in various parts of the food chain, for example through the application of HACCP-based controls and other quality assurance systems during food processing and distribution.~~

*c)* Assurance schemes and certification of food of animal origin ~~animal products~~ for international trade

~~The *Veterinary Services* have an important role in providing public health assurance for products of *animal* origin. When assurance is required for *animal* products *international trade* assurance may take the form of certification of consignments. In which case, the *Veterinary Services* ensure that *international veterinary certificates* comply with *animal* health and food safety standards. Certification of *animal* products in relation to *animal diseases*, including foodborne *zoonoses*, and *meat* hygiene should be the responsibility of the *Veterinary Services*. Certification may be provided by other professionals in connection with food processing and hygiene (e.g. pasteurisation of *milk products*).~~

*Veterinary Services* have an important role in overseeing assurance schemes and an essential role in certifying that food of animal origin complies with animal health and food safety standards.

Other *Competent Authorities* may also be involved in providing assurances and certification of food of animal origin (for example, pasteurisation of *milk products*) for *international trade*.

3. Foodborne disease outbreaks

~~Most reported *outbreaks* of foodborne disease in humans are due to contamination of foods with zoonotic agents during primary production or processing. The~~ *Veterinary Services* play a key role in the investigation of, and response to, ~~such~~ foodborne disease outbreaks which may be attributable to or involve animal products, ~~throughout the food chain and in formulating and~~ including the implementation of ~~implementing~~ control measures ~~as appropriate once the source of the *outbreak* has been identified~~. This work should be carried out in close collaboration with ~~human and environmental~~ public health professionals, analysts, epidemiologists, food producers, processors and traders and any others involved.

~~The *Veterinary Services* can play a leading role in development and application of new epidemiological and diagnostic tools to better attribute outbreaks of foodborne diseases to specific *animal* reservoirs.~~

~~In the view~~ Because of the global nature of the food trade, ~~the~~ *Veterinary Services* should work with other national agencies in reporting to international emergency foodborne disease networks, such as the International Network of Food Safety Authorities (INFOSAN), and in utilising such information for preparedness.

~~4. Animal and public health roles of the Veterinary Services~~

~~This complementary role of the *Veterinary Services* is clearly illustrated in relation to inspection and monitoring at the *slaughterhouse*, for both *animal* health and public health hazards.~~

~~The *Veterinary Services* contribute to the development and management of coordinated *surveillance* and control programmes related to foodborne pathogens of public health importance, such as *Salmonella* and *Trichinella*.~~

Annex 12

# CHAPTER 6.7.

# HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES

**EU position**

**The EU thanks the OIE for having taken into account some of its previous comments.**

**However, we cannot support the adoption of this modified chapter unless the important comments inserted in the text below have been addressed.**

**Furthermore, as Table 1 is being deleted, references to the subsequent tables should be amended accordingly throughout the text.**



Article 6.7.1.

**Objective**

This chapter provides criteria for the~~:~~

~~1)~~ development of national antimicrobial resistance surveillance and monitoring programmes, and the

~~2)~~ harmonisation of existing national antimicrobial resistance surveillance and monitoring programmes~~,~~

in food-producing animals and in products of animal origin intended for human consumption.

Article 6.7.2.

**Purpose of surveillance and monitoring**

Active ~~(targeted)~~ surveillance and monitoring are core parts of national antimicrobial resistance surveillance programmes. Passive surveillance and monitoring may offer additional information (refer to Chapter 1.4.). The OIE encourages ~~C~~cooperation ~~between~~ among all Member Countries conducting antimicrobial resistance surveillance and monitoring ~~should be encouraged~~.

Surveillance and monitoring of antimicrobial resistance is necessary to:

1) assess and determine the trends and sources of antimicrobial resistance in bacteria;

2) detect the emergence of new antimicrobial resistance mechanisms;

3) provide the data necessary for conducting *risk analyses* as relevant to animal and human health;

4) provide a basis for policy recommendations for animal and human health;

5) provide information for evaluating antimicrobial prescribing practices and, for prudent use recommendations;

6) assess and determine effects of actions to combat antimicrobial resistance.

Article 6.7.3.

**General aspects ~~The development~~ of antimicrobial resistance surveillance and monitoring programmes**

~~1. General aspects~~

Surveillance of antimicrobial resistance and ~~at targeted intervals or ongoing~~ monitoring of the prevalence of, and trends in, resistance in bacteria from *animals*, food~~, environment~~ and humans, constitutes a critical part of animal health and food safety strategies aimed at limiting the spread of antimicrobial resistance and optimising the choice of *antimicrobial agents* used in therapy. ~~Animal~~ ~~f~~*Feed* and the environment should also be considered according to national priorities.

**EU comment**

**The EU reiterates its previous comments re. the importance of surveillance/monitoring of antimicrobial resistance in the environment (available here https://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_position_tahsc-report_201709.pdf, cf. p. 100).**

**We wish to point out again that OIE's own 2016 *Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials* recognises the importance of the environment as part of the One Health strategy ("*involving human and animal health, agricultural and environmental needs*", cf. http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/PortailAMR/EN_OIE-AMRstrategy.pdf).**

**We thus request reinstating the environment among animals, food and humans, i.e. reverting that part of the paragraph above back to the way it is drafted in the current version of the Code (i.e. "[…] bacteria from animals, food, environment and humans, constitutes […]").**

**The last sentence should hence also be amended accordingly ("Feed ~~and the environment~~ should also be considered […]").**

**Finally, the words "their environment" should be inserted in point 3 below, after "flocks". Indeed, this would be consistent with the overall consideration of the environment in this chapter.**

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

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

1~~a~~) statistically based surveys;

2~~b~~) sampling and testing of food-producing animals on the farm, at live animal markets or at *slaughter*;

3~~c~~) ~~an~~ organised sentinel programme, for example targeted sampling of food-producing animals, *herds*, *flocks*, and *vectors* (e.g. birds, rodents);

4~~d~~) analysis of veterinary practice and diagnostic *laboratory* records;

5~~e~~) sampling and testing of products of animal origin intended for human consumption~~.~~;

6) sampling and testing of feed ingredients or feed.

Article 6.7.4.

**Sampling**

1~~2~~. Sampling strategies

*a)* Sampling should be conducted on a statistical basis. The sampling strategy should ensure:

- the sample is representative of the population of interest and meets the objectives of the surveillance;
- the robustness of the sampling method.

*b)* The following criteria are to be considered:

- sample source such as food-producing animal, food, animal feed;
- animal species;
- category of *animal* within species such as age group, production type;
- health status of the *animals* such as healthy, diseased;
- sample selection method such as targeted, systematic random, non-random;
- type of sample ~~(e.g.~~ such as ~~faecal,~~ faeces, caeca, carcass, food product~~)~~;
- sample size.

2~~3~~. Sample size

The sample size should be large enough to allow detection or determine prevalence of, or trends in, existing and emerging antimicrobial resistance phenotypes.

The sample should avoid bias and be representative of the animal *population*, process, product or other unit of interest whilst taking into account the expected prevalence of the bacteria in the sample type, the expected prevalence of the resistance phenotype and the desired level of precision and confidence.

**EU comment**

**The information contained in the first part of the paragraph above (on avoiding bias and being representative of units of interest) is not related to sample size but clarifies that different populations of interest might be considered. It would thus be better placed in the first indent of point 1 a) above on sampling strategy, which could be amended as follows:**

**" - the sample is representative of the population of interest (i.e. animal population, process, product or other unit of interest) and meets the objectives of the surveillance;".**

The sample size calculation ~~in Table 1 is~~ should be based on independent samples. However, ~~I~~if there is any clustering at the *establishment* or animal level, the sample size should be adjusted accordingly. At low levels of expected prevalence, exact methods of sample size calculation should be preferred to approximate methods. Samples from which bacteria were not isolated cannot be used in the calculation of prevalence of the resistance phenotype.

**EU comment**

**In line with the suggestion of the *ad hoc* group, the EU requests the deletion of the last sentence of the paragraph above (starting with "Samples from […]"). Indeed, the sample size determines the number of samples from the population (i.e. animals), where a certain bacterial species and phenotype is looked for. In case the sample is negative for the bacterial species, it will also be negative for the phenotype. These samples should therefore be considered when indicating the prevalence rate for a sampled population.**

**On the other hand, a completely different sample size is calculated for the number of bacterial isolates to be tested to detect a certain phenotype amongst these bacterial isolates (i.e. population). In that case, the outcome of testing of the primary sample**

**(from the animal) would not be relevant.**

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

**~~Table 1. Sample size estimates for prevalence in a large population~~**

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

3~~4~~. Sample sources (Table 2)

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

~~*a)* Animal feed~~

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

*a~~b~~)* Food-producing animals

Categories of food-producing animals considered for sampling should be relevant to the country's production system. Resource allocation should be guided by criteria such as production volume of the food-producing animal species and the *prevalence* of resistant bacteria.

**EU comment**

**The EU suggests inserting a reference to "animal categories" in addition to animal species in point a) above. Indeed, while designing an AMR monitoring program, in particular the sampling strategy, but also allocating resources and presenting monitoring results, it has been shown to be of utmost scientific interest/importance to consider separately the different animal categories (within the meaning of the 3rd indent of point 1 b) of Article 6.7.4.) where relevant - even though they belong to the same animal species -, as their exposure risks with regard to antimicrobial treatments, sanitary status, farming and hygienic practices, and housing conditions may differ significantly and the assessed prevalence of resistance varies markedly between these different animal categories. For example, it is highly recommended that resource allocation, sampling design and presentation of results should clearly distinguish between laying hens and broilers of *Gallus gallus*, although those populations belong to the same animal species. Merging AMR data at the animal species level, when the animal species includes animal categories characterised by differing prevalence of**

**resistance, may result in wrong assessment of the AMR situation.**

*b*~~c~~) Food

Member Countries should consider including products of animal origin intended for human consumption, produced locally or imported, in surveillance and monitoring programmes, as foodborne transmission is considered to be an important route for the transfer of antimicrobial resistance.

*c)* ~~Animal f~~Feed

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

*d)* Environment

Member Countries should consider including the environment (the animal-immediate environment or the wider environment) in surveillance and monitoring programmes as the environment of animals can be an important route for transfer or persistance of antimicrobial resistance.

4~~5~~. Type of sample to be collected (Table 2)

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

Feed samples representative of the batch should be collected in amounts sufficient for isolation of resistant bacteria of concern (at least 25 g) and should be linked to any pathogen surveillance programme~~s~~ that may be in place.

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

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

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

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

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

| Source | Type | Output | Additional information required or additional stratification |
|---|---|---|---|
| Herd or flock of origin | Faeces or bulk milk | Prevalence of resistant bacteria originating from animal populations (of different production types)<br>Relationship between resistance and antimicrobial use | Age categories, production types, etc.<br>Antimicrobial use over time |
| Abattoir | Faeces | Prevalence of resistant bacteria originating from animals at slaughter | |
| | Caeca or intestines | As above | |
| | Carcass | Prevalence of resistant bacteria after carcass dressing. | |

| | | |
|---|---|---|
| | | representative of the ~~H~~hygiene~~,~~ of the process and the contamination during slaughter |
| Processing, packing | Food products | Prevalence of resistant bacteria after processing, representative of the ~~H~~hygiene~~,~~ of the process and the contamination during processing and handling |
| Point of sale (Retail) | Food products | Prevalence of resistant bacteria originating from food, exposure data for consumers |
| Various origins | Animal feed | Prevalence of resistant bacteria originating from animal feed, exposure data for animals |
| Various origins | Environment | Occurrence of resistant bacteria originating from the animal-immediate or the wider environment |

**EU comment**

**The EU notes that Table 2 above only lists types of samples to be collected in relation to isolation of "zoonotic bacteria" and "commensal bacteria". In the section below, also "animal bacterial pathogens" are covered, however the type of samples relevant for isolation of these types of bacteria (e.g. milk samples, samples from the respiratory tract etc.) are not mentioned. As this may cause some confusion, and for the sake of clarity and completeness, we suggest that recommendations on the relevant sample types for animal bacterial pathogens also be included.**

Article 6.7.5.

**Bacteria subjected to surveillance and monitoring**

~~6.~~ ~~Bacterial isolates~~

The following categories of bacteria ~~could~~ may be included in surveillance and monitoring programmes ~~monitored~~:

1~~a~~) Animal bacterial pathogens relevant to the countries' priorities

*a)* Surveillance and monitoring of antimicrobial resistance in animal bacterial pathogens is important~~, both~~ to:

~~*i)*~~ - detect emerging resistance that may pose a concern for animal and human health;

~~*ii)*~~ - detect changes in susceptibility patterns;

~~*iii)*~~ - provide information for *risk analysis*;

~~*iv)*~~ - provide data ~~guide~~ for veterinarians ~~in~~ to inform their ~~prescribing~~ treatment decisions~~.~~;

- provide information for epidemiological studies and trend analysis.

*b)* Information on the occurrence of antimicrobial resistance in animal bacterial pathogens is in general either derived from ~~routine~~ clinical material sent to veterinary diagnostic *laboratories* or from an active monitoring programme. ~~These samples, often derived from severe or recurrent clinical cases including therapy failure, may provide biased information.~~ Although antimicrobial resistance information provided by diagnostic *laboratories* is primarily for treatment purposes, it is also useful for identification of novel resistance patterns and can possibly assist in identifying emerging resistance. However, in order to estimate accurately the prevalence of antimicrobial resistance in the bacterial pathogen, in a larger population of animals, an active sampling programme should be implemented.

*c)* To promote a harmonised global approach to the selection of animal bacterial pathogens for inclusion in national surveillance and monitoring programmes, bacteria should be selected using one or more of the following criteria:

- impact on animal health and welfare;
- implication of antimicrobial resistance in the bacterial pathogen on therapeutic options in veterinary practice;
- impact on food security and on production (economic importance of associated diseases);
- bacterial diseases responsible for the majority of veterinary antimicrobial usage (stratified by usage of different classes or their importance);
- existence of validated susceptibility testing methodologies for the bacterial pathogen;
- existence of quality assurance programmes or other pathogen reduction options that are non-antimicrobial, such as vaccines and Good Agricultural Practices.

The table below, derived using the above criteria, lists suggested animal bacterial pathogens for inclusion in a surveillance or monitoring programme of food-producing animals. This list is not exhaustive and should be adapted according to the situation in the country.

**Table 3. Examples of target animal species and animal bacterial pathogens that may be included in resistance surveillance and monitoring programmes**

| **Target animals** | **Respiratory pathogens** | **Enteric pathogens** | **Udder pathogens** | **Other pathogens** |
|---|---|---|---|---|
| Cattle | *Pasteurella multocida* | *Escherichia coli* | *Staphylococcus aureus* | |
| | *Mannheimia haemolytica* | *Salmonella* spp. | *Streptococcus* spp. | |
| Pigs | *Actinobacillus pleuropneumoniae* | *Escherichia coli* | | *Streptococcus suis* |
| | | *Salmonella* spp. | | |
| Poultry | | *Salmonella* spp. | | *Escherichia coli* |

2~~b~~) Zoonotic bacteria

*a~~i~~)* *Salmonella*

*Salmonella* should be sampled from ~~animal feed,~~ food-producing animals, ~~and~~ animal-derived food products and if relevant, ~~animal~~ *feed*. For the purposes of consistency and harmonisation, animal samples should ~~be~~ preferably be taken from healthy *animals* at the *slaughterhouse/abattoir* ~~from healthy *animals*~~ and *feed* samples should preferably be taken at the *feed* mill.

**EU comment**

**The sentence above does not read well, as *Salmonella* are not sampled. For clarity, we suggest slightly amending it as follows:**

**"Samples for the isolation of *Salmonella* should be taken ~~sampled~~ from […]".**

Surveillance and monitoring programmes may also include sampling of the environment at places where animals are kept or handled or bacterial isolates originating from other sources obtained from designated ~~national~~ *laboratories* ~~originating from other sources~~.

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

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

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

*bii) Campylobacter*

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

**EU comment**

**Similarly, the sentence above does not read well. For clarity, we suggest slightly amending it as follows:**

**"Samples for the isolation of *Campylobacter* should be taken sampled from […]".**

*ciii)* Other bacteria that are pathogenic for humans emerging bacterial pathogens

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

**EU comment**

**In the paragraph above, verocytotoxic *E. coli* (VTEC) should be included, instead of *Listeria monocytogenes*. Indeed, the latter currently is less relevant than VTEC as regards antimicrobial resistance (especially in relation to Hemolytic-uremic syndrome).**

**Furthermore, ESBL/pAmpC and carbapememase-producing *Enterobacteriaceae* could also be considered for inclusion in surveillance/monitoring programs due to the rising impact they have on treatment strategies in human medicine.**

3c) Commensal bacteria

*E. coli* and *enterococci* (*Enterococcus faecium* and *E. faecalis*) may be sampled from animal *feed,* food-producing animals, their environment and products of animal origin intended for human consumption.

**EU comment**

**Again, the sentence above does not read well. For clarity, we suggest slightly amending it as follows:**

**"Samples for the isolation of *E. coli* and enterococci (*Enterococcus faecium* and *E. faecalis*) may be taken sampled from […]".**

These bacteria are commonly used in surveillance and monitoring programmes as indicators, providing information on the potential reservoir of antimicrobial resistance genes, which may be transferred to pathogenic bacteria. It is considered that For the purposes of consistency and harmonisation, these bacteria should preferably be isolated from healthy *animals*, preferably at the *slaughterhouse/abattoir*, for the purpose of consistency and harmonisation and be monitored for antimicrobial resistance.

Article 6.7.6.

**7.Storage of bacterial strains**

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

Article 6.7.7.

~~8.~~ **Antimicrobial susceptibility testing**

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

**EU comment**

**The EU suggests inserting the words "at least" before "refer to the OIE list" in the paragraph above. Indeed, the first sentence includes a requirement to consider clinically important antimicrobial agents / classes used in human medicine, however this is not covered by the OIE list. For example, resistance to carbapenems should be monitored, even if carbapenems are not included in the OIE list. Insertion of the words "at least" would therefore reflect that additional antimicrobial classes relevant for human medicine should be considered as well.**

Appropriately validated antimicrobial susceptibility testing methods should be used in accordance with ~~Guideline~~ Chapter 3.1. of the *Terrestrial Manual*, concerning laboratory methodologies for bacterial antimicrobial susceptibility testing. Antimicrobial susceptibility data should be reported not only qualitatively (susceptible or resistant), but also quantitatively (minimum inhibitory concentrations [MICs] or inhibition zone diameters)~~, rather than qualitatively~~.

Article 6.7.8.

~~9.~~ **Recording, storage and interpretation of data**

1~~a~~) Because of the volume and complexity of the information to be stored and the need to keep these data available for an undetermined period of time, careful consideration should be given to database design.

2~~b~~) The storage of raw (primary, non-interpreted) data is essential to allow the evaluation in response to various kinds of questions, including those arising in the future.

3~~c~~) Consideration should be given to the technical requirements of computer systems when an exchange of data between different systems (comparability or compatibility of automatic recording of laboratory data and transfer of these data between and within resistance surveillance and monitoring programmes) is envisaged. Results should be collected in a suitable national database~~. They should be~~ and recorded quantitatively:

*a~~i~~)* as distributions of MICs in micrograms per millilitre;

*b~~ii~~)* or inhibition zone diameters in millimetres.

4~~d~~) The information to be recorded should include, where possible, the following aspects:

*a~~i~~)* sampling programme;

*b~~ii~~)* sampling date;

*c~~iii~~)* animal species and production type;

*d~~iv~~)* type of sample;

*e~~v~~)* purpose of sampling;

f[vi]) type of antimicrobial susceptibility testing method used;

g[vii]) geographical origin (geographical information system data where available) of *herd*, *flock* or *animal*;

h[viii]) *animal* factors ~~(e.g.~~ such as age, condition, health status, identification, sex~~).~~;

i) exposure of *animals* to *antimicrobial agents*;

j) bacterial isolation rate.

5~~e~~) The reporting of *laboratory* data should include the following information:

a[i]) identity of *laboratory*,

b[ii]) isolation date,

c[iii]) reporting date,

d[iv]) bacterial species,

and, where relevant, other typing characteristics, such as:

e[v]) serotype or serovar,

f[vi]) phage type,

g[vii]) antimicrobial susceptibility result or resistance phenotype,

h[viii]) genotype.

6~~f~~) ~~The proportion of isolates regarded as resistant should be reported,~~ The number of isolates regarded as resistant should be reported as a proportion of the number of isolates tested, including the defined interpretive criteria used.

7~~g~~) In the clinical setting, breakpoints are used to categorise bacterial strains as susceptible, intermediate or resistant. These clinical breakpoints may be elaborated on a national basis and may vary between Member Countries.

8~~h~~) The bacterial isolation methods, antimicrobial susceptibility testing methods, standards and guidelines used should be recorded.

9~~i~~) For surveillance and monitoring purposes, use of the microbiological breakpoint (also referred to as epidemiological cut-off point), which is based on the distribution of MICs or inhibition zone diameters of the specific bacterial species tested, is preferred. When using microbiological breakpoints, only the bacterial population with acquired resistance that clearly deviates from the distribution of the normal susceptible population will be designated as resistant. Clinical breakpoints, when available, should also be reported.

10j) Ideally, data should be collected at the individual isolate level~~.~~. This will allow ~~allowing~~ antimicrobial resistance patterns to be recorded over time ~~to be recorded~~, along with, when available, relevant data on usage of *antimicrobial agents* and management practices.

Article 6.7.9.

~~10.~~ **Reference laboratory and annual reports**

1~~a~~) Member Countries should designate a national reference centre that assumes the responsibility to:

a[i]) coordinate the activities related to the antimicrobial resistance surveillance and monitoring programmes;

*b~~ii~~)* coordinate and collect information from participating ~~surveillance~~ laboratories within the country;

*c~~iii~~)* produce an annual report on the antimicrobial resistance situation in the country.

2~~b~~) The national reference centre should have access to the:

*a~~i~~)* raw data;

*b~~ii~~)* complete results of quality assurance and inter-laboratory calibration activities;

*c~~iii~~)* inter-laboratory proficiency testing results;

*d~~iv~~)* information on the structure of the surveillance or monitoring system;

*e~~v~~)* information on the chosen laboratory methods.

Annex 13

# CHAPTER 6.8.

# MONITORING OF THE QUANTITIES AND USAGE PATTERNS OF ANTIMICROBIAL AGENTS USED IN FOOD-PRODUCING ANIMALS

**EU position**

**The EU thanks the OIE for having taken into account some of its previous comments.**

**However, we cannot support the adoption of this modified chapter unless the important comments inserted in the text below have been addressed.**

**Furthermore, we note that further to our previous comments, the OIE proposes certain deletions with a view to have short descriptive, explanatory definitions and not to include recommendations on prudent use of antimicrobials within the definitions contained in the present chapter. While the EU welcomes this, and as stated in our previous comments, we would invite the OIE to include such concrete recommendations concerning treatment, control and preventive use of antimicrobial agents in Chapter 6.9., which would benefit from a thorough revision. A comment to that effect is inserted in the EU comment on the Code Commission work program (cf. Annex 42).**

Article 6.8.1.

~~**Definition and** **P**~~**purpose**

~~For the purpose of this chapter, therapeutic use of *antimicrobial agents* means the administration of *antimicrobial agents* to *animals* for treating and controlling infectious diseases.~~

The purpose of thes~~e~~ recommendations in this chapter is to describe an approach to the monitoring of the quantities of *antimicrobial agents* used in food-producing animals.

In order to evaluate antimicrobial exposure in food-producing animals, quantitative information should be collected to monitor usage patterns by animal species, *antimicrobial agents* or class of *antimicrobial agents*, route of administration and type of use: ~~(~~therapeutic (to treat, control or prevent infectious disease) or nontherapeutic (including growth promotion) ~~and route of administration~~.

**EU comment**

**As explained in our previous comments (available here https://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_position_tahsc-report_201709.pdf, cf. p. 109-112), we do not support use of the term "therapeutic" to subsume "to treat, control or to prevent", as the terms "therapeutic" and "treatment" are very similar and this would lead to confusion.**

**The EU therefore suggests deleting the term "therapeutic" from the paragraph above, as it is not strictly necessary to use this chapeau term for the purposes of this chapter, i.e. data collection. The sentence should thus be reworded as follows:**

**"[…] and type of use: ~~therapeutic (to~~ use for treatment, control or prevention of infectious disease~~,~~ or nontherapeutic use (including growth promotion)."**

**Indeed, this would still cater for the current OIE data collection format, where 2 types**

**of use are distinguished: treat / control / prevent combined as one type of use ("Type 1 use") on the one hand, and non-therapeutic use including growth promotion ("Type 2 use") on the other.**

Article 6.8.1bis.

**Definitions**

For the purposes of the *Terrestrial Code*,

**Therapeutic use of antimicrobial agents** means the administration of an *antimicrobial agent* to an individual or a group of *animals* to treat, control or prevent ~~*infection* or~~ infectious disease:

- to treat means to administer an *antimicrobial agent* to an individual or a group of *animals* showing clinical signs of an infectious disease;

- to control means to administer an *antimicrobial agent* to a group of *animals* containing sick *animals* and healthy *animals* (presumed to be infected), to minimise or resolve clinical signs and to prevent further spread of the disease;

- to prevent means to administer~~, using an appropriate dose and for a limited, defined duration,~~ an *antimicrobial agent* to an individual or a group of *animals* at risk of ~~developing~~ acquiring a specific *infection* or in a specific situation where infectious disease is likely to occur if the drug is not administered.

**EU comment**

**Furthermore, in line with the EU comment above, we suggest deleting the above definition of "Therapeutic use of antimicrobial agents", and bringing the definitions of "to treat", "to control" and "to prevent" to the same level as the below definitions of "Nontherapeutic use of antimicrobial agents" and "Growth promotion", as follows:**

**"For the purposes of the Terrestrial Code,**

~~**Therapeutic use of antimicrobial agents means the administration of an antimicrobial agent to an individual or a group of animals to treat, control or prevent infectious disease:**~~

**– ~~to t~~Treatment means to administer an antimicrobial agent to an individual or a group of animals showing clinical signs of an infectious disease~~;~~.**

**– ~~to c~~Control means to administer an antimicrobial agent to a group of animals containing sick animals and healthy animals (presumed to be infected), to minimise or resolve clinical signs and to prevent further spread of the disease~~;~~.**

**– ~~to p~~Prevention means to administer an antimicrobial agent to an individual or a group of animals at risk of acquiring a specific infection or in a specific situation where infectious disease is likely to occur if the drug is not administered~~;~~.**

**Nontherapeutic use of antimicrobial agents means […]."**

**Furthermore, consequential changes would need to be made in point 2 b) of Article 6.8.3., where the parenthesis should be amended a follows:**

**"(~~therapeutic~~ use for treatment, control or prevention of infectious disease, or non-therapeutic use)".**

**As an alternative, the terms "infectious disease-related use" and "use not related to infectious diseases", or "Type 1 use" and "Type 2 use" could also be introduced.**

**Nontherapeutic use of antimicrobial agents** means the administration of *antimicrobial agents* to *animals* for any purpose other than to treat, control or prevent ~~*infection* or~~ infectious disease; it includes growth promotion.

**Growth promotion** means the administration of *antimicrobial agents* to *animals* ~~in their feed or water~~ only to increase the rate of weight gain or the efficiency of feed utilisation.

[…]

Annex 14

CHAPTER 6.13.

# PREVENTION AND CONTROL OF *SALMONELLA* IN COMMERCIAL PIG PRODUCTION SYSTEMS

**EU position**

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

[…]

Article 6.13.2.

**Definitions**

For the purpose of this chapter:

**Commercial pig production systems:** means those systems in which the purpose of the operation includes some or all of the following: breeding, rearing and management of pigs for the production and sale of ~~commercially traded~~ pigs or pig *meat*.

Article 6.13.3.

**Purpose and scope**

This chapter provides recommendations for the prevention and control of *Salmonella* in commercial pig production systems, including outdoor pig production systems, where practicable, in order to reduce the burden of *infection* in pigs and the *risk* of human illness through foodborne contamination as well as human *infections* resulting from direct or indirect contact with infected pigs.

This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Good Animal Feeding (CAC/RCP 54-2004), and the Guidelines for the Control of Nontyphoidal *Salmonella* spp. in Beef and Pork Meat (CAC/GL 87-2016), and the OIE/FAO Guide to Good Farming Practices for Animal Production Food Safety.

[…]

Article 6.13.16.

**Outdoor pig production**

For outdoor pigs in commercial production systems, in addition to ~~Where practicable, t~~he prevention and control measures described in Articles 6.13.5. to 6.13.15.~~,~~ ~~should also be applied to outdoor pigs in commercial pig production systems to reduce *Salmonella infection*. In addition,~~ it is recommended that:

1) field rotation programmes be used to minimise *Salmonella* contamination and accumulation in soil and surface water and therefore ingestion by pigs;

2) systems used to provide feed, and where possible water, be designed to minimise attraction of, or access by, *wild*life ~~birds~~;

3) the location of other outdoor pig *herds* and the concentration and behaviour of *wild*life ~~birds~~ in the area be considered.

Annex 15

# CHAPTER 6.X.

# INTRODUCTION TO RECOMMENDATIONS FOR VETERINARY PUBLIC HEALTH

**EU position**

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

**A comment is inserted in the text below.**

Article 6.X.1.

Veterinary public health is a component of public health that focuses on the application of veterinary science and that includes all actions directly or indirectly linked with *animals*, their products and by-products, so long as they contribute to the protection and improvement of the physical, mental and social well-being of humans.

Veterinary science has a rich history of contributions to public health, especially with regard to the provision of safe and adequate food, the prevention, control and eradication of zoonoses, the improvement of *animal welfare* and contributing to biomedical research.

*Veterinary Services* play a key role in preventing, mitigating and controlling *risks* to public health at the origin or sources of *infection*. In particular, *Veterinary Services* contribute to public health in several areas such as food security, food safety (with respect to foodborne diseases as well as residues and pollutants), control of zoonoses and responses to natural disasters and bioterrorism.

Furthermore, a number of anthropogenic factors influence the occurrence of *emerging diseases*, some of which are zoonotic. These factors include among others: population growth and changing food consumption patterns ~~eating habits~~ and their consequences such as increasing food demand and intensification of production systems; increased movements and trade of *animals* and their products and derived products; the use and misuse of *antimicrobial agents* generating resistance; the disruption of ecosystems; ~~and~~ climate change~~, among others~~.

In this context, *Veterinary Services* are integrated into the “One Health” approach to the prevention and management of health risks ~~contagious diseases~~ and preservation of the integrity of ecosystems for the benefit of human health, the health of ~~and~~ domestic *animals* and *wildlife*, ~~animal health, including domestic *animals* and *wildlife*,~~ and biodiversity.

**EU position**

**The EU suggests amending the sentence above as follows:**

**"[...] to the prevention, assessment, ~~and~~ management and communication of health risks and preservation of [...]".**

**Indeed, whether for the prevention of a health risk or for addressing an existing one, the one health appoach includes a number of elements, namely: risk identification, risk assessment, risk management (including mitigation measures) and risk communication (e.g. awareness campaigns, sharing of information, publicising), i.e. all elements of risk analysis.**

Veterinary training and education should take into account the role of *Veterinary Services* in public health at national, regional and global level in the development of ~~these~~ veterinary public health capabilities ~~in the local, regional and global context~~.

Annex 16

CHAPTER 7.1.

# INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

**EU position**

**The EU thanks the OIE for its work on the revision of Article 7.1.1. and for taking some of the EU comments into account. The EU can agree with the proposed changes and support the adoption of this revised article.**

Article 7.1.1.

~~**Definition**~~ **General considerations**

*Animal welfare* means the physical and ~~psychological~~ mental state of ~~how~~ an *animal* ~~is coping with~~ in relation to the conditions in which it lives and dies.

An *animal* ~~is in a good state of~~ ~~enjoys~~ experiences good welfare if ~~(as indicated by scientific evidence)~~ ~~it~~ the animal is healthy, comfortable, well nourished, safe, ~~it~~ is not suffering from unpleasant states such as pain, fear and distress, and ~~it~~ is able to express ~~innate~~ behaviours that are important for its physical and ~~psychological~~ mental state~~. and if it is not suffering from unpleasant states such as pain, fear, and distress~~.

Good *animal welfare* requires disease prevention and appropriate veterinary ~~treatment~~ care, shelter, management and nutrition, a stimulating and safe environment, humane handling and humane *slaughter* or *killing*. While a~~A~~*nimal welfare* refers to the state of the *animal*~~:~~, the treatment that an *animal* receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

Annex 17

CHAPTER 7.1.

# INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

**EU position**

**The EU thanks the OIE for its work on the revision of draft Article 7.1.3bis. The EU can agree with the proposed changes and in general supports the adoption of this draft article. The EU would also like to present two additional comments.**

[...]

Article 7.1.3bis.

**Guiding principles for the use of measures to assess animal welfare**

1) For the OIE *animal welfare* standards to be applicable globally, they should emphasise favourable outcomes for the *animals*, although, in some circumstances, it may be necessary to recommend specific conditions of the *animals*' environment and management. Outcomes are generally measured by assessing the extent to which *animals*' experience ~~enjoyment of~~ the "five freedoms" decribed in Article 7.1.2.

2) For each principle listed in Article 7.1.4., the most relevant criteria (or measurables), ideally comprising animal-based measures, should be included in the standard. Any given animal-based measure may be linked to more than one principle.

3) ~~Standards~~ Recommendations should, whenever possible, define explicit targets or thresholds that should be met for animal-based measures. Such target values should be based on relevant science and experience of experts. To guide users, *Competent Authorities* ~~and other relevant bodies~~ should collect all relevant data that can be used to set ~~relevant~~ target values.

**EU comments**

**1. The EU would like to suggest modifying the beginning of the above point 3 as follow:**

**"3) Recommendations within the standards should, …."**

**Justification**

**The proposed modification underlines the weight of these recommendations for Competent Authorities as being part of the OIE standards.**

**2. In addition, the EU suggests presenting the last sentence of the above point 3 as a separate point 4. The EU would also suggest modifying this sentence as follow:**

**"4) To guide users, Competent Authorities ~~and other relevant bodies~~ , with the support of other relevant bodies if necessary, should collect all relevant data that can be used to set ~~relevant~~ target and threshold values."**

**Justification**

**Clarity. While the first 2 sentences of point 3 refer to how OIE standards should be set, the last sentence refers to the responsibilities of the Competent Authorities. Competent Authorities may also request the technical support of other relevant bodies for the**

**collection of the relevant data. Furthermore such data can be used to set both target and threshold value.**

~~4~~) In addition to animal-based measures, resource-based measures and management-based measures may be used and should be defined on the basis of science and expert experience showing that a welfare

5) Users of the standard should select the most appropriate animal-based measures for their farming system or ~~conditions~~ environment, from among those listed in the standard. Outcomes can be measured by an assessment of individuals or animal groups, or a representative sample of those, using data from *establishments*, transport or *slaughterhouses/abattoirs*. outcome is clearly linked to a resource or to a management procedure.

6) Whatever the basis of the measure, if outcomes are unsatisfactory, users should consider what changes to resources or management are necessary to improve outcomes.

[. . .]

Annex 18

CHAPTER 7.X.

# ANIMAL WELFARE AND PIG PRODUCTION SYSTEMS

**EU position**

**The EU thanks the OIE for its work on the revision of the draft chapter and for taking some of the EU comments into account. The EU can agree with the proposed changes and support the adoption of this draft chapter.**

**Nevertheless given the importance of this chapter, the EU asks the OIE to reconsider the EU comments reiterated in the text below, in particular as regards group housing of sows, for future revisions of the chapter following adoption. The EU will provide additional scientific information as soon as it becomes available.**

**Furthermore, the EU would like to present some additional comments for further fine-tuning of the chapter following its adoption.**



Article 7.X.1.

**Definitions**

'Commercial pig production systems' means those systems in which the purpose of the operation includes some or all of the following: breeding, rearing and management of pigs *(Sus scrofa)* for the production and sale of ~~commercially traded~~ pigs or pig *meat*.

For the purposes of this chapter, 'management' is defined at the farm management level and at the *animal handler* level. At the level of farm management, human resources management practices, including selection and training of handlers, and animal management practices, such as best practice in housing and husbandry and implementation of welfare protocols and audits, all have an impact on *animal welfare*. At the *animal handler* level this requires a range of well-developed husbandry skills and knowledge of how to care for animals.

For the purposes of this chapter, 'environmental enrichment' means increasing the complexity (e.g. foraging opportunities, social housing) of the animal's environment to foster the expression of normal behaviour, provide cognitive stimulation and reduce the expression of abnormal behaviour. The aim of providing enrichment should be to improve the physical and ~~psychological~~ mental state of the animal (Newberry, 1995; Mellor, 2015 and 2016).

For the purposes of this chapter 'stereotypy' is a repetitive behaviour induced by frustration, repeated attempts to cope or central nervous system dysfunction. It is expressed as a sequence of abnormal behaviours which appear to have no obvious purpose or function. Permanent dysfunction of the central nervous system in response to stressful conditions may mean that developed stereotypies may not resolve despite later changes to the environment or other treatments such as those relating to feeding levels or diet composition. Some stereotypies commonly observed in pigs include sham chewing, stone chewing, tongue rolling, teeth grinding, bar biting and floor licking (NFACC, 2014; Tuyttens, 2007; Mason, 2008).

For the purposes of this chapter 'apathy' means that the animal ceases to respond to stimuli that would normally elicit a response (Wood-Gush and Vestergaard, 1989). Furthermore, apathetic behaviour has been described as an abnormal or maladaptive behaviour, indicated by reduced activity, lack of interest or concern (i.e. indifference) and lack of feeling or emotion (impassiveness) (Mills and Caplen, 2010).

For the purposes of this chapter 'agonistic behaviour' is a continuum of behaviours expressed in conflict situations, and includes offence, defence and submissive or escape components. The behaviours involved may include contact, such as biting and pushing, or non-contact, such as threats in the form of body postures and gestures. Aggressive behaviour (i.e. fighting) is a component of agonistic behaviour (Petherick and Blackshaw, 1987).

For the purposes of this chapter, 'play behaviour' is characterised by specific neuroendocrinological responses and the appearance of having fun (Spinka et al, 2001; Reimert et al, 2013). It is often prompted by novel or

unpredictable stimuli, and is related to exploration. It functions to prepare animals for unexpected situations by increasing the versatility of movements and enhancing their ability to cope with unexpected stressful situations (Spinka et al, 2001). Animals actively seek and create unexpected situations in play, deliberately relaxing their movements or putting themselves into disadvantageous positions.

Article 7.X.2.

**Scope**

This chapter addresses the welfare aspects of commercial domestic pig production systems. *Captive wild* pigs are not considered.

Article 7.X.3.

**Commercial pig production systems**

Commercial pig production systems include:

1. Indoor systems

   These are systems in which pigs are kept indoors~~,~~ and are fully dependent on humans to provide for basic animal needs such as *feed* and water. The type of housing depends on the environment, climatic conditions and management system. The animals may be kept in groups or individually.

2. Outdoor systems

   These are systems in which pigs live outdoors with shelter or shade, have some autonomy over access to shelter or shade, but may be fully dependent on humans to provide for basic animal needs such as *feed* and water. Pigs are typically ~~confined~~ kept in paddocks or pastures according to their production stage. The animals may be kept in groups or individually.

3. Combination systems

   These are systems in which pigs are managed in any combination of indoor and outdoor production systems.

Article 7.X.4.

**Criteria (or measurables) for the welfare of pigs**

The following outcome-based criteria (or measurables), specifically animal-based criteria, can be useful indicators of *animal welfare*. The use of these indicators and their appropriate thresholds should be adapted to the different situations in which pigs are managed such as regional differences, herd health, pig breed or crossbreed, and climate. Consideration should also be given to the resources provided and the design of the systems~~.~~ These criteria can be considered as tools to monitor the efficiency of design and management, given that ~~both of these~~ they can affect *animal welfare.*

1. Behaviour

   Certain behaviours appear to be indicators of good animal welfare and health in pigs such as play and specific vocalisations (Boissy et al. 2007; Reimert ert al., 2013).

   Certain behaviours could indicate an *animal welfare* and health problem. These include sudden immobility, escape attempts, changes in *feed* and water intake, altered locomotory behaviour or posture, altered lying time, postures and patterns, altered respiratory rate and panting, coughing, shivering and huddling, high-pitched vocalisations and increased call rate, ~~and~~ increased agonistic (including aggression), stereotypic, apathetic or other abnormal behaviours (Weary and Fraser, 1975; Weary et al., 1997; Puppe et al., 2005; Düpjan et al., 2006; Reimert et al., 2013).

**EU comment**

**At the beginning of the above paragraph, the EU suggests OIE including the word "other" so as to read:**

**"Certain other behaviours"**

**Justification**

**For clarity, and to differentiate behaviours indicating animal welfare and health problems from behaviours in the first paragraph indicating good welfare.**

~~Certain behaviours are indicators of good *animal welfare*. These may include positive social and play behaviour.~~

Environments that induce stereotypies typically also reduce animal welfare. Although stereotypies are generally held to indicate poor welfare, there are some instances where there is a poor association between stereotypies and stress. For example, frustration-induced stress may be somewhat rectified if the behaviour itself reduces the underlying motivation. Within a group, individuals that perform stereotypies may thus be coping more successfully than those that do not. Nevertheless, stereotypies indicate either a present problem for the animal or a past problem that has resolved. As with other indicators, caution should be used when using stereotypies as a welfare measure in isolation from other indicators (NFACC, 2014; Tuyttens, 2007; Mason, 2006).

2. Morbidity rates

Rates of infectious and metabolic diseases, lameness, peripartum and post-procedural complications, injury and other forms of morbidity, above recognised thresholds, may be direct or indirect indicators of *animal welfare* at the *herd* level. Understanding the aetiology of the disease or syndrome is important for detecting potential *animal welfare* problems. Mastitis and metritis, leg and hoof problems, shoulder ulcers in sows, skin lesions, respiratory and digestive diseases, and reproductive diseases are also particularly important animal health problems for pigs. Scoring systems, such as for body condition (Coffey et al, 1999), lameness and injuries (Hodgkiss et al. ,1998; de Koning, 1984 and Herskin et al, 2011), and information gathered at the *slaugtherhouse/abattoir*, can provide additional information (Van Staaveren et al, 2017 and Faucitano, 2001).

Both clinical and *post mortem* pathologic examination should be utilised as indicators of disease, injuries and other problems that may compromise *animal welfare*.

3. Mortality and culling rates

Mortality and culling rates affect the length of productive life and, like morbidity rates, may be direct or indirect indicators of *animal welfare* at the *herd* level. Depending on the production system, estimates of mortality and culling rates can be obtained by analysing the causes of *death* and culling and their temporal and spatial patterns of occurrence. Mortality and culling rates, and their causes, when known, should be recorded regularly, e.g. daily, and used for monitoring e.g. monthly, annually.

Necropsy is useful in establishing the cause of *death*.

4. Changes in body weight and body condition

In growing animals, body weight changes outside the expected growth rate, especially excessive sudden weight loss, are indicators of poor *animal welfare* and health (Coffey et. al, 1999).

Body condition outside an acceptable range or large variation amongst individual animals in the group may be an indicator of compromised *animal welfare* and health, and reproductive efficiency in mature animals.

5. Reproductive efficiency

Reproductive efficiency can be an indicator of *animal welfare* and health status. Poor reproductive efficiency, compared with the targets expected for a particular breed or ~~hybrid~~ crossbreed, can indicate *animal welfare* problems (Hemsworth *et al.*, 1981, 1986, 1989, 1994; Munsterjelm *et al.*, 2006).

Examples may include:

– low conception rates,

– high abortion rates,

– metritis and mastitis,

– small litter size (total born),

– low numbers born alive,

– high numbers of stillborns or mummies.

6. Physical appearance

Physical appearance may be an indicator of *animal welfare* and health. Attributes of physical appearance that may indicate compromised *animal welfare* include:

– body condition outside an acceptable range (Coffey et. al, 1999),

– presence of ectoparasites,

– abnormal texture or hair loss,

– excessive soiling with faeces,

– skin discolouration, including sunburn,

– swellings, injuries or lesions (Hodgkiss et al. ,1998; de Koning, 1984 and Herskin et al, 2011),

– discharges (e.g. from nose or eyes, including tear staining) (Telkänranta *et al.*, 2016),

– feet and leg abnormalities (Seddon et al, 2013),

– abnormal posture (e.g. rounded back, head low),

– emaciation or dehydration.

7. Handling response

Improper handling or lack of human contact can result in fear and distress in pigs. Fear of humans may be an indicator of poor *animal welfare* (Hemsworth and Coleman, 2011). Indicators may include:

– evidence of poor human-animal relationship, such as marked avoidance of handlers and abnormal or excessive vocalisation when being moved or when *animal handlers* interact with pigs,

– animals slipping or falling during handling,

– injuries sustained during handling, such as bruising, lacerations and fracturesd ~~legs~~,

8. Lameness

Pigs are susceptible to a variety of infectious and non-infectious musculoskeletal disorders. These disorders may cause lameness and gait abnormalities. Pigs that are lame or have gait abnormalities may have difficulty reaching *feed* and water and may experience pain and distress. Musculoskeletal problems have many causes, including genetic, nutrition, sanitation, floor quality, and other environmental and management factors. There are several gait scoring systems available (Main et. al, 2000; Grégoire et Al, 2013; Seddon et al, 2013).

9. Complications from common procedures

Some painful or potentially painful procedures such as surgical castration, tail docking, teeth clipping or grinding, tusk trimming, identification, nose ringing and hoof care are performed ~~in~~ on pigs to facilitate management, meet market or environmental requirements and improve human safety or safeguard *animal welfare*.

However, if these procedures are not performed properly, *animal welfare* and health can be unnecessarily compromised.

Indicators of problems associated with these procedures could include:

– post-procedure *infection* and swelling,

– post-procedure lameness,

– behaviour indicating pain, fear, distress or suffering (Mellor and Patterson-Kane, 2009),

– increased morbidity, mortality and culling rates,

– reduced *feed* and water intake,

– post procedure body condition and weight loss.

Article 7.X.5.

**Recommendations**

Ensuring good welfare of pigs is contingent on several management factors, including system design, environmental management, and animal management practices which include responsible husbandry and provision of appropriate care. Serious problems can arise in any system if one or more of these elements are lacking.

Articles 7.X.6. to 7.X.27. provide recommendations for measures applied to pigs.

Each recommendation in Article 7.X.6. to 7.X.24. includes a list of relevant animal-based criteria (or measurables) derived from Article 7.X.4.

This does not exclude other criteria (or measurables) being used where or when appropriate.

Article 7.X.6.

**Training of personnel**

Pigs should be cared for by a sufficient number of personnel, who collectively possess the ability, knowledge and competence necessary to maintain the welfare and health of the animals.

All people responsible for pigs should be competent through formal training or practical experience in accordance with their responsibilities. This includes understanding of and skill in animal handling, nutrition, reproductive management techniques, behaviour, *biosecurity*, signs of disease, and indicators of poor *animal welfare* such as stress, pain and discomfort, and their alleviation.

Animal-based criteria (or measurables): handling response, physical appearance, behaviour, changes in body weight, body condition, reproductive efficiency, lameness and morbidity, mortality and culling rates and complications from common procedures.

Article 7.X.7.

**Handling and inspection**

*Animal handlers* with positive attitudes to handling and caring for pigs can lead to positive welfare outcomes. This may be shown by the length of time taken for the animals to approach a human, a short flight distance, or a willingness to interact with humans (Coleman and Hemsworth, 2014).

Pigs should be inspected at least once a day when fully dependent on humans to provide for basic needs such as *feed* and water and to identify welfare and health problems.

Some animals should be inspected more frequently, for example, farrowing sows, new born piglets, newly weaned pigs, newly-mixed gilts and sows, sick or injured pigs and those showing abnormal behaviours such as tail biting.

Pigs identified as sick or injured should be given appropriate treatment ~~at the first available opportunity~~ as soon as possible by competent *animal handlers*. If *animal handlers* are unable to provide appropriate treatment, the services of a *veterinarian* should be sought.

Recommendations on the handling of pigs are also found in Chapter 7.3. In particular handling aids that may cause pain and distress (e.g. electric goads) should be used only when other methods fail and provided that the animal can move freely and is able to move away from the handling aid. The use of electric goads should be avoided (see also point 3 of Article 7.3.8.), and should not be repeatedly used on the same animal, and not be used in sensitive areas including the udder, face, eyes, nose, ears or anogenital region. *Animal handlers* should be alert for signs of stress in pigs and know when to release handling pressure (by giving pigs more time and space) to reduce the level of threat (National Pork Board, 2014).

Exposure of pigs to sudden movement, loud noises or changes in visual contrasts should be minimised where possible to prevent stress and fear reactions. Pigs should not be improperly or aggressively handled (e.g. kicked, thrown, dropped, walked on top of, held or pulled by one front leg, ears or tail). Pigs that become distressed during handling should be attended to immediately.

Pigs should be restrained only for as long as necessary and only appropriate, well-maintained restraint devices should be used.

Well designed and maintained handling facilities assists proper handling.

Animal-based criteria (or measurables): physical appearance, behaviour, changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.

Article 7.X.8.

**Painful procedures**

Some procedures such as surgical castration, tail docking, teeth clipping or grinding, tusk trimming, identification, and nose ringing may be performed on ~~in~~ pigs. These procedures should only be performed by trained personnel, when necessary to facilitate management, ~~to~~ meet market or environmental requirements, improve human safety or safeguard *animal welfare*.

These procedures are painful or have the potential to cause pain. They should be performed in such a way as to minimise any pain, distress or suffering to the animal.

Options for enhancing *animal welfare* in relation to these procedures include the internationally recognised 'three Rs': replacement (e.g. using entire males or immunocastrated males rather than surgically castrated males), reduction (e.g. tail docking and teeth clipping only when necessary) and refinement (e.g. providing analgesia or anaesthesia under the recommendation or supervision of a *veterinarian*) (Bonastre *et al.*, 2016 and Hansson *et al.*, 2011).

Ovariectomy should not be performed without anaesthesia and prolonged analgesia. An immunological product that reversibly and effectively suppresses ovarian function in pigs is available. Immunological prevention of oestrus should be encouraged to avoid ovariectomy (Dalmau *et al.*, 2015).

Animal-based criteria (or measurables): complications from common procedures, morbidity rates, mortality and culling rates, abnormal behaviour, physical appearance and changes in weight and body condition.

Article 7.X.9.

**~~Feeding and p~~Provision of feed and water~~ing of animals~~**

The amount of *feed* and nutrients pigs require in any management system is affected by factors such as climate, the nutritional composition and quality of the diet, the age, gender, genetics, size and physiological state of the pigs (e.g. pregnancy, lactation, growth), and their state of health, growth rate, previous feeding levels and level of activity and exercise.

All pigs should receive adequate ~~quantities~~ quantity and quality of *feed* and nutrients each day to enable each pig to:

– maintain good health;

– meet its physiological requirements and,

– meet its requirements for foraging and feeding behaviour (Bergeron *et al.*, ~~2008~~2006; Brouns *et al.*, 1994; Ramonet *et al.*, 1999; Robert *et al.*, 1993 and 1997).

*Feed* and water should be provided in such a way as to prevent excessive or injurious competition.

Pigs should be fed a diet with the intention of minimising the occurrence of gastric ulcers (e.g. increasing dietary fiber or reducing crude protein) (Herskin *et al.*, 2016, Jha and Berrocoso, 2016).

All pigs should have access to an adequate supply of drinkable water that meets their physiological requirements and is free from contaminants hazardous to pig health (Patience, 2013). Water flow rates in drinkers should be set according to the age of the animal, stage of production and environmental conditions (Patience, 2014).

In outdoor systems where pigs have some autonomy over diet selection, stocking density should be matched to the available natural *feed* supply.

Animal-based criteria (or measurables): changes in body weight and body condition, physical appearance (emaciation, dehydration), behaviour (agonistic behaviour at feeding and watering places and abnormal behaviour such as tail biting), mortality and culling rates, and morbidity rates.

Article 7.X.10.

**Environmental enrichment**

Animals should be provided with an environment that provides complexity, manipulability and cognitive stimulation ~~(e.g. foraging opportunities, social housing)~~ to foster normal behaviour (e.g. ~~rooting, and biting/~~exploration, foraging such as rooting, biting and ~~or~~ chewing materials other than feedstuffs, and social interaction), reduce abnormal behaviour (e.g. tail, ear, leg and flank biting, sham chewing, bar biting and apathetic behaviour) and improve their physical and ~~psychological~~ mental state (Bergeron and Gonyou, 1997, Dudnik *et al.*, 2006; Elmore *et al.*, 201; Newberry, 1995; Spoolder et al., 1995; Van de Weerd *et al.*, 2006; Wittaker *et al.*, 1999).

Pigs should be provided with ~~multiple forms of~~ enrichments that aim to improve their welfare through the enhancement of their physical and social environments, such as:

– sufficient quantity of suitable materials to enable pigs to fulfil their needs to explore and look for *feed* (edible materials), bite (chewable materials), root (investigable materials) and manipulate materials (Bracke *et al.*, 2006). Novelty is another aspect that is important in maintaining interest in the provided materials (Trickett *et al.*, 2009; Abou-Ismaila and Mendl, 2016; Tarou and Bradshaw 2007);

– social enrichment that involves either keeping pigs in groups or individually with visual, olfactory and auditory contact with other pigs;

– positive human contact (such as regular direct physical contact associated with positive events, which may include *feed*, pats, rubs, scratching and talking when the opportunity arises) (Hemsworth and Coleman, 2011; Hemsworth and Coleman, 1994).

Animal-based criteria (or measurables): physical appearance (injuries), behaviour (stereotypies, tail biting), changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.

Article 7.X.11.

**Prevention of abnormal behaviour**

In pig production there is a number of abnormal behaviours that can be prevented or minimised with appropriate management procedures.

Many of these problems are multifactorial and minimising their occurrence requires an examination of the whole environment and of several management factors. Management procedures that may reduce the occurrence of some of these behavioural problems include:

1) Oral stereotypies (e.g. bar biting, sham chewing, excessive drinking) ~~can~~ may be minimised by providing environmental enrichment and increasing feeding time and satiety by increasing fibre content in the diet or foraging roughage (Robert *et al.*,1997; Bergeron *et al.*, 2000).

2) Tail biting may be reduced by providing an adequate enrichment material and an adequate diet (avoiding deficiencies of minerals (Fraser, 1987) or essential amino acids), and avoiding high stocking densities and competition for resources, such as *feed* and water (Walker and Bilkei, 2005). Other factors to consider include animal characteristics (breed, genetics, gender) and social environment (*herd* size, mixing animals) (Schroder-Petersen and Simonsen, 2001; EFSA, 2007; Taylor *et al.*, 2010), general health, thermal comfort and air quality.

3) Belly nosing and ear sucking may be reduced by increasing the weaning age, and providing *feed* to piglets prior to weaning to avoid the abrupt change of *feed* (Marchant-Forde, 2009; Sybesma, 1981; Worobec, 1999).

4) Vulva biting may be reduced by minimising competition for resources, including *feed* and water, and reducing group size (Bench *et al.*, 2013; Leeb *et al.*, 2001; Rizvi *et al.*, 1998).

Animal-based criteria (or measurables): physical appearance (injuries), behaviour (abnormal behaviour), morbidity rates, mortality and culling rates, reproductive efficiency and changes in body weight and body condition.

Article 7.X.12.

**Housing (including outdoor production systems)**

When new facilities to accommodate pigs are planned or existing facilities are modified, professional advice on design in regards to welfare and health of animals should be sought.

Housing systems and their components should be designed, constructed and regularly inspected and maintained in a manner that reduces the risk of injury, disease and stress for pigs. Facilities should allow for the safe, efficient and humane management and movement of pigs. In systems where pigs could be exposed to adverse weather conditions they should have access to shelter to avoid thermal stress and sunburn.

There should be a separate pen or area where sick and injured animals or animals that exhibit abnormal behaviour can be isolated, treated and monitored. Certain animals may need to be kept individually. When a separated space is provided, this should accommodate all the needs of the animal e.g. recumbent or lame animals or animals with severe wounds may require additional bedding or an alternative floor surface, and water and *feed* should be within reach.

Pigs should not be tethered as part of their normal housing systems.

Good outcomes in the welfare and health of animals can be achieved in a range of housing systems. The design and management of the system are critical for achieving these outcomes.

Sows and gilts, like other pigs, are social animals and prefer living in groups (Stolba and Wood-Gush, 1989; Newberry and Wood-Gush, 1988; Gonyou, 2001), therefore pregnant sows and gilts should preferably be housed in groups (Anil *et al.*, 2005; Barnett *et al.*, 2001; Boyle *et al.*, 2002; Broom *et al.*, 1995; Karlen *et al.*, 2007; Marchant and Broom, 1996; McGlone *et al.*, 2004; AVMA, 2015). Boars may need to be housed in individual pens.

**EU comment**

**The EU would like to reiterate its previous comment.**

**The EU would like to re-introduce the following sentence, previously included in the draft paragraph above, and proposes to replace the word "breeding" with "service":**

**"Sows and gilts can be successfully mixed early after service ~~breeding~~, without any reproduction consequences (Spoolder *et al.*, 2009)."**

**Justification**

**Scientific research showing that mixing pregnant sows within a few days of insemination, can result in equivalent or better reproductive performance than later mixing was produced.**

**The same term should be used in the entire draft chapter for consistency and clarity.**

**References**

**Report of the Scientific Veterinary Committee "The Welfare of Intensively Kept Pigs" 30.09.1997**
**https://ec.europa.eu/food/sites/food/files/animals/docs/aw_arch_1997_intensively_kept_pigs_en.pdf**

**Spoolder, H.A.M, Geudeke, M.J., Van der Peet-Schwering, C.M.C and Soede, N.M., 2009. Group housing of sows in early pregnancy: a review of success and risk factors. Livestock Science, 125: 1-14.**

Animal-based criteria (or measurables): physical appearance (injuries), behaviour, changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.

Article 7.X.13.

**Space allowance**

Space allowance should be managed taking into account different areas for lying, standing, feeding and elimination. Stocking density should not adversely affect normal behaviour of pigs and durations of time spent lying.

Insufficient and inadequate space allowance may increase stress, the occurrence of injuries and have an adverse effect on growth rate, *feed* efficiency, reproduction and behaviour such as locomotion, resting, feeding and drinking, agonistic and abnormal behaviour (Gonyou *et al.*, 2006; Ekkel, 2003; Turner, 2000).

1. Group housing

Floor space may interact with a number of factors such as temperature, humidity, floor type and feeding systems to affect pig welfare (Marchant–Forde, 2009; Verdon, 2015). All pigs should be able to lie down simultaneously and to stand up and move freely. Sufficient space should be provided to enable animals to have access to *feed*, water, to separate lying and elimination areas and to avoid aggressive animals.

Group housing systems should provide sufficient space and opportunities to avoid or escape from potential aggressors.

**EU comment**

**The EU would like to reiterate its previous comment.**

**Given its importance, the EU asks the OIE to consider including the following sentence at the end of the above paragraph:**

**"Group housing systems of pigs should be encouraged compared to other systems, causing health and welfare problems ( for example gestation stalls)."**

**Justification:**

**Pigs are highly social animals and it is important for their welfare that they are kept in groups as much as possible so that they have the possibility to express natural and social behaviour. Farrowing crates and stalls limit the pig's possibility for free movement and possibility to express natural/normal behaviour. It is therefore important for the welfare of the pigs that the time they are kept in crates and stalls is limited. Furthermore, sows kept in stalls or farrowing crates where they cannot turn around have reduced bone and muscular strength, reduced cardiovascular fitness and a higher incidence of foot and leg pathologies and stereotypies.**

**References**

**EFSA. 2007. Scientific Report on animal health and welfare aspects of different housing and husbandry systems for adult breeding boars, pregnant, farrowing sows and unweaned piglets. European Food Safety Authority. The EFSA Journal 572:1-107. www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/572.pdf.**

**Edwards, S.A. 1992: Scientific perspective on loose housing systems for sow. Pig Veterinary Journal 28, pp. 40-51**

**Marchant, J.N., Rudd, A.R., Broom, D.M. (1997): The effects of housing on heart rate of gestating sows during specific behaviours. Appl. Anim. Behav. Sci., 55, 67-78.**

**Marchant, J.N. and Broom, D.M. (1996): Effects of dry sow housing conditions on muscle weight and bone strength, Animal Science, 62, 105-113.**

**Rhodes, R.T., Appleby, M.C., Chinn, K., Douglas, L., Firkins, L.D., Houpt, K.A., Irwin, C., McGlone, J.J., Sundberg, P., Tokach, L., Wills, R.W. (2005): A comprehensive review of housing for pregnant sows. J. Am. Vet. Med. Assoc., 227, 1580-1590.**

**Schenck, E.L., McMunn, K.A., Rosenstein, D.S., Stroshine, R.L., Nielsen, B.D., Richert, B.T., Marchant-Forde, J.N., Lay, D.C. (2008): Exercising stall-housed gestating gilts: Effects on lameness, the musculo-skeletal system, production, and behavior. J. Anim. Sci. 2008, 86, 3166-3180.**

**Li, Y.Z. and Gonyou, H.W. (2007): Effects of stall width and sow size on behavior of gestating sows. Canadian Journal of Animal Science, 87, 129-138.**

**Report of the Scientific Veterinary Committee "The Welfare of Intensively Kept Pigs" 30.09.1997**
**https://ec.europa.eu/food/sites/food/files/animals/docs/aw_arch_1997_intensively_kept_pigs_en.pdf**

**Barnett, J. L., Winfield, C. G., Cronin, G. M., Hemsworth, P. H., & Dewar, A. M. (1985). The effect of individual and group housing on behavioural and physiological responses related to the welfare of pregnant pigs. *Applied Animal Behaviour Science*, *14*(2), 149-161.**

**Barnett, J. L., Hemsworth, P. H., Cronin, G. M., Jongman, E. C., & Hutson, G. D. (2001). A review of the welfare issues for sows and piglets in relation to housing. *Australian journal of agricultural research*, *52*(1), 1-28.**

If abnormally aggressive behaviour is seen, corrective measures should be taken, such as increasing space allowance and providing barriers where possible or individually housing the aggressive pig.

~~In outdoor systems where pigs have some autonomy over diet selection, stocking density should be matched to the available *feed* supply.~~

Animal-based criteria (or measurables): reduction or variation in body weight and body condition, increasing agonistic and abnormal behaviour such as tail biting, injuries, morbidity, mortality and culling rates, and physical appearance (e.g. excessive presence of faeces on the skin).

2. Individual pens

Pigs should only be housed in individual pens if necessary. In individual pens, pigs should be provided with sufficient space so that they can stand up, turn around and lie comfortably in a natural position, and that provides separate areas for elimination, lying and eating.

Animal-based criteria (or measurables): increasing abnormal behaviour (stereotypies), morbidity, mortality and culling rates, and physical appearance (e.g. excessive presence of faeces on the skin, injuries).

3. Stalls and crates

Feeding, insemination and gestation stalls and farrowing crates should be sized appropriately to allow pigs to:

– stand up in their natural stance without contact with either side of the stall or crate,

– stand up in their natural stance without contact with the top bars,

– stand without simultaneously touching both ends of the stall or crate,

– lie comfortably on their sides without disturbing neighbouring pigs or being injured by another pig~~.~~ except in the case of stalls used only for feeding.

**EU comment**

**The EU would like to reiterate its previous comment.**

**Given its importance, the EU would like to reiterate its previous comment and asks the OIE to consider including above the following sentence.**

"**When sows or gilts are kept in gestation stalls, it is recommended to keep them only up to a maximum of 4 weeks/28 days after service.**"

**Justification**

**Sows and gilts can succesfully be mixed into groups directly after service, without any reproduction consequences. The use of stalls can and should be limited to a restricted amount of days at most. The scientific references reported below highlight that confining sows in stalls for the first four weeks of pregnancy is not necessary to prevent stress that could disrupt implantation of the embryos. Well-managed mixing of sows before, or within a few days of insemination, can result in equivalent or better reproductive performance than later mixing.**

**Reference**

**Report of the Scientific Veterinary Committee "The Welfare of Intensively Kept Pigs" 30.09.1997**
**https://ec.europa.eu/food/sites/food/files/animals/docs/aw_arch_1997_intensively_kept_pigs_en.pdf**

**Anil, L., Anil, S.S., Deen, J., Baidoo, S.K., Wheaton, J.E. (2005): Evaluation of well-being, productivity, and longevity of pregnant sows housed in groups in pens with an electronic sow feeder or separately in gestation stalls. Am. J. Vet. Res., 66, 1630-1638.**

**Marchant, J.N., Rudd, A.R., Broom, D.M. (1997): The effects of housing on heart rate of gestating sows during specific behaviours. Appl. Anim. Behav. Sci., 55, 67-78.**

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**However, as in the Scientific Report of EFSA (2007) it is mentioned that if grouping takes place 1-2 weeks after mating, higher re-mating percentages and smaller litter have been found in sows kept in large dynamic groups without bedding compared to sows that have been tethered until testing four weeks after mating (Arey and Edwards, 1998, Te Brake and Bressers, 1990), a maximum period of sows and gilts in gestation stalls of 4 weeks after service could be acceptable as a maximum in the international context.**

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Animal-based criteria (or measurables): physical appearance (e.g. injuries), increasing abnormal behaviour (stereotypies), reproductive efficiency, lameness and morbidity, mortality and culling rates (e.g. piglets).

Article 7.X.14.

**Flooring, bedding, resting surfaces**

In all production systems, pigs need a well-drained, dry and comfortable place to rest~~.~~, except in situations where sprinklers or misters may be used to prevent heat stress.

Floor management in indoor production systems can have a significant impact on pig welfare (Temple *et al.*, 2012; Newton *et al.*, 1980). Flooring, bedding, resting surfaces and outdoor yards should be cleaned as conditions warrant, to ensure good hygiene, comfort and minimise risk of diseases and injuries. Areas with excessive faecal accumulation are not suitable for resting.

Floors should be designed to minimise slipping and falling, promote foot health, and reduce the risk of claw injuries.

If a housing system includes areas of slatted floor, the slat and gap widths should be appropriate to the claw size of the pigs to prevent injuries.

Slope~~s~~ of the floor should allow water to drain and not pool.

In outdoor systems, pigs should be rotated between paddocks or pastures to ensure good hygiene and minimise risk of diseases.

If bedding or rubber matting is provided it should be maintained to provide pigs with a clean, dry and comfortable place on which to lie.

Animal-based criteria (or measurables): physical appearance (e.g. injuries, presence of faeces on the skin, bursitis), lameness and morbidity rates (e.g. respiratory disorders, reproductive tract infections).

Article 7.X.15.

**Air quality**

Good air quality and ventilation are important for the welfare and health of pigs and reduce the risk of respiratory discomfort, diseases and abnormal behaviour. Dust, toxins, microorganisms and noxious gases, including ammonia, hydrogen sulphide, and methane caused by decomposing animal waste, can be problematic in indoor systems (Drummond *et al.*, 1980).

Air quality is influenced strongly by management and building design in housed systems. Air composition is influenced by stocking density, the size of the pigs, flooring, bedding, waste management, building design and ventilation system (Ni *et al.*, 1999).

Proper ventilation, without draughts (Scheepens et al., 1991a,b), particularly for young pigs, is important for effective heat dissipation in pigs and to prevent the build-up of effluent gases (e.g. ammonia and hydrogen sulphide), including those from manure and dust in the housing unit. The ammonia concentration in enclosed housing should not exceed 25 ppm. A useful indicator is that if air quality at the level of the pigs is unpleasant for humans it is most likely a problem for pigs.

Animal-based criteria (or measurables): morbidity, mortality and culling rates, physical appearance ~~(excessive soiling and tear staining),~~ behaviour (especially respiratory rate, coughing and tail biting), change in body weight and body condition.

**EU comment**

**The EU would like to retain the text currently deleted "~~excessive soiling and tear staining~~" in the above paragraph. Furthermore the EU would like to propose including the text "or bad eye condition" as to read:**

**"physical appearance (excessive soiling and tear staining or bad eye condition)".**

**Justification**

**It is not clear what "physical appearance" refers to.**

**Straw BE, Dewey CE and Wilson MR 2006. Differential diagnosis of disease. In Diseases of swine, 9th edition (eds Straw BE, Zimmerman JJ, D'Allaire S and Taylor DJ), pp. 241–286. Blackwell Publishing, Oxford, UK.**

**The above-mentioned paper by Straw et al. states: "Ammonia is highly soluble in water, and as such will react with the moist mucous membranes of the eye and respiratory passages. Consequently, excessive tearing, shallow breathing, and a clear or purulent nasal discharge are common symptoms of aerial NH3 toxicosis".**

**Herman M. Vermeer and Hans Hopster, Animals 2018, 8(4), 44; Operationalizing Principle-Based Standards for Animal Welfare—Indicators for Climate Problems in Pig Houses.**

Article 7.X.16.

**Thermal environment**

Although pigs can adapt to a range of thermal environments, particularly if appropriate breeds and housing are used for the anticipated conditions, sudden fluctuations in temperature can cause heat or cold stress.

1. Heat stress

Heat stress is a serious problem in pig production. It can cause significant discomfort, as well as reductions in weight gain and fertility, or sudden death (Werremann and Bazer, 1985).

The risk of heat stress for pigs is influenced by environmental factors including air temperature, solar radiation, relative humidity, wind speed, ventilation rates, stocking density, shade and wallow availability in outdoor systems and animal factors including breed, age and body condition (Heitman and Hughes, 1949; Quiniou and Noblet, 1999).

At a given temperature, the heavier pigs are, the more susceptible they are to heat stress (Renaudeau, 2011).

*Animal handlers* should be aware of the risk that heat stress poses to pigs and of the thresholds in relation to heat and humidity that may require action. If the risk of heat stress reaches too high levels the *animal handlers* should institute an emergency action plan that gives priority to access to additional water and could include provision of shade and wallows in outdoor systems, fans, reduction of stocking density, water-based cooling systems (dripping or misting), and provision of cooling systems as appropriate for the local conditions.

Animal-based criteria (or measurables): behaviour (feed and water intake, respiratory rate, panting, lying postures and patterns, agonistic behaviour), physical appearance (presence of faeces on the skin, sunburn), morbidity, mortality and culling rates, and reproductive efficiency.

2. Cold stress

Protection from cold should be provided when conditions are likely to compromise the welfare of pigs, particularly in neonates and young pigs and others that are physiologically compromised (e.g. ill animals).

Protection can be provided by insulation, extra bedding, heat mats or lamps and natural or man-made shelters in outdoor systems (Blecha and Kelley, 1981).

Animal-based criteria (or measurables): morbidity, mortality and culling rates, physical appearance (~~long hair,~~ piloerection), behaviour (especially abnormal postures, shivering and huddling) and changes in body weight and body condition.

Article 7.X.17.

**Noise**

Exposure of pigs to sudden or prolonged loud noises should be avoided to prevent increased aggression, stress and fear. 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 (Algers and Jensen, 1991; Parker et al, 2010).

Animal-based criteria (or measurables): behaviour (e.g. fleeing and abnormal or excessive vocalisation), physical appearance (e.g. injuries), reproductive efficiency, changes in body weight and body condition.

Article 7.X.18.

**Lighting**

Indoor systems should have light levels sufficient to allow all pigs to see one another, to investigate their surroundings visually and to show other normal behaviour patterns and to be seen clearly by staff to allow adequate inspection of the pigs. The lighting regime should be such as to prevent health and behavioural problems. It should follow a 24-hour rhythm and include sufficient uninterrupted dark and light periods, preferably no less than 6 hours for both.

Artificial light sources should be located so as not to cause discomfort to the pigs.

Animal-based criteria (or measurables): behaviour (locomotive behaviour), morbidity rate, reproductive efficiency, physical appearance (injuries) and changes in body weight and body condition.

Article 7.X.19.

**Farrowing and lactation**

Sows and gilts need time to adjust to their farrowing accommodation before farrowing. Nesting material should be available to sows and gilts where possible for at least one day prior to farrowing (Yun *et al.*, 2014; Lawrence *et al.*, 1994; Jarvis *et al.*, 1998). Sows and gilts should be observed frequently around their expected farrowing times. As some sows and gilts need assistance during farrowing, there should be sufficient space and competent staff.

Farrowing accommodation should also provide comfort, warmth and protection to the piglets.

Animal-based criteria (or measurables): mortality and culling rates (piglets; gilts and sows), morbidity rates (metritis and mastitis), behaviour (restlessness and savaging), reproductive efficiency, physical appearance (injuries).

Article 7.X.20.

**Weaning**

Weaning is a stressful time for sows and piglets and good management is required. Problems associated with weaning are generally related to the piglets' size and physiological maturity.

Weaned piglets should be moved into clean and disinfected housing separate from where sows are kept, in order to minimise the transmission of diseases to the piglets.

Piglets should be weaned at three weeks or older, unless otherwise recommended by a *veterinarian* for disease control purposes (Hameister *et al.*, 2010; Smith *et al.*, 2010; Gonyou *et al.*, 1998; Worobec *et al.*, 1999). Early weaning systems require good management and nutrition of the piglets.

Delaying weaning to the age of four weeks or more may produce benefits such as improved gut immunity, less

diarrhoea and less use of *antimicrobial agents* (EFSA, 2007; Hameister *et al.*, 2010; McLamb *et al.*, 2013; Smith *et al.*, 2010; Gonyou *et al.*, 1998, Bailey *et al.*, 2001).

Regardless of age, low weight piglets require additional care and can benefit from being kept in small groups in specialised pens until they are able to be moved to the common nursery area.

Newly weaned pigs are susceptible to disease challenges, so adherence to high-level hygiene protocols and appropriate diet is important. The area that piglets are weaned into should be clean, dry and warm.

All newly weaned pigs should be monitored carefully during the first two weeks after weaning for any signs of ill-health or abnormal stress.

Animal-based criteria (or measurables): mortality and culling rates (piglets), morbidity rates (respiratory disease, diarrhoea), behaviour (belly nosing and ear sucking), physical appearance (injuries) and changes in body weight and body condition.

Article 7.X.21.

**Mixing**

Mixing of unfamiliar pigs can result in fighting to establish a dominance hierarchy, and therefore mixing should be minimised as much as possible (Moore *et al.*, 1994; Fabrega *et al.*, 2013). When mixing, strategies to reduce aggression should be implemented. Animals should be observed after mixing and interventions applied if the aggression is intense or prolonged~~, and pigs becoming injured~~ to minimise stress and injury.

Measures to prevent excessive fighting and injuries can include (Arey and Edwards, 1998; Verdon *et al.*, 2015):

– providing additional space and a non-slippery floor,

– feeding before mixing,

– feeding on the floor in the mixing area,

– providing straw or other suitable enrichment materials in the mixing area,

– providing opportunities to escape and to hide from other pigs, such as visual barriers,

– mixing previously familiarised animals whenever possible,

– mixing young animals as soon after weaning as possible,

– avoiding the addition of one or small number of animals to a large established group.

Animal-based criteria (or measurables): mortality, morbidity and culling rates, behaviour (agonistic), physical appearance (injuries), changes in body weight and body condition and reproductive efficiency.

Article 7.X.22.

**Genetic selection**

Welfare and health considerations should balance any decisions on productivity and growth rate when choosing a breed or ~~hybrid~~ crossbreed for a particular location or production system.

Selective breeding can improve the welfare of pigs for example by selection to improve maternal behaviour, piglet viability, temperament and resistance to stress and disease and to reduce tail biting and aggressive behaviour (Turner *et al.*, 2006). Including genetic characteristics related to social behaviour ~~effects~~ into breeding programmes may also reduce negative social interactions and increase positive ones and may have major positive effects on group-housed animals (Rodenburg *et al.*, 2010; Rodenburg and Turner, 2012).

Animal-based criteria (or measurables): physical appearance, behaviour (e.g. maternal and agonistic behaviour), changes in body weight and body condition, handling response, reproductive efficiency, lameness, and morbidity, mortality and culling rates.

Article 7.X.23.

**Protection from predators and pests**

In outdoor and combination systems pigs should be protected from predators.

Where practicable, pigs should also be protected from pests such as excessive numbers of flies and mosquitoes.

Animal-based criteria (or measurables): morbidity, mortality and culling rates, behaviour, and physical appearance (injuries).

Article 7.X.24.

**Biosecurity and animal health**

1. Biosecurity and disease prevention

*Biosecurity plans* should be designed, implemented and maintained, commensurate with the best possible *herd* health status, available resources and infrastructure, and current disease risk and, for *listed diseases* in accordance with relevant recommendations in the *Terrestrial Code*.

These *biosecurity plans* should address the control of the major sources and pathways for spread of pathogenic agents including:

– introductions to the *herd*, especially from different sources,

– semen,

– other domestic animals, *wildlife* and pests,

– people, including sanitation practices,

– equipment, including *vehicles*, tools and facilities,

– air, water, *feed* and bedding,

– waste, including manure garbage and disposal of dead animals,

Animal -based criteria (or measurables): morbidity, mortality and culling rates, reproductive efficiency, changes in weight and body condition, physical appearance (signs of disease).

*a)* Animal health management

*Animal health management* should optimise the welfare and health of pigs in the *herd*. It includes the prevention, treatment and control of diseases and conditions affecting the *herd* (in particular respiratory, reproductive and enteric diseases).

There should be an effective programme for the prevention and treatment of *diseases* and conditions, formulated in consultation with a *veterinarian*. This programme should include *biosecurity* and quarantine protocols, the acclimatisation of replacements, *vaccinations*, and good colostrum management, the recording of production data (e.g. number of sows, piglets per sow per year, *feed* conversion, and body weight at weaning), morbidity, mortality and culling rate and medical treatments. It should be kept up to date by the *animal handler*. Regular monitoring of records aids management and quickly reveals problem areas for intervention.

For parasitic burdens (e.g. endoparasites, ectoparasites and protozoa) and insect and rodents control, a programme should be implemented to monitor, control and treat, as appropriate.

Lameness can be a problem in pigs. *Animal handlers* should monitor the state of feet and legs and take measures to prevent lameness and maintain foot and leg health.

Those responsible for the care of pigs should be aware of early specific signs of *disease*, pain, distress or suffering, such as coughing, abortion, diarrhoea, changes in locomotory behaviour or apathetic behaviour, and non-specific signs such as reduced *feed* and water intake, changes in weight and body condition, changes in behaviour or abnormal physical appearance.

Pigs at higher risk will require more frequent inspection by *animal handlers*. If *animal handlers* suspect the presence of a *disease* or are not able to correct the causes of *disease*, pain, distress or suffering, they should seek advice from those having training and experience, such as *veterinarians* or other qualified advisers, as appropriate.

Nonambulatory pigs should not be transported or moved unless absolutely necessary for treatment, recovery, or diagnosis. Such movements should be done carefully using methods that avoid dragging the animal or lifting it in a way that might cause further pain, suffering or exacerbate injuries.

*Animal handlers* should also be competent in assessing fitness to transport, as described in Chapter 7.3.

In case of disease or injury, when treatment has failed, is not feasible or recovery is unlikely (e.g. pigs that are unable to stand up unaided or refuse to eat or drink), or severe pain that cannot be alleviated the animal should be humanely killed as soon as possible in accordance with Chapter 7.6.

Animal-based criteria (or measurables): morbidity, mortality and culling rates, reproductive efficiency, behaviour (apathetic behaviour), lameness, physical appearance (injuries) and changes in body weight and body condition.

*b)* Emergency plans for disease outbreaks

Emergency plans should cover the management of the farm in the event of a disease *outbreak*, consistent with national programmes and recommendations of *Veterinary Services* as appropriate.

Article 7.X.25.

**Contingency plans**

Where the failure of power, water or *feed* supply systems could compromise *animal welfare,* pig producers should have contingency plans in place. These plans may include the provision of fail-safe alarms to detect malfunctions, back-up generators, contact information for key service providers, ability to store water on farm, access to water cartage services, adequate on-farm storage of *feed* and an alternative *feed* supply.

Preventive measures for emergencies should be input-based rather than outcome-based. ~~Contingency plans should be documented and communicated to all responsible parties.~~ Alarms and back-up systems should be checked regularly.

Contingency plans should be documented and communicated to all responsible parties.

Article 7.X.26.

**Disaster management**

Plans should be in place to minimise and mitigate the effect of disasters (e.g. earthquake, fire, flooding, blizzard and hurricane). Such plans may include evacuation procedures, identifying high ground, maintaining emergency *feed* and water stores, destocking and humane *killing* when necessary.

Procedures for humane *killing* of sick or injured pigs should be part of the disaster management plan and should follow the recommendations of Chapter 7.6. of the *Terrestrial Code*.

Reference to contingency plans can also be found in Article 7.X.25.

Article 7.X.27.

**Humane killing**

Allowing a sick or injured animal to linger unnecessarily is unacceptable. Therefore, for sick and injured pigs a prompt diagnosis should be made to determine whether the animal should be treated or humanely killed.

The decision to kill an animal humanely and the procedure itself should be undertaken by a competent person.

For a description of acceptable methods for humane *killing* of pigs see Chapter 7.6.

The *establishment* should have documented procedures and the necessary equipment for on-farm humane *killing*. Staff should be trained in humane *killing* procedures appropriate for each class of pig.

Reasons for humane *killing* may include:

– severe emaciation, weak pigs that are nonambulatory or at risk of becoming nonambulatory,

– severely injured or nonambulatory pigs that will not stand up, refuse to eat or drink, or have not responded to treatment,

– rapid deterioration of a medical condition for which treatment has been unsuccessful,
– severe pain that cannot be alleviated,
– multiple joint *infections* with chronic weight loss,
– piglets that are premature and unlikely to survive, or have a debilitating congenital defect, and
– as part of disaster management response.

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Annex 19

# CHAPTER 8.3.

# INFECTION WITH BLUETONGUE VIRUS

**EU position**

**The EU in general supports the adoption of this modified chapter.**

**A comments is inserted in the text below.**



## Article 8.3.1.

**General provisions**

For the purposes of the *Terrestrial Code*, bluetongue is defined as an *infection* of ruminants and camelids with bluetongue virus (BTV) that is transmitted by *Culicoides vectors*.

The following defines the occurrence of *infection* with BTV:

1) BTV has been isolated from a sample from a ruminant or camelid or a product derived from that ruminant or camelid, or

2) antigen or ribonucleic acid specific to BTV has been identified in a sample~~s~~ from a ruminant or camelid showing clinical signs consistent with bluetongue, or epidemiologically linked to a suspected or confirmed *case*, or

3) antigen or ribonucleic acid specific to a BTV live vaccine strain has been identified in a sample from a ruminant or camelid that is unvaccinated, or has been vaccinated with an inactivated vaccine, or with a different live vaccine strain, showing clinical signs consistent with bluetongue, or epidemiologically linked to a suspected or confirmed *case,* or

4~~3~~) antibodies to structural or nonstructural proteins of BTV that are not a consequence of *vaccination* have been identified in a sample from a ruminant or camelid that either shows clinical signs consistent with bluetongue, or is epidemiologically linked to a suspected or confirmed *case*.

For the purposes of the *Terrestrial Code*, the *infective period* for bluetongue shall be 60 days.

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

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BTV status of the ruminant and camelid populations of the *exporting country* or *zone*.

## Article 8.3.2.

**Safe commodities**

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any bluetongue-related conditions regardless of the bluetongue status of the *exporting country*:

1) *milk* and *milk products*;

2) *meat* and *meat products*;

3) hides and skins;

4) wool and fibre;

5) *in vivo* derived bovine embryos collected, processed and stored in accordance with Chapter 4.7.

Article 8.3.3.

**Country or zone free from bluetongue**

1) Historical freedom as described in Chapter 1.4. does not apply to bluetongue.

2) A country or a *zone* may be considered free from bluetongue when *infection* with BTV is notifiable in the entire country and either:

   *a)* a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17. has demonstrated no evidence of *infection* with BTV in the country or *zone* during the past two years; or

   *b)* an ongoing *surveillance* programme has found no *Culicoides* for at least two years in the country or *zone*.

3) A country or *zone* free from bluetongue in which ongoing *vector surveillance*, performed in accordance with point 5 of Article 8.3.16., has found no *Culicoides* will not lose its free status through the introduction of vaccinated, seropositive or infective ruminants or camelids, or their semen or embryos from *infected* countries or ~~infected~~ *zones*.

4) A country or *zone* free from bluetongue in which *surveillance* has found evidence that *Culicoides* are present will not lose its free status through the introduction of seropositive or vaccinated ruminants or camelids, or semen or embryos from infected countries *or ~~infected~~ zones*, provided:

   *a)* an ongoing *surveillance* programme focused on transmission of BTV and a consideration of the epidemiology of *infection* with BTV, in accordance with Articles 8.3.14. to 8.3.17. and Chapter 4.3., has demonstrated no evidence of transmission of BTV in the country or *zone*; or

   *b)* the ruminants or camelids, their semen and embryos were introduced in accordance with this chapter.

5) A country or *zone* free from bluetongue adjacent to an infected country or ~~infected~~ *zone* should include a *zone* in which *surveillance* is conducted in accordance with Articles 8.3.14. to 8.3.17.

Article 8.3.4.

**Country or zone seasonally free from bluetongue**

1) A country or *zone* seasonally free from bluetongue is, respectively, an infected country or a part of an infected country or ~~an *infected* zone~~, for which *surveillance* conducted in accordance with Articles 8.3.14. to 8.3.17. demonstrates no evidence either of transmission of BTV or of adult *Culicoides* for part of a year.

2) For the application of Articles 8.3.7., 8.3.9. and 8.3.11., the ~~seasonally~~ free ~~period~~ season is taken to commence the day following the last evidence of transmission of BTV (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides*.

3) For the application of Articles 8.3.7., 8.3.9. and 8.3.11., the ~~seasonally~~ free ~~period~~ season is taken to conclude either:

   *a*~~1~~) at least 28 days before the earliest date that historical data show transmission of BTV may recommence; or

   *b*~~2~~) immediately if current climatic data or data from a *surveillance* programme indicate transmission of BTV or an earlier resurgence of activity of adult *Culicoides*.

4) A seasonally free *zone* in which ongoing *surveillance* has found no evidence that *Culicoides* are present will not lose its free status through the introduction of vaccinated, seropositive or infective ruminants or camelids, or semen or embryos from infected countries or ~~*infected*~~ *zones*.

Annex 19 (contd)

Article 8.3.5.

**Country or zone infected with BTV**

For the purposes of this chapter, a country or *zone* infected with BTV is one that does not fulfil the requirements to qualify as either free or seasonally free from bluetongue.

Article 8.3.6.

**Recommendations for importation from countries or zones free from bluetongue**

For ruminants and camelids

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

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

AND

2) the animals were kept in a country or *zone* free from bluetongue since birth or for at least 60 days prior to shipment; or

3) the animals were kept in a country or *zone* free from bluetongue for at least 28 days, then were subjected, with negative results, to a serological test to detect antibodies to the BTV group and remained in the free country or *zone* until shipment; or

4) the animals were kept in a ~~free~~ country or *zone* free from bluetongue for at least 14 days, then were subjected, with negative results, to an agent identification test, and remained in the free country or *zone* until shipment; or

5) the animals:

   ~~*a) were kept in a country or zone free from bluetongue for at least seven days;*~~

   *a~~b~~)* were vaccinated, at least 60 days before the introduction into the free country or *zone*, from which they are to be exported, against all serotypes demonstrated to be present in the source population through a *surveillance* programme as described in Articles 8.3.14. to 8.3.17.;

   *b~~c~~)* were identified as having been vaccinated;

   *c~~d~~)* remained in the free country or *zone* for at least seven days until shipment;

AND

6) if the animals were exported from a free *zone* within an infected country, either:

   *a)* did not transit through an infected *zone* during transportation to the *place of shipment*; or

   *b)* were protected from attacks from *Culicoides* in accordance with point 2 of Article 8.3.13. at all times when transiting through an infected zone; or

   *c)* had been vaccinated in accordance with point 5 above.

Annex 19 (contd)

Article 8.3.7.

**Recommendations for importation from countries or zones seasonally free from bluetongue**

For ruminants and camelids

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

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

AND

2) were kept during the ~~seasonally~~ free ~~period~~ season in a seasonally free country or *zone* since birth or for at least 60 days prior to shipment; or

3) were kept during the ~~seasonally~~ free ~~period~~ season in a seasonally free country or *zone* for at least 28 days prior to shipment, and were subjected during that ~~the~~ residence period ~~in the *zone*~~ to a serological test to detect antibodies to the BTV group, with negative results, carried out at least 28 days after the commencement of the residence period; or

4) were kept during the ~~seasonally~~ free ~~period~~ season in a seasonally free country or *zone* for at least 14 days prior to shipment, and were subjected during that ~~the~~ residence period ~~in the *zone*~~ to an agent identification test, with negative results, carried out at least 14 days after the commencement of the residence period; or

5) were:

   *a)* ~~were kept during the seasonally free period in a seasonally free *zone* and were~~ vaccinated, at least 60 days before ~~the introduction into the free country or *zone*~~ shipment, against all serotypes demonstrated to be present in the source population through a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17.; ~~and~~

   *b)* ~~were~~ identified as having been vaccinated; ~~and~~

   *c)* kept during the free season ~~remained~~ in the seasonally free ~~country or~~ *zone* for at least seven days and until shipment;

**EU comment**

**For reasons of consistency, the words "country or" should not be deleted in point c) above. Indeed, the entire article refers to "country or zone seasonally free", so it is unclear why point c) would not also apply to the entire country.**

**Furthermore, for reasons of clarity, a comma should be inserted before "and before shipment".**

AND

6) either:

   *a)* did not transit through an infected *zone* during transportation to the *place of shipment*; or

   *b)* were protected from attacks from *Culicoides* in accordance with point 2 of Article 8.3.13. at all times when transiting through an *infected zone*; or

   *c)* were vaccinated in accordance with point 5 above.

Article 8.3.8.

**Recommendations for importation from countries or zones infected with BTV**

For ruminants and camelids

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

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

AND

2) were protected from attacks from *Culicoides* in accordance with Article 8.3.13. in a *vector*-protected *establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or

3) were protected from attacks from *Culicoides* in accordance with Article 8.3.13. in a *vector*-protected *establishment* for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test to detect antibodies to the BTV group, with negative results, carried out at least 28 days after introduction into the *vector*-protected *establishment*; or

4) were protected from attacks from *Culicoides* in accordance with Article 8.3.13. in a *vector*-protected *establishment* for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test, with negative results, carried out at least 14 days after introduction into the *vector*-protected *establishment*; or

5) were:

   *a)* vaccinated, at least 60 days before shipment, against all serotypes demonstrated to be present in the source population through a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17.;

   *b)* identified as having been vaccinated; or

6) were demonstrated to have antibodies for at least 60 days prior to ~~dispatch~~ shipment, against all serotypes demonstrated to be present in the source population through a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17.

Article 8.3.9.

**Recommendations for importation from countries or zones free or ~~zones~~ seasonally free from bluetongue**

For semen of ruminants and camelids

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

1) the donor males:

   *a)* showed no clinical sign of bluetongue on the day of collection~~;~~ and

   ~~*b)*~~ were kept in a country or *zone* free from bluetongue or in a seasonally free country or *zone* during the ~~seasonally~~ free season ~~period~~ for at least 60 days before commencement of, and during, collection of the semen; or

   *b~~c~~)* comply with point 1 of Article 8.3.10.;~~were subjected to a serological test to detect antibodies to the BTV group, with negative results, between 28 and 60 days after the last collection for this consignment, and, in case of a seasonally free *zone*, at least every 60 days throughout the collection period; or~~

   ~~*d)* were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;~~

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

Article 8.3.10.

**Recommendations for importation from countries or zones infected with BTV**

For semen of ruminants and camelids

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

1) the donor males:

*a)* showed no clinical sign of bluetongue on the day of collection;

AND

*b)* were kept in a *vector*-protected *establishment* in accordance with point 1 of Article 8.3.13. for at least 60 days before commencement of, and during, collection of the semen; or

c) were subjected to a serological test to detect antibodies to the BTV group, with negative results~~, at least every 60 days throughout the collection period and~~ between 28 and 60 days after ~~the final~~ each collection for this consignment; or

*d)* were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every ~~7~~ seven days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

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

Article 8.3.11.

**Recommendations for importation from countries or zones free or ~~zones~~ seasonally free from bluetongue**

For *in vivo* derived embryos of ruminants (other than bovine embryos) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

1) the donor females:

*a)* showed no clinical sign of bluetongue on the day of collection; and

~~*b)*~~ were kept in a country or *zone* free from bluetongue or in a seasonally free country or zone during the ~~seasonally~~ free ~~period~~ season for at least the 60 days prior to, and at the time of, collection of the embryos; or

*b)* comply with point 1 of Article 8.3.12.*:*

~~*c)* were subjected to a serological test to detect antibodies to the BTV group, between 28 and 60 days after collection, with negative results; or~~

~~*d)* were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;~~

2) the embryos were collected, processed and stored in accordance with Chapters 4.7., 4.8. and 4.9., as relevant.

3) the semen used to fertilise the oocytes complied with Article 8.3.9. or Article 8.3.10.

Article 8.3.12.

**Recommendations for importation from countries or zones infected with BTV**

For *in vivo* derived embryos of ruminants (other than bovine embryos) and other BTV susceptible animals and for *in vitro* produced bovine embryos

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

1) the donor females:

   *a)* showed no clinical sign of bluetongue on the day of collection;

   AND

   *b)* were kept in a *vector*-protected *establishment* in accordance with point 1 of Article 8.3.13. for at least 60 days before commencement of, and during, collection of the embryos; or

   *c)* were subjected to a serological test to detect antibodies to the BTV group, between 28 and 60 days after collection, with negative results; or

   *d)* were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;

2) the embryos were collected, processed and stored in accordance with Chapters 4.7., 4.8. and 4.9., as relevant;

3) the semen used to fertilise the oocytes complied with Article 8.3.9. or Article 8.3.10.

Article 8.3.13.

**Protecting animals from *Culicoides* attacks**

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, such as double-door entry-exit system;

   *b)* openings of the building are *vector* screened with mesh of appropriate gauge impregnated regularly with an approved insecticide in accordance with manufacturers' instructions;

   *c)* *vector surveillance* and control within and around the building;

   *d)* measures to limit or eliminate breeding sites for *vectors* in the vicinity of the *establishment* or facility;

   *e)* standard operating procedures, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of animals to the place of *loading*.

2. During transportation

   When transporting animals through infected countries or *zones*, *Veterinary Authorities* should require strategies to protect animals from attacks from *Culicoides* during transport, taking into account the local ecology of the *vector*.

Annex 19 (contd)

*a)* Transport by road

*Risk management* strategies may include:

*i)* treating animals with insect repellents prior to and during transportation;

*ii)* *loading*, transporting and *unloading* animals at times of low *vector* activity (i.e. bright sunshine, 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)* *surveillance* for *vectors* at common stopping and *unloading* points to gain information on seasonal variations;

*vi)* using historical information or information from appropriately verified and validated bluetongue epidemiological models to identify low risk ports and transport routes.

*b)* Transport by air

Prior to *loading* the animals, the crates, containers or jet stalls should be sprayed with an insecticide approved in the country of dispatch.

Crates, containers or jet stalls in which animals are being transported and the cargo hold of the aircraft should be sprayed with an approved insecticide when the doors have been closed and prior to take-off. 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 from bluetongue, prior to the opening of any aircraft door and until all doors are closed, netting of appropriate gauge impregnated with an approved insecticide should be placed over crates, containers or jet stalls.

Article 8.3.14.

**Introduction to surveillance**

Articles 8.3.14. to 8.3.17. define the principles and provide guidance on *surveillance* for *infection* with BTV, complementary to Chapter 1.4. and for *vectors* complementary to Chapter 1.5.

Bluetongue is a *vector*-borne *infection* transmitted by various species of *Culicoides* in a range of ecosystems.

The purpose of *surveillance* is the detection of transmission of BTV in a country or *zone* and not determination of the status of an individual animal or *herds*. *Surveillance* deals with the evidence of *infection* with BTV in the presence or absence of clinical signs.

An important component of the epidemiology of bluetongue is the capacity of its *vector*, which provides a measure of disease *risk* that incorporates *vector* competence, abundance, biting rates, survival rates and extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context. Therefore, *surveillance* for bluetongue should focus on transmission of BTV in domestic ruminants and camelids.

The impact and epidemiology of bluetongue widely differ in different regions of the world and therefore it is not appropriate to provide specific recommendations for all situations. Member Countries should provide scientific data that explain the epidemiology of bluetongue in the country or *zone* concerned and adapt the *surveillance* strategies for defining their status to the local conditions. There is considerable latitude available to Member Countries to justify their status at an acceptable level of confidence.

*Surveillance* for bluetongue should be in the form of a continuing programme.

Article 8.3.15.

**General conditions and methods for surveillance**

1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:

   *a)* a formal and ongoing system for detecting and investigating *outbreaks* of disease should be in place;

   *b)* a procedure should be in place for the rapid collection and transport of samples from suspected *cases* of *infection* with BTV to a *laboratory* for diagnosis;

   *c)* a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

2) The bluetongue *surveillance* programme should:

   *a)* in a free country or *zone* or seasonally free *zone*, have an early warning system which obliges farmers and workers, who have regular contact with domestic ruminants, as well as diagnosticians, to report promptly any suspicion of bluetongue to the *Veterinary Authority*.

   An effective *surveillance* system will periodically identify suspected *cases* that require follow-up and investigation to confirm or exclude whether the cause of the condition is bluetongue. The rate at which such suspected *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected *cases* of bluetongue should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment be available for those responsible for *surveillance*;

   AND

   *b)* conduct random or targeted serological and virological *surveillance* appropriate to the status of the country or *zone*.

Article 8.3.16.

**Surveillance strategies**

The target population for *surveillance* aimed at identification of *disease* or *infection* should cover susceptible domestic ruminants and camelids, and other susceptible herbivores of epidemiological significance within the country or *zone*. Active and passive *surveillance* for bluetongue should be ongoing as epidemiologically appropriate. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the status of the country or *zone*.

It may be appropriate to focus *surveillance* in an area adjacent to a border of an infected country or ~~*infected*~~ *zone* for up to 100 kilometres, taking into account relevant ecological or geographical features likely to interrupt the transmission of BTV or the presence in the bordering infected country or ~~*infected*~~ *zone* of a bluetongue *surveillance* programme (in accordance with Articles 8.3.14. to 8.3.17.) that supports a lesser distance.

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with BTV in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. sheep).

Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. bovines ~~cattle~~).

Annex 19 (contd)

In vaccinated populations, serological and virological *surveillance* is necessary to detect the BTV serotypes circulating to ensure that all circulating serotypes are included in the *vaccination* programme.

If a Member Country wishes to declare freedom from bluetongue in a specific *zone*, the design of the *surveillance* strategy should be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy should incorporate epidemiologically appropriate design prevalence. The sample size selected for testing should be large enough to detect evidence of *infection* if it were to occur at a predetermined minimum rate. The sample size and expected prevalence determine the level of confidence in the results of the survey. The Member 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 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 should be an effective procedure for following up positive

reactions to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles involved in *surveillance* for disease or *infection* are technically well defined. The design of *surveillance* programmes to prove the absence of *infection* with and transmission of, BTV should be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated.

1. Clinical surveillance

   Clinical *surveillance* aims to detect clinical signs of bluetongue at the *flock* or *herd* level, particularly during a newly introduced *infection*. In sheep and occasionally goats, clinical signs may include oedema, hyperaemia of mucosal membranes, coronitis and cyanotic tongue.

   Suspected *cases* of bluetongue detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

2. Serological surveillance

   An active programme of *surveillance* of host populations to detect evidence of transmission of BTV is essential to establish the bluetongue status of a country or *zone*. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested should reflect the epidemiology of bluetongue. Bovines ~~Cattle~~ are usually the most sensitive indicator species. Management variables that may influence likelihood of *infection*, such as the use of insecticides and animal housing, should be considered.

   Samples should be examined for antibodies against BTV. Positive test results can have four possible causes:

   *a)* natural *infection*,

   *b)* *vaccination*,

   *c)* maternal antibodies,

   *d)* the lack of specificity of the test.

It may be possible to use sera collected for other survey purposes for bluetongue *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of *infection* with BTV should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no *infection* with BTV 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 transmission of BTV, 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 bluetongue, either random or targeted sampling is suitable to select *herds* or animals for testing.

Serological *surveillance* in *infected zones* will identify changes in the boundary of the *zone*, and can also be used to identify the BTV types circulating. In view of the epidemiology of bluetongue, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis of BTV from a proportion of infected animals provides information on serotype and genetic characteristics of the viruses concerned.

Virological *surveillance* can be conducted:

*a)* to identify virus 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 are the preferred strategy for bluetongue *surveillance*. They comprise groups of unexposed animals that have not been vaccinated and are managed at fixed locations and sampled regularly to detect new *infections* with BTV.

The primary purpose of a sentinel animal programme is to detect *infections* with BTV occurring at a particular place, for instance sentinel groups may be located on the usual boundaries of *infected zones* to detect changes in distribution of BTV. In addition, sentinel animal programmes allow the timing and dynamics of *infections* to be observed.

A sentinel animal programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of bluetongue 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 transmission of BTV at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid bias, sentinel groups should comprise animals selected to be of similar age and susceptibility to *infection* with BTV. Bovines ~~Cattle~~ are the most appropriate sentinels but other domestic ruminant species may be used. The only feature distinguishing groups of sentinels should be their geographical location.

Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

Annex 19 (contd)

The frequency of sampling will depend on the reason for choosing the sampling site. In endemic areas, virus isolation will allow monitoring of the serotypes and genotypes of BTV circulating during each time period. The borders between infected and uninfected areas can be defined by serological detection of *infective period*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that *infection* with BTV is not occurring unobserved. In such cases, sampling prior to and after the possible period of transmission is sufficient.

Definitive information on the presence of BTV in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required, sentinels should be sampled at sufficiently frequent intervals to ensure that samples are collected during the period of viraemia.

5. Vector surveillance

BTV is transmitted between ruminant hosts by species of *Culicoides* which vary around 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* aims to demonstrate the absence of *vectors* or to determine areas of different levels of *risk* and local details of seasonality by determining the various *vector* species present in an area, their respective seasonal occurrence, and abundance. *Vector surveillance* has particular relevance to potential areas of spread.

Long term *surveillance* can also be used to assess *vector* 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 domestic ruminants, or the use of drop traps over ruminants.

*Vector surveillance* should be based on scientific sampling techniques. The choice of the number and type of traps to be used and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of *vector surveillance* sites at the same locations as sentinel animals is advisable.

The use of a *vector surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low *vector infection* rates mean that such detections can be rare.

Animal-based *surveillance* strategies are preferred to detect virus transmission.

Article 8.3.17.

**Documentation of bluetongue free status**

1. Additional surveillance requirements for Member Countries declaring freedom from bluetongue

In addition to the general requirements described above, a Member Country declaring freedom from bluetongue 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 in accordance with general conditions and methods described in this chapter, to demonstrate absence of *infection* with BTV during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a *laboratory* able to undertake identification of *infection* with BTV through virus detection and antibody tests. This *surveillance* should be targeted to unvaccinated animals. Clinical *surveillance* may be effective in sheep while serological *surveillance* is more appropriate in bovines ~~cattle~~.

2. Additional requirements for countries or zones that practise vaccination

*Vaccination* to prevent the transmission of BTV may be part of a disease control programme. The level of *flock* or *herd* immunity required to prevent transmission will depend on the *flock* or *herd* size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. The vaccine should also comply with the provisions stipulated for BTV vaccines in the *Terrestrial Manual*. Based on the epidemiology of bluetongue in the country or *zone*, it may be decided to vaccinate only certain species or other *subpopulations*.

In countries or *zones* that practise *vaccination*, virological and serological tests should be carried out to ensure the absence of virus transmission. These tests should be performed on unvaccinated *subpopulations* or on sentinels. The tests should be repeated at appropriate intervals in accordance with the purpose of the *surveillance* programme. For example, longer intervals may be adequate to confirm endemicity, while shorter intervals may allow on-going demonstration of absence of transmission.

Annex 20

CHAPTER 8.4.

# INFECTION WITH *BRUCELLA ABORTUS*, *B. MELITENSIS* AND *B.SUIS*

[…]

**EU position**

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

Article 8.4.10.

**Herd or flock free from infection with *Brucella* in bovids, sheep and goats, camelids or cervids without vaccination**

1) To qualify as free from *infection* with *Brucella* without *vaccination*, a *herd* or *flock* of 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 *infection* with *Brucella* without *vaccination* in 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 *infection* with *Brucella* with *vaccination* in 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)* *infection* with *Brucella* in animals is a *notifiable disease* in the entire country;

*ii)* no animal of the relevant category of the *herd* or *flock* has been vaccinated in the past three years;

*iii)* no *case* has been detected in the *herd* or *flock* for at least the past year;

*iv)* animals showing clinical signs consistent with *infection* with *Brucella* such as abortions have been subjected to the necessary diagnostic tests with negative results;

*v)* for at least the past year, there has been no evidence of *infection* with *Brucella* in other *herds* or *flocks* of the same *establishment*, or measures have been implemented to prevent any transmission of the *infection* with *Brucella* from these other *herds* or *flocks*;

*vi)* two tests have been performed with negative results on all sexually mature animals, i.e. except castrated males and spayed females, present in the *herd* at the time of testing, 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 ~~6~~ six and less than 12 months.

Annex 20 (contd)

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;

*b)* regular tests, at a frequency depending on the prevalence of *herd* or *flock infection* in the country or *zone*, demonstrate the continuing absence of *infection* with *Brucella*;

*c)* animals of the relevant category introduced into the *herd* or *flock* are accompanied by a certificate from an *Official Veterinarian* attesting that they come from:

*i)* a country or *zone* free from *infection* with *Brucella* in the relevant category without *vaccination*;

OR

*ii)* a country or *zone* free from *infection* with *Brucella* with *vaccination* and the animals of the relevant category have not been vaccinated in the past three years;

OR

*iii)* a *herd* or *flock* free from *infection* with *Brucella* with or without *vaccination* and that the animals have not been vaccinated in the past three years and were tested for *infection* with *Brucella* within 30 days prior to shipment with negative results; in the case of post-parturient females, the test is carried out at least 30 days after giving birth. This test is not required for sexually immature animals including castrated males and spayed females.

[…]

Annex 21

CHAPTER 8.16.

# INFECTION WITH RINDERPEST VIRUS

**EU position**

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

[…]

Article 8.16.2.

**Definitions and general provisions**

For the purpose of the *Terrestrial Code*:

1) RPV-containing material as referred to in Article 8.16.9., means field and laboratory strains of RPV; vaccine strains of RPV including valid and expired vaccine stocks; tissues, sera and other ~~clinical~~ ~~pathological~~ material from animals known or suspected to be infected; laboratory-generated ~~diagnostic~~ material containing ~~or encoding~~ live virus, recombinant morbilliviruses (segmented or nonsegmented) containing unique RPV nucleic acid or amino acid sequences, and full length genomic material including virus ~~ribonucleic acid (~~RNA~~)~~ and its cDNA copies ~~of virus RNA~~;

2) subgenomic fragments of RPV genome (either as plasmid or incorporated into recombinant viruses) ~~morbillivirus nucleic acid~~ that ~~are not capable of being~~ cannot be incorporated into ~~in~~ a replicating morbillivirus or morbillivirus-like virus are not considered ~~as~~ to be RPV-containing material~~;~~, neither are sera that have been either heat-treated to at least 56˚C for at least two hours, or shown to be free from RPV genome sequences by a validated RT-PCR assay;

3) a ban on *vaccination* against rinderpest means a ban on administering any vaccine containing RPV or ~~RPV~~ any components derived from RPV to any *animal*;

4) the *incubation period* for rinderpest shall be 21 days;

5) a *case* is defined as an *animal* infected with RPV whether or not showing clinical signs; and

6) for the purpose of this chapter, 'susceptible *animals*' means domestic, *feral* and *wild* artiodactyls.

[…]

Annex 22

CHAPTER 11.9.

# INFECTION WITH LUMPY SKIN DISEASE VIRUS

**EU position**

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

[...]

Article 11.9.4.

**Recovery of free status**

1) When a *case* of LSD occurs in a country or *zone* previously free from LSD, one of the following waiting periods is applicable to regain free status:

*a)* when a *stamping-out policy* has been applied:

*i)* 14 months after the *slaughter* or *killing* of the last *case*, or after the last *vaccination* if emergency *vaccination* has been used, whichever occurred last, and during which period clinical, virological and serological *surveillance* ~~has been~~ conducted in accordance with Article 11.9.15. has demonstrated no occurrence of *infection* with LSDV;

*ii)* 26 months after the *slaughter* or *killing* of the last *case*, or after the last *vaccination* if emergency *vaccination* has been used, whichever occurred last, and during which period clinical *surveillance* alone ~~has been~~ conducted in accordance with Article 11.9.15. has demonstrated no occurrence of *infection* with LSDV;

*b)* when a *stamping-out policy* is not applied, Article 11.9.3. applies.

2) When preventive *vaccination* is conducted in a country or *zone* free from LSD, in response to a threat but without the occurrence of a *case* of LSD, free status may be regained eight months after the last *vaccination* when clinical, virological and serological *surveillance* ~~has been~~ conducted in accordance with Article 11.9.15. has demonstrated no occurrence of *infection* with LSDV.

Article 11.9.5.

**Recommendations for importation from countries or zones free from LSD**

For ~~domestic~~ bovines and water buffaloes

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

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

2) come from a country or *zone* free from LSD.

Article 11.9.6.

**Recommendations for importation from countries or zones not free from LSD**

For ~~domestic~~ bovines and water buffaloes

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

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

2) were kept since birth, or for the past 60 days prior to shipment, in an *epidemiological unit* where no *case* of LSD occurred during that period;

3) were vaccinated against LSD according to manufacturer's instructions between 60 days and one year prior to shipment;

4) were demonstrated to have antibodies at least 30 days after *vaccination*;

5) were kept in a *quarantine station* for the 28 days prior to shipment during which time they were subjected to an agent identification test with negative results.

[...]

Article 11.9.15.

**Surveillance**

1. General principles of surveillance

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with LSDV, even in the absence of clinical signs, given the prevailing epidemiological situation, in accordance with Chapter 1.4. and Chapter 1.5. and under the responsibility of the *Veterinary Authority*.

The *Veterinary Services* should implement programmes to raise awareness among farmers and workers who have day-to-day contact with livestock, as well as *veterinary paraprofessionals*, *veterinarians* and diagnosticians, who should report promptly any suspicion of LSD.

In particular Member Countries should have in place:

*a)* a formal and ongoing system for detecting and investigating *cases*;

*b)* a procedure for the rapid collection and transport of samples from suspected *cases* to a *laboratory* for diagnosis;

*c)* a system for recording, managing and analysing diagnostic and *surveillance* data.

2. Clinical surveillance

Clinical *surveillance* is essential for detecting cases of infection with LSDV and requires the physical examination of susceptible animals.

*Surveillance* based on clinical inspection provides a high level of confidence of detection of disease if a sufficient number of clinically susceptible animals is examined regularly at an appropriate frequency and investigations are recorded and quantified. Clinical examination and *laboratory* testing should be pre-planned and applied using appropriate types of samples to clarify the status of suspected *cases*.

3. Virological and serological surveillance

An active programme of *surveillance* of susceptible populations to detect evidence of *infection* with LSDV is useful to establish the status of a country or *zone*. Serological and molecular testing of bovines and water buffaloes may be used to detect presence of *infection* with LSDV in naturally infected animals.

The study population used for a serological survey should be representative of the population at risk in the country or *zone* and should be restricted to susceptible unvaccinated animals. Identification of vaccinated animals may minimise interference with serological *surveillance* and assist with recovery of free status.

4. Surveillance in high-risk areas

Disease-specific enhanced *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with an infected country or *zone*, based upon geography, climate, history of infection and other relevant factors. The *surveillance* should be carried out over a distance of at least 20 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 LSDV. A country or *zone* free from LSD may be protected from an adjacent infected country or *zone* by a *protection zone*.

Annex 23

CHAPTER 12.10.

# INFECTION WITH *BURKHOLDERIA MALLEI* (GLANDERS)

**EU position**

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

Article 12.10.1.

**General provisions**

~~Most glanders susceptible animals are equids.~~ Equids are the major hosts and reservoirs of glanders although ~~S~~scientific data are not available ~~for~~ on the occurrence of *infection* in zebras. Camelids, goats and various carnivores including bears, canids and felids can also be infected but play no significant ~~epidemiological~~ role in the epidemiology of the disease. Glanders in humans is a ~~significant and~~ rare but potentially fatal ~~zoonotic~~ disease ~~with fatal outcome if not treated in a timely manner~~.

For the purposes of the *Terrestrial Code*, glanders is defined as an *infection* of equids with *Burkholderia mallei* ~~in an equid~~ with or without the presence of clinical signs.

~~The chapter deals not only with the occurrence of clinical signs caused by *B. mallei*, but also with the presence of *infection* with *B. mallei* in the absence of clinical signs.~~

The following defines the occurrence of ~~an~~ *infection* with *B. mallei*:

1) *B. mallei* has been isolated from a sample from an equid; or

2) antigen or genetic material specific to *B. mallei* has been identified in a sample from an equid showing clinical or pathological signs consistent with glanders, or epidemiologically linked to a confirmed or suspected ~~*outbreak*~~ *case* of ~~glanders~~ *infection with B. mallei*, or giving cause for suspicion of previous contact with *B. mallei*; or

3) antibodies specific to *B. mallei* have been identified by a testing regime appropriate to the species in a sample from an equid showing clinical or pathological signs consistent with glanders, or epidemiologically linked to a confirmed or suspected ~~*outbreak*~~ *case* of ~~glanders~~ *infection with B. mallei*, or giving cause for suspicion of previous contact with *B. mallei.*

For the purposes of the *Terrestrial Code*, the *infective period* of *B. mallei* in equids is lifelong and the *incubation period* ~~is~~ shall be six months.

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

Article 12.10.2.

**Country or zone free from infection with *B. mallei* ~~infection~~**

A country or a *zone* that does not comply with the point 1 *a)* of Article 1.4.6. may be considered free from *infection* with *B. mallei* when:

1) ~~glanders~~ *infection* with *B. mallei* ~~is~~ has been a *notifiable disease* in the entire country for at least the past three years;

2) ~~either:~~

~~a)~~ there has been no *case* ~~*outbreak* and no evidence~~ of *infection* with *B. mallei* ~~in equids~~ during the past three years~~, following the destruction of the last *case*; or~~

3~~b~~) ~~no evidence of *infection* with *B. mallei* has been found during the past six months following the destruction of the last *case*; and there is~~ a *surveillance* programme ~~in place demonstrating the absence of *infection*~~ in accordance with Article 12.10.8. has demonstrated no evidence of *infection* with *B. mallei* in the past 12 months;

~~AND~~

4~~3~~) imports of equids and their germplasm into the country or *zone* are carried out in accordance with this chapter.

Article 12.10.3.

**Recovery of free status**

When a *case* is detected in a previously free country or *zone*, freedom from *infection* with *B. mallei* can be regained after the following:

1) a standstill of ~~movements of~~ equids and their germplasm from *establishments* affected or suspected of being affected has been imposed until the destruction of the last *case*;

2) an epidemiological investigation, including ~~(~~trace-back~~,~~ and trace-forward~~), including investigations~~ to determine the likely source of the *outbreak,* ~~have~~ has been carried out;

3) a *stamping-out policy,* which includes at least the destruction of all infected equids and ~~cleansing and~~ the *disinfection* of the affected *establishments,* has been applied;

4) ~~increased~~ *surveillance* in accordance with Article 12.10.8. has been carried out and has demonstrated ~~not detected any~~ no evidence of *infection* in the ~~six~~ 12 months after ~~*stamping-out*~~ *disinfection* of the last affected *establishment* and during that period measures have been in place to control the movement of equids.

~~5) measures are in place to control the movement of equids to prevent the spread of *B. mallei.*~~

When the measures above are not carried out, Article 12.10.2. applies.

Article 12.10.4.

**Recommendations for importation of equids from countries or zones free from infection with *B. mallei* ~~infection~~**

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

1) showed no clinical signs of ~~glanders~~ *infection* with *B. mallei* on the day of shipment;

2) either:

*a)* was kept for six months prior to shipment, or since birth, in a ~~the *exporting*~~ country or *zone* or countries or *zones* free from *infection* with *B. mallei*; or

*b)* if kept at any time in the past six months in a country or *zone* not free from *infection* with *B. mallei*, was imported in accordance with Article 12.10.5. into a country or *zone* free from *infection* with *B. mallei* ~~kept in an *establishment* in the *exporting country* for at least 30 days and was subjected to a prescribed test with negative result on a sample taken during the 10 days prior to shipment~~.

Article 12.10.5.

**Recommendations for importation of equids from countries or zones ~~considered infected~~ not free from infection with *B. mallei***

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

1) showed no clinical signs of ~~glanders~~ *infection* with *B. mallei* on the day of shipment;

2) was kept for six months prior to shipment, or since birth, in an *establishment* where no *case* of ~~glanders~~ *infection* with *B. mallei* was reported during the ~~six~~ 12 months prior to shipment;

3) was isolated for at least 30 days prior to shipment, and during that time was subjected to ~~two~~ a ~~prescribed~~ test~~s~~ for *infection* with *B. mallei*~~,~~ with negative result~~s~~ carried out on ~~a~~ two sample~~s~~ taken ~~during the~~ 21 to 30 days apart ~~with the second sample taken within 10 days prior to shipment~~.

Article 12.10.6.

**Recommendations for the importation of equine semen**

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

1) on the day of collection, the donor males ~~animals~~:

   *a)* showed no clinical signs of ~~glanders~~ *infection* with *B. mallei* ~~on the day of collection~~; ~~and for the following 21 days;~~

   *b)* were examined clinically for signs of orchitis and cutaneous lesions ~~of~~ on the penis or other parts of the body, with negative results; ~~were kept continuously:~~

      ~~*i)* either for a period of at least 21 days prior to, and for until at least 21 days after, the collection in a country or a *zone* free from *infection* with *B. mallei*, or~~

      ~~*ii)* for at least six months prior to the collection of the semen and during the collection in an *establishment* or *artificial insemination centre* free from *infection* with *B. mallei* and were subjected to a prescribed test, with a negative result on a sample taken between 21 and 30 days before the collection, or in the case of frozen semen between 21 and 30 days after the collection;~~

2) the semen was collected, processed and stored in accordance with the relevant recommendations in Chapter 4.5. and in Articles 4.6.5. to 4.6.7.

Article 12.10.7.

**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:

1) the donor females ~~animals:~~

   ~~*a)*~~ showed no clinical signs of ~~glanders~~ *infection* with *B. mallei* on the day of collection ~~and for the following 21 days~~;

Annex 23 (contd)

~~*b)* were kept continuously:~~

~~*i)* either for a period of at least 21 days before, and for until at least 21 days after, the day of collection of the embryos in a country or a *zone* free from *infection* with *B. mallei*, or~~

~~*ii)* for at least six months prior to the collection and during the collection in an *establishment* free from *infection* with *B. mallei* and were subjected to a prescribed test, with a negative result on a sample taken between 21 and 30 days before the collection, or in the case of frozen embryos, between 21 and 30 days after the collection;~~

2) the embryos were collected, processed and stored in accordance with the relevant recommendations in Chapters 4.7. and 4.9.~~, as relevant~~;

3) the semen used for embryo production ~~to fertilise the oocytes~~ complies with ~~the recommendations in~~ Article 12.10.6.

Article 12.10.8.

**General principles of surveillance**

~~The purpose of *surveillance* is to determine the status of a country or a *zone* with respect to *infection* with *B. mallei*.~~

~~Populations of *captive wild*, *feral* and *wild* equids should be included in the *surveillance* programme, for example through roadkill or population control measures.~~

~~Clinical *surveillance* aims at detecting signs of glanders by close physical examination of susceptible animals. Clinical inspection is an important component of *surveillance* contributing to the desired level of confidence of detection of *disease*, if a sufficiently large number of clinically susceptible animals is examined.~~

~~Systematic pathological *surveillance* is an effective approach for glanders and should be conducted on dead equids on farm, at *slaughterhouses/abattoirs* and establishments for the disposal of carcasses of equids. Suspicious pathological findings should be confirmed by agent identification and isolates should be typed.~~

~~When conducting serological *surveillance* repeated testing of the equine population is necessary to reach an acceptable level of confidence.~~

~~Clinical examination and laboratory testing should be applied to clarify the status of suspects detected by either of these complementary diagnostic approaches. Laboratory testing and necropsy may contribute to confirm clinical suspicion, while clinical examination may contribute to confirmation of positive serology.~~

This article and Article 12.10.9. provide recommendations for *surveillance* for *infection* with *B. mallei* and are complementary to Chapter 1.4. The impact and epidemiology of *infection* with *B. mallei* vary in different regions of the world. The *surveillance* strategies employed should be adapted to the respective epidemiological situation.

*Surveillance* should address not only the occurrence of clinical signs caused by *B. mallei*, but also evidence of *infection* with *B. mallei* in the absence of clinical signs.

The *surveillance* systems should be designed:

— to demonstrate that equine populations in a country or *zone* show no evidence of *infection* with *B. mallei;* or

— to detect its introduction into a free population; or

— if *B. mallei* is known to be present, to allow the estimation of the *prevalence* and the determination of the distribution of the *infection*.

The *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority* and should have in place:

*a)* a system for detecting and investigating *outbreaks* ~~of *disease*~~;

*b)* a procedure for the collection and transport of samples from suspected *cases* to a *laboratory* with appropriate testing capability for diagnosis of *infection* with *B. mallei*;

*c)* a system for recording, managing and analysing diagnostic, epidemiological and *surveillance* data;

*d)* a procedure for confirmation of inconclusive test~~s~~ results in an OIE Reference Laboratory.

Diagnosticians and those with regular contact with equids, including private *veterinarians*, *veterinary paraprofessionals* and *animal handlers* should report promptly any suspicion of *infection* with *B. mallei*. The reporting system efficacy should be enhanced by awareness programmes and *animal identification* of equids.

The *Veterinary Services* should implement, when relevant and ~~according to~~ taking into account the results of ~~former~~ previous *surveillance*, regular and frequent clinical inspections of equids and targeted serological surveys of high-risk *subpopulations* or those neighbouring a country or *zone* infected with *B. mallei*.

An effective *surveillance* system is likely to identify suspected *cases* that require follow-up investigation to confirm or exclude that the cause of the condition is *infection* with *B. mallei*. All suspected *cases* should be investigated ~~immediately~~ as soon as possible and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment be available to those responsible for the *surveillance*. Details of the occurrence of suspected *cases* and how they were investigated and dealt with should be documented. This should include the results of diagnostic testing and the control measures to which the equids concerned or affected *establishments* were subjected during the investigation (quarantine, movement control, euthanasia).

~~Susceptible *c*~~*Captive wild*, *feral* and *wild* equine *populations* should be included in the *surveillance*.

~~*Surveillance* should address not only the occurrence of clinical signs caused by *B. mallei*, but also evidence of *infection* with *B. mallei* in the absence of clinical signs.~~

Article 12.10.9.

**Surveillance strategies**

The strategy employed should be based on the current knowledge of the epidemiological situation, and the expected results of the *surveillance*, such as the demonstration of a supposed free status. The *populations* of equids subject to the *surveillance* can be covered by passive clinical *surveillance*, active investigation of suspected *cases*, or randomised or targeted sampling.

Because ~~*i*~~*infection* with *B. mallei* usually occurs at a very low *prevalence*, ~~and~~ randomised samples should be collected in high numbers. If an increased likelihood of *infection* in particular geographical locations or *subpopulations* can be identified, targeted sampling ~~is~~ may be more appropriate.

To substantiate freedom from *infection* in a country or *zone*, *surveillance* should be conducted in accordance with the relevant provisions of Article 1.4.6. The relatively high rate of occurrence of false positive reactions to tests for *B. mallei* should be considered and the rate at which these false positives are likely to occur should be calculated in advance. Every positive result should be investigated to determine whether it is indicative of *infection* or not. This involves supplementary tests, trace-back and trace-forward, and inspection of individual *animals* and *herds* for clinical signs.

Clinical or pathological *surveillance* and laboratory testing are complementary diagnostic approaches that should always be applied in series to clarify the status of suspected *cases*. Agent identification should be carried out on any equid serologically positive or showing clinical signs consistent with glanders. Any suspected *case* should be considered infected until contrary evidence is produced.

Annex 23 (contd)

1. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs by close physical examination of equids. However, systematic clinical *surveillance* is of limited use only, as asymptomatic carrier animals are the main reservoir of the disease.

2. Pathological surveillance

Systematic pathological *surveillance* is an effective approach for the detection of *infection* with *B. mallei* and should be conducted on dead equids on farms, at *slaughterhouses/abattoirs* and facilities for the disposal of carcasses of equids. Pathological findings indicating possible *infection* with *B. mallei* should be confirmed by agent identification and any isolates ~~s~~ should be characterised.

3. Serological surveillance

Serological *surveillance* for *infection* with *B. mallei* is the preferred strategy. *Animal identification* and repeated testing of the *population* are necessary to establish its *infection* status.

4. Malleinisation

Frequently used as a *surveillance* method, malleinisation demonstrates hypersensitivity to antigens of *B. mallei*. However, this method has shortcomings, such as low sensitivity, interference with other tests and *animal welfare* concerns.

Annex 24

CHAPTER 1.6.

# PROCEDURES FOR SELF-DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE

**EU position**

**The EU in general supports the adoption of this modified chapter.**

**Comments are inserted in the text below.**

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* or from other animal diseases. 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 from 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).

**EU comment**

**The EU suggests deleting the word "<u>from</u>" before the words "bovine spongiform encephalopathy" in the paragraph above, as that word seems to be superfluous.**

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 their *Veterinary Services* with 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 <u>or requesting endorsement by the OIE of an *official control programme*</u>, the Member Country should submit to the OIE Status Department a dossier providing the information requested <u>in the following Chapters</u> (as appropriate)<u>: 1.7., 1.8., 1.9., 1.10., 1.11. or 1.12.</u>~~in Articles 1.6.5. (for BSE), 1.6.6. (for FMD), 1.6.7. (for CBPP), 1.6.8. (for AHS), 1.6.9. (for PPR) or 1.6.10. (for CSF).~~

**EU comment**

**The EU suggests inserting back the parenthesis after the chapter numbers, as this improves clarity and readability, as follows:**

**"[...] in the following Chapters (as appropriate): 1.7. (for AHS), 1.8. (for BSE), 1.9. (for CSF), 1.10. (for CBPP), 1.11. (for FMD) or 1.12. (for PPR).".**

The OIE framework for the official recognition and maintenance of disease status is described in Resolution N° XV (administrative procedures) and Resolution N° XVI (financial obligations) adopted during the 83rd General Session in May 2015.

~~Article 1.6.2.~~

~~**Endorsement by the OIE of an official control programme for FMD**~~

~~Member Countries may wish to request an endorsement by the OIE of their *official control programme* for FMD.~~

~~When requesting endorsement by the OIE of an *official control programme* for FMD, the Member Country should submit to the OIE Status Department a dossier providing the information requested in Article 1.6.11.~~

~~Article 1.6.3.~~

~~**Endorsement by the OIE of an official control programme for PPR**~~

~~Member Countries may wish to request an endorsement by the OIE of their *official control programme* for PPR.~~

~~When requesting endorsement by the OIE of an *official control programme* for PPR, the Member Country should submit to the OIE Status Department a dossier providing the information requested in Article 1.6.12.~~

~~Article 1.6.4.~~

~~**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 Status Department a dossier providing the information requested in Article 1.6.13.~~

[…]

Annex 25

CHAPTER 1.7.

~~ARTICLE 6.8.~~

# APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF FREE STATUS FOR AFRICAN HORSE SICKNESS

**EU position**

**The EU in general supports the adoption of this new chapter.**

**However, we note some inconsistences in relation to the title of the chapter and the titles of the articles, as well as with relevant articles in the disease specific chapter. Indeed, whereas Chapter 12.1. refers to "AHS free country or zone" (cf. Art. 12.1.2.), Article 1.7.1. below refers to "country free from infection with African horse sickness (AHS) virus" (this is also used further down in the chapter). The title of this present chapter in turn refers to "free status for African horse sickness".**

**Despite the general definition of AHS in the first paragraph of Article 12.1.1., this leaves room for uncertainty and possible confusion (i.e. freedom only from [clinical] disease vs. freedom also from [subclinical] infection). We suggest avoiding these inconsistencies for the sake of clarity and legal certainty.**

**Please note that this general comment is valid also for draft Chapters 1.9., 1.10., 1.11. and 1.12.**

**Furthermore, we note that this draft chapter consists of only 2 articles, despite it being rather long (14 pages). What's more, the numbering used within these 2 articles is not entirely logic and makes it difficult to refer to individual recommendations (e.g. there are 2 paragraphs in each of these 2 articles that are not numbered and that start with "In addition, [...]" and are then followed by either a), b) c) or 1), 2), 3) etc.). The EU thus suggests reviewing the numbering throughout the text. (This comment is also valid for draft Chapters 1.9., 1.10., 1.11. and 1.12.)**

**Further comments are provided in the text below.**

~~Questionnaires on African horse sickness (AHS)~~

Article 1.7.1.

**Country free from infection with African horse sickness virus**

**EU comment**

**The title of this Article 1.7.1. does not seem very pertinent. Indeed, the content of the article describes the information to be provided to support applications for country free status, and not the country free status *per se* (which is covered in Article 12.1.2.). To avoid confusion with the latter article, we would suggest amending the title of the present article along the following lines:**

**"Dossier in support of applications for country free from [...]."**

**This comment is valid also for the title of Article 1.7.2.**

The following information should be provided by OIE Member Countries to support applications for official

recognition of status as a country free from infection with African horse sickness (AHS) virus in accordance with Chapter 12.1. of the *Terrestrial Code*.

~~**AHS FREE COUNTRY**~~
~~Report of a Member Country which applies for recognition of status,~~
~~under Chapter 12.1. of the *Terrestrial Code*,~~
~~as an AHS free country~~

The dossier provided to the OIE should ~~Please~~ address concisely all the ~~following~~ topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how these ~~this complies~~ comply with the *Terrestrial Code*.

~~Please use~~ The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

~~Any~~ All annexes should be provided in one of the OIE official languages.

*[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]*

The Delegate of the Member Country applying for recognition of AHS freedom for a country must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 12.1.2. have been properly implemented and supervised.

**EU comment**

**The EU suggests avoiding the term "must" throughout the text. For reasons of consistency, it should preferably be replaced by "should", as is common practice throughout the Code (with the exception of chapter 1.1.).**

In addition, the Delegate of the Member Country must submit a declaration indicating that:

*a)* there has been no *case* of *infection* with AHS virus for at least the past two years;

*b)* no routine *vaccination* against AHS has been carried out during the past year;

*c)* and that any equids imported have been done so in accordance with Chapter 12.1.

**EU comment**

**For consistency with other chapters, the EU suggests rewording point c) above as follows (style):**

**"c) ~~and that any~~ importation of any equids ~~imported have been~~ is carried out ~~done so~~ in accordance with the relevant provisions of Chapter 12.1.".**

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 *a)* of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

   *a)* Geographical ~~entities~~ features (rivers, mountain ranges, etc.). Provide a general description of the country and, ~~when~~ where relevant, of the region, including physical, geographical and other factors that are relevant to ~~AHS~~ introduction of *infection* and ~~dissemination~~ spread of AHS virus, taking into account the ~~as well as a short description of~~ countries sharing common borders and other epidemiologic pathways ~~links~~ for the potential introduction of ~~AHS~~ *infection*.

   Provide maps identifying the ~~factors~~ features above.

Specify whether the application includes any noncontiguous territories.

*b)* Demographics of domestic equids. ~~What is~~ Describe the composition of the equine *population* by species (*e.g.,* horses, donkeys, mules, zebras, etc.) within the various sectors.

Equine sectors are defined as equids (including donkeys, mules, hinnies and zebras) used for:

~~sport and race~~ breeding stock, competition ~~horses~~, leisure, exhibition, ~~equids~~ working (including transport) ~~donkeys, mules, hinnies, zebras))~~ and production. ~~and other (donkeys, mules, hinnies, zebras).~~ How are ~~they~~ the equine sectors distributed (*e.g.,* density, etc.) throughout the country? Provide tables and maps as appropriate.

**EU comment**

**For consistency with other parts of the text, we suggest slightly amending the second sentence of the paragraph above as follows:**

**"Describe how ~~are~~ the equine sectors are distributed (e.g., density, etc.) throughout the country?"**

*c)* Equine sectors. Provide a general description of the relative economic importance of the equine sectors in the country. Consider the below-mentioned sector groupings and outline any recent significant changes observed within the sector groupings (~~if~~ attach relevant documents ~~are~~ if available. ~~please attach~~):

*i)* breeding stock equids~~.~~;

*ii)* competition ~~Sport and race~~ horses~~.~~;

*iii)* leisure equids~~.~~;

*iv)* exhibition equids; ~~Donkeys, mules and hinnies~~

*v)* working, transport and production equids (including donkeys, mules and hinnies).

**EU comment**

**The parenthesis at the end of point v) above is an unnecessary repetition and should be deleted. Indeed, this is already explicitly stated in point b).**

*d~~c~~)* *Wildlife* demographics. What *captive wild*, *wild* or *feral* equids are present in the country? Provide estimates of *population* sizes and geographic distribution.

2. Veterinary system

*a)* Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation~~s~~, regulations and *Veterinary Authority* directives in relation to AHS and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

*b)* *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code.* Describe how the *Veterinary Services* supervise, ~~and~~ control, enforce and monitor all AHS-related activities. Provide maps, figures and tables wherever possible.

*c)* Provide information on any OIE PVS evaluation conducted in ~~your~~ the country and follow-up steps within the PVS Pathway and highlight the results relevant to AHS and the susceptible species.

**EU comment**

**The OIE PVS pathway is entirely voluntary, i.e. OIE member countries may choose to request an OIE PVS evaluation, or use the PVS tool for a self-evaluation, or not to do so.**

**The EU therefore suggests inserting the words "Where relevant, " at the beginning of point c) above.**

*d)* Provide a description of the involvement and the participation of industry, producers, farmer, including subsistence and small-scale producers, keepers, ~~community animal health workers,~~ *veterinary paraprofessionals* including community animal health workers, and other relevant groups in AHS *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, ~~veterinary profession~~ in AHS *surveillance* and control. Include a description of continuing education and awareness programmes on AHS at all relevant levels.

*e)* *Animal identification*, registration, traceability and movement control. Are equids identified (individually or at a group level)?

Provide a description of the traceability system, including methods of *animal identification* and *establishment* ~~holding~~ or *herd* registration ~~and traceability for~~ applicable to all equine sectors ~~production systems~~.

How are movements of equids controlled in the country for all equine sectors ~~production systems~~? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months ~~two years~~.

**EU comment**

**For consistency with point "pre 1" a) of the present chapter and Article 12.1.2., the EU suggests reinstating the words "two years" (instead of "24 months") in the paragraph above (and throughout the text).**

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (*e.g.,* seasonal migration). Describe the actions available under national legislation.

**EU comment**

**For reasons of clarity, the EU suggests inserting the word "mitigating" before the words "actions available under national legislation" (in the sentence above and throughout the text).**

Provide information on illegal movements detected in the past 24 months and the action taken.

**EU comment**

**We suggest replacing the term "illegal" with "unofficial or unregulated" (in the sentence above and throughout the text). Indeed, "unofficial" seems more appropriate than "illegal" in an international standard, while "unregulated" would imply there are no legal controls in the first place.**

~~Describe the risk management strategy for uncontrolled movements of susceptible species (*e.g.,* seasonal migration). Describe the action available under legislation, and actually taken, when an illegal import is detected.~~

~~Provide information on illegal movements detected.~~

*f)* Leisure, exhibition and competition movements of equids. How are movements of ~~competition and leisure~~ these types of equids controlled in the country? ~~Please~~ Provide information on systems including any use of registration. Provide information on any events that include international movements of equids.

*g)* Describe the market systems for the sale of, or transfer of ownership of, equids, ~~in particular, if markets require~~ including where the international movement of equids occurs.

3. AHS eradication

*a)* History. If ~~the~~ *infection* has never occurred in the country ~~has never had the disease~~, or has not occurred ~~had it~~ within the past 25 years, ~~please~~ state explicitly whether or not the country is applying for recognition of historical freedom according to Article 1.4.6. of the *Terrestrial Code*.

If ~~the country has had the disease~~ *infection* has occurred in the country within the past 25 years, ~~please describe the following:~~ provide a description of the AHS history in the country, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of ~~the~~ last *case* or *eradication* in the country.

*b)* Strategy. Describe how AHS was controlled and eradicated (*e.g.,* isolation of *cases*, *stamping-out policy*, zoning, movement control, protection of equids against *vectors*). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~disease~~ *outbreaks* of AHS in response to any past ~~disease~~ incursions of AHS virus.

*c)* Vaccines and *vaccination*. Briefly answer the following:

*i)* Is there any legislation that prohibits *vaccination*? If so:

– Provide the date when *vaccination* was formally prohibited;

– Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.

– ~~Describe the action available under legislation, and actually taken, when an illegal *vaccination* is detected;~~

– ~~Provide information on detected illegal *vaccination* during the reporting period~~.

*ii)* Was *vaccination* ever used in the country? If so:

– Provide the date when the last *vaccination* was carried out;

– What type of vaccine was used?

– What species were vaccinated?

– How were vaccinated animals identified?

– What was the fate of those animals?

*iii)* In addition, if *vaccination* was ~~conducted~~ applied during the past 24 months ~~two years~~, provide a description and justification of the *vaccination* strategy and programme, including the following: ~~regime~~.

**EU comment**

**There seems to be a contradiction between point iii) above and the general prerequisite that no routine vaccination was carried out during the past year (cf. point "pre 1" b) on p. 2).**

~~Briefly answer the following:~~

– the vaccine strains;

– the species vaccinated;

– identification of vaccinated animals;

– the way in which the *vaccination* of animals was certified or reported and the records maintained;

– ~~Provide~~ evidence that the vaccine used complies with Chapter 2.5.1. of the *Terrestrial Manual.*

**EU comment**

**The EU suggests using the title of a Manual chapter, instead of its number, when referring to a disease-specific chapter of the Manual, as the numbering frequently changes when new Manual chapters are adopted or their order within the Manual is changed.**

**In this case, the sentence above could be changed as follows:**

**"[...] complies with the African horse sickness chapter of the Terrestrial Manual.".**

*d)* Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. AHS diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.5.1. of the *Terrestrial Manual* are applied. ~~In particular,~~ The following points should be addressed:

*a)* Is AHS *laboratory* diagnosis carried out in the country? If so, provide an overview of the AHS-approved *laboratories* in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.~~

~~*b)* Provide an overview of the AHS-approved laboratories in the country. Address the following points:~~

*i)* How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for ~~obtaining~~ reporting results;

*ii)* Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of ~~disease~~ AHS tests performed in the past 24 months ~~two years~~ in ~~the~~ national *laboratories* ~~as well as abroad~~ and in *laboratories* in other countries, if relevant;

*iii)* Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, *e.g.,* Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

*iv)* Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

*v)* Provide details of the handling of live pathogenic agent, ~~In particular, describe~~ including a description of the biosecurity and biosafety measures applied;

*vi)* Provide a table ~~linking~~ identifying the tests carried out ~~to~~ by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

*b)* If AHS *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

**EU comment**

**The EU suggests inserting "or transport" after "for shipment" in point b) above, as samples may also be transported by the VS directly to the laboratory without requiring shipment.**

5. AHS surveillance

Provide documentary evidence that *surveillance* for AHS in the country complies with Articles 12.1.11. to

12.1.13. of the *Terrestrial Code* and Chapter 2.5.1. of the *Terrestrial Manual*. ~~In particular,~~ The following information should be included: ~~points should be addressed:~~

*a)* What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

*b)* Describe how clinical *surveillance* is conducted, including which equine sectors ~~levels of the equine population system~~ are included in clinical *surveillance*, such as ~~*farms*~~ *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months ~~two years~~, the number of suspected *cases*, the number of samples tested for AHS, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude AHS. Provide details of follow-up actions taken on all suspicious and positive results.

*c)* Other *surveillance*. Is *surveillance* undertaken as described in Article 12.1.13., specifically:

*i)* Serological *surveillance*.

*ii)* Virological *surveillance* including genome or antigen detection.

*iii)* Sentinel animals.

*iv)* *Vector surveillance*.

If so, provide detailed information on the ~~survey designs including maps~~ target *population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 12.1.11. and 12.1.13. of the *Terrestrial Code*. How frequently are they conducted? Which ~~were the~~ equine species are included? Are *wildlife* species included? If not, explain the rationale. Provide a summary table and maps indicating detailed results for at least the past 24 months ~~two years~~. Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted *surveillance* and numbers of equids examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* ~~system~~ programme including indicators.

**EU comment**

**The EU suggests inserting "control measures and" before "follow-up actions" in the paragraph above (and throughout the text), as details on control measures would also be necessary.**

*d)* Provide information on risks in the different equine sectors ~~husbandry systems~~, and provide evidence that targeted studies are implemented to address gaps (*e.g.,* targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). ~~and~~ Provide evidence of how ~~that~~ the ~~acquired~~ knowledge acquired through these activities assisted ~~assists~~ in more effective implementation of control measures.

*e)* Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological, ~~and~~ virological and other *surveillance*, and the approaches used to increase community involvement in AHS *surveillance* programmes.

6. AHS prevention

Describe the procedures in place to prevent the introduction of AHS into the country, ~~In particular, provide~~ including ~~include~~ details of:

*a)* Coordination with other countries. Describe any relevant factors in ~~about~~ ~~adjacent~~ neighbouring countries that should be taken into account (*e.g.,* size, distance from the border to affected *herds* or animals, wind currents and possible *vector* spread)? Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

**EU comment**

**The EU suggests inserting "physical geographical boundaries" before "wind currents" in the paragraph above (and throughout the text), as details on such boundaries would also be relevant in this context.**

If the AHS free country borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the pathogenic agent or *vectors*, taking into consideration the seasonal *vector* conditions and existing physical, geographical and ecological barriers.

**EU comment**

**The EU suggests replacing "animal health measures" with "animal disease control measures" in the paragraph above (and throughout the text).**

Are *protection zones* in place? If so, provide details of the measures that are applied (*e.g., vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

*b)* Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the ~~propagation~~ spread of the pathogenic agent within the country ~~and through trade~~. Provide evidence that measures to reduce transmission of AHS are in place at markets, such as enhancing awareness of AHS transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity* ~~practices~~, hygiene ~~cleaning~~ and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

**EU comment**

**The EU suggests inserting "/gatherings/collection points" after "markets" in point b) above (and throughout the text), as these would be relevant as well.**

*c)* 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. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied ~~on~~ to entry of such animals and products, and subsequent internal movement. Describe the import ~~conditions~~ measures (*e.g.,* quarantine) 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~~ *international veterinary certificates* are required.

**EU comment**

**The EU suggests inserting "health" before "certificate" in point c) above (and throughout the text).**

Describe any other procedures used for assessing the *risks* ~~of~~ posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months ~~two years~~, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country.

Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic equids.

*i)* Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls 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)* Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:

– equids~~.~~;

– genetic material (semen, ~~ovocytes~~ oocytes and embryos of the equine species)~~.~~;

– equine derived (by-)products ~~and biologicals.~~;

– ~~AHS vaccines.~~

– *veterinary medicinal products.*

7. Control measures and contingency planning

*a)* List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of AHS. The contingency plan should be attached as an annex in one of the OIE official languages. ~~and.~~ If not available, provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for AHS that was conducted in the country in the past five years.

*b)* In the event of a suspected or confirmed AHS *outbreak*:

*i)* ~~Is~~ Are quarantine measures imposed on *establishments* ~~*premise*~~ with ~~suspicious~~ suspected *cases*, pending final diagnosis? What other procedures are followed ~~regarding~~ with respect to ~~suspicious~~ suspected *cases* (*e.g.,* standstills)?

**EU comment**

**The EU suggests inserting the word "movement restrictions" after "standstill" in point i) above (and throughout the text).**

*ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic ~~causative~~ agent;

*iii)* Describe the actions that would be taken to control the disease situation in and around the ~~*premises*~~ *establishments* where the *outbreak* ~~was~~ is confirmed;

*iv)* Provide a detailed description of the control or *eradication* procedures (*e.g.,* forward and backward tracing, movement control, *disinfection* of *establishments* ~~*premises*~~, *vehicles* and equipment, including verification methods, *vaccination*, *stamping-out policy*, *vector*-protected stabling, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

*v)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

*vi)* Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;

*vii)* Describe how control efforts, including *vaccination* and *biosecurity* ~~measures~~, would target critical risk control points.

~~8.~~ ~~Compliance with the *Terrestrial Code*~~*[NB moved to beginning of chapter]*

~~The Delegate of the Member Country applying for AHS freedom must submit documentary evidence that the provisions of Article 12.1.2. have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating that:~~

~~*a)* there has been no *case* of AHS for at least the past two years;~~

~~*b)* no routine *vaccination* against AHS has been carried out during the past year;~~

~~*c)* and that equids were imported in accordance with Chapter 12.1.~~

~~In addition, the Delegate of the Member Country applying for historical freedom must also submit~~

~~documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised~~.

8~~9~~. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 12.1.5. of the *Terrestrial Code* and provide detailed information as specified in Sections 4 *a)*, 4 *b)*, 4 *c)* and 6, and Sections 1–7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.7.2.

**Zone free from infection with African horse sickness virus**

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a *zone* free from infection with African horse sickness virus in accordance with Chapter 12.1. of the *Terrestrial Code*.

~~**AHS FREE ZONE**~~
~~Report of a Member Country which applies for recognition of status,~~
~~under Chapter 12.1. of the *Terrestrial Code*,~~
~~as an AHS free zone~~

The dossier provided to the OIE should ~~Please~~ address concisely all the ~~following~~ topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how ~~this~~ these ~~complies~~ comply with the *Terrestrial Code*.

~~Please use~~ The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

~~Any~~ All annexes should be provided in one of the OIE official languages.

*[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]*

The Delegate of the Member Country applying for recognition of AHS freedom for a *zone* must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 12.1.2. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

*a)* there has been no *case* of *infection* with AHS virus for at least the past two years in the *zone*;

*b)* no routine *vaccination* against AHS has been carried out during the past year in the *zone*;

*c)* and that any equids imported into the *zone* have been done so in accordance with Chapter 12.1.

**EU comment**

**The EU suggests rewording point c) above as follows (style):**

**"c) and that any importation of any equids imported into the zone have been is carried out done so in accordance with the relevant provisions of Chapter 12.1.".**

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 *a)* of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

*a)* Geographical ~~entities~~ features (rivers, mountain ranges, etc.). Provide a general description of the country and, where ~~when~~ relevant, of the region, including physical, geographical and other factors that are relevant to ~~AHS~~ introduction of *infection* and ~~dissemination~~ spread of AHS virus, taking into account ~~as well as a short description of~~ the countries sharing common borders and other epidemiologic pathways ~~links~~ for the potential introduction of ~~AHS~~ *infection*. The boundaries of the *zone* must be clearly defined, including a *protection zone*, if applied.

Provide maps identifying the ~~factors~~ features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

*b)* Demographics of domestic equids. ~~What is~~ Describe the composition of the equine *population* by species (*e.g.,* horses, donkeys, mules, zebras, etc.) within the various sectors.

Equine sectors are defined as equids (including donkeys, mules, hinnies and zebras) used for:

~~sport and race~~ breeding stock, competition ~~horses~~, leisure, exhibition, ~~equids~~ working (including transport) ~~donkeys, mules, hinnies, zebras))~~ and production. ~~and other (donkeys, mules, hinnies, zebras).~~ How are ~~they~~ the equine sectors distributed (*e.g.,* density, etc.) throughout the country? Provide tables and maps as appropriate.

*c)* Equine sectors. Provide a general description of the relative economic importance of the equine sectors in the country. Consider the below-mentioned sector groupings and outline any recent significant changes observed within the sector groupings (~~if~~ attach relevant documents ~~are~~ if available ~~please attach~~):

*i)* breeding stock equids~~.~~;

*ii)* competition ~~Sport and race~~ horses~~.~~;

*iii)* leisure equids~~.~~;

*iv)* exhibition equids; ~~Donkeys, mules and hinnies~~

*v)* working, transport and production equids (including donkeys, mules and hinnies).

**EU comment**

**The parenthesis at the end of point v) above is an unnecessary repetition and should be deleted. Indeed, this is already explicitly stated in point b).**

2. Veterinary system

*a)* Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation~~s~~, regulations and *Veterinary Authority* directives in relation to AHS and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

*b)* *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with ~~the provisions of~~ Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code.* Describe how the *Veterinary Services* supervise, ~~and~~ control, enforce and monitor all AHS-related activities. Provide maps, figures and tables wherever possible.

*c)* Provide information on any OIE PVS evaluation conducted in ~~your~~ the country and follow-up steps within the PVS Pathway and highlight the results relevant to AHS and the susceptible species.

**EU comment**

**The OIE PVS pathway is entirely voluntary, i.e. OIE member countries may choose to request an OIE PVS evaluation, or use the PVS tool for a self-evaluation, or not to do so. The EU therefore suggests inserting the words "Where relevant," at the beginning of point c) above.**

*d)* Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, ~~community animal health workers,~~ *veterinary paraprofessionals* including community animal health workers, and other relevant groups in AHS *surveillance* and control. Provide a description of the role and structure of the private veterinary sector,

including the number of *veterinarians* and their distribution, ~~and role of the~~ ~~private~~ ~~*veterinary profession*~~ in AHS *surveillance* and control. Include a description of continuing education and awareness programmes on AHS at all relevant levels.

*e)* *Animal identification*, registration, traceability and movement control. Are equids identified (individually or at a group level)?

Provide a description of the traceability system, including methods of *animal identification* and ~~holding~~ *establishment* or *herd* registration ~~and traceability for~~ applicable to all equine sectors ~~production systems~~.

How are movements of equids controlled in and between *zones* of the same or different status for all equine sectors ~~production systems~~? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months ~~two years~~.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (*e.g.*, seasonal migration). Describe the actions available under national legislation.

Provide information on illegal movements detected in the past 24 months and the action taken.

~~Describe the risk management strategy for uncontrolled movements of susceptible species (*e.g.*, seasonal migration). Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on illegal movements detected.~~

*f)* Leisure, exhibition and competition movements of equids. How are movements of these types of ~~competition and leisure~~ equids controlled in the country and ~~the~~ *zones*? ~~Please~~ Provide information on systems including any use of registration. Provide information on any events that include international movements of equids.

*g)* Describe the market systems for the sale of, or transfer of ownership of, equids in the country and ~~the~~ *zones*, ~~in particular, if markets~~ ~~require~~ including where the international movement of equids occurs.

3. AHS eradication

*a)* History. If ~~the~~ *infection* has never occurred in the country, ~~has never had the *disease*~~, or has not ~~had it~~ occurred within the past 25 years, ~~please~~ state explicitly whether or not the *zone* is applying for recognition of historical freedom according to Article 1.4.6. of the *Terrestrial Code*.

If ~~the *zone* has had~~ ~~the disease~~ *infection* has ~~been present~~ occurred in the *zone* within the past 25 years, ~~please~~ provide a description of the AHS history in the country and *zone*, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of ~~the~~ last *case* or *eradication* in the *zone*.

*b)* Strategy. Describe how AHS was controlled and eradicated in the *zone* (*e.g.,* isolation of *cases*, *stamping-out policy*, *zoning*, movement control, protection of equids against *vectors*). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~*disease*~~ *outbreaks* of AHS in response to any past ~~*disease*~~ incursions of AHS virus.

*c)* Vaccines and *vaccination*. Briefly answer the following:

*i)* Is there any legislation that prohibits *vaccination*? If so:

– Provide the date when *vaccination* was formally prohibited;

– Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.

– ~~Describe the action available under legislation, and actually taken, when an illegal *vaccination* is detected;~~

– ~~Provide information on detected illegal *vaccination* during the reporting period.~~

*ii)* Was *vaccination* ever used in the country? If so:

– Provide the date when the last *vaccination* was carried out;

– What type of vaccine was used in the *zone* and the rest of the country?

– What species were vaccinated?

– How were vaccinated animals identified?

– What was the fate of those animals?

*iii)* In addition, if *vaccination* was ~~conducted~~ applied during the past 24 months ~~two years~~, provide a description and justification of the *vaccination* strategy and programme, including ~~regime. Briefly answer~~ the following:

**EU comment**

**There seems to be a contradiction between point iii) above and the general prerequisite that no routine vaccination was carried out during the past year (cf. point "pre 1" b) on p. 9).**

– the vaccine strains;

– the species vaccinated;

– identification of vaccinated animals;

– the way in which the *vaccination* of animals was certified or reported and the records maintained;

– ~~Provide~~ evidence that the vaccine used complies with Chapter 2.5.1. of the *Terrestrial Manual.*

*d)* Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. AHS diagnosis

Provide documentary evidence that the relevant provisions ~~in~~ of Chapters 1.1.2., 1.1.3. and 2.5.1. of the *Terrestrial Manual* are applied. ~~In particular,~~ The following points should be addressed:

*a)* Is AHS *laboratory* diagnosis carried out in the country? If so, provide an overview of the AHS-approved *laboratories* in the country. ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.~~ Indicate the *laboratories* where samples originating from the *zone* are diagnosed.

~~*b)* Provide an overview of the AHS-approved laboratories in the country.~~ Address the following points:

*i)* How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for ~~obtaining~~ reporting results;

*ii)* Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of AHS tests performed in the past 24 months ~~two years~~ in ~~the~~ national *laboratories* ~~as well as abroad~~ and in *laboratories* in other countries, if relevant;

*iii)* Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, *e.g.,* Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

*iv)* Provide details of performance in inter-*laboratory* validation tests (ring tests), including the most recent results and, if applicable, the corrective measures applied.

*v)* Provide details of the handling of live pathogenic agent, ~~In particular, describe~~ including a description of the biosecurity and biosafety measures applied;

*vi)* Provide a table identifying ~~linking~~ the tests carried out ~~to~~ by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

*b)* If AHS *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

**EU comment**

**The EU suggests inserting "or transport" after "for shipment" in point b) above, as samples may also be transported by the VS directly to the laboratory without requiring shipment.**

5. AHS surveillance

Provide documentary evidence that *surveillance* for AHS in the *zone* complies with Articles 12.1.11. to 12.1.13. of the *Terrestrial Code* and Chapter 2.5.1. of the *Terrestrial Manual*. ~~In particular,~~ The following information should be included ~~points should be addressed~~:

*a)* What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

*b)* Describe how clinical *surveillance* is conducted, including which equine sectors ~~levels of the equine population system~~ are included in clinical *surveillance*, such as *establishments* ~~farms~~, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months ~~two years~~, the number of suspected *cases*, the number of samples tested for AHS, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude AHS. Provide details of follow-up actions taken on all suspicious and positive results.

*c)* Other *surveillance*. Is *surveillance* undertaken as described in Article 12.1.13., specifically:

*i)* Serological *surveillance*.

*ii)* Virological *surveillance* including genome or antigen detection.

*iii)* Sentinel animals.

*iv)* *Vector surveillance*.

If so, provide detailed information on the ~~survey designs including maps~~ target *population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 12.1.11. and 12.1.13. of the *Terrestrial Code*. How frequently are they conducted? Which ~~were the~~ equine species are included? Are *wildlife* species included? If not, explain the rationale. Provide a summary table and maps indicating detailed results for at least the past 24 months ~~two years~~. Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted *surveillance* and numbers of equids examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* ~~system~~ programme including indicators.

*d)* Provide information on risks in the different equine sectors ~~husbandry systems~~, and provide evidence that targeted studies are implemented to address gaps (*e.g.,* targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). ~~and~~ Provide evidence of how ~~that~~ the ~~acquired~~ knowledge acquired through these activities assisted ~~assists~~ in more effective implementation of control measures.

*e)* Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in AHS *surveillance* programmes.

6. AHS prevention

Describe the procedures in place to prevent the introduction of AHS into the country or *zone*, including details of:

*a)* Coordination with other countries. Describe any relevant factors in ~~about~~ ~~adjacent~~ neighbouring countries and *zones* that should be taken into account (*e.g.,* size, distance from the border to affected *herds* or animals, wind currents and possible *vector* spread)? Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

If the AHS free *zone* is established in an AHS infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the pathogenic agent or *vectors*, taking into consideration the seasonal *vector* conditions and existing physical, geographical and ecological barriers.

Are *protection zones* in place? If so, indicate whether or not the *protection zones* are included in the proposed free *zones.* Provide details of the measures that are applied (*e.g., vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

*b)* Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the ~~propagation~~ spread of the pathogenic agent within the country or *zone* ~~and through trade~~. Provide evidence that measures to reduce transmission of AHS are in place at markets~~,~~ such as enhancing awareness of AHS transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity,* ~~practices,~~ hygiene ~~cleaning~~ and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

~~*b)*~~ *c)* 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*, the controls applied ~~on~~ to entry of such animals and products, and subsequent internal movement. Describe the import measures ~~conditions~~ (*e.g.,* quarantine) 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~~ *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* ~~of~~ posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months ~~two years~~, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin and the quantity or volume and eventual destination in the country or *zone*.

Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic equids.

*i)* Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls 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)* Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and follow-up of the following:

– equids~~,~~;

– genetic material (semen, ~~ovocytes~~ oocytes and embryos of the equine species)~~,~~;

– equine derived (by-)products ~~and biologicals,~~;

~~— AHS vaccines.~~

– *veterinary* ~~medical~~ *medicinal products*.

7. Control measures and contingency planning

*a)* List any written guidelines, including contingency plans, available to the ~~official services~~ *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of AHS. The contingency plan should be attached as an annex in one of the OIE official languages. ~~and,~~ If not available, provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for AHS that was conducted in the country in the past five years.

*b)* In the event of a suspected or confirmed AHS *outbreak*:

*i)* ~~Is~~ Are quarantine measures imposed on *establishments* ~~premises~~ with ~~suspicious~~ suspected *cases*, pending final diagnosis? What other procedures are followed ~~regarding~~ with respect to ~~suspicious~~ suspected *cases* (*e.g.,* standstills)?

*ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the ~~causative~~ pathogenic agent;

*iii)* Describe the actions that would be taken to control the disease situation in and around the ~~premises~~ *establishments* where the *outbreak* ~~was~~ is confirmed;

*iv)* Provide a detailed description of the control or *eradication* procedures (*e.g.,* forward and backward tracing, movement control, *disinfection* of *establishments* ~~premises~~, *vehicles* and equipment, including verification methods, *vaccination*, *stamping-out policy*, *vector*-protected stabling, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken;

*v)* In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

*vi)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

*vii)* Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for *disease* control or *eradication* purposes and the prescribed timetable for payments;

*viii)* Describe how control efforts, including *vaccination* and *biosecurity* ~~measures~~, would target critical risk control points.

~~8.~~ ~~Compliance with the *Terrestrial Code* *[NB moved to beginning of chapter]*~~

~~The Delegate of the Member Country applying for AHS freedom must submit documentary evidence that the provisions of Article 12.1.2. of the *Terrestrial Code* have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating that:~~

~~*a)* there has been no *case* of AHS for at least the past two years in the *zone*;~~

~~*b)* no routine *vaccination* against AHS has been carried out during the past year in the *zone*;~~

~~*c)* and that equids were imported into the *zone* in accordance with Chapter 12.1.~~

~~In addition, the Delegate of the Member Country applying for historical freedom must submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.~~

~~9~~8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a *zone* should comply with the provisions of Article 12.1.5. of the *Terrestrial Code* and provide detailed information as specified in Sections 4 *a)*, 4 *b)*, 4 *c)* and 6, and Sections 1–7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Annex 26

CHAPTER 1.8.

~~Article 1.6.5.~~

# APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF RISK STATUS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

**EU position**

**The EU in general supports the adoption of this new chapter.**

**Comments are inserted in the text below.**

Article 1.8.1.

**EU position**

**We note that there is no title for Article 1.8.1.**

**The EU would suggest the following title:**

**"Dossier in support of applications for official BSE risk status recognition".**

The following information should be provided by OIE Member Countries to support applications for official recognition of risk status for bovine spongiform encephalopathy (BSE) in accordance with Chapter 11.4. of the *Terrestrial Code.*

*[Note: The following point has been moved from Article 1.8.2. to improve the logical flow of the document and remove duplication.]*

The Delegate of the Member Country submitting documentation ~~regarding~~ of the legislation under which the *Veterinary Services* ~~is~~ are mandated ~~it~~ should provide a description of the content of ~~any~~ the relevant legal acts ~~described~~ (in one of the three official languages of OIE), as well as the dates of official publication and implementation.

~~Please~~ The dossier provided to the OIE should address concisely all the ~~following~~ topics under the headings provided to describe the actual situation in the country and the procedures currently applied, ~~in the country~~ explaining how ~~this~~ these ~~complies~~ comply with the *Terrestrial Code*.

~~Please use~~ The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

~~Any~~ All annexes should be provided in one of the OIE official languages.

*[Note from the TAHSC – The following point has been moved from the end of the questionnaire to improve the logical flow of the document see below.]*

The Delegate of the Member Country applying for official recognition of ~~a~~ BSE risk status must submit documentary evidence that the provisions of Article 11.4.2. and Article 11.4.3. or Article 11.4.4. have been properly implemented and supervised.

**EU comment**

**The EU suggests avoiding the term "must" throughout the text. For reasons of consistency, it should preferably be replaced by "should", as is common practice throughout the Code (with the exception of chapter 1.1.).**

1. Introduction

Provide a general description of the bovine (*Bos taurus* and *B. indicus*) husbandry and slaughtering practices in the country. Provide figures and tables as appropriate.

2. Veterinary system

*a)* Describe how the *Veterinary Service*s of the country comply~~ies~~ with the provisions of Chapters 1.1., 3.1. and 3.2. ~~in~~ of the *Terrestrial Code*;

*b)* describe how the *Veterinary Services* supervise, control, enforce and monitor ~~and maintain~~ all BSE-related activities;

*c)* provide maps, figures and tables wherever possible;

*d)* provide information on any OIE PVS evaluation conducted in ~~your~~ the country and follow-up actions ~~steps~~ within the PVS Pathway ~~and~~ highlighting the results relevant to BSE and the susceptible species;

**EU comment**

**The OIE PVS pathway is entirely voluntary, i.e. OIE member countries may choose to request an OIE PVS evaluation, or use the PVS tool for a self-evaluation, or not to do so. The EU therefore suggests inserting the words "Where relevant, " at the beginning of point d) above.**

*e)* provide a description of the structure (including number and distribution) and role of private veterinary sector ~~veterinary profession~~ in BSE *surveillance* and control.

Article 1.8.2.

**BSE risk status requirements: Section 1 – risk assessment (see point 1) of Article 11.4.2.)**

Article 11.4.2. of the *Terrestrial Code* Chapter on BSE prescribes the criteria to determine the BSE risk status of the cattle population of a country or *zone*. ~~This~~ The Delegate of the Member Country applying for recognition of ~~he means whereby~~ a claim for negligible risk status (Article 11.4.3.) or controlled risk status (Article 11.4.4.) must demonstrate compliance with the *Terrestrial Code.* That is, the Delegate must submit documentary evidence that the provisions of Article 11.4.3. or Article 11.4.4. have been properly implemented and complied with. ~~can be made to the OIE~~.

*[NB the following point has been moved to Article 1.8.1. and modified to avoid duplication.]*

~~The Delegate of the Member Country submitting documentation regarding of the legislation under which the *Veterinary Services* is are mandated it should provide a description of the content of any the relevant legal acts described (in one of the three official languages of OIE), as well as the dates of official publication and implementation. The dossier submitted to the OIE should follow the format and numbering used in this document.~~

1. Introduction

The Delegate of the Member Country applying for official recognition by the OIE of BSE risk status of the cattle *population* of ~~a~~ the country or *zone* should submit documentary evidence demonstrating that ~~conduct~~ a *risk assessment* based on Section 2 and ~~3 and~~ Chapter ~~4.3~~11.4. of the *Terrestrial Code* has been carried out.

2. Entry assessment

*a)* The potential for the entry of the classical BSE agent through importation of meat-and-bone meal or greaves (including of non-ruminant origin)

Knowledge of the origin of *meat-and-bone meal*, *greaves* or ~~*feedstuffs*~~ *feed ingredients* containing either *meat-and-bone meal* or *greaves*, is necessary to assess the risk of entry of classical BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of undetermined or controlled BSE risk pose a higher likelihood of entry than that from negligible risk countries.

Has *meat-and-bone meal*, *greaves* (including of non-ruminant origin) or ~~*feedstuffs*~~ *feed ingredients* containing either, been imported within the past eight years? If not ~~so~~, provide documentary evidence, including supporting legislation, where relevant:

*i)* ~~official statistics,~~ to support claims that *meat-and-bone meal* (including of non-ruminant origin), *greaves* or ~~*feedstuffs*~~ *feed ingredients* containing either *meat-and-bone meal* or *greaves* have not been imported, OR

If *meat-and-bone meal*, *greaves* (including of non-ruminant origin) or ~~*feedstuffs*~~ *feed ingredients* containing either, has been imported within the past eight years, provide documentary evidence of the following:

*ii)* official statistics on annual volume, by country of origin, of *meat-and-bone meal* (including of non-ruminant origin), *greaves* or ~~*feedstuffs*~~ *feed ingredients* containing them ~~imported during the past eight years~~;

*iii)* the species composition of the *meat-and-bone meal*, *greaves* or ~~*feedstuffs*~~ *feed ingredients*;

*iv)* ~~from the *Veterinary Service* of the country of production that~~ the method used to reduce BSE infectivity complies with Article 11.4.19.

*b)* The potential for the entry of the classical BSE agent through the importation of potentially infected live cattle

The likelihood of entry is dependent on:

– the BSE status of the country or *zone* of origin;

– dairy versus meat breeds, where there are differences in exposure in the country or *zone* of origin because feeding practices result in greater exposure of one category;

– age of animals imported for *slaughter*;

– the effective implementation of the ban on feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants in the country or *zone* of origin before the birth of the imported animals.

Have live cattle been imported within the past seven years? Provide documentary evidence of the following:

*i)* ~~official statistics,~~ to support claims that live cattle have not been imported including supporting legislation, OR

*ii)* the country or *zone* of origin and volume of imports, official statistics, where relevant, in table form, and evidence of compliance with the requirements of Articles 11.4.6. to 11.4.9.

*c)* The potential for the entry of the classical BSE agent through the importation of potentially infected products of ruminant origin

The likelihood of entry is dependent on:

– the BSE status of the country or *zone* of origin and whether these products contain tissues known to contain BSE infectivity (Article 11.4.13.);

– dairy versus meat breeds, where there are differences in exposure in the country or *zone* of origin because feeding practices result in greater exposure of one category;

– age at *slaughter*.

What products of ruminant origin have been imported within the past seven years? This includes all products of ruminant origin that are not considered as *safe commodities* in Article 11.4.1., in particular products listed in points 1 *a) v), vi)* and *vii)* of Article 11.4.2. Provide documentary evidence of the following:

*i)* the country or *zone* of origin and volume of imports, in table form, of all products of ruminant origin that are not considered as safe commodities in Article 11.4.1.;

*ii)* evidence of compliance with the requirements of ~~Chapter~~ Article 11.4.26.

3. Exposure assessment

*a)* The origin of ruminant carcasses, by-products and slaughterhouse/abattoir waste, the parameters of the rendering processes

The overall risk of BSE in the cattle *population* of a country or *zone* is proportional to the potential for recycling and amplification of the infectivity through rendering practices. For the *risk assessment* to conclude that the cattle *population* of a country or *zone* is of negligible or controlled BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified. If potentially infected cattle or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity.

~~The~~ Rendering is a process by which inedible animal by-products and *slaughter* waste, including bones and fallen stock, are transformed into *meat-and-bone meal*.

How have ruminant carcasses, by-products and *slaughterhouse/abattoir* waste been processed over the past eight years? Provide the following:

*i)* A description of the collection and disposal of fallen stock, ~~non~~-inedible animal by-products, and materials condemned as unfit for human consumption. If ~~your country manages~~ by-products derived from imported cattle are managed differently, describe the process.

*ii)* A description of the definition, collection and disposal of material listed in Article 11.4.14.

*iii)* A description of the rendering industry and processes and parameters used to produce ruminant *meat-and-bone meal* and *greaves*.

*iv)* Documentation describing monitoring and enforcement of the above.

*v)* Information in a table (see below), ~~on~~ including the audit findings in rendering plants processing material of ruminant origin (including mixed species containing ruminant material) and only material of non-ruminant origin (*e.g.,* fish, *poultry*, pig, horse), related to the prohibition of the feeding to ruminants of *meat-and-bone meal* and *greaves*. The sampling objectives to detect whether material of non-ruminant origin could have been contaminated with ruminant material.

| **Year (information should be provided for each of the eight years for which effectiveness is claimed)** | **Type of renderers** | **Number of plants** | **Number of plants in (A) inspected under Competent Authority supervision** | **Number of inspections in (B) in total** | **Total number of plants in (B) with infractions** | **Total number of plants in (B) inspected under Competent Authority supervision with sampling** | **Total number of plants in (E) with positive test results** |
|---|---|---|---|---|---|---|---|
| | | **(A)** | **(B)** | **(C)** | **(D)** | **(E)** | **(F)** |
| Year 1 | Material of ruminant origin (or mixed species) | | (e.g.: < or = to A) | (e.g.: > or = to B) | (e.g.: < or = to B) | Not applicable for the purpose of the dossier | Not applicable for the purpose of the dossier |
| | Only material of non-ruminant origin | | (e.g.: < or = to A) | (e.g.: > or = to B) | (e.g.: < or = to B) | (e.g.: < or = to B) | (e.g.: < or = to E) |
| Year 2, etc. | Material of ruminant origin (or mixed species) | | | | | Not applicable for the purpose of the dossier | Not applicable for the purpose of |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | | the dossier |
| | Only material of non-ruminant origin | | | | | | |

*vi)* Information in a table (see below)~~,~~ on each rendering plant referred to above processing material of ruminant origin (including mixed species containing ruminant material) and only material of non-ruminant origin (*e.g.*, fish, *poultry*, pig, horse) with infractions, specifying the type of infraction (columns D and F of the table above) and the method of resolution.

| **Year (information should be provided for each of the eight years for which effectiveness is claimed)** | **Type of renderers** | **Plant ID** | **Nature of infraction** | **Method of resolution** | **Follow-up results** |
|---|---|---|---|---|---|
| Year 1 | Material of ruminant origin (or mixed species) | ID 1 | | | |
| | | ID 2 | | | |
| | | ID 3, etc. | | | |
| | Only material of non-ruminant origin | ID 1 | | | |
| | | ID 2 | | | |
| | | ID 3, etc. | | | |
| Year 2, etc. | Material of ruminant origin (or mixed species) | | | | |
| | Only material of non-ruminant origin | | | | |

*b)* The potential for the exposure of cattle to the classical and atypical BSE agents through consumption of meat-and-bone meal or greaves of ruminant origin

The overall risk of BSE in the cattle *population* of a country or *zone* is proportional to the level of known or potential exposure to BSE infectivity. If cattle have not been fed products of ruminant origin (other than *milk* or blood) potentially containing *meat-and-bone meal* or *greaves* of ruminant origin within the past eight years, *meat-and-bone meal* and *greaves* can be dismissed as a risk. Where *meat-and-bone meal* is utilised in the production of any ~~cattle~~ ruminant *feed*, ~~the~~ a risk of cross-contamination exists.

Countries applying for negligible risk status will be required to demonstrate that the ruminant *feed* ban has been effective for at least eight years.

*Feed* mills are processing plants where different *feed ingredients* are mixed and processed together to produce compound *feed* for animals. This should include on-farm *feed* producers that keep cattle.

Has *meat-and-bone meal* or *greaves* of ruminant origin been fed to cattle within the past eight years (Articles 11.4.3. and 11.4.4. in the *Terrestrial Code*)? Describe the following:

*i)* the *feed* industry, including repartition between *feed* mills producing *feed* for ruminant only, *feed* for non-ruminant only and *feed* for both;

*ii)* methods of animal *feed* production, including details of ingredients used, the extent of use of *meat-and-bone meal* (including of non-ruminant origin) in any livestock *feed*;

*iii)* the use of imported *meat-and-bone meal* and *greaves* (including of non-ruminant origin), their country or *zone* of origin, including the feeding of any animal species;

*iv)* the use made of *meat-and-bone meal* and *greaves* produced from ruminants, including the feeding of any animal species;

*v)* the measures taken to control cross-contamination of ruminant ~~*feedstuffs*~~ *feed ingredients* with the *meat-and-bone meal* and *greaves* including the risk of cross-contamination during production, transport, storage and feeding;

*vi)* provide details in a table, on the audit findings in *feed* mill processing *feed* for ruminant only, for non-ruminant only and for both, related to the prohibition of the feeding to ruminants of *meat-and-bone meal* and *greaves*. The sampling aims to detect whether material of ruminant origin could have contaminated *feed* intended to ruminant;

| **Year (information should be provided for each of the eight years for which effectiveness is claimed)** | **Type of feed mill** | **Number of feed mills** | **Number of feed mills in (A) inspected under Competent Authority supervision** | **Number of inspections in (B) in total** | **Total number of feed mills in (B) with infractions** | **Total number of inspected feed mills in (B) with sampling** | **Total number of feed mills in (E) with positive test results** |
|---|---|---|---|---|---|---|---|
| | | **(A)** | **(B)** | (C) | (D) | **(E)** | (F) |
| Year 1 | For ruminant only | | | | | | |
| | For non-ruminant only | | | | | Not applicable for the purpose of the dossier | Not applicable for the purpose of the dossier |
| | For both | | | | | | |
| Year 2, etc. | For ruminant only | | | | | | |
| | For non-ruminant only | | | | | Not applicable for the purpose of the dossier | Not applicable for the purpose of the dossier |
| | For both | | | | | | |

*vii)* details in a table, on each *feed* mill processing *feed* for ruminant only, for non-ruminant only and for both, with infractions, specifying the type of infraction (columns D and F of the table above) and the method of resolution;

| **Year (information should be provided for each of the eight years for which effectiveness is claimed)** | **Type of feed mills** | **Feed mills ID** | **Nature of infraction** | **Method of resolution** | **Follow-up results** |
|---|---|---|---|---|---|
| Year 1 | For ruminant only | ID 1 | | | |
| | | ID 2 | | | |
| | | ID 3, etc. | | | |
| | For non-ruminant only | ID 1 | | | |
| | | ID 2 | | | |
| | | ID 3, etc. | | | |
| | For both | ID 1 | | | |
| | | ID 2 | | | |
| | | ID 3, etc. | | | |
| Year 2, etc. | For ruminant only | | | | |
| | For non-ruminant | | | | |

*viii)* why, in light of the findings displayed in the preceding four tables (of Sections 4 and 5), it is considered that there has been no significant exposure of cattle to the BSE agent through consumption of *meat-and-bone meal* or *greaves* of ruminant origin;

*ix)* husbandry practices (multiple species farms) which could lend themselves to cross-contamination of ruminant *feed* with *meat-and-bone meal* and *greaves* destined to other species.

Article 1.8.3.

**BSE risk status requirements: Section 2 – other requirements (see points 2) to 4) of Article 11.4.2.)**

1. Awareness programme (see point 2) of Article 11.4.2.)

   An awareness programme is essential in ensuring detection and reporting of BSE, especially in countries of low prevalence and competing differential diagnoses. Provide documentary evidence of the following:

   *a)* when the awareness programme was implemented and its continuous application and geographical coverage;

   *b)* the number and occupation of persons who have participated in the awareness programme (farmers, livestock owners, *animal handlers, veterinarians*, ~~producers,~~ workers at livestock markets or auctions, workers at *slaughterhouses/abattoirs*, etc.);

   *c)* a description of the materials used in the awareness programme (the manual, supportive documents, or other teaching materials) (Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.);

   *d)* ~~the~~ contingency plans or preparedness plans to deal with an occurrence of BSE.

2. Compulsory notification and investigation (see point 3) of Article 11.4.2.)

   In order to ensure appropriate detection and follow-up of any BSE *cases*, appropriate legislation to support BSE control and *eradication* and effective regulatory controls and verification should be in place.

   The socioeconomic implications ~~associated with~~ of BSE require that there be incentives and~~/or~~ obligations to notify and investigate suspected cases.

   *a)* Describe ~~What~~ the guidance ~~is~~ given to farmers, livestock owners, *animal handlers, veterinarians*, workers at livestock markets or auctions, workers at *slaughterhouses/abattoirs,* ~~*veterinarians*, producers, workers at auctions, *slaughterhouses/abattoirs*~~, etc. in terms of the criteria that would initiate the investigation of an *animal* suspected as being a *case* of ~~as a~~ BSE. ~~suspect?~~ Have these criteria evolved and, if so, how?

   *b)* What was the date and content of the legal act making notification of suspected *cases* of BSE ~~suspects~~ compulsory?

   *c)* Describe the measures in place to stimulate notification, such as compensation payments or penalties for not notifying a suspected *case*.

3. Examination in an approved laboratory of brain or other tissues collected within the framework of the ~~aforementioned~~ surveillance system described above (see point 4) of Article 11.4.2.)

Provide documentary evidence that the relevant provisions of Chapter 2.4.5~~6~~. of the *Terrestrial Manual* are **applied, including the following:**

**EU comment**

**The EU suggests using the title of a Manual chapter, instead of its number, when referring to a disease-specific chapter of the Manual, as the numbering frequently changes when new Manual chapters are adopted or their order within the Manual is changed.**

**In this case, the sentence above could be changed as follows:**

**"[...] relevant provisions of the Bovine spongiform encephalopathy chapter of the Terrestrial Manual [...]".**

*a)* if BSE *laboratory* diagnosis carried out in the country provide an overview of the approved *laboratories* where samples of cattle tissues from the country or *zone* are examined for BSE;

*b)* if BSE *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results; ~~information should be provided on the cooperation agreement)~~;

**EU comment**

**The EU suggests inserting "or transport" after "for shipment" in point b) above, as samples may also be transported by the VS directly to the laboratory without requiring shipment.**

*c)* that these diagnostic procedures and methods have been applied through the entire *surveillance* period.

Article 1.8.4.

**Section 3: BSE surveillance and monitoring systems (see point 1 *b) iv)* and point 4) of Article 11.4.2.)**

**EU comment**

**For consistency with the titles of Articles 1.8.2. and 1.8.3., the EU suggests inserting "BSE risk status requirements: [...]" also at the beginning of the titles of Articles 1.8.4. and 1.8.5.**

Articles 11.4.20. to 11.4.22. prescribe the number of cattle, by subpopulation, that need to be tested in order to ensure the detection of BSE at or above a minimal threshold prevalence.

1) Does the BSE *surveillance* programme comply with the guidelines in Articles 11.4.20. to 11.4.22. of the *Terrestrial Code*? Provide documentary evidence of the following:

*a)* that the samples collected are representative of the distribution of the cattle *population* in the country or *zone*, including by age and subpopulations as described in Article 11.4.21.;

*b)* the methods applied to assess the ages of animals sampled and the proportions for each method (individual identification, dentition, other methods to be specified);

*c)* the means and procedures whereby samples were assigned to the cattle subpopulations described in Article 11.4.21., including the specific provisions applied to ensure that animals described as clinical met the conditions of point 1) of Article 11.4.21. and that at least three of the four subpopulations have been sampled.

2) In a table (see below), provide details of all clinically suspected cases notified complying with the definition in point 1) of Article 11.4.21.

| Laboratory identification number | Age | Description of observed clinical signs | Point of detection (farm, market channels, slaughterhouse) | Final diagnosis |
|---|---|---|---|---|
| | | | | |
| | | | | |

3) In a table (see below), provide details of the number of target points applicable to the country or *zone* and its BSE *surveillance* requirements (~~T~~type A or type B *surveillance* as a result of the *risk assessment* of Section 1) are met as described in Articles 11.4.21. and 11.4.22.

| SUMMARY TABLE FOR BSE SURVEILLANCE | |
|---|---|
| Year: (complete a separate table for each year of surveillance) | |
| | Surveillance subpopulations |

| | Routine slaughter | | Fallen stock | | Casualty slaughter | | Clinical suspect | |
|---|---|---|---|---|---|---|---|---|
| | Samples | Points | Samples | Points | Samples | Points | Samples | Points |
| **>1 and <2 years** | | | | | | | | |
| **>2 and <4 years** | | | | | | | | |
| **>4 and <7 years** | | | | | | | | |
| **>7 and <9 years** | | | | | | | | |
| **>9 years** | | | | | | | | |
| **Subtotals** | | | | | | | | |
| **Total points** | | | | | | | | |

4) Provide the number of adult cattle (over 24 months of age) in the country or *zone*.

Article 1.8.5.

**Section 4: BSE history of the country or zone (see Articles 11.4.3. and 11.4.4.)**

The categorisation of a country or *zone* ~~in~~ as either negligible or controlled risk is dependent upon, the outcome of the *risk assessment* described in Section 1, compliance with the provisions described in Section 2, the results of *surveillance* described in Section 3, and the history of BSE in the country or *zone*. Describe the BSE history in the country or *zone* by providing documentary evidence of the following:

1) Whether a *case* of BSE has ever been diagnosed in the country or *zone*.

2) In the case of positive BSE findings:

*a)* the numbers of BSE *cases* (classical and atypical), the origin of each BSE *case* in respect to the country or *zone*. Indicate the birth date and place of birth;

*b)* the most recent year of birth of the classical BSE *cases*;

*c)* that the *case(s*); and

*d)* all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation could not rule out consumption of the same potentially contaminated *feed* during that period; or

*e)* if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE *cases*; and

f) if alive in the country or *zone*, how they are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Article 1.8.6.

**Recovery of BSE risk status**

Member Countries applying for recognition of recovery of BSE risk status for a country or *zone* should comply with the provisions of Article 11.4.2. and Article 11.4.3. or Article 11.4.4. of the *Terrestrial Code* and provide detailed information as specified in this questionnaire.

Annex 27

CHAPTER 1.9

~~Article 1.6.10.~~

# APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF FREE STATUS FOR CLASSICAL SWINE FEVER

**EU position**

**The EU in general supports the adoption of this new chapter.**

**Reference is made to the general EU comments included in the top box in Annex 25.**

**Further comments are provided in the text below.**

Article 1.9.1

**Country or zone free from infection with classical swine fever virus**

**EU comment**

**The title of this Article 1.9.1. does not seem very pertinent. Indeed, the content of the article describes the information to be provided to support applications for country free status, and not the country free status *per se* (which is covered in Article 15.2.3.). To avoid confusion with the latter article, we would suggest amending the title of the present article along the following lines:**

**"Dossier in support of applications for country free from [...]."**

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country or *zone* free from infection with classical swine fever (CSF) virus in accordance with Chapter 15.2. of the *Terrestrial Code*.

**~~CSF FREE COUNTRY OR ZONE~~**
~~Report of a Member Country which applies for recognition of status,~~
~~under Chapter 15.2. of the *Terrestrial Code*,~~
~~as a CSF free country or zone~~

~~Please~~ The dossier provided to the OIE should address concisely all the ~~following~~ topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how ~~this~~ these ~~complies~~ comply with the *Terrestrial Code*.

~~Please use~~ The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

~~Any~~ All annexes should be provided in one of the OIE official languages.

*[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]*

~~8. Compliance with the *Terrestrial Code*~~

The Delegate of the Member Country applying for recognition of CSF freedom for a country or *zone* must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Articles 15.2.2. and 15.2.3. have been properly implemented and supervised.

**EU comment**

**The EU suggests avoiding the term "must" throughout the text. For reasons of consistency, it should preferably be replaced by "should", as is common practice throughout the Code (with the exception of chapter 1.1.).**

In addition, the Delegate of the Member Country must submit a declaration indicating that:

*a)* there has been no *outbreak* of CSF or evidence of CSFV *infection* in domestic and *captive wild* pigs in the country or *zone* during the past 12 months;

*b)* no *vaccination* against CSF has been carried out in domestic and *captive wild* pigs in the country or *zone* during the past 12 months; or, if *vaccination* is carried out, vaccinated and infected pigs can be distinguished by a means validated according to Chapter 2.8.3. of the *Terrestrial Manual*;

**EU comment**

**The EU suggests using the title of a Manual chapter, instead of its number, when referring to a disease-specific chapter of the Manual, as the numbering frequently changes when new Manual chapters are adopted or their order within the Manual is changed.**

**In this case, the sentence above could be changed as follows:**

**"[...] complies with the Classical swine fever chapter of the Terrestrial Manual.".**

*c)* imported pigs and pig *commodities* comply with the relevant requirements in Chapter 15.2.

**EU comment**

**For consistency with other chapters, the EU suggests rewording point c) above as follows (style):**

**"c) imported importation of pigs and pig commodities is carried out in accordance comply with the relevant requirements in provisions of Chapter 15.2.".**

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 *a)* of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

*a)* Geographical ~~entities~~ features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone* and, ~~when~~ where relevant, of the region, including physical, geographical and other factors that are relevant to ~~CSF~~ introduction of *infection* and ~~dissemination~~ spread of CSF virus, taking into account the ~~as well as a short description of~~ countries or *zones* sharing common borders and other epidemiologic pathways ~~links~~ for the potential introduction of ~~CSF~~ *infection*. The boundaries of the country or *zone* must be clearly defined, including a *protection zone,* if applied.

Provide maps identifying the ~~factors~~ features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the country or *zone*.

Specify whether the application includes any noncontiguous territories.

*b)* Pig industry. ~~Provide a general description of~~ Describe the composition of the domestic and *captive wild* pig industry in the country and the *zone*. In particular, describe:

*i)* the types of production systems in the country and the *zone*;

*ii)* the number of *herds*;

*iii)* their geographical distribution;

*iv)* *herd* density;

*v)* the degree of integration and role of producer organisations in the different production systems;

*vi)* any recent significant changes observed in the production (~~if~~ attach relevant documents ~~are~~ if available~~, please attach~~).

Provide tables and maps.

*c)* *Wildlife* demographics. What *captive wild*, *wild* or *feral* pigs are present in the country and the *zone*? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and *captive wild* pigs, and *wild* and *feral* pig *populations*?

*d)* *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (*e.g.,* fairs, shows, competitions). Where are the major pig marketing or collection centres? What are the patterns of pig movement for marketing within the country or *zone*, and between *zones* of the same or different status? How are the pigs sourced, transported and handled during these transactions? What proportions of slaughtered pigs are subjected to meat inspection in different production systems? Provide maps as appropriate.

2. Veterinary system

*a)* Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation~~s~~, regulations and *Veterinary Authority* directives in relation to CSF and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

*b)* *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code.* Describe how the *Veterinary Services* supervise, ~~and~~ control, enforce and monitor all CSF-related activities. Provide maps, figures and tables wherever possible.

*c)* Provide information on any OIE PVS evaluation conducted in ~~your~~ the country and follow-up steps within the PVS Pathway and highlight the results relevant to CSF and pigs.

**EU comment**

**The OIE PVS pathway is entirely voluntary, i.e. OIE member countries may choose to request an OIE PVS evaluation, or use the PVS tool for a self-evaluation, or not to do so. The EU therefore suggests inserting the words "Where relevant, " at the beginning of point c) above.**

*d)* Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in CSF *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including number of *veterinarians* and their distribution, ~~and role of the private *veterinarians* veterinary profession~~ in CSF *surveillance* and control. Include a description of continuing education and awareness programmes on CSF at all relevant levels.

**EU comment**

**The EU suggests replacing the term "industry" in point d) above (and throughout the text) with "production sector", for consistency with draft revised Chapter 4.3. (cf. Item 4.5. of the report).**

*e)* *Animal identification,* registration, traceability and movement control. Are pigs identified (individually or at a group level)?

Provide a description of the traceability system, including methods of *animal identification* and *establishment,* ~~holding~~ or *herd* registration ~~and traceability for~~ applicable to all susceptible species ~~production systems~~.

How are pig movements controlled in the country or *zone*, or between *zones* of the same or different status for all susceptible species ~~production systems~~?

Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, origin and destination of the pigs and their products moved within the country in the past ~~two years~~ 24 months.

Describe the *risk management* strategy for uncontrolled movements of pigs. Describe the actions available under national legislation.

**EU comment**

**For reasons of clarity, the EU suggests inserting the word "mitigating" before the words "actions available under national legislation".**

~~Describe the action available under legislation, and actually taken, when an illegal import is detected~~. Provide information on illegal movements detected in the past 24 months and the action taken.

**EU comment**

**We suggest replacing the term "illegal" with "unofficial or unregulated" (in the sentence above and throughout the text). Indeed, "unofficial" seems more appropriate than "illegal" in an international standard, while "unregulated" would imply there are no legal controls in the first place.**

3. CSF eradication

*a)* History. If *infection* has never occurred in the country ~~has never had the *disease*~~, or has not ~~had it~~ occurred within the past 25 years, ~~please~~ state explicitly whether or not the country or *zone* is applying for recognition of historical freedom according to Article 1.4.6. of the *Terrestrial Code*.

If *infection* has occurred in the country or *zone* ~~has had the *disease*~~ within the past 25 years, ~~please~~ provide a description of the CSF history in the country and *zone*, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the pigs involved, and the date of last *case* or *eradication* in the country or *zone*.

*b)* Strategy. Describe how CSF was controlled and eradicated in the country or *zone* (*e.g., stamping-out policy*, movement control, zoning). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~*disease*~~ *outbreaks* of CSF in response to any past ~~*disease*~~ incursions of CSF virus.

*c)* Vaccines and *vaccination*. Briefly answer the following:

*i)* Is there any legislation that prohibits *vaccination*? If so:

– Provide the date when *vaccination* was formally prohibited;

– Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.

– ~~Describe the action available under legislation, and actually taken, when an illegal *vaccination* is detected;~~

– ~~Provide information on detected illegal *vaccination* during the reporting period~~.

*ii)* Was *vaccination* ever used in the country? If so:

– Provide the date when the last *vaccination* was carried out;

– What type of vaccine was used? If DIVA vaccine has been used, describe the type of differential tests and results;

– Which pigs were vaccinated?

**EU comment**

**The EU suggests further information is required in the indent above to indicate what information is required, e.g. number and types of animals (domestic/feral), production types (breeder/fattening/etc.). This comment also applies to the second indent of point iii) below.**

– How were vaccinated pigs identified?

– What was the fate of those pigs?

*iii)* In addition, if *vaccination* was ~~conducted~~ applied during the past ~~two years~~ 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following: ~~regime. Briefly answer the following:~~

– the vaccine serotypes;

– the pigs vaccinated;

– identification of vaccinated pigs;

– the way in which the *vaccination* of pigs was certified or reported and the records maintained;

– ~~Provide~~ evidence that the vaccine used complies with Chapter 2.8.3. of the *Terrestrial Manual*.

*d)* Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. CSF diagnosis

Provide documentary evidence that the relevant provisions in Chapters 1.1.2., 1.1.3. and 2.8.3. of the *Terrestrial Manual* are applied. ~~In particular,~~ The following points should be addressed:

*a)* Is CSF *laboratory* diagnosis carried out in the country? If so, provide an overview of the CSF-approved *laboratories* in the country. ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.~~ Indicate the *laboratories* where samples originating from the *zone* are diagnosed.

~~*b)* Provide an overview of the CSF approved laboratories in the country.~~ Address the following points:

*i)* How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for ~~obtaining~~ reporting results;

**EU comment**

**The EU suggests inserting "or transport" after "for shipment" in point b) above, as samples may also be transported by the VS directly to the laboratory without requiring shipment.**

*ii)* Details ~~on~~ of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of CSF tests

performed in the past ~~two years~~ 24 months in ~~the~~ national *laboratories* and in *laboratories* in other countries, if relevant ~~as well as abroad~~;

*iii)* Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, *e.g.,* Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

*iv)* Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

*v)* Provide details of the handling of live pathogenic agent, ~~. In particular, describe~~ including a description of the biosecurity and biosafety measures applied;

*vi)* Provide a table ~~linking~~ identifying the tests carried out ~~to~~ by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

*b)* If CSF *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

**EU comment**

**The EU suggests inserting "or transport" after "for shipment" in point b) above, as samples may also be transported by the VS directly to the laboratory without requiring shipment.**

5. CSF surveillance

Provide documentary evidence that *surveillance* for CSF in the country or *zone* complies with Articles 15.2.26. to 15.2.32. of the *Terrestrial Code* and Chapter 2.8.3. of the *Terrestrial Manual*. ~~In particular,~~ The following information should be included ~~points should be addressed~~:

*a)* What are the criteria for raising a suspicion of CSF? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

*b)* Describe how clinical *surveillance* is conducted, including which ~~levels~~ sectors of the pig production ~~population~~ system are included in clinical *surveillance*, such as *establishments* ~~farms~~, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past ~~two years~~ 24 months, the number of suspected *cases*, the number of samples tested for CSF, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude CSF. Provide details ~~on~~ of follow-up actions taken on all suspicious and positive results.

**EU comment**

**The EU suggests inserting "control measures and" before "follow-up actions" in the paragraph above (and the paragraph below), as details on control measures would also be necessary.**

*c)* Serological ~~and~~ or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the ~~survey design~~ (target *population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used) in accordance with Articles 15.2.26. to 15.2.32. of the *Terrestrial Code*. How frequently are they conducted? Are *wild* and *feral* pigs included in *surveillance*? If not, explain the rationale. For both serological and virological *surveillance* provide a summary table indicating, for the past ~~12~~ 24 months, the number of samples tested for CSF, type of sample, testing methods and results (including differential diagnosis). Include in the table the number of false-positive results obtained on screening tests. Provide details ~~on~~ of follow-up actions taken on all suspicious and positive results and on how these findings are interpreted and acted upon. Provide criteria for selection of *populations* for targeted *surveillance* and numbers of pigs examined and samples tested in diagnostic *laboratories*. Provide details of ~~on~~ the methods selected and applied for monitoring the performance of the *surveillance* system including indicators.

*d)* Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (*e.g.,* targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how ~~and that the acquired~~ knowledge acquired through these activities assisted ~~assists~~ in more effective implementation of control measures.

*e)* Provide details ~~on~~ of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in CSF *surveillance* programmes.

6. CSF prevention

Describe the procedures in place to prevent the introduction of CSF into the country, including ~~In particular, provide~~ details of ~~on~~:

*a)* Coordination with other countries. Describe any relevant factors ~~about adjacent~~ in neighbouring countries or *zones* that should be taken into account (*e.g.,* size, distance from the border to affected *herds* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

If the CSF free *zone* is ~~situated~~ established in a CSF infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration existing physical or geographical barriers.

Are *protection zones* in place? If so, indicate whether or not the *protection zones* are included in the proposed free country or *zones*. Provide details ~~on~~ of the measures that are applied (*e.g., vaccination*, intensified *surveillance*, density control of pigs), and provide a geo-referenced map of the *zones*.

*b)* Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the ~~propagation~~ spread of the pathogenic agent within the country or *zone* ~~and through trade~~. Provide evidence that measures to reduce transmission of CSF are in place at markets, such as enhancing awareness of CSF transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity* ~~practices~~, hygiene~~,~~ ~~cleaning~~ and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

*c)* What measures are taken to limit access of susceptible domestic, *captive wild*, *feral* and *wild* pigs to waste products of animal origin? Is the feeding of swill ~~containing animal products~~ to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

*d)* Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of pigs or their products into the country or *zone.* Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied ~~on~~ to entry of such pigs and products and subsequent internal movement. Describe the import measures ~~conditions~~ (*e.g.,* quarantine) and test procedures required. Advise whether imported pigs are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and ~~health~~ *international veterinary certificates* are required.

**EU comment**

**The EU suggests inserting "health" before "certificate" in the paragraph above.**

Describe any other procedures used for assessing the *risks* posed by ~~of~~ import of pigs or their products. Provide summary statistics on imports of pigs and their products for at least the past ~~two years~~ 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country or *zone*.

Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

*i)* Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border ~~inspection~~ posts*, and between *border ~~inspection~~ posts*;

*ii)* Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past t~~wo years~~ 24 months, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?

*iii)* Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or *zone* or their final destination, concerning the import and follow-up of the following:

– pigs;

– genetic material (semen, oocytes and embryos);

– *fresh meat*, pig products and by-products;

– *veterinary medicinal products* ~~(i.e. biologics, vaccines),~~;

– other materials at risk of being contaminated with CSF virus.

7. Control measures and contingency planning

*a)* List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of CSF. The contingency plan should be attached as an annex in one of the OIE official languages. ~~and,~~ If not available, provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for CSF that was conducted in the country in the past five years.

*b)* In the event of a suspected or confirmed CSF *outbreak*:

*i)* ~~Is~~ Are quarantine measures imposed on *establishments* ~~premises~~ with ~~suspicious~~ suspected *cases*, pending final diagnosis? What other procedures are followed ~~regarding suspicious~~ with respect to suspected *cases* (*e.g.,* standstills)?

**EU comment**

**The EU suggests inserting the word "movement restrictions" after "standstill" in point i) above.**

*ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the ~~causative~~ pathogenic agent;

*iii)* Describe the actions that would be taken to control the disease situation in and around the *establishments* ~~premises~~ where the *outbreak* ~~was~~ is confirmed;

*iv)* Provide a detailed description of the control or *eradication* procedures (*e.g.,* forward and backward tracing, movement control, *disinfection* of *establishments* ~~premises~~, *vehicles* and equipment, including verification methods, policies on emergency *vaccination*, *stamping-out policy*, partial *slaughter*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

*v)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

*vi)* Give details of any compensation that would be made available to owners, farmers, etc. when pigs are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments.

*vii)* Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

*c)* If DIVA vaccine is used as part of risk mitigation, provide details of the vaccine and the differential tests.

~~8. Compliance with the *Terrestrial Code*~~

~~The Delegate of the Member Country applying for CSF freedom must submit documentary evidence that the provisions of Articles 15.2.2. and 15.2.3. have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating:~~

~~*a)* there has been no *outbreak* of CSF or evidence of CSFV *infection* in domestic and *captive wild* pigs in the country or *zone* during the past 12 months;~~

~~*b)* no *vaccination* against CSF has been carried out in domestic and *captive wild* pigs in the country or *zone* during the past 12 months; or, if *vaccination* is carried out, vaccinated and infected pigs can be distinguished by a means validated according to Chapter 2.8.3. of the *Terrestrial Manual*;~~

~~*c)* imported pigs and pig *commodities* comply with the relevant requirements in Chapter 15.2.~~

~~The Delegate of the Member Country applying for historical freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.~~

8~~9~~. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country or *zone* should comply with Article 15.2.6. of the *Terrestrial Code* and provide detailed information as specified in Sections 3 *a)*, 3 *b)*, 3 *c)*, 5 *b)* and 7 of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Annex 28

CHAPTER 1.10.

~~Article 1.6.7.~~

# APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF FREE STATUS FOR CONTAGIOUS BOVINE PLEUROPNEUMONIA

**EU position**

**The EU in general supports the adoption of this new chapter.**

**Reference is made to the general EU comments included in the top box in Annex 25.**

**Further comments are provided in the text below.**

~~**CBPP FREE COUNTRY**~~
~~Report of a Member Country which applies for recognition of status, under Chapter 11. 7~~5. ~~of the *Terrestrial Code*, as a CBPP free country~~

Article 1.10.1.

**Country free from infection with *Mycoplasma mycoides* subsp. *mycoides* SC (contagious bovine pleuropneumonia)**

**EU comment**

**The title of this Article 1.10.1. does not seem very pertinent. Indeed, the content of the article describes the information to be provided to support applications for country free status, and not the country free status *per se* (which is covered in Article 11.5.3.). To avoid confusion with the latter article, we would suggest amending the title of the present article along the following lines:**

**"Dossier in support of applications for country free from [...]."**

**This comment is valid also for the title of Article 1.10.2.**

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country free from infection with *Mycoplasma mycoides* subsp. *mycoides* SC (*MMms*SC) in accordance with Chapter 11.~~7~~5. of the *Terrestrial Code*.

The dossier provided to the OIE should ~~Please~~ address concisely all the ~~following~~ topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how these ~~this complies~~ comply with the *Terrestrial Code*.

~~Please use~~ The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

~~Any~~ All annexes should be provided in one of the OIE official languages.

*[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]*

The Delegate of the Member Country applying for recognition of CBPP freedom for a country must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 11. 5~~7~~.3. have been properly implemented and supervised.

**EU comment**

**The EU suggests avoiding the term "must" throughout the text. For reasons of consistency, it should preferably be replaced by "should", as is common practice throughout the Code (with the exception of chapter 1.1.).**

In addition, the Delegate of the Member Country must submit a declaration indicating that:

*a)* there has been no ~~*outbreak*~~ case of *infection* with ~~*Mycoplasma mycoides* subsp. *mycoides* SC~~ *MMms*SC during the past 24 months;

*b)* no evidence of ~~CBPP~~ *infection* with ~~*Mycoplasma mycoides* subsp. *mycoides* SC~~ *MMms*SC has been found during the past 24 months;

*c)* no *vaccination* against CBPP has been carried out during the past 24 months.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 *a)* of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

   *a)* Geographical ~~entities~~ features (rivers, mountain ranges, etc.). Provide a general description of the country and, ~~when~~ where relevant, of the region, including physical, geographical and other factors that are relevant to ~~CBPP~~ introduction of *infection* and ~~dissemination~~ spread of *MMms*SC, taking into account the ~~as well as a short description of~~ countries sharing common borders and other epidemiologic pathways ~~links~~ for the potential introduction of *infection* ~~CBPP~~.

   Provide maps identifying the ~~factors~~ features above.

   Specify whether the application includes any noncontiguous territories.

   *b)* Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country. In particular, describe:

      *i)* the susceptible animal *population* by species and types of production systems;

      *ii)* the number of *herds*, etc. of each susceptible species;

      *iii)* their geographical distribution;

      *iv)* *herd* density;

      *v)* the degree of integration and role of producer organisations in the different production systems;

      *vi)* any recent significant changes observed in the production (~~if~~ attach relevant documents ~~are~~ if available)~~, please attach~~.

   Provide tables and maps.

   *c)* *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?

   *d)* *Slaughterhouses*/*abattoirs,* markets and events associated with the congregation of susceptible livestock (*e.g.,* fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movements of domestic susceptible species for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

*a)* Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and *Veterinary Authority* directives in relation to CBPP and a brief description of the relevance of each. This list The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

*b)* *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with the provisions of Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, and control, enforce and monitor all CBPP-related activities. Provide maps, figures and tables wherever possible.

*c)* Provide information on any OIE PVS evaluation conducted in your the country and follow-up steps within the PVS Pathway and highlight the results relevant to CBPP and the susceptible species.

**EU comment**

**The OIE PVS pathway is entirely voluntary, i.e. OIE member countries may choose to request an OIE PVS evaluation, or use the PVS tool for a self-evaluation, or not to do so. The EU therefore suggests inserting the words "Where relevant, " at the beginning of point c) above.**

*d)* Provide a description of the involvement and the participation of industry, producers, farmers including subsistence and small-scale producers and keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in CBPP *surveillance* and control. Provide a description of the structure and role and structure of the private veterinary sector, including number of *veterinarians* and their distribution, in CBPP *surveillance* and control. Include a description of continuing education and awareness programmes on CBPP at all relevant levels.

**EU comment**

**The EU suggests replacing the term "industry" in point d) above (and throughout the text) with "production sector", for consistency with draft revised Chapter 4.3. (cf. Item 4.5. of the report).**

*e)* *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of *animal identification* and *establishment*, holding or *herd* registration and traceability for applicable to all susceptible species production systems.

How are animal movements controlled in the country for all susceptible species production systems?

Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past two years 24 months.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (*e.g.,* seasonal migration). Describe the actions available under national legislation.

**EU comment**

**For reasons of clarity, the EU suggests inserting the word "mitigating" before the words "actions available under national legislation" (in the sentence above and throughout the text).**

, and actually taken, when an illegal import is detected. Provide information on illegal movements detected in the past 24 months and the action taken.

**EU comment**

**We suggest replacing the term "illegal" with "unofficial or unregulated" (in the sentence above and throughout the text). Indeed, "unofficial" seems more appropriate than "illegal" in an international standard, while "unregulated" would imply there are no legal controls in the first place.**

3. CBPP eradication

*a)* History. If *infection* has never occurred in the country ~~has never had the *disease*~~, or has not occurred ~~had it~~ within the past 25 years, ~~please~~ state explicitly whether or not the country is applying for recognition of historical freedom according to Article 1.4.6. of the *Terrestrial Code*.

If ~~the country has had the *disease*~~ *infection* has occurred in the country within the past 25 years, provide a description of the CBPP history in the country, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of last case or *eradication* in the country.

*b)* Strategy. Describe how CBPP was controlled and eradicated (*e.g.,* slaughter policy, *zoning*, *vaccination*, movement control). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~*disease*~~ *outbreaks* of CBPP in response to any past ~~*disease*~~ incursions of *MMms*SC.

*c)* Vaccines and *vaccination*. Briefly answer the following:

*i)* Is there any legislation that prohibits *vaccination*? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.

  ~~Describe the action available under legislation, and actually taken, when an illegal *vaccination* is detected;~~

*ii)* Was *vaccination* ever used in the country? If so:

- Provide the date when the last *vaccination* was carried out;
- What type of vaccine was used?
- What species were vaccinated?
- How were vaccinated animals identified?
- What was the fate of those animals?

*iii)* In addition, if *vaccination* was ~~conducted~~ applied during the past ~~two years~~ 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following: ~~regime~~. ~~Briefly answer the following:~~

- the vaccine strains;
- the species vaccinated;
- identification of vaccinated animals;
- the way in which the *vaccination* of animals was certified or reported and the records maintained;
- ~~Provide~~ evidence that the vaccine used complies with Chapter 2.4.8. of the *Terrestrial Manual*.

**EU comment**

**The EU suggests using the title of a Manual chapter, instead of its number, when referring to a disease-specific chapter of the Manual, as the numbering frequently changes when new Manual chapters are adopted or their order within the Manual is changed.**

**In this case, the sentence above could be changed as follows:**

**"[...] complies with the Contagious bovine pleuropneumonia chapter of the Terrestrial Manual.".**

*d)* Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. CBPP diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.4.8. 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 an overview of the CBPP-approved *laboratories* in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.~~

~~*b)* Provide an overview of the CBPP approved laboratories in the country. Address the following points:~~

*i)* How the work is shared between different *laboratories,* logistics for shipment of samples, the follow-up procedures and the time frame for ~~obtaining~~ reporting results;

**EU comment**

**The EU suggests inserting "or transport" after "for shipment" in point b) above (and throughout the chapter), as samples may also be transported by the VS directly to the laboratory without requiring shipment.**

*ii)* Details ~~on~~ of test capability, and the types of tests undertaken, including procedures to isolate and identify *M. mycoides* subsp. *mycoides (Mmm)*, and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of CBPP tests performed in the past ~~two years~~ 24 months in ~~the~~ national *laboratories* and in *laboratories* in other countries, if relevant~~as well as abroad~~;

*iii)* Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, *e.g.,* Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

*iv)* Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

*v)* Provide details of the handling of live pathogenic agent, ~~In particular, describe~~ including a description of the biosecurity and biosafety measures applied;

*vi)* Provide a table ~~linking~~ identifying the tests carried out ~~to~~ by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

*b)* If CBPP *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the country complies with Articles 11.~~7~~5.13. to 11.~~7~~5.1~~7~~5. of the *Terrestrial Code* and Chapter 2.4.8. of the *Terrestrial Manual*. ~~In particular,~~ The following information should be included ~~points should be addressed~~:

*a)* What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

*b)* Describe how clinical *surveillance* is conducted, including which ~~levels of the~~ sectors of the livestock production system are included in clinical *surveillance*, such as *establishments* ~~farms~~, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past ~~two years~~ 24 months, the number of suspected cases, the number of samples tested for CBPP, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude CBPP. Provide details of follow-up actions taken on all suspicious and positive results.

**EU comment**

**The EU suggests inserting "control measures and" before "follow-up actions" in the paragraph above (and throughout the text), as details on control measures would also be necessary.**

*c)* Serological *surveillance*. Explain whether serological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the ~~survey design (~~target *population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used~~)~~ in accordance with Articles 11.~~7~~5.13. ~~and~~to 11.~~7~~5.~~15~~17. of the *Terrestrial Code*.

*d)* *Slaughterhouses/abattoirs* and slaughter slabs. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating, for the past ~~two years~~ 24 months, the number of suspected cases, the number of samples tested for CBPP agent, species, type of sample, testing methods and results (including differential diagnosis).

*e)* For countries where a significant proportion of animals are not slaughtered in controlled *slaughterhouses/abattoirs*, what are the alternative *surveillance* measures applied to detect CBPP (*e.g.,* active clinical *surveillance* programmes, *laboratory* follow-up).

*f)* Provide a description of the means employed during the ~~two years~~ 24 months preceding this application to rule out the presence of CBPP in the susceptible *population*. Provide criteria for selection of *populations* for targeted *surveillance* and numbers of animals examined and samples tested. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme ~~system~~ including indicators.

*g)* Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical and *slaughterhouse/abattoir surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.

6. CBPP prevention

Describe the procedures in place to prevent the introduction of CBPP into the country, ~~. In particular, provide~~ including details of:

*a)* Coordination with other countries. Describe any relevant factors ~~about~~ ~~adjacent~~ in neighbouring countries that should be taken into account (*e.g.,* size, distance from the border to affected *herds* or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

Are *protection zones* in place? If so, provide details of the measures that are applied (*e.g., vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

*b)* Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread ~~propagation~~ of the pathogenic agent within the country ~~and through trade~~. Provide

evidence that measures to reduce transmission of CBPP are in place at markets, such as enhancing awareness of CBPP transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity* ~~practices~~, hygiene ~~cleaning~~ and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

*c)* 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. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied ~~on~~ to entry of such animals and products and subsequent internal movement. Describe the import measures ~~conditions~~ (*e.g.,* quarantine) 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~~ *international veterinary certificates* are required.

**EU comment**

**The EU suggests inserting "health" before "certificate" in point c) above (and throughout the text).**

Describe any other procedures used for assessing the *risks* posed by ~~of~~ import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past ~~two years~~ 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country.

Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

*i)* Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls 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)* Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:

- animals;
- genetic material (semen, oocytes and embryos);
- *Mmm* strains including vaccines;
- *veterinary medicinal products*;
- other materials at risk of being contaminated with *Mmm*.

7. Control measures and contingency planning

*a)* List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of CBPP. The contingency plan should be attached as an annex in one of the OIE official languages. ~~and,~~ If not available, provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for CBPP that was conducted in the country in the past five years.

*b)* In the event of a suspected or confirmed CBPP *outbreak*:

*i)* ~~Is~~ Are quarantine measures imposed on *establishments* ~~premises~~ with ~~suspicious~~ suspected cases, pending final diagnosis? What other procedures are followed ~~regarding suspicious~~ with respect to suspected cases (*e.g.,* livestock standstills)?

**EU comment**

**The EU suggests inserting the word "movement restrictions" after "standstills" in point i) above (and throughout the text).**

*ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the ~~causative~~ pathogenic agent;

*iii)* Describe the actions that would be taken to control the disease situation in and around the ~~premises~~ *establishments* where the *outbreak* ~~was~~ is confirmed;

*iv)* Provide a detailed description of the control or *eradication* procedures (*e.g.,* forward and backward tracing, *disinfection* of ~~premises~~ *establishments* ~~premises~~, *vehicles* and equipment, including verification methods, *vaccination*, *stamping-out policy*, slaughter policy, movement control, pastured livestock and livestock as pets, control of offal, especially lungs, and carcasses, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken.

*v)* In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

*vi)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

*vii)* Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;

*viii)* Describe how control efforts, including *vaccination* and *biosecurity* ~~measures~~, would target critical risk control points.

~~8.~~ ~~Compliance with the *Terrestrial Code*~~*[NB moved to beginning of chapter]*

~~The Delegate of the Member Country applying for CBPP freedom must submit documentary evidence that the provisions of Article 11.5~~7.3. ~~have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating 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.~~

~~The Delegate of the Member Country applying for historical freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.~~

8~~9~~. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 11.5~~7~~.4. of the *Terrestrial Code* and provide detailed information as specified in Sections 3 *a)*, 3 *b)*, 3 *c)*, 5 *a)*, 5 *b)*, 5 *c)* and 5 *d)* of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.10.2.

**Zone free from infection with *Mycoplasma mycoides* subsp. *mycoides* SC (contagious bovine pleuropneumonia)**

The information should be provided by OIE Member Countries to support applications for official recognition of status as a *zone* free from infection with *Mycoplasma mycoides* subsp. *mycoides* SC (*MMms*SC) in accordance with Chapter 11.7. of the *Terrestrial Code*.

**~~CBPP FREE ZONE~~**

~~Report of a Member Country which applies for recognition of status, under Chapter 11.7. of the *Terrestrial Code*,~~

~~as a CBPP infection free zone~~

The dossier provided to the OIE should ~~Please~~ address concisely all the ~~following~~ topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how these ~~this complies~~ comply with the *Terrestrial Code*.

~~Please use~~ The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

~~Any~~ All annexes should be provided in one of the OIE official languages.

*[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]*

The Delegate of the Member Country applying for recognition of CBPP freedom for a *zone* must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 11. 5~~7~~.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

*a)* there has been no ~~*outbreak*~~ case of *infection* with *MMms*SC during the past 24 months;

*b)* no evidence of ~~CBPP~~ *infection* with *MMms*SC has been found during the past 24 months;

*c)* no *vaccination* against CBPP has been carried out during the past 24 months.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 *a)* of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

   *a)* Geographical ~~entities~~ features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone* and, ~~when~~ where relevant, of the region, including physical, geographical and other factors that are relevant to ~~CBPP~~ introduction of *infection* and spread of *MMms*SC ~~and dissemination~~, taking into account the ~~as well as a short description of~~ countries or *zones* sharing common borders and other epidemiologic pathways ~~links~~ for the potential introduction of *infection* ~~CBPP~~. The boundaries of the *zone* must be clearly defined, including a *protection zone*, if applied.

   Provide maps identifying the ~~factors~~ features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

   *b)* Livestock demographics. ~~Provide a general description~~ Describe the composition of the livestock industry in the country and the *zone*. In particular, describe:

      *i)* the susceptible animal *population* by species and types of production systems in the country and the *zone*;

      *ii)* the number of *herds*, etc. of each susceptible species;

      *iii)* their geographical distribution;

      *iv)* *herd* density;

      *v)* the degree of integration and role of producer organisations in the different production systems;

      *vi)* any recent significant changes observed in the production (~~if~~ attach relevant documents ~~are~~ if available~~, please attach~~).

      Provide tables and maps.

*c)* *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country and the *zone*? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?

*d)* *Slaughterhouses*/*abattoirs*, markets and events associated with the congregation of susceptible livestock (*e.g.,* fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movements of domestic susceptible species for marketing within the country or *zone*, and between *zones* of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

*a)* Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and *Veterinary Authority* directives in relation to CBPP and a brief description of the relevance of each. This list The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

*b)* *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with the provisions of Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, and control, enforce and monitor all CBPP-related activities. Provide maps, figures and tables wherever possible.

*c)* Provide information on any OIE PVS evaluation conducted in your the country and follow-up steps within the PVS Pathway and highlight the results relevant to CBPP and the susceptible species.

**EU comment**

**The OIE PVS pathway is entirely voluntary, i.e. OIE member countries may choose to request an OIE PVS evaluation, or use the PVS tool for a self-evaluation, or not to do so. The EU therefore suggests inserting the words "Where relevant, " at the beginning of point c) above.**

*d)* Provide a description of the involvement and the participation of industry, producers, farmers including subsistence and small-scale producers and keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in CBPP *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including number of *veterinarians* and their distribution, in CBPP *surveillance* and control. Include a description of continuing education and awareness programmes on CBPP at all relevant levels.

*e)* *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of the traceability system, *animal identification* and *establishment*, holding or *herd* registration and traceability applicable to for all susceptible species production systems.

How are animal movements controlled in and between *zones* of the same or different status for all susceptible species production systems?

Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past two years 24 months.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (*e.g.,* seasonal migration). Describe the actions available under national legislation. and actually taken, when an illegal import is detected.

Provide information on illegal movements detected in the past 24 months and the action taken.

3. CBPP eradication

*a)* History. If *infection* has never occurred in the *zone* ~~has never had the *disease*~~, or has not occurred ~~had it~~ within the past 25 years, ~~please~~ state explicitly whether or not the *zone* is applying for recognition of historical freedom in the *zone* according to Article 1.4.6. of the *Terrestrial Code*.

If *infection* has occurred in the *zone* ~~has had the *disease*~~ within the past 25 years, provide a description of the CBPP history in the country and *zone*, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of last case or *eradication* in the *zone*.

*b)* Strategy. Describe how CBPP was controlled and eradicated in the *zone* (*e.g.,* slaughter policy, *zoning*, *vaccination*, movement control~~, etc.~~). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~*disease*~~ *outbreaks* of CBPP in response to any past ~~*disease*~~ incursions of *MMms*SC.

*c)* Vaccines and *vaccination*. Briefly answer the following:

*i)* Is there any legislation that prohibits *vaccination*? If so:

– Provide the date when *vaccination* was formally prohibited;

– Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.

– ~~Describe the action available under legislation, and actually taken, when an illegal *vaccination* is detected;~~

— ~~Provide information on detected illegal *vaccination* during the reporting period.~~

*ii)* Was *vaccination* ever used in the country? If so:

– Provide the date when the last *vaccination* was carried out;

– What type of vaccine was used in the *zone* and the rest of the country?

– What species were vaccinated?

– How were vaccinated animals identified?

– What was the fate of those animals?

*iii)* In addition, if *vaccination* was ~~conducted~~ applied during the past ~~two years~~ 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following ~~regime. Briefly answer the following~~:

– the vaccine strains;

– the species vaccinated;

– identification of vaccinated animals;

– the way in which the *vaccination* of animals was certified or reported and the records maintained;

– ~~Provide~~ evidence that the vaccine used complies with Chapter 2.4.8. of the *Terrestrial Manual*.

*d)* Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. CBPP diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.4.8. 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 an overview of the CBPP-approved *laboratories* in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.~~ Indicate the *laboratories* where samples originating from the *zone* are diagnosed.

~~*b)* Provide an overview of the CBPP approved laboratories in the country.~~ Address the following points:

*i)* How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for ~~obtaining~~ reporting results;

*ii)* Details of ~~on~~ test capability, and the types of tests undertaken, including procedures to isolate and identify *M. mycoides* subsp. *mycoides* (*Mmm*), and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of CBPP tests performed in the past ~~two years~~ 24 months in ~~the~~ national *laboratories* and in *laboratories* in other countries, if relevant~~as well as abroad~~;

*iii)* Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, *e.g.,* Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

*iv)* Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

*v)* Provide details of the handling of live pathogenic agent, ~~In particular, describe~~ including a description of the biosecurity and biosafety measures applied;

*vi)* Provide a table ~~linking~~ identifying the tests carried out ~~to~~ by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

*b)* If CBPP *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the *zone* complies with Articles 11.~~7~~5.13. to 11.~~7~~5.1~~7~~5. of the *Terrestrial Code,* and Chapter 2.4.8. of the *Terrestrial Manual*. ~~In particular,~~ The following information should be included ~~points should be addressed~~:

*a)* What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

*b)* Describe how clinical *surveillance* is conducted, including which sectors ~~levels~~ of the livestock production system are included in clinical *surveillance*, such as *establishments* ~~farms~~, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past ~~two years~~ 24 months, the number of suspected cases, the number of samples tested for CBPP, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude CBPP. Provide details of follow-up actions taken on all suspicious and positive results.

*c)* Serological *surveillance*. Explain whether serological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the ~~survey design (~~target *population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used~~)~~ in accordance with Articles 11.~~7~~5.13. ~~and~~ to 11.~~7~~5.~~15~~17. of the *Terrestrial Code*.

*d)* *Slaughterhouses/abattoirs* and slaughter slabs. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating,

for the past ~~two years~~ 24 months, the number of suspected cases, the number of samples tested for CBPP agent, species, type of sample, testing methods and results (including differential diagnosis).

*e)* For countries where a significant proportion of animals in the *zone* are not slaughtered in controlled *slaughterhouses/abattoirs*, what are the alternative *surveillance* measures applied to detect CBPP (*e.g.,* active clinical *surveillance* programmes, *laboratory* follow-up).

*f)* Provide a description of the means employed during the ~~two years~~ 24 months preceding this application to rule out the presence of CBPP in the susceptible *population* of the *zone*. 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 selected and applied for monitoring the performance of the *surveillance* programme ~~system~~ including indicators.

*g)* Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical and *slaughterhouse/abattoir surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.

6. CBPP prevention

Describe the procedures in place to prevent the introduction of CBPP into the country or *zone,* ~~In particular, provide~~ including details of:

*a)* Coordination with other countries. Describe any relevant factors ~~about adjacent~~ in neighbouring countries and *zones* that should be taken into account (*e.g.,* size, distance from the border to affected *herds* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

If the CBPP free *zone* is ~~situated~~ established in a CBPP infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration existing physical or geographical barriers.

Are *protection zones* in place? If so, indicate whether or not the *protection zones* are included in the proposed free *zones*. Provide details of the measures that are applied (*e.g., vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

*b)* Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the ~~propagation~~ spread of the pathogenic agent within the country or *zone* ~~and through trade~~. Provide evidence that measures to reduce transmission of CBPP are in place at markets, such as enhancing awareness of CBPP transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity* ~~practices~~, hygiene~~,~~ ~~cleaning~~ and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

*c)* 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*, the controls applied ~~on~~ to entry of such animals and products and subsequent internal movement. Describe the import measures ~~conditions~~ (*e.g.,* quarantine) 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~~ *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by ~~of~~ import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past ~~two years~~ 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country.

Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

*i)* Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for

import controls 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)* Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and follow-up of the following:

– animals;

– genetic material (semen, oocytes and embryos);

– *Mmm* strains including vaccines;

– *veterinary medicinal products*;

– other materials at risk of being contaminated with *Mmm.*

7. Control measures and contingency planning

*a)* List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of CBPP. The contingency plan should be attached as an annex in one of the OIE official languages. ~~and,~~ If not available, provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for CBPP that was conducted in the country in the past five years.

*b)* In the event of a suspected or confirmed CBPP *outbreak*:

*i)* ~~is~~ Are quarantine measures imposed on *establishments* ~~premises~~ with ~~suspicious~~ suspected cases, pending final diagnosis? What other procedures are followed ~~regarding suspicious~~ with respect to suspected cases (*e.g.,* livestock standstills)?

*ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the ~~causative~~ pathogenic agent;

*iii)* Describe the actions that would be taken to control the disease situation in and around the *establishments* ~~premises~~ where the *outbreak* ~~was~~ is confirmed;

*iv)* Provide a detailed description of the control or *eradication* procedures (*e.g.,* forward and backward tracing, *disinfection* of *establishments* ~~premises~~, *vehicles* and equipment, including verification methods, *vaccination*, *stamping-out policy*, slaughter policy, movement control, pastured livestock and livestock as pets, control of offal, especially lungs, and carcasses, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken;

*v)* In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

*vi)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

*vii)* Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payment;

*viii)* Describe how control efforts, including *vaccination* and *biosecurity* ~~measures~~, would target critical risk control points.

~~8. Compliance with the *Terrestrial Code*~~

~~The Delegate of the Member Country applying for CBPP freedom must submit documentary evidence that the provisions of Article 11.57.3. have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating that in the *zone*:~~

~~*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,~~

~~The Delegate of the Member Country applying for historical freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.~~

8~~9~~. Recovery of free status

Member Countries applying for recognition of recovery of free status for a *zone* should comply with the provisions of Article 11.5~~7~~.4. of the *Terrestrial Code* and provide detailed information as specified in Sections 3 *a)*, 3 *b)*, 3 *c)*, 5 *a)*, 5 *b)*, 5 *c)* and 5 *d)* of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.10.3.~~1.6.13~~.

**Application for endorsement by the OIE of an official control programme for contagious bovine pleuropneumonia**

~~**Questionnaire on endorsement of official control programme for contagious bovine pleuropneumonia (CBPP)**~~

~~**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 11.7~~5. of the ~~*Terrestrial Code*~~

The following information should be provided by OIE Member Countries to support applications for endorsement by the OIE of an official control programme for contagious bovine pleuropneumonia (CBPP) in accordance with Chapter 11.~~7~~5. of the *Terrestrial Code*.

The dossier provided to the OIE should ~~In sections 1 to 3.5. please~~ address concisely all the ~~following~~ topics under the headings ~~please~~ provided in Sections 1 to 4 ~~3 e).5~~ to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

In Sections 3 f) to 3 i)~~3.6. to 3.9.~~ ~~please~~ ~~address~~ describe concisely the work plan and timelines of the control programme for the next five years.

~~Please use~~ The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

~~Any~~ All annexes should be provided in one of the OIE official languages.

**NB the paragraph below has been moved from the end of the chapter**

~~5. Compliance with the *Terrestrial Code*~~

The Delegate of the Member Country applying for endorsement of the official control programme should submit documentary evidence that the provisions of Article 11.5~~7~~.18. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for CBPP.

1. Introduction

*a)* Geographical ~~entities~~ features (rivers, mountain~~s~~ ranges, etc.). Provide a general description of the country and *zones* and, ~~when~~ where relevant, of the region, including physical, geographical and other factors that are relevant to ~~CBPP~~ introduction of *infection* and ~~dissemination~~ spread of CBBP, taking into account the ~~as well as a short description of~~ countries sharing common borders and other epidemiologic pathways ~~links~~ for the potential introduction of *infection* ~~CBPP~~.

Provide maps identifying the ~~factors~~ features above.

Specify whether the application includes any noncontiguous territories.

*b)* If the endorsed plan is ~~gradually~~ implemented in stages in ~~to~~ specific parts of the country, the boundaries of the *zones* should be clearly defined, including the *protection zones*, if applied. Provide a digitalised, geo-referenced map with a description of the geographical boundaries of the *zones*.

*c)* Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country or any *zones*. In particular, describe:

*i)* the susceptible animal *population* by species and types of production systems;

*ii)* the number of *herds* of each susceptible species;

*iii)* their geographical distribution;

*iv)* *herd* density, etc. Provide tables and maps as appropriate;

*v)* the degree of integration and role of producer organisations in the different production systems;

*vi)* any recent significant changes observed in the production (~~if~~ attach relevant documents if ~~are~~ available~~, please attach~~).

Provide tables and maps.

*d)* *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* ~~susceptible~~ species are present in the country and any *zones*? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* ~~susceptible~~ species?

*e)* *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (*e.g.*, fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic ~~susceptible~~ species ~~movement~~ for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

*a)* Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation~~s~~, regulations and *Veterinary Authority* directives in relation to the CBPP control programme and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation system~~s~~.

*b)* *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code.* Describe how the *Veterinary Services* supervise~~,~~ ~~and~~ control, enforce and monitor all CBPP-related activities. Provide maps, figures and tables wherever possible

*c)* Provide information on any OIE PVS evaluation conducted in ~~your~~ the country and follow-up steps within the PVS Pathway and highlight the results relevant to CBPP and the susceptible species.

**EU comment**

**The OIE PVS pathway is entirely voluntary, i.e. OIE member countries may choose to request an OIE PVS evaluation, or use the PVS tool for a self-evaluation, or not to do so. The EU therefore suggests inserting the words "Where relevant, " at the beginning of point c) above.**

*d)* Provide a description ~~on~~ of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in CBPP *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, ~~(~~including number of *veterinarians* and their distribution~~)~~, ~~and the role of the private *veterinarians* veterinary profession~~ in CBPP *surveillance* and control.

Include a description of continuing education and awareness programmes on CBPP at all relevant levels of the susceptible species value.

*e)* *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of animal identification and *establishment*~~, holding,~~ or *herd* registration ~~and traceability for~~ applicable to all susceptible species ~~production systems~~. How are animal movements controlled in the country for all susceptible species ~~production systems~~? Provide evidence ~~on~~ of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months ~~two years~~.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (*e.g.*, seasonal migration). Describe the actions available under national legislation. ~~and actually taken, when an illegal import is detected.~~

Provide information on illegal movements detected in the past 24 months and the action taken.

3. Official control programme for CBPP submitted for OIE endorsement

Submit a concise plan ~~on~~ of the measures for the control and eventual *eradication* of CBPP in the country, including:

*a)* Epidemiology

*i)* ~~Provide a description of~~ Describe the CBPP history in the country, with emphasis on recent years. Provide tables and maps showing the date of first detection, the number and location of *outbreaks* per year, the sources and routes of introduction of *infection*, the types and subtypes of *Mmm* present and the date of implementation of the control programme in the country.

*ii)* Describe the epidemiological situation of CBPP in the country and the surrounding countries or *zones* highlighting the current knowledge and gaps. Provide maps ~~on~~ of:

– the geography of the country with the relevant information concerning CBPP situation;

– livestock density and movements and estimated CBPP prevalence.

*b)* CBPP surveillance

Provide documentary evidence ~~on whether~~ that *surveillance* for CBPP in the country complies with Articles 11.5~~7~~.1~~4~~3. ~~to~~and 11.5~~7~~.15. of the *Terrestrial Code* and Chapter 2.4.8. of the *Terrestrial Manual*. ~~In particular~~, The following information should be included ~~points should be addressed~~:

*i)* What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom), and what incentives are there for reporting and what penalties are involved for failure to report?

*ii)* Describe how clinical *surveillance* is conducted, including which ~~levels of~~ sectors of the livestock production system are included in clinical *surveillance*, such as *establishments* ~~farms~~, markets, fairs, *slaughterhouses/abattoirs*, check points, etc. Provide details of follow-up actions taken on clinical suspicions.

*iii)* Serological *surveillance*. Explain whether serological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the ~~survey design (~~target *population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used~~)~~ in accordance with Articles 11.5~~7~~.13. and 11.5.14~~7~~.~~15~~ of the *Terrestrial Code*.

*iv)* *Surveillance* at *slaughterhouses/abattoirs*, slaughter slabs. Explain whether *slaughterhouses/ abattoirs* surveys are conducted and, if so, how frequently and for what purpose. What are the criteria for suspecting a lesion is CBPP? What is the procedure for notify (by whom and to whom)?

Annex 28 (contd)

*v)* Provide a summary table indicating, for at least the past 24 months ~~two years~~, the number of suspected cases, the number of samples tested for CBPP species, type of sample, testing methods and results (including differential diagnosis). Provide procedural details of follow-up actions taken on suspicious and positive results and on how these findings are interpreted and acted upon.

Provide criteria for selection of *population*s 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.

*vi)* 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).

*vii)* Provide information on the level of *risk* in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (*e.g.*, targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.) and that the acquired knowledge assists in more effective implementation of control measures.

*viii)* Provide details ~~on~~ of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical and *slaughterhouse/abattoir surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.

*ix)* Provide evidence that surveys are carried out to assess *vaccination* coverage and *population* immunity of the target *populations*, show analysis of *surveillance* data to assess the change in CBPP prevalence over time in the target *populations*, assess the control measures (cost effectiveness, degree of implementation, impact). Provide information on outcomes of *outbreak* investigations including *outbreaks* that have occurred despite control measures, documented inspections showing compliance with biosecurity and hygiene requirements.

*c)* CBPP ~~laboratory~~ diagnosis

Provide documentary evidence that the relevant provisions ~~in~~ of Chapters 1.1.1., 1.1.3. and 2.4.8. of the *Terrestrial Manual* are applied. ~~In particular,~~ The following points should be addressed:

*i)* Is CBPP *laboratory* diagnosis carried out in the country? If so, provide an overview of the CBPP-approved *laboratories* in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results~~.

~~*b)* Provide an overview of the CBPP approved *laboratories* in the country. Address the following points:~~

– How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for ~~obtaining~~ reporting results;

– Details of test capability and the types of tests undertaken including procedures to isolate and identify *M. mycoides* subsp. *mycoides* (*Mmm*) and their performance for their applied use (specificity and sensitivity per type of test). Provide details ~~on~~ of the number of CBPP tests performed in the ~~l~~past 24 months ~~two years~~ in ~~the~~ national *laboratories* and in *laboratories* in other countries, if relevant ~~as well as abroad~~;

– Procedures for quality assurance and, if available, for the official accreditation of *laboratories*. Give details of formal internal quality management systems, *e.g.*, Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

– Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

– Provide details ~~on~~ of the handling of live pathogenic agent, ~~In particular, describe~~ including a description of the biosecurity and biosafety measures applied;

– Provide a table identifying ~~linking~~ the tests carried out ~~to~~ by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

*ii)* If CBPP *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

*d)* Strategies

*i)* Provide a description of the legislation, organisation and implementation of the current CBPP control programme. Outline the legislation applicable to the control programme and how its implementation is organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

*ii)* Describe CBPP control strategies in the country or any *zones*, including in terms of animal movement control, fate of infected and in-contact animals, *vaccination* and possible use of antibiotics. Strategies should be based on the assessment of the CBPP situation in the *zones*, country and region.

*iii)* Provide information on what types of vaccines are used and which species are vaccinated. Provide evidence that the vaccine used complies with Chapter 1.1.8. of the *Terrestrial Manual*. 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~~ of the studies carried out to determine the *vaccination* coverage and the *population* immunity, including the study designs and the results.

*iv)* Provide a description of the policy on antibiotic treatment within the strategy. If it is banned how is the ban implemented?

*v)* Describe how the *stamping-out policy* is implemented in the country or any *zones* and under which circumstances.

~~*f)* Describe how the *stamping-out policy* is implemented in the country or any *zones* and under which circumstances.~~

*vi)* In the event of *outbreaks*, P~~p~~rovide evidence of the impact of the control measures already implemented ~~in the event of *outbreaks*,~~ on the~~ir~~ reduction in number of *outbreaks* and their distribution. If possible, provide information on primary and secondary *outbreaks*.

*e)* CBPP prevention

Describe the procedures in place to prevent the introduction of CBPP into the country, including ~~In particular provide~~ details of:

*i)* Coordination with other countries. Describe any relevant factors ~~about adjacent~~ in neighbouring countries and *zones* that should be taken into account (*e.g.*, size, distance from the border to affected *herds* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

Are *protection zones* in place? If so, provide details ~~on~~ of the measures that are applied (*e.g.*, *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

Annex 28 (contd)

*ii)* Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the ~~propagation~~ spread of the pathogenic agent within the country or *zone* ~~and through trade~~. Provide evidence that measures to reduce transmission of CBPP are in place at markets, ~~to reduce transmission of CBPP~~ such as enhancing awareness of CBPP transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity* ~~practices~~, hygiene~~,~~ ~~cleaning~~ and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

*iii)* 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 ~~into~~ any *zones*. Describe the criteria applied to approve such countries, *zones* or *compartments,* the controls applied ~~on~~ to entry of such animals and products and subsequent internal movement. Describe the import measures ~~conditions~~ (*e.g.*, quarantine) 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~~ *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* ~~of~~ posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months ~~two years~~, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

– Provide a map ~~with~~ showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls 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*.

– Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:

  – animals;

  – genetic material (semen, oocytes and embryos);

  – *Mmm* strains including vaccines;

  – *veterinary medicinal products*;

  – other materials at risk of being contaminated with *Mmm*.

*iv~~iii~~)* Describe the actions available under legislation~~, and actually taken,~~ when an illegal import is detected.

Provide information on ~~detected~~ illegal imports detected and the action taken.

*f)* Work plan and timelines of the control programme for the next five years, including cessation of *vaccination.* Describe the progressive objectives including expected status to be achieved ~~for~~ in the next five years: for *zones* (if applicable) and for the whole country.

*g)* Performance indicators and timeline. The performance indicators should relate to the most important areas and steps where improvements in the programme are needed. These may include, but are not restricted to, strengthening *Veterinary Services*, legislation, clinical and *slaughterhouse/abattoir* reporting, availability and quality of vaccines, *animal identification* systems, *vaccination* coverage, *population* immunity, movement control, disease awareness, CBPP seroprevalence reduction, cattle owners' participatory perception on the effectiveness of the programme, etc. The progressive reduction of *outbreak* incidence towards elimination of ~~CBPP~~ transmission of *Mmm* in all susceptible livestock in at least one *zone* of the country should also be measured and monitored.

*h)* Assessment of the evolution of the official control programme since the first date of implementation. This should include documented evidence demonstrating that the control programme has been implemented and that the first results are favourable. Measurable evidence of success such as the performance indicators should include, but not be limited to, *vaccination* data, decreased prevalence, successfully implemented import measures, control of animal movements and finally decrease or elimination of CBPP *outbreaks* in the whole country or selected *zones* as described in the programme.

This should include documented evidence of the ~~good~~ effective implementation of Sections 3 d) ~~3.4.~~ and 3 e) ~~3.5.~~ above.

*i)* ~~Description of~~ Describe the funding for the control programme and annual budgets for its duration.

4. Control measures and emergency response

*a)* List any written guidelines, including ~~emergency response~~ contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of CBPP. The contingency plan should be attached as an annex ~~and if not available~~ in one of the OIE official languages. If not available, provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for CBPP that was conducted in the country in the past five years.

*b)* In the event of a suspected or confirmed CBPP *outbreak*:

*i)* ~~is~~ Are quarantine measures imposed on *establishments* ~~premises~~ with suspected ~~suspicious~~ cases, pending final diagnosis? What other procedures are followed regarding suspected ~~suspicious~~ cases (*e.g.*, livestock standstills)?

*ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the ~~causative~~ pathogenic agent;

*iii)* Describe the actions that would be taken to control the disease situation in and around the *establishments* ~~premises~~ where the *outbreak* ~~was~~ is confirmed;

*iv)* Describe in detail ~~provide a detailed description of~~ the control or *eradication* procedures (*e.g.*, forward and backward tracing, *disinfection* of *establishments* ~~premises~~, *vehicles* and equipment, including verification methods, *vaccination*, *stamping-out policy*, *slaughter,* movement control, pastured livestock and livestock as pets, control of offal, especially lungs, and carcasses, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

*v)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

Annex 28 (contd)

*vi)* ~~give~~ Provide details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;

*vii)* Describe how control efforts, including *vaccination* and biosecurity ~~measures~~, would target critical risk control points.

~~5. Compliance with the *Terrestrial Code*~~

~~The Delegate of the Member Country must submit documentary evidence that the provisions of Article 11. 57.18. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for CBPP.~~

Annex 29

CHAPTER 1.11.

~~Article 1.6.6.~~

# APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF FREE STATUS FOR FOOT AND MOUTH DISEASE

**EU position**

**The EU in general supports the adoption of this new chapter.**

**Reference is made to the general EU comments included in the top box in Annex 25.**

**Further comments are provided in the text below.**

~~**Questionnaires on foot and mouth disease (FMD)**~~

~~**FMD FREE COUNTRY WHERE VACCINATION IS NOT PRACTISED**~~
~~Report of a Member Country which applies for recognition of status,~~
~~under Chapter 8.8. of the *Terrestrial Code*,~~
~~as a FMD free country not practising vaccination~~

Article 1.11.1.

**Country free from foot and mouth disease where vaccination is not practised**

**EU comment**

**The title of this Article 1.11.1. does not seem very pertinent. Indeed, the content of the article describes the information to be provided to support applications for country free status, and not the country free status per se (which is covered in Article 8.8.2.). To avoid confusion with the latter article, we would suggest amending the title of the present article along the following lines:**

**"Dossier in support of applications for country free from [...]."**

**This comment is valid also for the titles of Articles 1.11.2., 1.11.3. and 1.11.4.**

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country where vaccination is not practised, that is free from infection with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*.

~~Please~~ The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how ~~this~~ these ~~complies~~ comply with the *Terrestrial Code*.

~~Please use~~ The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

~~Any~~ All annexes should be provided in one of the OIE official languages.

*[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]*

~~8.~~ ~~Compliance with the *Terrestrial Code*~~

The Delegate of the Member Country applying for recognition of FMD freedom for a country where vaccination is not practised must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.2. have been properly implemented and supervised.

**EU comment**

**The EU suggests avoiding the term "must" throughout the text. For reasons of consistency, it should preferably be replaced by "should", as is common practice throughout the Code (with the exception of chapter 1.1.).**

In addition, the Delegate of the Member Country must submit a declaration indicating that:

*a)* there has been no *case* of FMD during the past 12 months;

*b)* no *vaccination* against FMD has been carried out during the past 12 months.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

*a)* Geographical ~~entities~~ features (rivers, mountain ranges, etc.). Provide a general description of the country and, ~~when~~ where relevant, of the region, including physical, geographical and other factors that are relevant to ~~FMD~~ introduction of *infection* and ~~dissemination~~ spread of FMD virus, taking into account the ~~as well as a short description of~~ countries or *zones* sharing common borders and other epidemiologic pathways ~~links~~ for the potential introduction of the *infection* ~~FMD~~.

Provide maps identifying the ~~factors~~ features above.

Specify whether the application includes any noncontiguous territories.

*b)* Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country. In particular, describe:

*i)* the susceptible animal *population* by species and types of production systems;

*ii)* the number of *herds* or *flocks*, etc. of each susceptible species;

*iii)* their geographical distribution;

*iv)* *herd* or *flock* density;

*v)* the degree of integration and role of producer organisations in the different production systems;

*vi)* any recent significant changes observed in the production (~~if~~ attach relevant documents ~~are~~ if available)~~, please attach~~.

Provide tables and maps.

*c)* *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* ~~susceptible~~ species?

*d)* *Slaughterhouses*/*abattoirs,* markets and events associated with the congregation of susceptible livestock (*e.g.*, fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic ~~susceptible~~ species ~~movement~~ for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

*a)* Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation~~s~~, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the

relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

*b)* *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with ~~the provisions of~~ Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise~~,~~ ~~and~~ control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.

*c)* Provide information on any OIE PVS evaluation conducted in the ~~your~~ country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.

**EU comment**

**The OIE PVS pathway is entirely voluntary, i.e. OIE member countries may choose to request an OIE PVS evaluation, or use the PVS tool for a self-evaluation, or not to do so. The EU therefore suggests inserting the words "Where relevant, " at the beginning of point c) above.**

*d)* Provide a description of ~~on~~ the involvement and the participation of industry, producers, farmers including subsistence and small-scale producers and keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including number of *veterinarians* and their distribution, ~~and role of the private veterinary profession~~ in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.

**EU comment**

**The EU suggests replacing the term "industry" in point d) above (and throughout the text) with "production sector", for consistency with draft revised Chapter 4.3. (cf. Item 4.5. of the report).**

*e)* *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of *animal identification*~~,~~ ~~holding,~~ and *establishment* or *herd* or *flock* registration ~~and traceability for~~ applicable to all susceptible species ~~production systems~~.

How are ~~animal~~ movements of all susceptible species controlled in the country ~~for all susceptible species production systems~~?

Provide evidence ~~on~~ of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months ~~two years~~.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (*e.g.*, seasonal migration). Describe the actions available under national legislation.

**EU comment**

**For reasons of clarity, the EU suggests inserting the word "mitigating" before the words "actions available under national legislation" (in the sentence above and throughout the text).**

~~Describe the action available under legislation, and actually taken, when an illegal import is detected.~~ Provide information on illegal movements detected in the past 24 months and the action taken.

**EU comment**

**We suggest replacing the term "illegal" with "unofficial or unregulated" (in the sentence above and throughout the text). Indeed, "unofficial" seems more appropriate**

**than "illegal" in an international standard, while "unregulated" would imply there are no legal controls in the first place.**

3. FMD eradication

*a)* History. If *infection* has never occurred in the country ~~has never had the *disease*~~, or has not ~~had it~~ occurred within the past 25 years, ~~please~~ state explicitly whether or not the country is applying for recognition of historical freedom according to point 1 of Article 1.4.6. of the *Terrestrial Code*.

If *infection* has occurred in the country ~~has had the *disease*~~ within the past 25 years, provide a description of the FMD history in the country, with emphasis on recent years. If applicable, provide tables and maps ~~to~~ showing the date of first detection, the sources and routes of introduction of *infection,* the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last *case* or *eradication*, and the types and strains in the country.

*b)* Strategy. Describe how FMD was controlled and eradicated (*e.g.*, *stamping-out policy*, zoning, *vaccination*, movement control). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~*disease*~~ *outbreaks* of FMD in response to any past ~~*disease*~~ incursions of FMD virus.

*c)* Vaccines and *vaccination*. Briefly answer the following:

*i)* Is there any legislation that prohibits *vaccination*? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.
- ~~Describe the action available under legislation, and actually taken, when an illegal *vaccination* is detected;~~
- ~~Provide information on detected illegal *vaccination* during the reporting period.~~

*ii)* Was *vaccination* ever used in the country? If so:

- Provide the date when the last *vaccination* was carried out;
- What type of vaccine was used?
- What species were vaccinated?
- How were vaccinated animals identified?
- What was the fate of those animals?

*iii)* In addition, if *vaccination* was ~~conducted~~ applied during the past 24 months ~~two years~~, provide a description and justification of the *vaccination* strategy and programme, including the following: ~~regime~~. ~~Briefly answer the following:~~

- the vaccine strains;
- potency and formulation, purity, details of any vaccine matching performed;
- the species vaccinated;
- identification of vaccinated animals;
- the way in which the *vaccination* of animals was certified or reported and the records maintained;
- ~~Provide~~ evidence that the vaccine used complies with Chapter 2.1.8. of the *Terrestrial Manual*.

**EU comment**

**The EU suggests using the title of a Manual chapter, instead of its number, when referring to a disease-specific chapter of the Manual, as the numbering frequently changes when new Manual chapters are adopted or their order within the Manual is changed.**

**In this case, the sentence above could be changed as follows:**

**"[...] complies with the Foot and mouth disease chapter of the Terrestrial Manual.".**

*d)* Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.1.8. of the *Terrestrial Manual* are applied. ~~In particular,~~ The following points should be addressed:

*a)* Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results~~.

~~*b)* Provide an overview of the PPR approved laboratories in the country. Address the following points:~~

*i)* How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting ~~obtaining~~ results;

**EU comment**

**The EU suggests inserting "or transport" after "for shipment" in point i) above (and throughout the chapter), as samples may also be transported by the VS directly to the laboratory without requiring shipment.**

*ii)* Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months ~~two years~~ in ~~the~~ national *laboratories* and in *laboratories* in other countries, if relevant ~~as well as abroad~~;

*iii)* Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, *e.g.*, Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

*iv)* Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

*v)* Provide details of the handling of live pathogenic agent, including a description of the ~~In particular, describe~~ biosecurity and biosafety measures applied;

*vi)* Provide a table identifying ~~linking~~ the tests carried out by each of ~~to~~ the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

*b)* If FMD *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code* and Chapter 2.1.8. of the *Terrestrial Manual*. ~~In particular,~~ The following information should be included ~~points should be addressed~~:

*a)* What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

*b)* Describe how clinical *surveillance* is conducted, including which ~~levels~~ sectors of the livestock production system are included in clinical *surveillance*, such as *establishments* ~~farms~~, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months ~~two years~~, the number of suspected *cases*, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.

**EU comment**

**The EU suggests inserting "control measures and" before "follow-up actions" in the paragraph above (and throughout the text), as details on control measures would also be necessary.**

*c)* Serological ~~and~~ or virological *surveillance*. ~~Have~~ Are serological ~~and~~ or virological surveys ~~been~~ conducted ~~to demonstrate freedom from *infection*~~? If so, provide detailed information on the ~~survey design (~~target *population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used~~)~~ in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are ~~they~~ surveys conducted? Are susceptible *wildlife* species included in serological ~~and~~ or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past 24 months ~~two years~~, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and on how these findings are interpreted and acted upon. Provide criteria for selection of *populations* for targeted *surveillance* based on the risk 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.

*d)* Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (*e.g.*, targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the ~~and that the acquired~~ knowledge acquired through these activities assisted ~~assists~~ in more effective implementation of control measures.

*e)* Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, ~~In particular provide~~ including details of:

*a)* Coordination with other countries. Describe any relevant factors ~~about adjacent~~ in neighbouring countries that should be taken into account (*e.g.*, size, distance from the border to affected *herds, flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

Are *protection zones* in place? If so, provide details of the measures that are applied (*e.g.*, *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

*b)* Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the ~~propagation~~ spread of the pathogenic agent within the country or *zone* ~~and through trade~~. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity* ~~practices~~, hygiene, ~~cleaning~~ and *disinfection*

routines at critical points all along the production and marketing networks (typically where animals are being moved~~,~~ and marketed through the country or region).

*c)* What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill ~~containing animal products~~ to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

*d)* 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. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied ~~on~~ to entry of such animals and products and subsequent internal movement. Describe the import measures ~~conditions~~ (*e.g.*, quarantine) 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~~ *international veterinary certificates* are required.

**EU comment**

**The EU suggests inserting "health" before "certificate" in point c) above (and throughout the text).**

Describe any other procedures used for assessing the *risks* ~~of~~ posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months ~~two years~~, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

*i)* Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border* ~~inspection~~ *posts* and between *border* ~~inspection~~ *posts*.

*ii)* Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months ~~two years~~, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?

*iii)* Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:

– animals;

– genetic material (semen, oocytes and embryos);

– animal products;

– *veterinary medicinal products* ~~(i.e. biologics)~~;

– other materials at risk of being contaminated with FMD virus, including bedding, litter and feed.

7. Control measures and contingency planning

*a)* List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex ~~and if not available~~ in one of the OIE official languages. If not available, provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.

*b)* In the event of a suspected or confirmed FMD *outbreak*:

*i)* ~~Is~~ Are quarantine measures imposed on *establishments* ~~premises~~ with ~~suspicious~~ suspected *cases*, pending final diagnosis? What other procedures are followed ~~regarding suspicious~~ with respect to suspected *cases* (*e.g.*, livestock standstills)?

**EU comment**

**The EU suggests inserting the word "movement restrictions" after "standstills" in point i) above (and throughout the text).**

*ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the ~~causative~~ pathogenic agent;

*iii)* Describe the actions that would be taken to control the disease situation in and around the ~~premises~~ *establishments* where the *outbreak* was is confirmed;

*iv)* Provide a detailed description of the control or *eradication* procedures (*e.g.*, forward and backward tracing, movement control, *disinfection* of *establishments* ~~premises~~, *vehicles* and equipment, including verification methods, *vaccination* including ~~*vaccination*~~ vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

*v)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

*vi)* Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;

*vii)* Describe how control efforts, including *vaccination* and *biosecurity* ~~measures~~, would target critical risk control points.

~~8.~~ ~~Compliance with the *Terrestrial Code*~~

~~The Delegate of the Member Country applying for FMD freedom must submit documentary evidence that the provisions of Article 8.8.2. have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating that:~~

~~*a)* there has been no *case* of FMD during the past 12 months;~~

~~*b)* no *vaccination* against FMD has been carried out during the past 12 months.~~

~~In addition, the Delegate of the Member Country applying for historical freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.~~

~~9~~8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 8.8.7. and points 1, 3 and 4 of Article 8.8.2. of the *Terrestrial Code* and provide detailed information as specified in Sections 1–7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.11.2.

~~**FMD FREE COUNTRY WHERE VACCINATION IS PRACTISED**~~
~~Report of a Member Country which applies for recognition of status,~~
~~under Chapter 8.8. of the *Terrestrial Code*,~~
~~as a FMD free country practising vaccination~~

**Country where vaccination is practised**

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country where vaccination is practised, that is free from infection with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*.

~~Please~~ The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how ~~this~~ these ~~complies~~ comply with the *Terrestrial Code*.

~~Please use~~ The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

~~Any~~ All annexes should be provided in one of the OIE official languages.

*[Note from the TAHSC – Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]*

~~8. Compliance with the *Terrestrial Code*~~

The Delegate of the Member Country applying for recognition of FMD freedom for a country where vaccination is practised must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

*a)* there has been no *case* of FMD for the past 24 months ~~two years~~;

*b)* no evidence of FMDV transmission for the past 12 months;

*c)* *surveillance* for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. and is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;

*d)* routine *vaccination* is carried out for the purposes of the prevention of FMD;

*e)* the vaccine used complies with the standards described in the *Terrestrial Manual*.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

*a)* Geographical ~~entities~~ features (rivers, mountain ranges, etc.). Provide a general description of the country and, ~~when~~ where relevant, of the region, including physical, geographical and other factors that are relevant to ~~FMD~~ introduction of *infection* and ~~dissemination~~ spread of FMD virus, taking into account the ~~as well as a short description of~~ countries or *zones* sharing common borders and other epidemiologic pathways ~~links~~ for the potential introduction of the *infection* ~~FMD~~.

Provide maps identifying the ~~factors~~ features above.

Specify whether the application includes any noncontiguous territories.

*b)* Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country. In particular, describe:

*i)* the susceptible animal *population* by species and types of production systems;

*ii)* the number of *herds* or *flocks*, etc. of each susceptible species;

*iii)* their geographical distribution;

*iv)* *herd* or *flock* density;

*v)* the degree of integration and role of producer organisations in the different production systems;

*vi)* any recent significant changes observed in the production (~~if~~ attach relevant documents ~~are~~ if available)~~, please attach~~.

Provide tables and maps.

*c)* *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* ~~susceptible~~ species are present in the country? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* ~~susceptible~~ species?

*d)* *Slaughterhouses*/*abattoirs,* markets and events associated with the congregation of susceptible livestock (*e.g.*, fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic ~~susceptible~~ species ~~movement~~ for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

*a)* Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation~~s~~, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

*b)* *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with ~~the provisions of~~ Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise~~,~~ ~~and~~ control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.

*c)* Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.

**EU comment**

**The OIE PVS pathway is entirely voluntary, i.e. OIE member countries may choose to request an OIE PVS evaluation, or use the PVS tool for a self-evaluation, or not to do so. The EU therefore suggests inserting the words "Where relevant, " at the beginning of point c) above.**

*d)* Provide a description of the involvement and the participation of industry, producers, farmers including subsistence and small-scale producers and keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including number of *veterinarians* and their distribution, ~~and role of the private veterinary profession~~ in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.

*e)* *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of *animal identification*~~,~~ ~~holding,~~ and *establishment* or *herd* or *flock* registration ~~and traceability for~~ applicable to all susceptible species ~~production systems~~.

How are ~~animal~~ movements of all susceptible species controlled in the country ~~for all production systems~~?

Provide evidence of ~~on~~ the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the ~~last~~ past 24 months ~~two years~~.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (*e.g.*, seasonal migration). Describe the actions available under national legislation.

~~Describe the action available under legislation, and actually taken, when an illegal import is detected.~~ Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

*a)* History. Provide a description of the FMD history in the country, with emphasis on recent years. If applicable, provide tables and maps ~~to~~ showing the date of first detection, the sources and routes of introduction of *infection,* the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last *case* or *eradication*, and the types and strains in the country.

*b)* Strategy. Describe how FMD was controlled and eradicated (*e.g.*, *stamping-out policy*, modified stamping-out policy, zoning*, vaccination*, movement control). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~*disease*~~ *outbreaks* of FMD in response to any past ~~*disease*~~ incursions of FMD virus.

*c)* Vaccines and *vaccination*. Describe any legislation regulating *vaccination*. Provide a description and justification of the *vaccination* strategy and programme, including the following: ~~regime~~. ~~Briefly answer the following~~:

*i)* the vaccine strains;

*ii)* potency and formulation, purity, details of any vaccine matching performed;

*iii)* the species vaccinated;

*iv)* identification of vaccinated animals;

*v)* the way in which the *vaccination* of animals was certified or reported and the records maintained;

*vi)* the date on which the last *vaccination* was performed;

*vii)* ~~Provide~~ evidence that the vaccine used complies with Chapter 2.1.8. of the *Terrestrial Manual*.

*d)* Provide detailed evidence of *vaccination* coverage and *population* immunity as follows:

Describe how the number of animals intended for *vaccination* and the number of vaccinated animals are estimated.

For serological surveys to estimate *population* immunity, provide detailed information on the sampling frame (target population, age, species and *vaccination* status) and survey design (expected prevalence, acceptable error, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How long after *vaccination* are samples collected? Describe how the threshold for protective immunity has been established.

Provide the results of the *vaccination* coverage and *population* immunity by year, serotype, species, as relevant.

Provide details of any additional methods applied for monitoring the performance of *vaccination*.

*e)* Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions in Chapters 1.1.2., 1.1.3. and 2.1.8. of the *Terrestrial Manual* are applied. ~~In particular, I~~ The following points should be addressed:

*a)* Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results~~.

~~*b)* Provide an overview of the PPR approved laboratories in the country. Address the following points:~~

*i)* How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting ~~obtaining~~ results;

*ii)* Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months ~~two years~~ in ~~the~~ national *laboratories* and in *laboratories* in other countries, if relevant ~~as well as abroad~~;

*iii)* Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, *e.g.*, Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

*iv)* Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

*v)* Provide details of the handling of live pathogenic agent, including a description of the ~~In particular, describe~~ biosecurity and biosafety measures applied;

*vi)* Provide a table identifying ~~linking~~ the tests carried out by each of ~~to~~ the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

*b)* If FMD *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code* and Chapter 2.1.8. of the *Terrestrial Manual*. ~~In particular,~~ The following information should be included~~points should be addressed~~:

*a)* What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

*b)* Describe how clinical *surveillance* is conducted, including which ~~levels~~ sectors of the livestock production system are included in clinical *surveillance*, such as *establishments* ~~farms~~, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months ~~two years~~, the number of suspected *cases*, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.

*c)* Serological ~~and~~ or virological *surveillance*. Are serological ~~and~~ or virological surveys conducted ~~to demonstrate freedom from *infection* with FMDV in unvaccinated animals and of FMDV transmission in vaccinated animals, in particular applying the provisions of Article 8.8.42~~? If so, provide detailed information on the ~~survey design~~ (target *population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used~~)~~ in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are ~~they~~ surveys conducted? Are susceptible *wildlife* species included in serological ~~and~~ or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past 24 months ~~two years~~, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and how these findings are interpreted and acted upon. Provide criteria for selection of *populations* for targeted *surveillance* based on the risk 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.

*d)* Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (*e.g.*, targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the ~~and that the acquired~~ knowledge acquired through these activities assisted ~~assists~~ in more effective implementation of control measures.

*e)* Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

*f)* Provide evidence that surveys are carried out to assess *vaccination* coverage and *population* immunity of the target *populations*, show *laboratory* evidence that the vaccine strains used is appropriate.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country~~. I~~, including ~~In particular, provide~~ details of:

*a)* Coordination with other countries. Describe any relevant factors ~~about adjacent~~ in neighbouring countries that should be taken into account (*e.g.*, size, distance from the border to affected *herds, flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

Are *protection zones* in place? If so, provide details of the measures that are applied (*e.g.*, *vaccination*, intensified *surveillance*, density control of susceptible species) and provide a geo-referenced map of the *zones*.

*b)* Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the ~~propagation~~ spread of the pathogenic agent within the country or *zone* ~~and through trade~~. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity* ~~practices~~, hygiene~~, cleaning~~ and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved~~,~~ and marketed through the country or region).

*c)* What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill ~~containing animal products~~ to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

*d)* 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. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied ~~on~~ to entry of such animals and products and subsequent internal movement. Describe the import measures ~~conditions~~ (*e.g.*, quarantine) 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~~ *international veterinary* certificates are required.

Describe any other procedures used for assessing the *risks* ~~of~~ posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months ~~two years~~, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

*i)* Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border* ~~inspection~~ *posts* and between *border* ~~inspection~~ *posts*.

*ii)* Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months ~~two years~~, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?

*iii)* Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the point of entry into the country or their final destination, concerning the import and follow-up of the following:

– animals;

– genetic material (semen, oocytes and embryos);

– animal products;

– *veterinary medicinal products* ~~(i.e. biologics)~~;

– other materials at risk of being contaminated with FMD virus, including bedding, litter and feed.

7. Control measures and contingency

*a)* List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex ~~and if not available~~ in one of the OIE official languages. If not available, provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for FMD that was conducted in the country in the last five years.

*b)* In the event of a suspected or confirmed FMD *outbreak*:

*i)* ~~Is~~ Are quarantine measures imposed on *establishments* ~~premises~~ with suspected ~~suspicious~~ *cases*, pending final diagnosis? What other procedures are followed ~~regarding suspicious~~ with respect to suspected *cases* (*e.g.*, livestock standstills)?

*ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the ~~causative~~ pathogenic agent;

*iii)* Describe the actions that would be taken to control the disease situation in and around the ~~premises~~ *establishments* where the *outbreak* ~~was~~ is confirmed;

*iv)* Provide a detailed description of the control or *eradication* procedures (*e.g.*, forward and backward tracing, movement control, *disinfection* of *establishments* ~~premises~~, *vehicles* and equipment, including verification methods, *vaccination* including ~~*vaccination*~~ vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

*v)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

*vi)* Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;

*vii)* Describe how control efforts, including *vaccination* and *biosecurity* ~~measures~~, would target critical risk control points.

~~8.~~ ~~Compliance with the *Terrestrial Code*~~

~~The Delegate of the Member Country must submit documentary evidence that the provisions of Article 8.8.3. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit a declaration indicating that:~~

~~*a)* there has been no *case* of FMD for the past two years;~~

~~*b)* no evidence of FMDV transmission for the past 12 months;~~

~~*c)* *surveillance* for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. and is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;~~

~~*d)* routine *vaccination* is carried out for the purpose of the prevention of FMD;~~

~~*e)* the vaccine used complies with the standards described in the *Terrestrial Manual*.~~

8~~9~~. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 8.8.7. and points 1, 3 and 4 of Article 8.8.3. of the *Terrestrial Code* and provide detailed information as specified in Sections 1–7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.11.3.

**~~FMD FREE ZONE WHERE VACCINATION IS NOT PRACTISED~~**
~~Report of a Member Country which applies for recognition of status,~~
~~under Chapter 8.8. of the *Terrestrial Code*,~~
~~as a FMD free zone not practising vaccination~~

**Zone free from foot and mouth disease where vaccination is not practised**

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a *zone* where vaccination is not practised that is free from infection with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code.*

~~Please~~ The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how ~~this~~ these ~~complies~~ comply with the *Terrestrial Code*.

~~Please use~~ The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

~~Any~~ All annexes should be provided in one of the OIE official languages.

*[Note from the TAHSC – Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below:]*

~~8. Compliance with the *Terrestrial Code*~~

The Delegate of the Member Country applying for recognition of FMD zonal freedom must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.2. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

*a)* there has been no *case* of FMD during the past 12 months;

*b)* no *vaccination* against FMD has been carried out during the past 12 months.

In addition, the Delegate of the Member Country applying for recognition of historical zonal freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

*a)* Geographical ~~entities~~ features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone* and, ~~when~~ where relevant, of the region, including physical, geographical and other factors that are relevant to ~~FMD~~ introduction of *infection* and ~~dissemination~~ spread of FMD virus, taking into account the ~~as well as a short description of~~ countries or *zones* sharing common borders and other epidemiologic pathways ~~links~~ for the potential introduction of the *infection* ~~FMD~~.

The boundaries of the *zone* must be clearly defined, including a *protection zone*, if applied.

Provide maps identifying the ~~factors~~ features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

*b)* Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country and the *zone*. In particular, describe:

*i)* the susceptible animal *population* by species and types of production systems in the country and the *zone*;

*ii)* the number of *herds* or *flocks*, etc. of each susceptible species;

*iii)* their geographical distribution;

*iv)* *herd* or *flock* density;

*v)* the degree of integration and role of producer organisations in the different production systems;

*vi)* any recent significant changes observed in the production (~~if~~ attach relevant documents ~~are~~ if available~~, please attach~~).

Provide tables and maps.

*c)* *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* ~~susceptible~~ species are present in the country and the *zone*? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* ~~susceptible~~ species?

*d)* *Slaughterhouses*/*abattoirs,* markets and events associated with the congregation of susceptible livestock (*e.g.*, fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic ~~susceptible~~ species ~~movement~~ for marketing within the country or *zone*, and between *zones* of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

*a)* Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation~~s~~, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

*b)* *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with ~~the provisions of~~ Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise~~,~~ ~~and~~ control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.

*c)* Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.

**EU comment**

**The OIE PVS pathway is entirely voluntary, i.e. OIE member countries may choose to request an OIE PVS evaluation, or use the PVS tool for a self-evaluation, or not to do so. The EU therefore suggests inserting the words "Where relevant, " at the beginning of point c) above.**

*d)* Provide a description of the involvement and the participation of industry, producers, farmers including subsistence and small-scale producers and keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including number of *veterinarians* and their distribution, ~~and role of the private veterinary profession~~ in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.

*e)* *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of *animal identification*~~,~~ and ~~holding~~, *establishment* or *herd* or *flock* registration ~~and traceability~~ applicable to ~~for~~ all susceptible species ~~production systems~~.

How are ~~animal~~ movements of all susceptible species controlled in and between *zones* of the same or different status for all production systems?

Provide evidence of ~~on~~ the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the ~~last~~ past 24 months ~~two years~~.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (*e.g.*, seasonal migration). Describe the actions available under national legislation.

~~Describe the action available under legislation, and actually taken, when an illegal import is detected.~~ Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

*a)* History. If *infection* has never occurred in the country ~~has never had the *disease*~~, or has not ~~had it~~ occurred within the last 25 years, ~~please~~ state explicitly whether or not the *zone* is applying for recognition of historical freedom according to point 1 of Article 1.4.6. of the *Terrestrial Code*.

If *infection* has occurred in the *zone* ~~has had the *disease*~~ within the past 25 years, provide a description of the FMD history in the country and *zone,* with emphasis on recent years. If applicable, provide tables and maps ~~to~~ showing the date of first detection, the sources and routes of introduction of *infection,* the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last *case* or *eradication* and the types and strains in the country.

*b)* Strategy. Describe how FMD was controlled and eradicated in the *zone* (*e.g.*, *stamping-out policy*, modified stamping-out policy, zoning*, vaccination*, movement control). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~*disease*~~ *outbreaks* of FMD in response to any past ~~*disease*~~ incursions of FMD virus.

*c)* Vaccines and *vaccination.* Briefly answer the following:

*i)* Is there any legislation that prohibits *vaccination*? If so:

– Provide the date when *vaccination* was formally prohibited;

– Provide information on cases of detection of illegal *vaccination* during the reporting period and actions take in response to the detection. ~~Describe the action available under legislation, and actually taken, when an illegal *vaccination* is detected;~~

– ~~Provide information on detected illegal *vaccination* during the reporting period.~~

*ii)* Was *vaccination* ever used in the *zone*? If so:

– Provide the date when the last *vaccination* was carried out;

– What type of vaccine was used?

– What species were vaccinated?

– How were vaccinated animals identified?

– What was the fate of those animals?

*iii)* In addition, if *vaccination* was ~~conducted~~ applied during the past 24 months ~~two years~~, provide a description and justification of the *vaccination* strategy and programme, including the following ~~regime. Briefly answer the following~~:

– the vaccine strains;

– potency and formulation, purity, details of any vaccine matching performed;

– the species vaccinated;

– identification of vaccinated animals;

– the way in which the *vaccination* of animals was certified or reported and the records maintained;

– ~~Provide~~ evidence that the vaccine used complies with Chapter 2.1.8. of the *Terrestrial Manual*.

*iv)* If *vaccination* continues to be used in the rest of the country, give details of the species vaccinated and on the post-*vaccination* monitoring programme.

*d)* Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of ~~in~~ Chapters 1.1.2., 1.1.3. and 2.1.8. of the *Terrestrial Manual* are applied. ~~In particular,~~ The following points should be addressed:

*a)* Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results. Indicate the *laboratories* where samples originating from the *zone* are diagnosed.~~

~~*b)* Provide an overview of the FMD approved laboratories in the country. Address the following points:~~

*i)* How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting ~~obtaining~~ results;

*ii)* Details of test capability and the type of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the past 24 months ~~two years~~ in national *laboratories* and in *laboratories* in other countries, if relevant ~~as well as abroad~~;

*iii)* Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, *e.g.*, Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

*iv)* Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

*v)* Provide details of the handling of live pathogenic agent, ~~In particular, describe~~ including a description of the biosecurity and biosafety measures applied;

*vi)* Provide a table ~~linking~~ identifying the tests carried out ~~to~~by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

*b)* If FMD *laboratory* diagnosis is not carried out in the country, provide the names of the laboratories in other countries providing the service as well as arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code* and Chapter 2.1.8. of the *Terrestrial Manual*. ~~In particular,~~ The following information should be included ~~points should be addressed~~:

*a)* What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

*b)* Describe how clinical *surveillance* is conducted, including which ~~levels~~ sectors of the livestock production system are included in clinical *surveillance*, such as *establishments* ~~farms~~, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months ~~two years~~, the number of suspected *cases*, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.

*c)* Serological ~~and~~ or virological *surveillance*. ~~Have~~ Are serological ~~and~~ or virological surveys ~~been~~ conducted ~~to demonstrate freedom from *infection*~~? If so, provide detailed information on the ~~survey design (~~target *population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used~~)~~ in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are ~~they~~ surveys conducted? Are susceptible *wildlife* species included in serological ~~and~~ or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past 24 months ~~two years~~, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and of how these findings are interpreted and acted upon. Provide criteria for selection of *populations* for targeted *surveillance* based on the risk 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.

*d)* Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (*e.g.*, targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how ~~and that the acquired~~ the knowledge acquired through these activities assisted ~~assists~~ in more effective implementation of control measures.

*e)* Provide details of the oversight of *surveillance* programmes by the V*eterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, ~~In particular, provide~~ including details of:

*a)* Coordination with other countries. Describe any relevant factors about ~~adjacent~~ in neighbouring countries and *zones* that should be taken into account (*e.g.*, size, distance from the border to affected *herds, flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

If the FMD free *zone* without *vaccination* is situated in a FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers.

Annex 29 (contd)

Are *protection zones* in place? If so, indicate whether or not the *protection zones* are included in the proposed FMD free *zones*, provide details of the measures that are applied (*e.g.*, *vaccination*, intensified *surveillance*, density control of susceptible species) and provide a geo-referenced map of the *zones.*

*b)* Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the ~~propagation~~ spread of the pathogenic agent within the country or *zone* ~~and through trade~~. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity* ~~practices~~, hygiene~~,~~ ~~cleaning~~ and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved~~,~~ and marketed through the country or region).

*c)* What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill ~~containing animal products~~ to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

*d)* 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 *zone.* Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied ~~on~~ to entry of such animals and products and subsequent internal movement. Describe the import measures ~~conditions~~ (*e.g.*, quarantine) 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~~ *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* ~~of~~ posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months ~~two years~~, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

*i)* Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border ~~inspection~~ posts* and between *border ~~inspection~~ posts.*

*ii)* Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months ~~two years~~, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?

*iii)* Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and follow-up of the following:

– animals;

– genetic material (semen, oocytes and embryos);

– animal products;

– *veterinary medicinal products* ~~(i.e. biologics)~~;

– other materials at risk of being contaminated with FMD virus, including bedding, litter and feed.



7. Control measures and contingency planning

*a)* List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex ~~and if not available~~ in one of the OIE official languages. If not available, provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.

*b)* In the event of a suspected or confirmed FMD *outbreak*:

*i)* ~~Is~~ Are quarantine measures imposed on *establishments* ~~premises~~ with ~~suspicious~~ suspected *cases*, pending final diagnosis? What other procedures are followed ~~regarding suspicious~~ with respect to suspected *cases* (*e.g.*, livestock standstills)?

*ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the ~~causative~~ pathogenic agent;

*iii)* Describe the actions that would be taken to control the disease situation in and around the ~~premises~~ *establishments* where the *outbreak* ~~was~~ is confirmed;

*iv)* Provide a detailed description of the control or *eradication* procedures (*e.g.*, forward and backward tracing, movement control, *disinfection* of *establishments* ~~premises~~, *vehicles* and equipment, including verification methods, *vaccination* including ~~*vaccination*~~ vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

*v)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

*vi)* Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;

*vii)* Describe how control efforts, including *vaccination* and *biosecurity* ~~measures~~, would target critical risk control points.

~~8. Compliance with the *Terrestrial Code*~~

~~The Delegate of the Member Country must submit documentary evidence that the provisions of Article 8.8.2. have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating that:~~

~~*a)* there has been no *case* of FMD during the past 12 months;~~

~~*b)* no *vaccination* against FMD has been carried out during the past 12 months;~~

~~In addition, the Delegate of the Member Country applying for historical zonal freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.~~

8~~9~~. Recovery of free status

Member Countries applying for recognition of recovery of free status for a *zone* where vaccination is not practised should comply with the provisions of Article 8.8.7. and points 1, 3 and 4 of Article 8.8.2. of the *Terrestrial Code* and provide detailed information as specified in Sections 1–7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.11.4.

**~~FMD FREE ZONE WHERE VACCINATION IS PRACTISED~~**
~~Report of a Member Country which applies for recognition of status,~~
~~under Chapter 8.8. of the *Terrestrial Code*,~~
~~as a FMD free zone practising vaccination~~

**Zone where vaccination is practised**

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a *zone* where vaccination is practised, that is free from infection with food and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code.*

~~Please~~ The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how this complies with the *Terrestrial Code*.

~~Please use~~ The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

~~Any~~ All annexes should be provided in one of the OIE official languages.

*[Note from the TAHSC – Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below:]*

~~8. Compliance with the *Terrestrial Code*~~

The Delegate of the Member Country applying for recognition of FMD zonal freedom must demonstrate compliance with the *Terrestrial Code.* That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

*a)* there has been no *case* of FMD for the past 24 months ~~two years~~;

*b)* no evidence of FMDV transmission for the past 12 months;

*c)* *surveillance* for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. and is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;

*d)* routine *vaccination* is carried out for the purposes of the prevention of FMD;

*e)* the vaccine used complies with the standards described in the *Terrestrial Manual*.

In addition, the Delegate of the Member Country applying for recognition of historical zonal freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

   *a)* Geographical ~~entities~~ features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone* and, ~~when~~ where relevant, of the region, including physical, geographical and other factors that are relevant to ~~FMD~~ introduction of *infection* and spread of FMD virus, ~~dissemination~~,

taking into account the ~~as well as a short description of~~ countries or *zones* sharing common borders and other epidemiologic pathways ~~links~~ for the potential introduction of the *infection* ~~FMD~~.

The boundaries of the *zone* must be clearly defined, including a *protection zone,* if applied.

Provide maps identifying the ~~factors~~ features above, including a digitalised, geo-referenced map with a description of the geographical boundaries of the *zone*.

*b)* Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country and the *zone*. In particular, describe:

*i)* the susceptible animal *population* by species and types of production systems in the country and the *zone*;

*ii)* the number of *herds* or *flocks*, etc. of each susceptible species;

*iii)* their geographical distribution;

*iv)* *herd* or *flock* density;

*v)* the degree of integration and role of producer organisations in the different production systems;

*vi)* any recent significant changes observed in the production (~~if~~ attach relevant documents if ~~are~~ available~~, please attach~~).

Provide tables and maps.

*c)* *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* ~~susceptible~~ species are present in the country and the *zone*? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?

*d)* *Slaughterhouses*/*abattoirs,* markets and events associated with the congregation of susceptible livestock (*e.g.*, fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic ~~susceptible~~ species ~~movement~~ for marketing within the country or *zone*, and between *zones* of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

*a)* Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation~~s~~, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. ~~This list~~ This table should include, but not be limited to, the legislation on disease control measures and compensation systems.

*b)* *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with ~~the provisions of~~ Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise~~,~~ ~~and~~ control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.

*c)* Provide information on any OIE PVS evaluation conducted in ~~your~~ the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.

**EU comment**

**The OIE PVS pathway is entirely voluntary, i.e. OIE member countries may choose to request an OIE PVS evaluation, or use the PVS tool for a self-evaluation, or not to do so. The EU therefore suggests inserting the words "Where relevant, " at the beginning of point c) above.**

*d)* Provide a description of the involvement and the participation of industry, producers, farmers including subsistence and small-scale producers and keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a

description of the role and structure of the private veterinary sector, including number of *veterinarians* and their distribution), ~~and role of the private veterinary profession~~ in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.

*e)* *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of *animal identification*~~,~~ and *establishment* or ~~holding,~~ *herd* or *flock* registration ~~and traceability for~~ applicable to all susceptible species ~~all production systems~~.

How are ~~animal~~ movements of all susceptible species controlled in and between *zones* of the same or different status ~~for all production systems~~?

Provide evidence of ~~on~~ the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the ~~last~~ past 24 months ~~two years~~. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (*e.g.*, seasonal migration). Describe the actions available under national legislation.

~~Describe the action available under legislation, and actually taken, when an illegal import is detected.~~ Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

*a)* History. Provide a description of the FMD history in the country and *zone*, with emphasis on recent years. If applicable, provide tables and maps ~~to~~ showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last *case* or *eradication* and the types and strains in the country.

*b)* Strategy. Describe how FMD was controlled and eradicated in the *zone* (*e.g.*, *stamping-out policy*, zoning, *vaccination*, movement control). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~*disease*~~ *outbreaks* of FMD in response to any past ~~*disease*~~ incursions of FMD virus.

*c)* Vaccines and *vaccination*. Describe any legislation regulating *vaccination*. Provide a description and justification of the *vaccination* strategy and programme, including the following: ~~regime~~. ~~Briefly answer the following:~~:

*i)* the vaccine strains;

*ii)* potency and formulation, purity, details of any vaccine matching performed;

*iii)* the species vaccinated;

*iv)* identification of vaccinated animals;

*v)* the way in which the *vaccination* of animals was certified or reported and the records maintained;

*vi)* the date on which the last *vaccination* was performed;

*vii)* evidence that the vaccine used complies with Chapter 2.1.8. of the *Terrestrial Manual*.

*d)* Provide detailed evidence of *vaccination* coverage and *population* immunity as follows:

Describe how the number of animals intended for *vaccination* and the number of vaccinated animals are estimated.

For serological surveys to estimate *population* immunity, provide detailed information on the sampling frame (target population, age, species and *vaccination* status) and survey design (expected prevalence, acceptable error, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How long after *vaccination* are samples collected? Describe how the threshold for protective immunity has been established.

Provide the results of the *vaccination* coverage and *population* immunity by year, serotype, species, as relevant.

Provide details of any additional methods applied for monitoring the performance of *vaccination*.

*e)* Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.1.8. of the *Terrestrial Manual* are applied. ~~In particular,~~ The following points should be addressed:

*a)* Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results. Indicate the laboratories where samples originating from the *zone* are diagnosed.~~

~~*b)* Provide an overview of the FMD-approved laboratories in the country. Address the following points:~~

*i)* How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for ~~obtaining~~ reporting results;

*ii)* Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months ~~two years~~ in the national *laboratories* and in *laboratories* in other countries, if relevant ~~as well as abroad~~;

*iii)* Procedures for quality assurance and for the official accreditation of laboratories. Give details of formal internal quality management systems, *e.g.*, Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system;

*iv)* Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

*v)* Provide details of the handling of live pathogenic agent~~., In particular, describe~~ ~~I~~including a description of the biosecurity and biosafety measures applied;

*vi)* Provide a table ~~linking~~ identifying the tests carried out ~~to~~ by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

*b)* If FMD *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code* and Chapter 2.1.8. of the *Terrestrial Manual*. ~~In particular,~~ The following information should be included: ~~points should be addressed:~~

*a)* What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

*b)* Describe how clinical *surveillance* is conducted, including which sectors ~~levels~~ of the livestock production system are included in clinical *surveillance*, such as *establishments* ~~farms~~, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months ~~two years~~, the number of suspected *cases*, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.

*c)* Serological ~~and~~ or virological *surveillance*. Are serological ~~and~~ or virological surveys conducted ~~to demonstrate freedom from *infection* with FMDV in unvaccinated animals and of FMDV transmission in vaccinated animals, in particular applying the provisions of Article 8.8.42~~? If so, provide detailed information on the ~~survey design~~ (target *population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used~~)~~ in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are ~~they~~ surveys conducted? Are susceptible *wildlife* species included in serological ~~and~~ or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past 24 months ~~two years~~, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis).

Provide details of follow-up actions taken on all suspicious and positive results and how these findings are interpreted and acted upon. Provide criteria for selection of *populations* for targeted *surveillance* based on the risk 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.

*d)* Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (*e.g.*, targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.) Provide evidence of how the ~~and that the acquired~~ knowledge acquired through these activities assisted ~~assists~~ in more effective implementation of control measures.

*e)* Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance* and the approaches used to increase community involvement in FMD *surveillance* programmes.

*f)* Provide evidence that surveys are carried out to assess *vaccination* coverage and *population* immunity of the target *populations*, show laboratory evidence that the vaccine strains used are appropriate.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country~~.~~ ~~In particular, provide~~ including details of:

*a)* Coordination with other countries. Describe any relevant factors ~~about adjacent~~ in neighbouring countries and *zones* that should be taken into account (*e.g.*, size, distance from the border to affected *herds, flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

If the FMD free *zone* with *vaccination* is situated in a FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

Are *protection zones* in place? If so, indicate whether or not the *protection zones* are included in the proposed FMD free *zones*, provide details of the measures that are applied (*e.g.*, *vaccination*, intensified *surveillance*, density control of susceptible species) and provide a geo-referenced map of the *zones*.

*b)* Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the ~~propagation~~ spread of the pathogenic agent within the country or *zone* ~~and through trade~~. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity* ~~practices~~, hygiene~~,~~ ~~cleaning~~ and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved~~,~~ and marketed through the country or region).

*c)* What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill ~~containing animal products~~ to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

*d)* 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*, the controls applied ~~on~~ to entry of such animals and products and subsequent internal movement. Describe the import measures ~~conditions~~ (*e.g.*, quarantine) 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~~ *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* ~~of~~ posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months ~~two years~~, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

*i)* Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border i*~~nspection~~ *posts* and between *border* ~~inspection~~ *posts*.

*ii)* Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months ~~two years~~, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?

*iii)* Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and follow-up of the following:

– animals;

– genetic material (semen, oocytes and embryos);

– animal products;

– *veterinary medicinal products* ~~(i.e. biologics)~~;

– other materials at risk of being contaminated with FMD virus, including bedding, litter and feed.

Annex 29 (contd)

7. Control measures and contingency planning

*a)* List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex ~~and if not available~~ in one of the OIE official languages. If not available, provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for FMD that was conducted in the country in the last five years.

*b)* In the event of a suspected or confirmed FMD *outbreak*:

*i)* ~~Is~~ Are quarantine measures imposed on ~~premises~~ *establishments* with ~~suspicious~~ suspected *cases*, pending final diagnosis? What other procedures are followed ~~regarding suspicious~~ with respect to suspected *cases* (*e.g.*, livestock standstills)?

*ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the ~~causative~~ pathogenic agent;

*iii)* Describe the actions that would be taken to control the disease situation in and around the ~~premises~~ *establishments* where the *outbreak* was confirmed;

*iv)* Provide a detailed description of the control or *eradication* procedures (*e.g.*, forward and backward tracing, movement control, *disinfection* of *establishments* ~~premises~~, *vehicles* and equipment, including verification methods, *vaccination* including ~~*vaccination*~~ vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

*v)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

*vi)* Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;(17

*vii)* Describe how control efforts, including *vaccination* and *biosecurity* ~~measures~~, would target critical risk control points.

~~8. Compliance with the *Terrestrial Code*~~

~~The Delegate of the Member Country must submit documentary evidence that the provisions of Article 8.8.3. are have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating that:~~

~~*a)* there has been no *case* of FMD for the past two years;~~

~~*b)* no evidence of FMDV transmission for the past 12 months;~~

~~*c)* *surveillance* for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. and is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;~~

~~*d)* routine *vaccination* is carried out for the purpose of the prevention of FMD;~~

~~*e)* the vaccine used complies with the standards described in the *Terrestrial Manual*.~~

8~~9~~. Recovery of status

Member Countries applying for recognition of recovery of free status for a *zone* where vaccination is practised should comply with the provisions of Article 8.8.7 and points 1, 3 and 4 of Article 8.8.3. of the *Terrestrial Code* and provide detailed information as specified in Sections 1–7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

~~Article 1.6.11.~~

**~~Questionnaire on endorsement of official control programme for foot and mouth disease (FMD)~~**

**~~COUNTRY WITH AN OIE ENDORSED OFFICIAL CONTROL PROGRAMME FOR FMD~~**
~~Report of a Member Country which applies for the OIE endorsement~~
~~of its official control programme for FMD~~
~~under Chapter 8.8. of the *Terrestrial Code*~~

Article 1.11.5.

**Application for endorsement by the OIE of an official control programme for foot and mouth disease**

The following information should be provided by OIE Member Countries to support applications for endorsement by the OIE of an official control programme for foot and mouth disease (FMD) in accordance with Chapter 8.8. of the *Terrestrial Code.*

The dossier provided to the OIE should ~~In sections 1 to 3.5., please~~ address concisely all the ~~following~~ topics under the headings provided in Sections 1 to ~~3.e).~~4 to describe the actual situation in the country and procedures currently applied, explaining how these comply with the *Terrestrial Code*.

In Sections 3 f) to 3 i) ~~3.6. to 3.9~~. ~~please address~~ describe concisely the work plan and timelines of the control programme for the next five years.

~~Please use~~ The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

~~Any~~ All annexes should be provided in one of the OIE official languages.

**NB the paragraph below has been moved from the end of the chapter**

~~5. Compliance with the *Terrestrial Code*~~

The Delegate of the Member Country applying for endorsement of the official control programme should submit documentary evidence that the provisions of Article 8.8.39. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for FMD.

1. Introduction

*a)* Geographical ~~entities~~ features (rivers, mountain~~s~~ ranges, etc.). Provide a general description of the country, *zones* and, ~~when~~ where relevant, of the region, including physical, geographical and other factors that are relevant to ~~FMD~~ introduction of *infection* and ~~dissemination~~ spread of FMD, taking into account the ~~as well as a short description of~~ countries or *zones* sharing common borders and other epidemiologic pathways ~~links~~ for the potential introduction of *infection* ~~FMD~~.

Provide maps identifying the ~~factors~~ features above.

Specify whether the application includes any noncontiguous territories.

*b)* If the endorsed plan is ~~gradually~~ implemented in stages to ~~in~~ specific parts of the country, the boundaries of the *zones* should be clearly defined, including the *protection zones*, if applied. Provide a digitalised, geo-referenced map with a description of the geographical boundaries of the *zones*.

Annex 29 (contd)

*c)* Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country and any *zones*. In particular, describe:

*i)* the susceptible animal *population* by species and types of production systems;

*ii)* the number of *herds* or *flocks*, etc. of each susceptible species;

*iii)* their geographical distribution;

*iv)* *herd* or *flock* density;

*v)* the degree of integration and role of producer organisations in the different production systems;

*vi)* any recent significant changes observed in the production (~~if~~ attach relevant documents ~~are~~ if available~~, please attach~~).

Provide tables and maps.

*d)* *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* ~~susceptible~~ species are present in the country and any *zones*? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* ~~susceptible~~ species?

*e)* *Slaughterhouses/abattoirs,* markets and events associated with the congregation of susceptible livestock (*e.g.,* fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic ~~susceptible~~ species ~~movement~~ for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

*a)* Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation~~s~~, regulations and *Veterinary Authority* directives in relation to the FMD control programme and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

*b)* *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with ~~the provisions of~~ Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, ~~and~~ control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.

*c)* Provide information on any OIE PVS evaluation conducted in ~~your~~ the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.

**EU comment**

**The OIE PVS pathway is entirely voluntary, i.e. OIE member countries may choose to request an OIE PVS evaluation, or use the PVS tool for a self-evaluation, or not to do so. The EU therefore suggests inserting the words "Where relevant, " at the beginning of point c) above.**

*d)* Provide a description of ~~on~~ the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, ~~(~~including number of *veterinarians* and their distribution~~)~~, ~~and role of the private veterinary profession~~ in FMD *surveillance* and control.

Include a description of continuing education and awareness programmes on FMD at all relevant levels.

*e)* *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of animal identification and ~~holding,~~ *establishment* or *herd* or *flock* registration ~~and traceability~~ applicable to all susceptible species ~~production systems~~. How are animal movements controlled in the country for all susceptible species ~~production systems~~? Provide evidence ~~on~~ of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months ~~last two years~~.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (*e.g.,* seasonal migration). Describe the actions available under national legislation.~~, and actually taken, when an illegal import is detected.~~

Provide information on illegal movements detected in the past 24 months and the action taken.

3. Official control programme for FMD submitted for OIE endorsement

Submit a concise plan ~~on~~ of the measures for the control and eventual *eradication* of FMD in the country, including:

~~3.1.~~*~~a)~~* Epidemiology

~~*a)*~~*i)* ~~Provide a description of~~ Describe the FMD history in the country, with emphasis on recent years. Provide tables and maps showing the date of first detection, the number and location of *outbreaks* per year, the sources and routes of introduction of *infection*, the types and strains present, the susceptible species involved and the date of implementation of the control programme in the country.

~~*b)*~~*ii)* Describe the epidemiological situation of FMD in the country and the surrounding countries or *zones* highlighting the current knowledge and gaps. Provide maps ~~on~~ of:

~~*i)*~~ the geography of the country with the relevant information concerning FMD situation;

~~*ii)*~~ livestock density and movements and estimated FMD prevalence.

~~3.2.~~*~~b)~~* FMD surveillance

Provide documentary evidence ~~on whether~~ that *surveillance* for FMD in the country complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code* and Chapter 2.1.8. of the *Terrestrial Manual*. ~~In particular,~~ The following information should be included ~~points should be addressed~~:

~~*a*~~*i)* What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

~~*b*~~*ii)* Describe how clinical *surveillance* is conducted, including which ~~levels~~ sectors of the livestock production system are included in clinical *surveillance*, such as *establishments* ~~farms~~, markets, fairs, *slaughterhouses/abattoirs*, check points, etc. Provide details of ~~on~~ follow-up actions taken on clinical suspicions.

~~*c*~~*iii)* Serological ~~and~~ or virological *surveillance*. Explain whether or not serological ~~and~~ or virological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the ~~survey design (~~target *population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used~~)~~ in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. Are susceptible *wildlife* species included in serological ~~and~~ or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for at least the past 24 months ~~two years~~, the number of suspected *cases*, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide procedural details of follow-up actions taken on suspicious and positive results and on how these findings are interpreted and acted upon.

Provide criteria for selection of *populations* for targeted *surveillance* and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of ~~on~~ the methods applied for monitoring the performance of the *surveillance* system including indicators.

~~d~~*iv)* Provide information on circulating strains and the level of *risk* in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (*e.g.,* targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.) and that the acquired knowledge assists in more effective implementation of control measures.

~~e~~*v)* Provide details ~~on~~ of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

~~f~~*vi)* Provide evidence that surveys are carried out to assess *vaccination* coverage and *population* immunity of the target *populations*, show laboratory evidence that the vaccine used is appropriate for circulating strains of virus, show analysis of *surveillance* data to assess the change in FMD prevalence over time in the target *populations*, assess the control measures (cost effectiveness, degree of implementation, impact). Provide information on outcomes of *outbreak* investigations including *outbreaks* that have occurred despite control measures, documented inspections showing compliance with biosecurity and hygiene requirements.

~~3.3.~~*c)* FMD ~~laboratory~~ diagnosis

Provide documentary evidence that the relevant provisions ~~on~~ of Chapters 1.1.2., 1.1.3. and 2.1.8. of the *Terrestrial Manual* are applied. ~~In particular,~~ The following points should be addressed:

~~a~~*i)* Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD~~-~~ approved *laboratories* in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.~~

~~b)~~ ~~Provide an overview of the FMD approved laboratories in the country. Address the following points:~~

~~i)~~ How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for ~~obtaining~~ reporting results;

~~ii)~~ Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details ~~on~~ of the number of FMD tests performed in the past 24 months ~~last two years~~ in ~~the~~ national *laboratories* and in *laboratories* in other countries, if relevant ~~as well as abroad~~;

~~iii)~~ Procedures for quality assurance and, if available~~,~~ the official accreditation of *laboratories*. Give details of formal internal quality management systems, *e.g.,* Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

~~iv)~~ Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

~~v)~~ - Provide details ~~on~~ of the handling of live pathogenic agent~~. In particular~~, including a description of the ~~describe~~ biosecurity and biosafety measures applied;

~~vi)~~ Provide a table ~~linking~~ identifying the tests carried out by each of ~~to~~ the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

*ii)* If FMD *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

~~3.4.~~*~~d)~~* Strategies

~~a~~*i)* Provide a description of the legislation, organisation and implementation of the current FMD control programme. Outline the legislation applicable to the control programme and how its implementation is organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

~~b~~*ii)* Describe FMD control strategies in the country or any *zones*, including in terms of animal movement control, fate of infected and in-contact animals and *vaccination*. Strategies should be based on the assessment of the FMD situation in the *zones*, country and region.

~~c~~*iii)* Provide information on what types of vaccines are used and which species are vaccinated. Provide information on the licensing process ~~of~~ for the vaccines used. Describe the *vaccination* programme in the country and any *zones*, including records kept, and provide evidence to show its effectiveness, such as *vaccination* coverage, *population* immunity, etc. Provide details of the studies carried out to determine the *vaccination* coverage and the *population* immunity, including the study designs and the results.

~~d~~*iv)* Describe how the *stamping-out policy* is implemented in the country or any *zones* and under which circumstances.

~~e~~*v)* In the event of *outbreaks*, provide evidence of the impact of the control measures already implemented ~~in the event of *outbreaks*~~ on the reduction in number of *outbreaks* and their distribution. If possible, provide information on primary and secondary *outbreaks*.

~~3.5.~~e) FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, ~~. In particular provide~~ including details of ~~on~~:

~~a~~*i)* Coordination with other countries. Describe any relevant factors in neighbouring ~~about adjacent~~ countries and *zones* that should be taken into account (*e.g.,* size, distance from the border to affected *herds, flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

Are *protection zones* in place? If so, provide details of the measures that are applied (*e.g., vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

~~b~~*ii)* Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the ~~propagation~~ spread of the pathogenic agent within the country or *zone* ~~and through trade~~. Provide evidence that measures to reduce transmission of FMD are in place at markets, ~~to reduce transmission of FMD~~ such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity* ~~practices~~, hygiene ~~cleaning~~ and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

~~c~~*iii)* What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill ~~containing animal products~~ to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

~~d~~*iv)* 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 any *zones*. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied ~~on~~ to entry of such animals and products and subsequent internal movement. Describe the import measures ~~conditions~~ (*e.g.,* quarantine) 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~~ *international veterinary certificates* are required.

Annex 29 (contd)

Describe any other procedures used for assessing the *risks* ~~of~~ posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months ~~two years~~, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

~~*i)*~~ Provide a map showing ~~with~~ the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border* ~~inspection~~ *posts*, and between *border* ~~inspection~~ *posts*.

~~*ii)*~~ Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months ~~two years~~, of the quantity disposed of and the disposal locations. What ~~are the~~ *biosecurity* ~~measures~~ is in place at waste disposal sites?

~~*iii)*~~ Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:

– animals;

– genetic material (semen, oocytes and embryos);

– animal products;

– *veterinary medicinal products*; ~~i.e. biologics, vaccines,~~

– other materials at risk of being contaminated with FMD virus, including bedding, litter and feed.

*v)* Describe the actions available under legislation when an illegal import is detected.

Provide information on illegal imports detected and the action taken.

*f)*~~3.6.~~ Work plan ~~Workplan~~ and timelines of the control programme for the next five years, including cessation of *vaccination*. Describe the progressive objectives including expected status to be achieved ~~for~~ in the next five years: for *zones* (if applicable) and for the whole country.

*g)*~~3.7.~~ Performance indicators and timeline. The performance indicators should relate to the most important areas and steps where improvements in the programme are needed. These may include, but are not restricted to, strengthening *Veterinary Services*, legislation, reporting, availability and quality of vaccines, *animal identification* systems, *vaccination* coverage, *population* immunity, movement control, disease awareness, livestock owners' participatory perception on the effectiveness of the programme, etc. The progressive reduction of *outbreak* incidence towards elimination of FMD virus transmission in all susceptible livestock in at least one *zone* of the country should also be measured and monitored.

*h)*~~3.8.~~ Assessment of the evolution of the official control programme since the first date of implementation. This should include documented evidence demonstrating that the control programme has been implemented and that the first results are favourable. Measurable evidence of success such as the performance indicators should include, but not be limited to, *vaccination* data, decreased prevalence, successfully implemented import measures, control of animal movements and finally decrease or elimination of FMD *outbreaks* in the whole country or selected *zones* as described in the programme. Where relevant, the transition to the use of vaccines, which are fully compliant with the *Terrestrial Manual* in order to enable demonstration of no evidence of FMD virus transmission, should be included in the timeline.

This should include documented evidence of the effective ~~good~~ implementation of Sections 3 d) and 3 e) ~~3.4. and 3.5.~~ above.

*i)*~~3.9. Description of~~ Describe the funding for the control programme and annual budgets for its duration.

4. Control measures and emergency response

*a)* List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex ~~and if not available~~ in one of the OIE official languages. If not available, provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for FMD that was conducted in the country in the last five years.

*b)* In the event of a suspected or confirmed FMD *outbreak*:

*i)* ~~is~~ Are quarantine measures imposed on *establishments* ~~premises~~ with suspected ~~suspicious~~ *cases*, pending final diagnosis? What other procedures are followed regarding suspected ~~suspicious~~ *cases* (*e.g.,* livestock standstills)?

*ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the ~~causative~~ pathogenic agent;

*iii)* Describe the actions that would be taken to control the disease situation in and around the ~~premises~~ *establishments* where the *outbreak* ~~was~~ is confirmed;

*iv)* ~~provide a detailed description of~~ Describe in detail the control or *eradication* procedures (*e.g.,* forward and backward tracing, *disinfection* of ~~premises~~ *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including *vaccination* delivery and cold chain, *stamping-out policy*, movement control, control of *wildlife*, pastured livestock and livestock as pets, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

*v)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

*vi*) ~~give~~ Provide details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for *disease* control or *eradication* purposes and the prescribed timetable for payments;

*vii)* Describe how control efforts, including *vaccination* and biosecurity ~~measures~~, would target critical risk control points.

~~5. Compliance with the *Terrestrial Code*~~

~~The Delegate of the Member Country must submit documentary evidence that the provisions of Article 8.8.39. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for FMD.~~

Annex 30

# CHAPTER 1.12.

~~Article 1.6.9.~~

# APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF FREE STATUS FOR PESTE DES PETITS RUMINANTS

**EU position**

**The EU in general supports the adoption of this new chapter.**

**Reference is made to the general EU comments included in the top box in Annex 25.**

**Further comments are provided in the text below.**

~~Questionnaires on peste des petits ruminants (PPR)~~

~~**PPR FREE COUNTRY**~~

~~Report of a Member Country which applies for recognition of status, under Chapter 14.7. of the *Terrestrial Code*, as a PPR free country~~

Article 1.12.1.

**Country free from infection with peste des petits ruminants virus**

**EU comment**

**The title of this Article 1.12.1. does not seem very pertinent. Indeed, the content of the article describes the information to be provided to support applications for country free status, and not the country free status *per se* (which is covered in Article 14.7.3.). To avoid confusion with the latter article, we would suggest amending the title of the present article along the following lines:**

**"Dossier in support of applications for country free from [...]."**

**This comment is valid also for the title of Article 1.12.2.**

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country free from infection with peste des petits ruminants (PPR) virus in accordance with Chapter 14.7. of the *Terrestrial Code*.

~~Please~~ The dossier provided to the OIE should address concisely all the ~~following~~ topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how ~~this~~ these ~~complies~~ comply with the *Terrestrial Code*.

~~Please use~~ The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

~~Any~~ All annexes should be provided in one of the OIE official languages.

*[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]*

~~8. Compliance with the *Terrestrial Code*~~

The Delegate of the Member Country applying for recognition of PPR freedom for a country must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 14.7.3. have been properly implemented and supervised.

**EU comment**

**The EU suggests avoiding the term "must" throughout the text. For reasons of consistency, it should preferably be replaced by "should", as is common practice throughout the Code (with the exception of chapter 1.1.).**

In addition, the Delegate of the Member Country must submit a declaration indicating that:

*a)* there has been no *outbreak* of PPR during the past 24 months;

*b)* no evidence of ~~PPRV~~ *infection* with PPR virus has been found during the past 24 months;

*c)* no *vaccination* against PPR has been carried out during the past 24 months;

*d)* importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with Articles 14.7.8. to 14.7.26.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 *a)* of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

*a)* Geographical ~~entities~~ features (rivers, mountain ranges, etc.). Provide a general description of the country and, ~~when~~ where relevant, of the region, including physical, geographical and other factors that are relevant to ~~PPR~~ introduction of *infection* and ~~dissemination~~ spread of PPR virus, taking into account the ~~as well as a short description of~~ countries sharing common borders and other epidemiologic pathways ~~links~~ for the potential introduction of *infection*.

Provide maps identifying the ~~factors~~ features above.

Specify whether the application includes any noncontiguous territories.

*b)* Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country. In particular, describe:

*i)* the susceptible animal *population* by species and types of production systems;

*ii)* the number of *herds* or *flocks*, etc. of each susceptible species;

*iii)* their geographical distribution;

*iv)* *herd* or *flock* density;

*v)* the degree of integration and role of producer organisations in the different production systems;

*vi)* any recent significant changes observed in the production (~~if~~ attach relevant documents ~~are~~ if available)~~, please attach~~.

Provide tables and maps.

*c)* *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* ~~susceptible~~ species are present in the country? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* ~~susceptible~~ species?

*d)* *Slaughterhouses/abattoirs,* markets and events associated with the congregation of susceptible livestock (*e.g.,* fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of ~~domestic~~ susceptible domestic species ~~movement~~ for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

*a)* Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation~~s~~, regulations and *Veterinary Authority* directives in relation to PPR and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease

control measures and compensation systems.

*b)* *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with ~~the provisions of~~ Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, ~~and~~ control, enforce and monitor all PPR-related activities. Provide maps, figures and tables wherever possible.

*c)* Provide information on any OIE PVS evaluation conducted in ~~your~~ the country and follow-up steps within the PVS Pathway and highlight the results relevant to PPR and the susceptible species.

**EU comment**

**The OIE PVS pathway is entirely voluntary, i.e. OIE member countries may choose to request an OIE PVS evaluation, or use the PVS tool for a self-evaluation, or not to do so. The EU therefore suggests inserting the words "Where relevant, " at the beginning of point c) above.**

*d)* Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in PPR *surveillance* and control. Provide a description of the structure and role of the private veterinary sector, including number of *veterinarians* and their distribution, ~~and role of the private veterinarians veterinary profession~~ in PPR *surveillance* and control. Include a description of continuing education and awareness programmes on PPR at all relevant levels.

**EU comment**

**The EU suggests replacing the term "industry" in point d) above (and throughout the text) with "production sector", for consistency with draft revised Chapter 4.3. (cf. Item 4.5. of the report).**

*e)* *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of *animal identification* and ~~holding,~~ *establishment* or *herd* or *flock* registration ~~and traceability~~ applicable to ~~for~~ all susceptible species ~~production systems~~.

How are animal movements controlled in the country for all susceptible species ~~production systems~~?

Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past ~~two years~~ 24 months.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (*e.g.,* seasonal migration for pastures and water). Describe the actions available under national legislation.

**EU comment**

**For reasons of clarity, the EU suggests inserting the word "mitigating" before the words "actions available under national legislation" (in the sentence above and throughout the text).**

~~Describe the action available under legislation, and actually taken, when an illegal import is detected.~~ Provide information on illegal movements detected in the past 24 months and the action taken.

**EU comment**

**We suggest replacing the term "illegal" with "unofficial or unregulated" (in the sentence above and throughout the text). Indeed, "unofficial" seems more appropriate than "illegal" in an international standard, while "unregulated" would imply there are no legal controls in the first place.**

3. PPR eradication

*a)* History. If *infection* has never occurred in the country ~~has never had the *disease*~~, or has not ~~had it~~ occurred within the past 25 years, ~~please~~ state explicitly whether or not the country or *zone* is applying for recognition of historical freedom according to Article 1.4.6. of the *Terrestrial Code*.

If ~~the~~ *infection* has occurred in the country ~~has had the *disease*~~ within the past 25 years, provide a description of the PPR history in the country, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of last *case* or *eradication* in the country.

*b)* Strategy. Describe how PPR was controlled and eradicated (*e.g., stamping-out policy*, modified stamping-out policy, zoning, *vaccination*, movement control). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~*disease*~~ *outbreaks* of PPR in response to any past ~~*disease*~~ incursions of PPR virus.

*c)* Vaccines and *vaccination*. Briefly answer the following:

*i)* Is there any legislation that prohibits *vaccination*? If so:

– Provide the date when *vaccination* was formally prohibited;

– Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.

– ~~Describe the action available under legislation, and actually taken, when an illegal *vaccination* is detected;~~

– ~~Provide information on detected illegal *vaccination* during the reporting period.~~

*ii)* Was *vaccination* ever used in the country? If so:

– Provide the date when the last *vaccination* was carried out;

– What type of vaccine was used?

– What species were vaccinated?

– How were vaccinated animals identified?

– What was the fate of those animals?

*iii)* In addition, if *vaccination* was ~~conducted~~ applied during the past ~~two years~~ 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following: ~~regime~~. ~~Briefly answer the following:~~

– the vaccine strains;

– the species vaccinated;

– identification of vaccinated animals;

– the way in which the *vaccination* of animals was certified or reported and the records maintained;

– ~~Provide~~ evidence that the vaccine used complies with Chapter 2.7.10. of the *Terrestrial Manual*.

**EU comment**

**The EU suggests using the title of a Manual chapter, instead of its number, when referring to a disease-specific chapter of the Manual, as the numbering frequently**

**changes when new Manual chapters are adopted or their order within the Manual is changed.**

**In this case, the sentence above could be changed as follows:**

**"[...] complies with the *Peste des petits ruminants* chapter of the *Terrestrial Manual*.".**

*d)* Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. PPR diagnosis

Provide documentary evidence that the relevant provisions in Chapters 1.1.2., 1.1.3. and 2.7.10. of the *Terrestrial Manual* are applied. ~~In particular,~~ The following points should be addressed:

*a)* Is PPR *laboratory* diagnosis carried out in the country? If so, provide an overview of the PPR-approved *laboratories* in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results~~.

~~*b)* Provide an overview of the PPR approved laboratories in the country. Address the following points:~~

*i)* How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting ~~obtaining~~ results;

**EU comment**

**The EU suggests inserting "or transport" after "for shipment" in point i) above (and throughout the chapter), as samples may also be transported by the VS directly to the laboratory without requiring shipment.**

*ii)* Details ~~on~~ of test capability, and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details ~~on~~ of the number of PPR tests performed in the past ~~two years~~ 24 months in ~~the~~ national *laboratories* and in *laboratories* in other countries, if relevant ~~as well as abroad~~;

*iii)* Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, *e.g.,* Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

*iv)* Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

*v)* Provide details of the handling of live pathogenic agent, ~~In particular, describe~~ including a description of the biosecurity and biosafety measures applied;

*vi)* Provide a table ~~linking~~ identifying the tests carried out ~~to~~ by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

*b)* If PPR *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. PPR surveillance

Provide documentary evidence that *surveillance* for PPR in the country complies with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code* and Chapter 2.7.10. of the *Terrestrial Manual*. ~~In particular,~~ The following information should be included ~~points should be addressed~~:

*a)* What are the criteria for raising a suspicion of PPR? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to

report?

*b)* Describe how clinical *surveillance* is conducted, including which ~~levels~~ sectors of the livestock production system are included in clinical *surveillance*, such as *establishments* ~~farms~~, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past ~~two years~~ 24 months, the number of suspected *cases*, the number of samples tested for PPR, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude PPR. Provide details of follow-up actions taken on all suspicious and positive results.

**EU comment**

**The EU suggests inserting "control measures and" before "follow-up actions" in the paragraph above (and throughout the text), as details on control measures would also be necessary.**

*c)* Serological *surveillance*. Are serological surveys conducted? If so, provide detailed information on the ~~survey design~~ target *population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code*. Are susceptible *wildlife* species included in serological surveys? If not, explain the rationale. Provide a summary table indicating, for the past 24 months ~~two years~~, the number of samples tested for PPR, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and on how these findings are interpreted and acted upon. 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 selected and applied for monitoring the performance of the *surveillance* system including indicators.

*d)* Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (*e.g.,* targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the ~~and that the acquired~~ knowledge acquired through these activities assisted ~~assists~~ in more effective implementation of control measures.

*e)* Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical and serological *surveillance*, and the approaches used to increase community involvement in PPR *surveillance* programmes.

6. PPR prevention

Describe the procedures in place to prevent the introduction of PPR into the country, ~~. In particular~~ including ~~provide~~ details ~~on~~ of:

*a)* Coordination with other countries. Describe any relevant factors ~~about adjacent~~ in neighbouring countries that should be taken into account (*e.g.,* size, distance from the border to affected *herds* or *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

Are *protection zones* in place? If so, provide details of the measures that are applied (*e.g., vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

*b)* Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the ~~propagation~~ spread of the pathogenic agent within the country ~~and through trade~~. Provide evidence that measures to reduce transmission of PPR are in place at markets ~~to reduce transmission of PPR~~, such as enhancing awareness of PPR transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity* ~~practices~~, hygiene~~,~~ ~~cleaning~~ and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

*c)* 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. Describe the criteria applied to approve such countries, *zones* or *compartments,* the controls applied ~~on~~ to entry of such animals and products and subsequent internal movement. Describe the import measures ~~conditions~~ (*e.g.,* quarantine) 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~~ *international veterinary certificates* are required.

**EU comment**

**The EU suggests inserting "health" before "certificate" in point c) above (and throughout the text).**

Describe any other procedures used for assessing the *risks* posed by ~~of~~ import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past ~~two years~~ 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country.

*i)* Provide a map ~~with~~ showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls 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)* Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:

– animals;

– genetic material (semen, oocytes and embryos);

– animal products;

– *veterinary medicinal products* ~~(i.e. biologics, vaccines)~~;

– other materials at risk of being contaminated with PPR virus.

7. Control measures and contingency planning

*a)* List any written guidelines, including contingency plans, available to the *Veterinary Services* ~~official services~~ for dealing with suspected or confirmed *outbreaks* of PPR. The contingency plan should be attached as an annex in one of the OIE official languages. ~~and,~~ If not available, provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for PPR that was conducted in the country in the past five years.

*b)* In the event of a suspected or confirmed PPR *outbreak:*

*i)* Are ~~is~~ quarantine measures imposed on *establishments* ~~premises~~ with ~~suspicious~~ suspected *cases*, pending final diagnosis? What other procedures are followed ~~regarding suspicious~~ with respect to suspected *cases* (*e.g.,* livestock standstills)?

**EU comment**

**The EU suggests inserting the word "movement restrictions" after "standstills" in point i) above (and throughout the text).**

*ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the ~~causative~~ pathogenic agent;

*iii)* Describe the actions that would be taken to control the disease situation in and around the ~~premises~~ *establishments* where the *outbreak* ~~was~~ is confirmed;

*iv)* Provide a detailed description of the control or *eradication* procedures (*e.g.,* forward and backward tracing, *disinfection* of *establishments* ~~premises~~, *vehicles* and equipment, including verification methods, *vaccination, stamping-out policy,* movement control, control of *wildlife*, pastured sheep and goats, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers, etc.) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

*v)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

*vi)* Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;

*vii)* Describe how control efforts, including *vaccination* and *biosecurity* ~~measures~~, would target critical risk control points.

~~8.~~ ~~Compliance with the *Terrestrial Code*~~

~~The Delegate of the Member Country applying for PPR freedom must submit documentary evidence that the provisions of Article 14.7.3. have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating 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) no *vaccination* against PPR has been carried out during the past 24 months;~~

~~d) importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with Articles 14.7.8. to 14.7.26.~~

~~The Delegate of the Member Country applying for historical freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.~~

Annex 30 (contd)

~~9~~8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 14.7.7. of the *Terrestrial Code* and provide detailed information as specified in Sections 1 to 7 of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.12.2.

**Zone free from infection with peste des petits ruminants virus**

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a *zone* free from infection with peste des petits ruminants (PPR) virus in accordance with Chapter 14.7. of the *Terrestrial Code*.

~~**PPR FREE ZONE**~~

~~Report of a Member Country which applies for recognition of status, under Chapter 14.7. of the *Terrestrial Code*, as a PPR free zone~~

~~Please~~ The dossier provided to the OIE should address concisely all the ~~following~~ topics under the headings

provided to describe the actual situation in the country and the procedures currently applied, explaining how ~~this~~ these ~~complies~~ comply with the *Terrestrial Code*.

~~Please use the~~ The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

~~Any~~All annexes should be provided in one of the OIE official languages.

*[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]*

~~8. Compliance with the *Terrestrial Code*]~~

The Delegate of the Member Country applying for recognition of PPR freedom for a *zone* must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 14.7.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

*a)* there has been no *outbreak* of PPR during the past 24 months;

*b)* no evidence of ~~PPRV~~ *infection* with PPR virus has been found during the past 24 months;

*c)* no *vaccination* against PPR has been carried out during the past 24 months;

*d)* importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with Articles 14.7.8. to 14.7.26.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 *a)* of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

   *a)* Geographical ~~entities~~ features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone* and, ~~when~~ where relevant, of the region, including physical, geographical and other factors that are relevant to ~~PPR~~ introduction of *infection* and ~~dissemination~~ spread of PPR virus, taking into account the ~~as well as a short description of~~ countries or *zones* sharing common borders and other epidemiologic pathways ~~links~~ for the potential introduction of ~~PPR~~ *infection*. The boundaries of the *zone* must be clearly defined, including a *protection zone,* if applied.

   Provide maps identifying the ~~factors~~ features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

   *b)* Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country and the *zone*. In particular, describe:

      *i)* the susceptible animal *population* by species and types of production systems in the country and the *zone*;

      *ii)* the number of *herds* or *flocks*, etc. of each susceptible species;

      *iii)* their geographical distribution;

      *iv)* *herd* or *flock* density;

      *v)* the degree of integration and role of producer organisations in the different production systems;

      *vi)* any recent significant changes observed in the production (~~if~~ attach relevant documents ~~are~~ if available~~, please attach~~).

      Provide tables and maps.

*c)* *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* ~~susceptible~~ species are present in the country and the *zone*? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?

*d)* *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (*e.g.,* fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species ~~movement~~ for marketing within the country or *zone*, and between *zones* of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

*a)* Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation~~s~~, regulations and *Veterinary Authority* directives in relation to PPR and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

*b)* *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with ~~the provisions of~~ Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, ~~and~~ control, enforce and monitor all PPR-related activities. Provide maps, figures and tables wherever possible.

*c)* Provide information on any OIE PVS evaluation conducted in ~~your~~ the country and follow-up steps within the PVS Pathway and highlight the results relevant to PPR and the susceptible species.

**EU comment**

**The OIE PVS pathway is entirely voluntary, i.e. OIE member countries may choose to request an OIE PVS evaluation, or use the PVS tool for a self-evaluation, or not to do so. The EU therefore suggests inserting the words "Where relevant, " at the beginning of point c) above.**

*d)* Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in PPR *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, ~~(~~including number of *veterinarians* and their distribution,~~) and role of the private veterinary profession~~, in PPR *surveillance* and control. Include a description of continuing education and awareness programmes on PPR at all relevant levels.

*e)* *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of *animal identification* and ~~holding,~~ *establishment* or *herd* or *flock* registration ~~and traceability~~ applicable to ~~for~~ all susceptible species ~~production systems~~.

How are animal movements controlled in and between *zones* of the same or different status for all susceptible species ~~production systems~~?

Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past ~~two years~~ 24 months.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (*e.g.,* seasonal migration for pastures and water). Describe the actions available under national legislation.

~~Describe the action available under legislation, and actually taken, when an illegal import is detected~~. Provide information on illegal movements detected in the past 24 months and the action taken.

3. PPR eradication

*a)* History. If *infection* has never occurred in the *zone* ~~has never had the *disease*~~, or has not ~~had it~~

occurred within the past 25 years, ~~please~~ state explicitly whether or not the *zone* is applying for recognition of historical freedom according to Article 1.4.6. of the *Terrestrial Code*.

If *infection* has occurred in the *zone* ~~has had the *disease*~~ within the past 25 years, provide a description of the PPR history in the country and *zone*, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of last *case* or *eradication* in the *zone*.

*b)* Strategy. Describe how PPR was controlled and eradicated in the *zone* (*e.g., stamping-out policy*, modified stamping-out policy, zoning, *vaccination*, movement control). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~*disease*~~ *outbreaks* of PPR in response to any past ~~*disease*~~ incursions of PPR virus.

*c)* Vaccines and *vaccination*. Briefly answer the following:

*i)* Is there any legislation that prohibits *vaccination*? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.
- ~~Describe the action available under legislation, and actually taken, when an illegal *vaccination* is detected;~~
- ~~Provide information on detected illegal *vaccination* during the reporting period~~.

*ii)* Was *vaccination* ever used in the country? If so:

- Provide the date when the last *vaccination* was carried out;
- What type of vaccine was used in the *zone* and the rest of the country?
- What species were vaccinated?
- How were vaccinated animals identified?
- What was the fate of those animals?

*iii)* In addition, if *vaccination* was applied ~~conducted~~ during the past ~~two years~~ 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following: ~~regime. Briefly answer the following:~~

- the vaccine strains;
- the species vaccinated;
- identification of vaccinated animals;
- the way in which the *vaccination* of animals was certified or reported and the records maintained;
- ~~provide~~ evidence that the vaccine used complies with Chapter 2.7.10. of the *Terrestrial Manual*.

*d)* Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. PPR diagnosis

Provide documentary evidence that the relevant provisions in Chapters 1.1.2., 1.1.3. and 2.7.10. of the *Terrestrial Manual* are applied. ~~In particular,~~ The following points should be addressed:

*a)* Is PPR *laboratory* diagnosis carried out in the country? If so, provide an overview of the PPR-approved *laboratories* in the country, including the following: ~~If not, provide the names of the~~

~~laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results. Indicate the laboratories where samples originating from the *zone* are diagnosed.~~

~~*b)* Provide an overview of the PPR approved laboratories in the country. Address the following points:~~

*i)* How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for ~~obtaining~~ reporting results;

*ii)* Details ~~on~~ of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of PPR tests performed in the past ~~two years~~ 24 months in ~~the~~ national *laboratories* and in *laboratories* in other countries, if relevant~~as well as abroad~~;

*iii)* Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, *e.g.,* Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

*iv)* Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

*v)* Provide details of the handling of live pathogenic agent~~. In particular, describe~~, including a description of the biosecurity and biosafety measures applied;

*vi)* Provide a table ~~linking~~ identifying the tests carried out ~~to~~ by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

*b)* If PPR *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. PPR surveillance

Provide documentary evidence that *surveillance* for PPR in the *zone* complies with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code* and Chapter 2.7.10. of the *Terrestrial Manual*. ~~In particular, t~~The following information should be included~~points should be addressed~~:

*a)* What are the criteria for raising a suspicion of PPR? What is the procedure to notify (by whom and to whom), what incentives are there for reporting and what penalties are involved for failure to report?

*b)* Describe how clinical *surveillance* is conducted, including which ~~levels~~ sectors of the livestock production system are included in clinical *surveillance*, such as *establishments* ~~farms~~, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past ~~two years~~ 24 months, the number of suspected *cases*, the number of samples tested for PPR, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude PPR. Provide details of follow-up actions taken on all suspicious and positive results.

*c)* Serological *surveillance*. Are serological surveys conducted? If so, provide detailed information on the ~~survey design~~ target *population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code*. Are susceptible *wildlife* species included in serological surveys? If not, explain the rationale. Provide a summary table indicating, for the past 24 months ~~two years~~, the number of samples tested for PPR, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and on how these findings are interpreted and acted upon. Provide criteria for selection of *population*s for targeted *surveillance* and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* system including indicators.

*d)* Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (*e.g.,* targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how ~~and that the acquired~~ knowledge acquired through these activities assisted ~~assists~~ in more effective implementation of control measures.

*e)* Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical and serological *surveillance*, and the approaches used to increase community involvement in PPR *surveillance* programmes.

6. PPR prevention

Describe the procedures in place to prevent the introduction of PPR into the country or *zone*, ~~In particular, provide~~ including details of:

*a)* Coordination with other countries. Describe any relevant factors in ~~about adjacent~~ neighbouring countries and *zones* that should be taken into account (*e.g.,* size, distance from the border to affected *herds* or *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

If the PPR free *zone* is ~~situated~~ established in a PPR infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration existing physical or geographical barriers.

Are *protection zones* in place? If so, indicate whether or not the *protection zones* are included in the proposed free *zones.* Provide details of the measures that are applied (*e.g., vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

*b)* Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the ~~propagation~~ spread of the pathogenic agent within the country or *zone* ~~and through trade~~. Provide evidence that measures to reduce transmission of PPR are in place at markets ~~to reduce transmission of PPR~~, such as enhancing awareness of PPR transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity* ~~practices~~, hygiene~~, cleaning~~ and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

*c)* 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*, the controls applied ~~on~~ to entry of such animals and products and subsequent internal movement. Describe the import measures ~~conditions~~ (*e.g.,* quarantine) 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~~ *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past ~~two years~~ 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country or *zone*.

*i)* Provide a map ~~with~~ showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls 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)* Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and follow-up of the following:

– animals;

– genetic material (semen, oocytes and embryos);

– animal products;

– *veterinary medicinal products* ~~(i.e. biologics, vaccines)~~;

– other materials at risk of being contaminated with PPR virus.

7. Control measures and contingency planning

*a)* List any written guidelines, including contingency plans, available to the *Veterinary Services* ~~official services~~ for dealing with suspected or confirmed *outbreaks* of PPR. The contingency plan should be attached as an annex in one of the OIE official languages. ~~and,~~ If not available, provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for PPR that was conducted in the country in the past five years.

*b)* In the event of a suspected or confirmed PPR *outbreak*:

*i)* ~~Is~~ Are quarantine measures imposed on *establishments* ~~premises~~ with ~~suspicious~~ suspected *cases*, pending final diagnosis? What other procedures are followed ~~regarding suspicious~~ with respect to suspected *cases* (*e.g.,* livestock standstills)?

*ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the ~~causative~~ pathogenic agent;

*iii)* Describe the actions that would be taken to control the disease situation in and around the *establishments* ~~premises~~ where the *outbreak* ~~was~~ is confirmed;

*iv)* Provide a detailed description of the control or *eradication* procedures (*e.g.,* forward and backward tracing, *disinfection* of *establishments* ~~premises~~, *vehicles* and equipment, including verification methods, *vaccination*, *stamping-out policy,* movement control, control of *wildlife*, pastured sheep and goats, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers, etc.) that would be taken; in the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

*v)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

*v)* Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;

*vii)* Describe how control efforts, including *vaccination* and *biosecurity* ~~measures~~, would target critical risk control points.

~~8. Compliance with the *Terrestrial Code*~~

~~The Delegate of the Member Country applying for PPR freedom must submit documentary evidence that the provisions of Article 14.7.3. have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating 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)* no *vaccination* against PPR has been carried out during the past 24 months;~~

~~*d)* importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with Articles 14.7.8. to 14.7.26.~~

~~The Delegate of the Member Country applying for historical zonal freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.~~

8~~9~~. Recovery of free status

Member Countries applying for recognition of recovery of free status for a *zone* should comply with the provisions of Article 14.7.7. of the *Terrestrial Code* and provide detailed information as specified in Sections 1 to 7 of this questionnaire. Information in relation to other sections need only be supplied if relevant.

~~Article 1.6.12.~~

~~**Questionnaire on endorsement of official control programme for peste des petits ruminants (PPR)**~~

~~**COUNTRY WITH AN OIE ENDORSED OFFICIAL CONTROL PROGRAMME FOR PPR**~~
~~Report of a Member Country which applies for the OIE endorsement~~
~~of its official control programme for PPR~~
~~under Chapter 14.7. of the *Terrestrial Code*~~

Article 1.12.3.

**Application for endorsement by the OIE of an official control programme for peste des petits ruminants**

The following information should be provided by OIE Member Countries to support applications for endorsement by the OIE of an official control programme for peste des petits ruminants (PPR) in accordance with Chapter 14.7. of the *Terrestrial Code*.

The dossier provided to the OIE should ~~In sections 1 to 3.5. please~~ address concisely all the ~~following~~ topics under the headings ~~please~~ provided in Sections 1 to 4 ~~3.e)~~. to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

In Sections 3 f) to 3 i) ~~3.6. to 3.9. please address~~ describe concisely the work plan and timelines of the control programme for the next five years.

~~Please use~~ The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

~~Any~~ All annexes should be provided in one of the OIE official languages.

**NB the paragraph below has been moved from the end of the chapter**

~~5. Compliance with the *Terrestrial Code*~~

The Delegate of the Member Country applying for endorsement of the official control programme should submit documentary evidence that the provisions of Article 14.7.34. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for PPR.

1. Introduction

*a)* Geographical ~~entities~~ features (rivers, mountain~~s~~ ranges, etc.). Provide a general description of the country, *zones* and, ~~when~~ where relevant, of the region, including physical, geographical and other factors that are relevant to ~~PPR~~ introduction of *infection* and spread of PPR~~dissemination~~, taking into account the ~~as well as a short description of~~ countries or *zones* sharing common borders and other epidemiologic pathways ~~links~~ for the potential introduction of *infection* ~~PPR~~.

Provide maps identifying the ~~factors~~ features above.

Specify whether the application includes any noncontiguous territories.

*b)* If the endorsed plan is ~~gradually~~ implemented in stages ~~to~~ in specific parts of the country, the boundaries of the *zones* should be clearly defined, including the *protection zones*, if applied. Provide a digitalised, geo-referenced map with a description of the geographical boundaries of the *zones*.

*c)* Livestock demographics. ~~Provide a general description of~~Describe the composition of the livestock industry in the country and any *zones*. In particular, describe:

*i)* the susceptible animal *population* by species and types of production systems;

*ii)* the number of *herds* or *flocks*, etc. of each susceptible species;

*iii)* their geographical distribution;

*iv)* *herd* or *flock* density;

*v)* the degree of integration and role of producer organisations in the different production systems;

*vi)* any recent significant changes observed in the production (~~if~~ attach relevant documents if ~~are~~ available~~, please attach~~).

Provide tables and maps.

*d)* *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* ~~susceptible~~ species are present in the country and any *zones*? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* ~~susceptible~~ species?

*e)* *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock *(e.g.*, fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic ~~susceptible~~ species ~~movement~~ for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

*a)* Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation~~s~~, regulations and *Veterinary Authority* directives in relation to the PPR control programme and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

*b)* *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with ~~the provisions of~~ Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise~~,~~ ~~and~~ control, enforce and monitor all PPR-related activities. Provide maps, figures and tables wherever possible.

*c)* Provide information on any OIE PVS evaluation conducted in ~~your~~ the country and follow-up steps within the PVS Pathway and highlight the results relevant to PPR and the susceptible species.

*d)* Provide a description of ~~on~~ the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in PPR *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, ~~(~~including number of *veterinarians* and their distribution~~) and role of the private veterinary profession~~, in PPR *surveillance* and control.

Include a description of continuing education and awareness programmes on PPR at all relevant levels.

*e)* *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of animal identification and ~~holding,~~ *establishment* or *herd* or *flock* registration ~~and traceability~~ applicable to all susceptible species ~~production systems~~. How are animal movements controlled in the country for all susceptible species ~~production systems~~? Provide evidence ~~on~~ of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months~~last two years~~.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (*e.g.*, seasonal migration for pastures and water). Describe the actions available under national legislation~~, and actually taken, when an illegal import is detected~~.

Provide information on illegal movements detected in the past 24 months and the action taken.

3. Official control programme for PPR submitted for OIE endorsement

Submit a concise plan ~~on~~ of the measures for the control and eventual *eradication* of PPR in the country, including:

*a)* Epidemiology

*i)* ~~Provide a description of~~Describe the PPR history in the country, with emphasis on recent years. Provide tables and maps showing the date of first detection, the number and location of *outbreaks* per year, the sources and routes of introduction of *infection*, the types and lineages present, the susceptible species involved and the date of implementation of the control programme in the country.

*ii)* Describe the epidemiological situation of PPR in the country and the surrounding countries or *zones* highlighting the current knowledge and gaps. Provide maps ~~on~~ of:

– the geography of the country with the relevant information concerning PPR situation;

– small ruminant density and movements and estimated PPR prevalence.

*b)* PPR surveillance

Provide documentary evidence ~~on whether~~ that *surveillance* for PPR in the country complies with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code* and Chapter 2.7.10. of the *Terrestrial Manual*. ~~In particular,~~ The following information should be included ~~points should be addressed~~:

*i)* What are the criteria for raising a suspicion of PPR? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

*ii)* Describe how clinical *surveillance* is conducted, including which ~~levels~~ sectors of the livestock production system are included in clinical *surveillance*, such as *establishments* ~~farms~~, markets, fairs, *slaughterhouses/abattoirs*, check points, etc. Provide details of follow-up actions taken on clinical suspicions.

*iii)* Serological ~~and~~ or virological *surveillance*. Explain whether or not serological ~~and~~ or virological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the ~~survey design (~~target *population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used~~) —~~in accordance with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code*. Are susceptible *wildlife* species included in serological ~~and~~ or virological surveys? If not, explain the rationale.

Annex 30 (contd)

Provide a summary table indicating, for at least the past 24 months ~~two years~~, the number of suspected cases, the number of samples tested for PPR, species, type of sample, testing methods and results (including differential diagnosis). Provide procedural details ~~on~~ of follow-up actions taken on suspicious and positive results and on how these findings are interpreted and acted upon.

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.

*iv)* Provide information on the level of *risk* in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (*e.g.*, targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.) and that the acquired knowledge assists in more effective implementation of control measures.

*v)* Provide details ~~on~~ of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in PPR *surveillance* programmes.

*vi)* Provide evidence that surveys are carried out to assess *vaccination* coverage and *population* immunity of the target *populations*, show analysis of *surveillance* data to assess the change in PPR prevalence over time in the target *populations*, assess the control measures (cost effectiveness, degree of implementation, impact). Provide information on outcomes of *outbreak* investigations including *outbreaks* that have occurred despite control measures, documented inspections showing compliance with biosecurity and hygiene requirements.

*c)* PPR ~~laboratory~~ diagnosis

Provide documentary evidence that the relevant provisions of ~~in~~ Chapters 1.1.2., 1.1.3. and 2.7.10. of the *Terrestrial Manual* are applied. ~~In particular,~~ The following points should be addressed:

*i)* Is PPR *laboratory* diagnosis carried out in the country? If so, provide an overview of the PPR-approved *laboratories* in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.~~

~~*b)* Provide an overview of the PPR approved *laboratories* in the country. Address the following points:~~

– How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for ~~obtaining~~ reporting results;

– Details ~~on~~ of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of ~~on~~ the number of PPR tests performed in the past 24 months ~~two years~~ in ~~the~~ national *laboratories* and in *laboratories* in other countries, if relevant~~as well as abroad~~;

– Procedures for quality assurance and, if available, the official accreditation of *laboratories*. Give details of formal internal quality management systems, *e.g.*, Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

– Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

– Provide details ~~on~~ of the handling of live pathogenic agent~~. In particular, describe~~, including a description of the biosecurity and biosafety measures applied;

– Provide a table identifying ~~linking~~ the tests carried out ~~to~~ by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

*ii)* If PPR *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

*d)* Strategies

*i)* Provide a description of the legislation, organisation and implementation of the current PPR control programme. Outline the legislation applicable to the control programme and how its implementation is organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

*ii)* Describe PPR control strategies in the country or any *zones*, including in terms of animal movement control, fate of infected and in-contact animals and *vaccination*. Strategies should be based on the assessment of the PPR situation in the *zones*, country and region.

*iii)* Provide information on what types of vaccines are used and which species are vaccinated. Provide evidence that the vaccine used complies with Chapter 1.1.8. of the *Terrestrial Manual*. Provide information on the licensing process ~~of~~ for the vaccines used. Describe the *vaccination* programme in the country and any *zones*, including records kept, and provide evidence to show its effectiveness, such as *vaccination* coverage, *population* immunity, etc. Provide details ~~on~~ of the studies carried out to determine the *vaccination* coverage and the *population* immunity, including the study designs and the results.

*iv)* Describe how the *stamping-out policy* is implemented in the country or any *zones* and under which circumstances.

*v)* In the event of *outbreaks*, p~~P~~rovide evidence of the impact of the control measures already implemented ~~in the event of *outbreaks*~~ on the~~ir~~ reduction in number of *outbreaks* and their distribution. If possible, provide information on primary and secondary *outbreaks*.

*e)* PPR prevention

Describe the procedures in place to prevent the introduction of PPR into the country, ~~In particular provide~~ including details of:

*i)* Coordination with other countries. Describe any relevant factors ~~about adjacent~~ in neighbouring countries and *zones* that should be taken into account (*e.g.*, size, distance from the border to affected *herds, flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

Are *protection zones* in place? If so, provide details of ~~on~~ the measures that are applied (*e.g.*, *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

*ii)* Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread ~~propagation~~ of the pathogenic agent within the country or *zone* ~~and through trade~~. Provide evidence that measures to reduce transmission of PPR are in place at markets, ~~to reduce transmission of PPR~~ such as enhancing awareness of PPR transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity* ~~practices~~, hygiene ~~cleaning~~ and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

Annex 30 (contd)

*iii)* 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 any *zones*. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to ~~on~~ entry of such animals and products and subsequent internal movement. Describe the import measures ~~conditions~~ (*e.g.*, quarantine) 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~~ *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* ~~of~~ posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months ~~two years~~, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

– Provide a map ~~with~~ showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls 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*.

– Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:

  – animals;

  – genetic material (semen, ~~ova,~~ oocytes and embryos);

  – animal products;

  – *veterinary medicinal products*~~,~~ ~~i.e. biologics, vaccines~~;

  – other materials at risk of being contaminated with PPR virus.

*iv)* Describe the actions available under legislation when an illegal import is detected.

Provide information on illegal imports detected and the action taken .

*f)* Work plan and timelines of the control programme for the next five years, including cessation of *vaccination*. Describe the progressive objectives including expected status to be achieved ~~for~~ in the next five years: for *zones* (if applicable) and for the whole country.

*g)* Performance indicators and timeline. The performance indicators should relate to the most important areas and steps where improvements in the programme are needed. These may include, but are not restricted to, strengthening *Veterinary Services*, legislation, reporting, availability and quality of vaccines, *animal identification* systems, *vaccination* coverage, *population* immunity, movement control, disease awareness, livestock owners' participatory perception on the effectiveness of the programme, etc. The progressive reduction of *outbreak* incidence towards elimination of PPR virus transmission in all susceptible livestock in at least one *zone* of the country should also be measured and monitored.

*h)* Assessment of the evolution of the official control programme since the first date of implementation. This should include documented evidence demonstrating that the control programme has been implemented and that the first results are favourable. Measurable evidence of success such as the performance indicators should include, but not be limited to, *vaccination* data, decreased prevalence, successfully implemented import measures, control of animal movements and finally decrease or elimination of PPR *outbreaks* in the whole country or selected *zones* as described in the programme.

This should include documented evidence of the ~~good~~ effective implementation of Sections 3 d) to 3 e) ~~3.4. and 3.5.~~ above.

*i)* ~~Description of~~ Describe the funding for the control programme and annual budgets for its duration.

4. Control measures and emergency response

*a)* List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of PPR. The contingency plan should be attached as an annex ~~and if not available~~ in one of the OIE official languages. If not available, provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for PPR that was conducted in the country in the past five years.

*b)* In the event of a suspected or confirmed PPR *outbreak*:

*i)* Are ~~is~~ quarantine measures imposed on *establishments* ~~premises~~ with suspected ~~suspicious~~ *cases*, pending final diagnosis? What other procedures are followed regarding suspected ~~suspicious~~ *cases* (*e.g.*, livestock standstills)?

*ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the ~~causative~~ pathogenic agent;

*iii)* Describe the actions that would be taken to control the disease situation in and around the *establishments* ~~premises~~ where the *outbreak* ~~was~~ is confirmed;

*iv)* ~~provide a detailed description of~~ Describe in detail the control or *eradication* procedures (*e.g.*, forward and backward tracing, *disinfection* of *establishments* ~~premises~~, *vehicles* and equipment, including verification methods, *vaccination, stamping-out policy,* movement control, control of *wildlife*, pastured sheep and goats, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

*v)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

*vi)* ~~give~~ Provide details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;

*vii)* Describe how control efforts, including *vaccination* and *biosecurity* ~~measures~~, would target critical risk control points.

~~5. Compliance with the *Terrestrial Code*~~

~~The Delegate of the Member Country must submit documentary evidence that the provisions of Article 14.7.34. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for PPR.~~

Annex 31

# CHAPTER 1.3

# DISEASES, INFECTIONS AND INFESTATIONS LISTED BY THE OIE

**EU position**

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

**A specific comment is inserted in the text below.**

**Furthermore, in order to avoid this type of inconsistency between Chapter 1.3. and the disease-specific chapters in the future, it would be preferable to make this type of editorial amendment in Chapter 1.3. whenever a disease-specific chapter with a modified title is adopted. For example this may well be the case for the glanders chapter in May 2018, resulting in the need to amend the relevant entry in Article 1.3.4.**

[…]

## Article 1.3.1.

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

- Anthrax
- ~~Bluetongue~~
- Crimean Congo hemorrhagic fever
- ~~Epizootic haemorrhagic disease~~
- Equine encephalomyelitis (Eastern)
- Heartwater
- Infection with Aujeszky's disease virus
- Infection with bluetongue virus
- Infection with *Brucella abortus, Brucella melitensis, Brucella suis*
- Infection with *Echinococcus granulosus*
- Infection with *Echinococcus multilocularis*
- Infection with epizootic hemorrhagic disease virus
- Infection with foot and mouth disease virus
- Infection with *Mycobacterium tuberculosis* complex
- Infection with rabies virus
- Infection with Rift Valley fever virus
- Infection with rinderpest virus
- Infection with *Trichinella* spp.
- Japanese encephalitis
- New World screwworm (*Cochliomyia hominivorax*)

- Old World screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Surra (*Trypanosoma evansi*)
- Tularemia
- West Nile fever.

Article 1.3.2.

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
- Infection with lumpy skin disease virus
- Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- ~~Lumpy skin disease~~
- Theileriosis
- Trichomonosis
- Trypanosomosis (tsetse-transmitted).

[…]

Article 1.3.5.

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

- Infection with African swine fever virus
- Infection with classical swine fever virus
- Infection with porcine reproductive and respiratory syndrome

**EU comment**

**Please insert the word "virus" after "syndrome" in the indent above (editorial).**

- Infection with *Taenia solium* (Porcine cysticercosis)
- Nipah virus encephalitis
- ~~Porcine reproductive and respiratory syndrome~~
- Transmissible gastroenteritis.

[…]

Annex 32

CHAPTER 7.12.

# WELFARE OF WORKING EQUIDS

**EU position**

**The EU thanks the OIE for its work on the revision of Article 7.12.7 and for taking into account a previous EU comment. The EU can agree with the proposed change and in general support the adoption of this revised article. The EU would also like to present a specific comment that could be taken into account either at adoption or during a future revision of the article, once adopted.**

[...]

Article 7.12.7.

**Shelter**

Effective shelter should be provided for working equids both in the resting and working environments. Shelter should provide protection against adverse weather conditions and against predators and injury as well as good ventilation and the ability to rest comfortably. Resting space should be dry, clean and large enough for the equid to lie down, get up and turn around easily.

**EU comment**

**The EU would like to suggest including in the second sentence of the above paragraph the words " insects", as to read:**

**"and against predators, ~~and~~ injury and insects as well as good …"**

**Justification**

**Insects cause nuisance and distress to horses and can be vectors for disease. Insects can get into wounds and cause or spread infection. Some horses have insect bite hypersensitivity and this makes them react to the saliva of culicoides midge, causing irritation, rubbing and breaks to the skin. Given freedom to move around, equines will select shelter from insects or position themselves in alignment with other equines so that they can protect each other from insects.**

https://ker.com/equinews/insect-bite-hypersensitivity/

1. Heat stress

   Heat stress is a common condition in working equids in hot, humid environments and *animal handlers* should be aware of the risk that heat stress poses. Equid owners and handlers should be aware of how to prevent it through provision of appropriate shade or shelter along with sufficient drinking water and avoiding work at extreme high temperatures. Owners may also be trained in effective treatment of hyperthermia as timely veterinary assistance may not be available.

   Behaviours which indicate heat stress include increased respiratory rate and effort; flared nostrils; increased head movement and lack of response to the environment; excessive sweating.

   Outcome-based measurables: behaviour, morbidity, mortality, body condition and physical appearance and fitness to work.

2. […]

3. […]

[...]

_____

Annex 36

CHAPTER 7.Y.

# KILLING OF REPTILES FOR THEIR SKINS, MEAT AND OTHER PRODUCTS

**EU comment**

**The EU thanks the OIE for its work on the revision of the draft chapter and for taking some of the EU comments into account.**

**The EU can agree with the proposed changes. In addition the EU would like to reiterate some previous comments.**

Article 7.Y.1.

**Scope**

The recommendations in this chapter address the need to ensure the welfare of chelonians, crocodilians, lacertilians and ophidians, during the process of *killing* them for their skins, *meat* and other products.

Article 7.Y.2.

**Definitions**

Some of the definitions in this chapter differ from those in the Glossary and Chapter 7.5., as they are adapted to reptiles, given the specific characteristics of these animals.

For the purposes of this chapter:

**Restraint:** means any acceptable physical or chemical method of reducing, or eliminating, voluntary or reactive movement of the reptile, to facilitate efficient *stunning* or *killing*.

**Stunning:** means the procedure that causes immediate loss of ~~un~~consciousness until the ~~animal~~ reptile is dead, or causes the absence of pain, distress and suffering until the onset of unconsciousness, according to the outcomes defined in this chapter for the species covered.

**Unconsciousness:** means the state of unawareness caused by temporary or permanent disruption of brain function.

**Pithing:** means a method carried out by inserting a rod or probe through the foramen magnum (or the hole from a penetrative captive bolt or gunshot), into the brain to ensure thorough brain destruction.

**EU comment**

**The EU suggests including, after Article 7.Y.2, a new Article 7.Y.2bis including the part of text presented under the current Article 7.Y.3., as follow:**

**"Article 7.Y.2bis**

**Animals should be acquired legally in accordance with national legislation and international treaties, including the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).**

**Relevant documentation related to the source of the animals should accompany the animals. "**

**Justification**

**The above text does not deal specifically with animal welfare but refers to more general relevant and legal issues on the source of the animals. Given its importance, this part could be highlighted in a stand-alone new article 7.Y.2bis.**

Article 7.Y.3.

**General considerations**

Because of the anatomy and physiology of reptiles, specific factors should be considered when choosing the appropriate stunning and killing method. Such factors include the size of the animal, tolerance and intolerance of certain species to particular methods, animal handling and restraint, ease of access to veins and safety of the *animal handlers*.

1. Animal welfare plan

Facilities in which reptiles are killed should have an *animal welfare* plan and associated procedures. The purposes of such a plan should be to maintain good *animal welfare* at all stages of handling of ~~animals~~ reptiles until their *death*.

The *animal welfare* plan should contain standard operating procedures for each step of animal handling to ensure that it is properly implemented, based on relevant recommendations in this chapter, including criteria ~~indicators shown~~ in Article 7.Y.5. It should also include corrective actions to address specific risks, for example, power failures or other circumstances that could negatively affect the welfare of animals.

2. Competency and training of the personnel

*Animal handlers* should be competent in handling and moving, stunning and monitoring effective stun, and killing of reptiles, as well as understanding relevant behaviours of these animals and the underlying *animal welfare* and technical principles necessary to carry out their tasks.

**EU comment**

**The EU suggests including in the above paragraph the following text "in recognising species and ", as to read:**

**"as well as in recognising species and understanding relevant…"**

**Justification**

**It is important that personnel are able to recognise the species, as to consider the specie-specific factors to be taken into account while they carry out their tasks.**

There should be sufficient number of personnel, who should be competent and familiar with the recommendations outlined in this chapter and their application within the national context.

The manager of the facility should ensure that personnel are competent and carry out their tasks in accordance with the guiding principles for *animal welfare* in Article 7.1.2.

The manager of the facility should ensure that personnel are physically and mentally able to carry out their tasks through the period of their work shift.

Competence may be gained through formal training or practical experience. This competence should be verified by the *Competent Authority* or an independent body accredited by it.

3. Source of animals

Animals should be acquired legally in accordance with national ~~jurisdictions~~ legislation and international treaties, including the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

Relevant documentation related to the source of the animals should accompany the animals.

If animals captured in the wild are to be used, capture and transport techniques should not compromise ~~be humane and give due regard to~~ human and animal health, welfare and safety.

**EU comment**

**The EU suggests the OIE moving the first two paragraphs of the above point 3 at the beginning of the chapter, as a draft article 7.Y.2bis.**

**Furthermore, the EU suggests modifying the title of the above point 3, as for point 3 to read as follow:**

**"3. ~~Source of animals~~ Animals captured in the wild**

**~~Animals should be acquired legally in accordance with national jurisdictions~~ legislation ~~and international treaties, including the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).~~**

**~~Relevant documentation related to the source of the animals should accompany the animals.~~**

**If animals captured in the wild are to be used, capture and transport techniques should not compromise ~~be humane and give due regard to~~ human and animal health, welfare and safety."**

**Justification**

**The first two sentences of the above paragraph do not deal specifically with animal welfare but refer to relevant more general and legal issues on the source of the animals. Given its importance, this part could be highlighted by moving it in a stand-alone new article 7.Y.2bis.**

4. Behaviour

**EU comment**

**The EU suggests modifying the title of the above point 4 as follow:**

**"4. Behaviour during handling and killing"**

**Justification**

**To clarify that point 4 refers to the behaviours that reptiles may have during handling and killing, influencing the outcomes of such procedures.**

Handling and *killing* methods should take into account specific reptile behaviours such as:

– ~~reptiles are sensitive to and will respond~~ sensitivity and responsiveness to visual, ~~and~~ tactile, auditory and vibrational stimuli ~~as well as noise and vibrations~~;

**EU comment**

**In the above bullet point, the EU suggests including the following text ", olfactory", as for the paragraph to read as follow:**

**"- ……, auditory, olfactory and vibrational stimuli…"**

**Justification**

**Some scientific evidence shows that reptiles have an olfactory system, well developed in particular in squamate reptiles. They could react to presence of smells by modifying their behaviour.**

**Rehorek S. J., Firth B. T., Hutchinson M., 2000, The structure of the nasal chemosensory system in squamate reptiles. 1. The olfactory organ, with special reference to olfaction in geckos; J. Biosci. | vol. 25 | No. 2 | June 2000 | 173–179 | Indian Academy of Sciences.**

**Naumann R. K., Ondracek J. M., Reiter S., Shein-Idelson M., Tosches M. A., Yamawaki T. M., Gilles L, 2015, The reptile brain, Current Biology 25, R301–R327, April 20, 2015, Elsevier.**

**Schwenk K.,1993, The evolution of chemoreception in squamate reptiles: a phylogenetic approach, Brain Behav Evol.**

- ability to escape handling and restraint ~~the restraint and handling of reptiles can be difficult~~ because of their agility and strength;
- ability to ~~reptiles can~~ inflict significant bite wounds to handlers, ~~and~~ frequently with wound infection or envenomation ~~are not uncommon~~;
- ~~low body temperatures may result in slow movements, torpor and~~ reduced responsiveness due to low body temperatures which may result in slow movements, and torpor that should not be regarded as indicators of quiescence or unconsciousness;
- absence of vocalisation, ~~is~~ common or normal in reptiles, even in highly traumatic situations.

Article 7.Y.4.

**Selection of a killing process**

In the case of reptiles, the *killing* process ~~may involve a stunning and a subsequent *killing* step or a direct *killing* method~~ should involve either prior stunning followed by a *killing* method or an instantaneous method of *killing*. When prior stunning is used and the stunning is not irreversible, reptiles should be killed before consciousness is recovered.

Criteria which may influence the choice of methods used in the killing process include:

- species and size of the reptile;
- level of knowledge and skill required to perform the procedure effectively;
- safety of the operator;
- compatibility with processing requirements and animal product purposes;
- in the case of the use of drugs, the drug availability, licensing and use requirements, possible human abuse, and implications for other product uses such as consumption by animals or humans;
- ability to maintain equipment in proper working order;
- cost of the method.

**EU comment**

**The EU would like to reiterate its previous comment.**

**The EU suggests the OIE deleting the above bullet point "cost of method".**

**Justification**

**The criteria listed in this draft article are "animal welfare" criteria. The cost of the method is not a welfare criterion.**

The *killing* process used should:

– avoid ~~excitement~~ agitation, fear and stress to the animal;

– be appropriate for the species, size, age and health of the ~~animal~~ reptile;

– be reliable and reproducible;

– ensure that any stunning used is in accordance with Article 7.Y.2.; ~~and~~

– include the use of a *killing* method if the stunning method does not result in *death* of the ~~animal~~ reptile during unconsciousness; and

– where it includes a stunning step, kill the reptile while it is unconscious.

Article 7.Y.5.

**Criteria (or measurables) for the outcome of the stunning and killing of reptiles**

The following animal-based criteria (or measurables) can be useful indicators of *animal welfare*. The use of these criteria and their appropriate thresholds should be adapted to the different methods used to stun and kill reptiles. These criteria can be considered as tools to monitor the impact of the method and management used, given that both of these can affect *animal welfare*.

Criteria to measure the effectiveness of stunning and killing methods

Whilst multiple criteria are preferable for the establishment of unconsciousness or *death*, the presence of any of the following criteria should be regarded as sufficient to establish suspicion of consciousness:

– pupillary response to light or movement;

– ~~pupillary response to objects or movement;~~

– eye movement in response to objects or movement;

– blink or nictitating membrane responses to touch or contact of the cornea;

– spontaneous eyelid opening or closing;

– intentional defensive responses;

– tongue movement~~.~~;

– jaw tone.

Annex 36 (contd)

In addition to the absence of all the criteria above, *death* may be inferred by confirming permanent cessation of the following:

– response to ~~somatic~~ stimuli applied to the head, indicating brain activity;

– respiration;

– cardiac activity (while presence of a heartbeat does not necessarily mean that an animal is alive, permanent cessation of a heartbeat indicates *death*). It is important to note that a reptile's heartbeat may change from beats per minute to beats per hour.

Article 7.Y.6.

**Physical restraint**

Physical restraint is often required in the process of *stunning* and *killing* of reptiles to control movement and improve the precision of application. Special considerations for the restraint of reptiles are needed due to the physical and behavioural characteristics of this taxonomic group.

Recommendations for effective physical restraint in relation to animal welfare

The method of restraint should:

– avoid injuries due to excessive pressure applied by equipment or personnel;

– be applied rapidly to avoid excessive or prolonged struggling of the ~~animal~~ reptile;

– exclude features that may cause pain or injury;

– not hoist or suspend animals by the feet, legs, tail or head;

– not restrain only one area of the body (e.g. head or neck) leaving the rest able to move excessively;

– ensure animals can breathe freely through the nostrils where the mouth is restrained;

– adequately support the animal's body when moving it;

– avoid taping or binding the legs or feet of the animals as the sole method of restraint, and where required, the method should not cause injuries or pain.

Procedures or practices unacceptable on *animal welfare* grounds are:

– ~~not~~breaking legs, cuting limb tendons or ~~blind animals~~ damaging the eyes of the reptiles in order to immobilise them;

– ~~not~~severing the spinal cord to immobilise ~~animals~~ the reptiles.

**EU comment**

**The EU would like to reiterate its previous comment.**

**The EU suggests adding the following sentence:**

**"- pulling or probing sensitive body parts."**

**Justification**

**This is a common requirement for all species. The EU has noted the report of the OIE *ad hoc* group on killing methods for farmed reptiles and its answer to this EU comment.**

**However, the EU would like to note that this article refers to restraint, and therefore to a phase during which reptiles can still experience pain if pulled or probed in sensitive parts of their body.**

Animal-based criteria (or measurables): excessive struggling, excessive movements, vocalisation, trauma and injuries.

Article 7.Y.7.

**Introduction to stunning and killing methods**

Stunning may be used to facilitate the *killing* of reptiles. *Stunning* methods may result in the *death* of the animal following unconsciousness, or may require an additional *killing* step.

If *stunning* is used, the method should:

– be appropriate for the species, size, age and health of the animal;

– be reliable and reproducible;

– avoid excitement, fear and stress to the animal;

– avoid or minimise restraint in accordance with Article 7.Y.6.;

– result in the immediate onset of unconsciousness or the absence of pain, distress and suffering until the onset of unconsciousness that lasts until the animal is dead;

– be followed by a killing method if stunning does not result in *death* of the animal during unconsciousness.

The equipment used should be maintained and operated properly and in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the animal. The maintenance of the equipment is the responsibility of the management of the facility, and should be under the supervision of the *Competent Authority* or accredited delegated body. If the primary method of stunning fails to produce unconsciousness as described in Article 7.Y.5. and in accordance with this article, a back-up stunning or *killing* method should be used immediately (Articles 7.Y.8. to 7.Y.15.).

Animal-based criteria (or measurables): immediate onset of unconsciousness or *death* as described in Article 7.Y.5.

Article 7.Y.8.

**Electrical stunning (for crocodilians only)**

Electrical stunning is the application, through the brain of an electric current of sufficient strength and duration, and suitable frequency to ~~through electrodes for the purpose of~~ cause~~ing~~ immediate unconsciousness that lasts until *death*.

Recommendations for effective use in relation to *animal welfare*:

– the equipment and the procedure for its application should be approved by the *Competent Authority* or an accredited designated authority;

– the apparatus should deliver sufficient current through the brain;

– the equipment should be scientifically validated, tested and calibrated prior to use and maintained according to a set protocol;

– minimum electrical parameters (current, voltage and frequency) should be applied;

– minimum length of time of application of the current ~~stun duration~~ should be achieved;

– animals should be killed in accordance to Articles 7.Y.9. to 7.Y.15. without delay following confirmation of effective stunning to avoid recovery of consciousness.

**EU comment**

**The EU would like to reiterate its previous comment.**

**The EU suggests adding the following bullet points:**

**"- <u>animals should be effectively restrained</u>;**

**- <u>equipment should be selected to suit the type and size of animal</u>;**

**- <u>equipment should be cleaned, maintained and stored, following manufacturer's recommendations</u>."**

**Justification**

**Restraining may be required for precise placement of electrodes. Equipment and electrodes needs to fit the animals' dimensions. Equipment used for electrical stunning needs cleaning and maintenance (electrodes, for example, may require regular cleaning and sharpening). Furthermore, this inclusion is in consistency with Articles 7.Y.10, 7.Y.11, 7.Y.12 and 7.Y.15.**

**The EU has noted the report of the OIE *ad hoc* group on killing methods for farmed reptiles and its answer to this EU comment. However, the above points do not seem to be covered to the same extent and meaning, as proposed in the EU comment.**

Animal-based criteria (or measurables): immediate onset of unconsciousness as described in Article 7.Y.5.

Article 7.Y.9.

**Penetrative captive bolt**

The aim of this method is to produce a state of unconsciousness and cause severe damage to the brain by the impact and penetration of a captive bolt using a mechanical device. The force of impact and the physical damage caused by the passage of the bolt should result in immediate unconsciousness and *death*. If *death* does not occur following the passage of the penetrative bolt, then an additional *killing* method in accordance with Articles 7.Y.9. to 7.Y.15. should be used immediately to ensure *death*.

<u>Annex 36</u> (contd)

Recommendations for the effective use in relation to *animal welfare*:

– animals should be effectively restrained;

– the device should be correctly positioned on the head to result in the penetration of the brain by the bolt;

– the bolt should be of appropriate mass, length, diameter and shape;

– cartridge or compressed air specifications should be determined to deliver the correct bolt velocity;

– equipment and charge should be selected to suit the <u>species,</u> type and size of ~~animal~~ <u>the reptile</u>;

– equipment should be cleaned, maintained and stored, following manufacturer's recommendations.

Animal-based criteria (or measurables): immediate onset of unconsciousness ~~and~~ <u>or</u> *death* as described in Article 7.Y.5.

Article 7.Y.10.

**Non-penetrative captive bolt**

The non-penetrative captive bolt method is sometimes called ‘concussive stunning’, although concussion is the underlying principle for both penetrative and non-penetrative methods. The concussion may result in both unconsciousness and *death*. If *death* does not occur following the application of the percussive blow, then an additional *killing* method in accordance with Articles 7.Y.9. to 7.Y.15. should be used immediately to assure *death*.

Recommendations for an effective use in relation to *animal welfare*:

– animals should be effectively restrained;

– the device should be correctly positioned on the head to allow optimum transfer of energy to the brain;

– the bolt should be of appropriate mass, diameter and shape;

– cartridge or compressed air specifications should be determined to deliver the correct bolt velocity;

– equipment and charge should be selected to suit the species, type and size of ~~animal~~ the reptile;

– equipment should be cleaned, maintained and stored, ~~preferably~~ following manufacturer’s recommendations.

Outcome-based criteria (or measurable): immediate onset of unconsciousness or *death* as described in Article 7.Y.5.

Article 7.Y.11.

**Percussive blow to the head**

A percussive blow to the head to induce cerebral concussion can be achieved manually. A concussive state is normally associated with a sudden loss of consciousness with associated loss of reflexes. Inducing unconsciousness requires the transfer of sufficient energy into the brain to disrupt normal neural function. If the severity of the blow is sufficient then it will result in the *death* of the animal. If *death* does not occur following the application of the percussive blow, then an additional *killing* method in accordance with Articles 7.Y.9. to 7.Y.15. should be used immediately to ensure *death*.

Recommendations for effective use in relation to *animal welfare*:

– animals should be effectively restrained;

– the blow should be correctly applied to result in optimum transfer of energy to the brain;

– the tool should be of appropriate size and weight, and the blow of sufficient force to induce concussion;

– equipment and method should be selected to suit the species, type and size of ~~animal~~ the reptile.

**EU comment**

**The EU would like to reiterate its previous comment.**

**The EU suggests OIE including the following additional bullet points:**

**"- maximum animal live-weight and/or**

**- maximum number of animals stunned/killed per person and day"**

**Justification**

**Achieving a successful stun/kill with percussive blow may be difficult above a certain live-weight. A person may become exhausted after a certain amount of stuns/kills during a single shift, leading to a reduced precision and force of manual blows.**

Animal-based criteria (or measurables): immediate onset of unconsciousness or *death* as described in Article 7.Y.5.

Article 7.Y.12.

**Gunshot**

An effective gunshot, where the projectile enters the brain, can cause immediate unconsciousness and *death*. A gunshot to the heart or neck does not immediately render an animal unconscious and therefore should not be used. If *death* does not occur following the gunshot, then an additional *killing* method in accordance with Articles 7.Y.9. to 7.Y.15. should be used immediately to ensure *death*.

Manual restraint of the animal should not be used due to safety concerns for humans in the line of fire.

Recommendations for effective use in relation to *animal welfare*:

– ensure accurate targeting of the brain;

– select firearm and projectile suitable for the species, type and size of ~~animal~~ the reptile;

– equipment should be cleaned and stored following manufacturer's recommendations.

Animal-based criteria (or measurables): immediate onset of unconsciousness or *death* as described in Article 7.Y.5.

Article 7.Y.13.

**Pithing**

Pithing is an adjunct method used to ensure *death* by destruction of brain tissue. It is carried out by inserting a rod or probe through the foramen magnum or shot hole from a penetrative captive bolt or gunshot, into the brain ~~to ensure thorough brain destruction~~. After insertion of the rod or probe it should be promptly turned a minimum of four ~~to six~~ times in a centrifugal motion to ensure destruction of the brain tissue.

Recommendations for effective use in relation to *animal welfare*:

– should only be used in unconscious ~~animal~~ reptiles;

– movement of the pithing implement should ensure maximum destruction of brain tissue.

Animal-based criteria (or measurables): confirmation of *death* as described in Article 7.Y.5.

Article 7.Y.14.

**Decapitation or spinal cord severance**

Decapitation involves cutting the neck of the animal, between the skull and the first cervical vertebra using a sharp instrument (guillotine, axe or blade) leading to severance of the head. For some reptile species, ~~this method~~ decapitation is not anatomically feasible. For severance of the spinal cord, complete separation of the head from the neck is not necessary. Some reptiles may remain conscious for over an hour after decapitation or spinal cord severance, which makes ~~this method~~ decapitation or severance of the spinal cord acceptable only in stunned and unconscious animals and when followed by immediate destruction of the brain ~~by pithing or percussive blow~~.

Annex 36 (contd)

Recommendations for effective use in relation to *animal welfare*:

– should only be used on unconscious ~~animal~~ reptiles;

– should always be followed immediately by physical intervention to destroy the brain, i.e. immediate crushing of the brain or pithing.

Animal-based criteria (or measurables): confirmation of *death* as described in Article 7.Y.5.

Article 7.Y.15.

**Chemical agents**

There are a number of ~~acceptable~~ chemical agents that, subject to relevant regulatory approvals, can be used for the restraint or *killing* of reptiles. The use of these agents for either restraint or *killing* should be supervised by *veterinarians* or *veterinary paraprofessionals* in accordance with the requirements of the *Competent Authority*. If *death* does not occur following administration of the agent, then an additional *killing* method in accordance with Articles 7.Y.9. to 7.Y.15. should be used immediately to ensure *death*.

The effectiveness of the chemical agent will vary according to the metabolic rate of reptiles.

Recommendations for effective use in relation to *animal welfare*:

– ensure proper physical restraint is used for administration;

– ensure chemicals and dosage used are appropriate for the ~~animal~~ reptiles;

– ensure the route of administration is appropriate for the ~~animal~~ reptiles.

Animal-based criteria (or measurables): confirmation of *death* as described in Article 7.Y.5.

Article 7.Y.16.

**Methods that are unacceptable for stunning and killing reptiles**

Due to particular anatomical and physiological characteristics of reptiles the use of any method other than those described in Articles 7.Y.9. to Article 7.Y.15., are considered inappropriate and unacceptable. Some examples of unacceptable methods are:

– exsanguination,

– freezing or cooling,

– heating or boiling,

– suffocation or drowning,

– inflation using compressed gas or liquid,

– live evisceration or skinning,

– constriction bands to induce cardiac arrest,

– ~~inhaled~~ inhalation of asphyxiating gases carbon dioxide ($CO_2$), carbon monoxide (CO) or nitrogen (N),

– use of paralysing ~~paralytic agent~~ drugs;

= cervical dislocation.

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Annex 41

**NOTE:**

The Code Commission invites Member Countries to react to the following proposals of the *ad hoc* Group on avian influenza before the next General Session (10 May 2018) to inform the OIE Headquarters and assist them in drafting Terms of Reference of the next *ad hoc* Group which it was planning to hold in June or July 2018 so that the outcomes would be available for the September meeting of the Code Commission.

The Code Commission will consider the comments and outputs of the *ad hoc* Group (if there is a need) at its September 2018 meeting.

CHAPTER 10.4.

# INFECTION WITH AVIAN INFLUENZA VIRUSES

**EU comment**

**The EU in general supports the proposals of the *ad hoc* group on avian influenza on Chapter 10.4.**

**Comments are inserted in the text below.**

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% 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% 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% 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.

| **The a*d hoc* Group's proposal** | **Definition of 'AI'**<br><br>The Group acknowledged that 'AI' as defined in the AI chapter has broad implications for the sanitary measures applied by Member Countries, including disease notification, prevention and control of AI and trade conditions.<br><br>It was therefore decided that the Group should address the following issues as particularly useful in its work to better define the definition of 'AI, as shown below:<br><br>The Group agreed that LPAI should not be treated the same as HPAI in the *Terrestrial Code*, and there is a need to improve transparency of notifications of avian influenza while minimising unjustified trade restrictions arising from notification of strains of low pathogenicity.<br><br>The Group carefully considered three different options as follows:<br><br>(1) two separate chapters for HPAI and LPAI viruses; |
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| | (2) maintaining the status quo but implement other initiatives that may address this issue (*e.g.*, improved information-sharing, training and cooperation with the World Health Organization (WHO) to make sanitary measures employed proportional to the level of zoonotic risk of AI, etc.);<br>(3) making a clear distinction between HPAI and LPAI in the same chapter. Defining AI as HPAI for immediate notification and having a separate article or articles that highlight the need for LPAI surveillance, the possibility of mutation to HPAI, public health consequences, only six monthly reporting and the application of appropriate risk management measures in order to avoid unjustified barriers to trade.<br>After examining the three options, the Group noted that the first option was not practical and would not solve the challenge of striking a balance between the potential zoonotic risk of LPAI and the trade implications. With regard to the second option, there is an acceptance on the part of the majority of Member Countries that the status quo cannot be maintained.<br>The Group agreed to recommend the third option of separating LPAI and creating new articles in the same chapter dedicated to LPAI addressing the following key areas:<br>• the importance of surveillance;<br>• the need for proportional responses to the potential zoonotic risk of AI viruses;<br>• the possibility of including recommendation or requirements for Member Countries to only notifiy LPAI in six-monthly reports;<br>• and avoiding unjustified barriers to trade caused by notification of LPAI outbreaks.<br>The Group believed that this approach would provide Member Countries with a degree of certainty and flexibility as to how to apply sanitary measures against LPAI, while maintaining continuity and stability for the existing AI chapter. |

**EU comment**

**The EU fully supports the proposals of the *ad hoc* group on the definition of avian influenza, and agrees that option 3 is indeed the preferred one that best addresses the trade related challenges currently experienced by member countries.**

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 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*.

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| **The a*d hoc* Group's proposal** | **Definition of 'poultry'**<br>The Group discussed the definition of 'poultry' and the reporting obligations of Member Countries, and revised the definition taking into account Member Countries' requests to clarify the use of the term 'backyard poultry', specifically to exclude this sector of the population or redefine them in the AI chapter.<br>The Group noted that the categories of birds listed in the definition of 'poultry' should have an epidemiological role in the spread of the disease. Based on the epidemiology of the disease, the Group discussed the definition of 'poultry' and the likelihood of spread of viruses rather than the likelihood of exposure in assessing the risks associated with all categories of birds listed in the AI chapter. |

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| | With regard to the term 'backyard poultry', the Group noted that because backyard production systems vary between Member Countries, it was not possible to define a term that could be uniformly applied to all situations. The Group suggested that the words 'including backyard poultry' be removed from the definition as these were covered by 'all domesticated birds'. |
| **The a*d hoc* Group's proposal (contd)** | In addition, given the much lower risk of transmission of viruses in these types of birds compared to commercially traded poultry, and the absence of any data to the contrary, the Group proposed that the category of birds that are used exclusively for self consumption be removed from the definition of 'poultry' and proposed additional modifications to improve the clarity of the text.<br><br>The Group consequently proposed to revise point 3) of Article 10.4.1., deleting the words 'including backyard poultry' and inserting the words 'except those birds used exclusively for self-consumption' from the definition, to read:<br><br>3) *Poultry* is defined as 'all domesticated birds, ~~including backyard *poultry*,~~ used for the production of *meat* or eggs for consumption except those birds used exclusively for self-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 or all birds used for restocking supplies of game[2].<br><br>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*' |
| **The Code Commission's comments** | The Code Commission considered the *ad hoc* Group proposed revised definition of *poultry*, it noted that the definition had been revised to take into account those categories of birds that could have an epidemiological role in the spread of the disease.<br><br>It further noted the difficulty of defining a term that covered backyard production systems that could be uniformly applied to all situations and that this was not only problematic for this disease.<br><br>The Code Commission still had some difficulty in understanding the meaning of self-consumption, how the birds are used, purchased, how their products are used but in principle supported the proposed revised definition. The Code Commission agreed with the definition proposed by the *ad hoc* Group. |

**EU comment**

**The EU in general supports the revised definition of poultry as proposed by the *ad hoc* group. However, we propose to place the newly proposed wording regarding the exception for self-consumption in parenthesis for better readability and clarity of the sentence. Furthermore, we note that moving the part on "birds used for restocking supplies of game" to the end of the definition leads to uncertainty as to whether birds used for breeding these types of birds would still be included. We therefore suggest moving that part back to where it originally was, in order to avoid any possible confusion, as follows:**

**"*Poultry* is defined as 'all domesticated birds, ~~including backyard *poultry*,~~ used for the production of *meat* or eggs for consumption (except those birds used exclusively for self-consumption), for the production of other commercial products, all birds used for restocking supplies of game ~~for restocking supplies of game,~~ or for breeding these categories of birds, as well as fighting cocks used for any purpose. ~~or all birds used for restocking supplies of game'.~~".**

**Finally, we share the concerns of the Code Commission as to the exact meaning (and delimitation) of "self-consumption" (of meat and eggs). The EU would therefore propose**

**replacing the term "self-consumption" with the words "<u>private domestic use and consumption</u>". We would understand "private domestic" as referring to the private household (i.e. contrary to domestic sometimes being understood as "national" or "within the country"). "Private domestic use" is also to be understood as excluding any placing on the market, i.e. any moving away from the household for commercial or non-commercial purposes by selling or in any other way giving away birds or their products to consumers beyond the private household, either directly (e.g. on-farm shops) or indirectly (e.g. retailers or local markets). Indeed, while these types of birds (and their products) are possibly more likely to become infected (and contaminated) from contact with wild birds, the risk of onward spread of AI via such commodities is negligible as long as the dissemination of these commodities outside the "household" of their owners is effectively excluded.**

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.

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* and *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*.

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| **The Code Commission's comments** | Invite Member Countries to provide scientific data or references to assist in the revision of the chapter or that might assist in resolving the issues highlighted in the *ad hoc* Group report. |

Annex 42

**WORK PROGRAMME FOR**
**THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

**EU comment**

**The EU thanks the Code Commission for having taken its previous comments into consideration, and in general supports the proposed revised work programme.**

**In particular, we commend the OIE for having initiated the important work on the revision of the Code chapter on avian influenza by swiftly convening an *ad hoc* group ahead of the February Specialist Commission meetings, and for submitting its proposals for member country comment. We fully support this process and are ready to continue providing expert advice for this crucial activity.**

**We also take note that preparations are underway to continue the revision of the Code chapter on BSE at *ad hoc* group level, however no concrete progress seems to have been made on this important project for some time now. This is a bit disappointing especially considering the urgent need to revise the surveillance recommendations in the context of the considerably improved epidemiological situation, which will have an important impact on the annual reconfirmation of the BSE status of member countries, particularly those with small cattle populations. From the Code Commission report it seems that progress is dependent on resources and capacity of OIE Headquarters. We'd like to reiterate again at this stage that for the EU, maximum priority should be given by the OIE to the finalisation of the comprehensive revision of the BSE Code chapter, both as regards the surveillance requirements and the specificities of Atypical BSE. The EU therefore urges the OIE to convene an *ad hoc* group as soon as possible. We are committed to actively participate in that work and are ready to offer all the support needed by the OIE to make the necessary progress on this essential matter.**

**With reference to the EU comments in Annex 13 and the ones submitted previously on Chapter 6.8. (available here https://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_position_tahsc-report_201709.pdf, cf. p. 109-112), the EU suggests a thorough revision of Chapter 6.9. on *Responsible and prudent use of antimicrobial agents in veterinary medicine* with a view to including concrete principles and further recommendations as to the conditions of use, in the context of treatment, control and prevention of infectious diseases in animals, of *antimicrobial agents* as defined in the glossary on the one hand and antibiotics (i.e. substances targeting bacterial micro-organism only) on the other. The EU is ready to provide concrete text proposals for consideration by the Code Commission before its September 2018 meeting.**

**Finally, as regards the glossary definitions of Wildlife and feral / captive wild / wild animals, the EU in general notes some difficulties of member countries in interpreting the exact meaning and delimitation of "direct human supervision or control". This is relevant for example in the context of the Code chapter on African swine fever, and has potential important consequences for international trade. We would therefore invite the Code Commission to provide some clarifications in this respect, incl. possible amendments of the relevant Glossary definitions, with a view to facilitating the correct and consistent interpretation and implementation of the OIE recommendations relating to wildlife.**

| Subject | Issue by priority order (Reason for new work) | Status and Action (Start date, # of rounds for comments) |
|---|---|---|
| **Restructuring of the *Code*** | 1) Work with AAHSC towards harmonisation, as appropriate, of the horizontal parts of the *Codes,* notably Glossary, User's Guide and Section 4 on disease control and Section 6 on Veterinary Public Health (MCs comments) | Ongoing |
| | 2) Work with BSC for accurate disease description and diagnostic in the *Manual* and case definitions in the *Code* and names of diseases and country and zone disease status (MCs comments) | Ongoing |
| | 3) Revision and formatting of chapters (articles numbering, tables and figures) (MCs comments and to improve consistency) | Ongoing |
| | 4) Revision of the Users' guide (MCs comments and changes in the *Code*) | Ongoing |
| **Glossary** | 1) Compartment, containment zone, free zone, infected zone, protection zone, vaccination, zone (MCs comments and to improve consistency) | Revised definitions proposed for adoption in 2018 (Feb 2016/5th) |
| | 2) Disease (to improve consistency) | Deleted definition proposed for adoption in 2018 (Sep 2016/4th) |
| | 3) Early warning system and sanitary measures (experts comments) | Revised definitions sent for comments (Sep 2016/2nd and Feb 2018/1st) |
| **Horizontal issues not yet in the *Code*** **Sec.4. Disease control** | 1) New CH on vaccination (MCs comments) | Revised new CH proposed for adoption in 2018 (Sep 2016/4th) |
| | 2) New CH on official control of emerging and listed diseases (MCs comments and part of restructuring of Section 4) | Revised new CH sent for comments (Feb 2017/3rd) |
| | 3) New introductory CH in Section 4 (Part of restructuring of Section 4) | Revised new CH sent for comments (Sep 2017/2nd) |
| | 4) New CH on biosecurity (Discussion with ACC) | Preliminary discussion |
| | 5) New CH on zoning application (MCs comments) | Preliminary discussion |
| **Horizontal issues not yet in the *Code*** **Sec.6. VPH** | 1) New introductory CH in Section 6 (APFSWG proposal) | Revised new CH proposed for adoption in 2018 (Feb 2017/3rd) |
| | 2) Control of Shiga toxin-producing *E. coli* (STEC) in food-producing animals (MCs comments) | Preliminary discussion pending FAO/WHO expert consultation |

Annex 42 (contd)

| Subject | Issue by priority order (Reason for new work) | Status and Action (Start date, # of rounds for comments) |
|---|---|---|
| **Horizontal issues not yet in the *Code* Sec.7. AW** | 1) New CH on AW and pig production systems (MCs comments) | Revised new CH proposed for adoption in 2018 (Sep 2016/4th) |
| | 2) New CH on slaughter and killing methods of farmed reptiles (MCs comments) | Revised new CH sent for comments (Sep 2017/2nd) |
| | 3) New CH on AW and laying hen production systems (MCs comments) | Revised new CH pending AHG (Sep 2017/1st) |
| **Horizontal issues in need of revision: Sec.1. Notification** | 1) Revision of CH 1.4. on animal health surveillance (MCs comments and implications for status recognition) | Revised CH sent for comments (Feb 2016/3rd) |
| | 2) CH 1.6. on status: revision and reorganisation (MCs comments and implications for status recognition) | Revised questionnaires proposed for adoption in 2018 (Feb 2017/2nd) Revised CH sent for comments (Feb 2018/1st) |
| | 3) CH 1.3. on listed diseases: assess CWD, WNF, PED, Theileria (orientalis, for small ruminants), *M. tuberculosis*, *M. paratuberculosis* against the listing criteria (MCs comments) | Pending expert's advice |
| **Horizontal issues in need of revision: Sec.2. RA** | 1) Revision of Article 2.1.2. (Consequential changes to reflect the proposed deletion of Glossary definition of 'transparency') | Revised article proposed for adoption in 2018 (Feb 2017/3rd) |
| **Horizontal issues in need of revision: Sec.3. VS** | 1) Revision of CHs of Section 3 in the light of the return of experience of the PVS Pathway | Pending outcome of discussion at PVS think tank and of AHG on PVS Pathway (veterinary legislation) |
| **Horizontal issues in need of revision: Sec.4. Disease control** | 1) Revision of CH 4.3. on zoning and compartmentalisation (MCs comments and implications for status recognition) | Revised CH proposed for adoption in 2018 (Feb 2016/5th) |
| | 2) Revision of CH 4.8. on collection and processing of *in vitro* produced oocytes or embryos from livestock and horses (MCs comments) | Revised CH proposed for adoption in 2018 (Sep 2016/4th) |
| | 3) Revision of CH 4.13. on disinfection (MCs comments) | Preliminary discussion |
| | 4) Revision of CH 4.6. on collection and processing of semen (MCs comments and trade implications) | Pending expert's advice |
| | 5) Revision of CH 4.7. on ollection and processing of *in vivo* derived embryos (MCs comments) | Pending expert's advice |
| **Horizontal issues in need of revision: Sec.5. Trade measures** | 1) Revision of CHs 5.4. to 5.7. on measures applicable at departure and on arrival (MCs comments) | Preliminary discussion and pending decision on AHG |
| | 2) Revision of CH 5.12. on model certificates for competition horses (MCs comments) | Preliminary discussion and pending revision of CHs on horse diseases |
| | 3) Revision CH 5.10. to include a model certificate for petfood (NGO comments) | Preliminary discussion and pending supporting data from industry |

Annex 42 (contd)

| Subject | Issue by priority order (Reason for new work) | Status and Action (Start date, # of rounds for comments) |
|---|---|---|
| **Horizontal issues in need of revision:** **Sec.6. VPH** | 1) Revision of CH 6.1. on the role of VS in food safety (Planned work by TAHSC) | Revised CH proposed for adoption in 2018 (Feb 2016/4th) |
| | 2) Revision of CH 6.7. on AMR surveillance and monitoring programme (MCs comments and to align with Codex work) | Revised CH proposed for adoption in 2018 (Sep 2015/5th) |
| | 3) Revision of Article 6.8.1. on monitoring of AMR in food producing animals (In conjunction with Codex work on AMR) | Revised CH proposed for adoption in 2018 (Feb 2017/3rd) |
| | 4) Revision of CH 6.2. on meat inspection (Planned work by TAHSC) | Preliminary discussion |
| **Horizontal issues in need of revision:** **Se.7. AW** | 1) Revision of CH 7.5. on slaughter and CH 7.6. on killing of animals (MCs comments) | Pending work of AHG |
| | 2) Revision of CH 7.1. on introduction to recommendations on AW (AWWG proposals) | Revised CH proposed for adoption in 2018 (Feb 2017/3rd) |
| | 3) Revision of Art. 7.12.12. on AW of working equids (MCs comments) | Pending advice from MCs |
| **Diseases issues not yet in the *Code*** | 1) New CH on non-equine surra and revision of CH on Dourine (Non-tsetse transmitted Trypanosomosis) (MCs comments) | New/revised CHs sent for comments and pending work of AHG (Sep 2017/2nd) |
| | 2) New CH on Tsetse transmitted trypanosomosis (MCs comments) | Pending work of AHG |
| | 3) New CH on Crimean Congo hemorrhagic fever (MCs comments, listed disease without chapter) | Preliminary discussion |
| **Listed disease CHs in need of revision:** **Sec. 8 to 15** | 1) Revision of CH 10.4. on AI (MCs comments and trade implications) | AHG report sent for comments (Feb 2018/1st) |
| | 2) Revision of CH 12.10. on glanders (outdated CH and trade implications) | Revised CH proposed for adoption in 2018 (Sep 2014/5th) |
| | 3) Revision of CH 8.13. on rabies (MCs comments) | Revised CH sent for comments (Feb 2018/1st) |
| | 4) Revision of CH 11.4. on BSE (MCs comments and trade implications) | Pending work of AHGs (Feb 2015/1st) |
| | 5) Revision of CH 8.3. on bluetongue (MCs comments) | Revised CH proposed for adoption in 2018 (Sep 2016/4th) |
| | 6) Revision of CH 11.12. on Theileriosis and new CH 14.X. on infection with *Theileria* in small ruminants (outdated CH) | Revised/new CHs sent for experts advice on listing pathogenic agents (Sep 2017/1st) |
| | 7) Revision of CH 8.8. on FMD (MCs comments and implications for status recognition) | Pending outcome of discussion on zoning (Sep 2015/2nd) |

Annex 42 (contd)

| Subject | Issue by priority order (Reason for new work) | Status and Action (Start date, # of rounds for comments) |
|---|---|---|
| **Listed disease CHs in need of revision:**<br>**Sec. 8 to 15** | 8) Revision of CH 15.2. on CSF (MCs comments and implications for status recognition) | Revised CH sent back to HQs for evaluation and SCAD review (Feb 2017/1st) |
| | 9) Revision of Art. 15.3.9. on import of semen from countries not free from PRRS (MCs comments) | Pending experts advice |
| | 10) Revision of CH 14.8. on scrapie (MCs comments) | Pending experts opinion on MCs comments |
| | 11) Revision of CH 10.5. on avian mycoplasmosis (MCs comments and trade implications) | Pending experts opinion |
| | 12) Revision of CH 11.7. on CBPP (Implications for status recognition) | Pending HQs advice |
| | 13) Revision of Article 8.15.2. on rinderpest (MCs comments and proposal by JAC) | Revised Art proposed for adoption in 2018 (Feb 2017/3rd) |
| | 14) Consistency between articles on disease status | Pending SCAD evaluation |
| **Follow-up revision of CHs adopted at 85$^{th}$ GS:** | 1) Further revision of Arts 15.1.1bis., 15.1.2, and 15.1.22. on ASF (MCs comments at 85GS) | Revised CH sent for comments (Sep 2017/2nd) |
| | 2) Revision of CH 11.11. on LSD (MCs comments at 85GS ) | Revised CH proposed for adoption in 2018 (Sep 2017/2nd) |
| | 3) Revision of CH 2.2. on criteria for assessing safety of commodities (MCs comments at 85GS ) | Revised CH proposed for adoption in 2018 (Sep 2017/2nd) |
| | 4) Revision of Arts 6.13.3. and 6.13.16. on *Salmonella* in commercial pig production systems (MCs comments at 85GS ) | Revised CH proposed for adoption in 2018 (Sep 2017/2nd) |

Annex 42 (contd)

| List of abbreviations | |
|---|---|
| AAHSC | Aquatic Animal Health Standards Commission |
| AHG | *ad hoc* Group |
| AMR | Antimicrobial resistance |
| AI | Avian influenza |
| APFSWG | Animal Production Food Safety Working Group |
| ASF | African swine fever |
| AW | Animal Welfare |
| AWWG | Animal Welfare Working Group |
| BSC | Biological Standards Commission |
| BSE | Bovine Spongiform Encephalopathy |
| CBPP | Contagious bovine pleuropneumonia |
| CH | Chapters |
| CSF | Classical swine fever |
| CWD | Chronic wasting disease |
| FMD | Foot and mouth disease |
| HQs | Headquarters |
| JAC | FAO-OIE Rinderpest Joint Advisory Committee |
| LSD | Lumpy skin disease |
| NGO | Non-Governmental Organisation |
| PRRS | Porcine reproductive and respiratory syndrome |
| PVS | Performance of Veterinary Service |
| RA | Risk Analysis |
| TAHSC | Terrestrial Animal Health Standards Commission |
| VPH | Veterinary Public Health |
| VS | Veterinary Service |
| WNF | West nile fever |