

## Annex 1

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September 2019

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

Paris, 10–19 September 2019

#### 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 September 2019 meeting of the Code Commission are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report.**

**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 OIE 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 10 to 19 September 2019. The list of participants is attached as [Annex 1](#).

The Code Commission thanked the following Members for providing comments: Argentina, Australia, Canada, Chile, China (People's Republic), Chinese Taipei, Japan, Korea (Republic), Mexico, New Caledonia, New Zealand, Singapore, South Africa, Switzerland, Thailand, USA, the Member States of European Union (EU), the African Union Interafrican Bureau for Animal Resources (AU-IBAR) on behalf of African Member Countries of the OIE and the Comité Veterinario Permanente del Cono Sur (CVP) on behalf of Argentina, Bolivia, Brazil, Chile, Paraguay and Uruguay.

The Code Commission reviewed Member 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 Code Commission did not consider comments where a rationale had not been provided or that were difficult to interpret.** Due to 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. Where amendments were of an editorial nature, no explanatory text has been provided. The Code Commission wished to note that not all texts proposed by Members to improve clarity were accepted; in these cases it considered the text clear as currently written.

The amendments are presented in the usual manner by 'double underline' and '~~striketrough~~' and the chapters are annexed to this report. In Annexes **4** to **28** amendments proposed at this meeting are highlighted with a coloured background to distinguish them from those proposed previously.

The Code Commission encourages Members to refer to previous reports when preparing comments on longstanding issues. The Code Commission also draws the attention of Members 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 Members 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 Members are encouraged to review these reports together with the report of the Code Commission. These reports are readily available on the [OIE website](#).

Members should note that texts in **Part A (Annexes 4 to 17)** of this report are circulated for Member comments and will be proposed for adoption at the 88th General Session in May 2020. **Part B (Annexes 3, 18 to 28)** includes texts that are circulated for Members comments only. The reports of meetings of *ad hoc* Groups and other related documents are attached for information in **Part C**.

All comments on relevant texts in **Part A** and **Part B** must reach OIE Headquarters **by 20 December 2019** for them to be considered at the February 2020 meeting of the Code Commission. Comments received after the due date will not be submitted to the Code Commission for its consideration. In addition, the Code Commission would like to highlight that comments should be submitted through the OIE Delegate of Member Countries or organisations which the OIE has a Cooperative Agreement with.

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 Members to participate in the development of the OIE's international standards by submitting comments on this report. Members are also reminded that 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 '~~strike through~~' and additions using 'double underline'. Members should not use the automatic 'track-changes' function provided by word processing software as such changes are lost in the process of collating submissions into the Code Commission's working documents. Members 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. Welcome from the Deputy Director General**

Dr Matthew Stone, OIE Deputy Director General International Standards and Science, welcomed the members of the Commission and thanked them, their institutions and their governments for making their expertise and time available to support the OIE's work.

Dr Stone provided the Commission with a brief overview of the development of the draft 7<sup>th</sup> Strategic Plan, noting its focus on scientific expertise and the use of multidisciplinary evidence in standard setting and capacity building; ensuring the OIE is a good partner, and targets collaborations for impact, including in multilateral fora related to UN's Sustainable Development Goals; improving monitoring and evaluation to demonstrate performance across our strategies, programmes and projects; and the development of internal data management, stewardship and governance practices that support the ongoing digital transformation of the OIE. He also provided a brief update on the culmination of the design phase of the OIE Observatory project; the OIE-WAHIS development project; and the ongoing work on the OIE Reference Centre system.

Dr Stone noted that the OIE's continuous improvement approach to ensuring good coordination across all the Specialist Commissions through the internal mechanism of the Common Secretariat is maturing and demonstrating its benefits. The recent focus had been on identifying and supporting discussions between Commissions on common issues. He finished his opening remarks by reassuring members that the OIE's performance management system for Specialist Commissions was providing very useful feedback, and all parties could now appreciate the process was important to optimise the performance and transparency of the elected Commissions and the OIE Secretariat working in partnership.

## **2. Meeting with the Director General**

Dr Monique Eloit, the OIE Director General, met with the Code Commission met on 16 September 2019 and thanked its members for their support and commitment to achieving OIE objectives. Dr Eloit updated the Code Commission on the work currently being undertaken to develop the 7<sup>th</sup> Strategic Plan. She also discussed the work programme of the Code Commission and other topics related to its work and performance.

The Code Commission expressed its satisfaction for the work of the Secretariat and highlighted certain points of priority in the work programme.

## **3. Adoption of agenda**

The proposed agenda was discussed, taking into consideration priorities of the work programme and time availability. The adopted agenda of the meeting is attached as **Annex 2**.

## **4. Cooperation with other Specialist Commissions**

### **4.1. Scientific Commission for Animal Diseases**

The opinion of the Scientific Commission was requested and coordinated through the OIE Secretariat for relevant comments received on draft chapters circulated in February 2019. The Code Commission wished to thank the Scientific Commission for this collaborative work as well as its advice on a number of other topics identified in the February 2019 meeting report. Consideration of the Scientific Commission's inputs is noted under the relevant agenda items.

During the September 2019 meeting, two side meetings were held:

- **Meeting of the Bureaus of the Code Commission and Scientific Commission**

The Bureaus (i.e. the President and two Vice-Presidents) of the Code Commission and the Scientific Commission held a meeting chaired by Dr Matthew Stone, the OIE Deputy Director General for International Standards and Science. The purpose of the meeting was to provide an occasion where the two Bureaus could be informed about the planning and coordination of relevant topics of common interest and, where necessary, prioritise them and agree on the process to manage these topics. This meeting also allowed for better alignment of the work programme and agenda of both the Code Commission and Scientific Commission.

- **Technical working group meeting related to the concept of ‘protection zone’**

The Presidents and First Vice-Presidents of the Code Commission and Scientific Commission held a third technical working group meeting chaired by Dr Matthew Stone. Previous meetings had been held in September 2018 and February 2019.

The aim of these discussions was to agree on a mechanism that would allow Members to implement enhanced preventive measures to protect their animal health status in response to an increased risk of disease incursion, while minimising the impact on their status and consequently on trade.

Possible amendments to existing provisions in Chapter 4.4 of the *Terrestrial Code* were discussed, in particular those related to a protection zone, and participants agreed on the principles to apply for these amendments. The potential impact on the OIE procedure for official recognition of disease status was also noted, mainly in relation to the maintenance of ‘freedom’ from disease in the rest of the country or zone when an outbreak occurs within the protection zone.

The OIE Secretariat was requested to prepare draft amendments to Chapter 4.4 based on the outcome of the discussions, to be considered by both Commissions in February 2020.

The outcome of discussions and the respective amendments to Chapter 4.4 will impact on some disease-specific chapters under revision, such as Chapter 8.8 Infection with foot and mouth disease virus.

#### **4.2. Biological Standards Commission**

The OIE Secretariat to the Biological Standards Commission provided a brief update to the Code Commission on relevant activities of the Biological Standards Commission, including chapters in the *Terrestrial Manual* that are being revised as well as other items of interest. A similar report was presented by the OIE Secretariat to the Code Commission to the Biological Standards Commission on relevant activities of the Code Commission. Both Commissions agreed that this new item on information sharing was very useful and helped to strengthen the linkages between the two Commissions.

The Code Commission also sought the advice of the Biological Standards Commission on some of the comments received on draft chapters circulated in the Code Commission’s February 2019 meeting report. The Code Commission wished to thank the Biological Standards Commission for its support.

### **5. Code Commission’s work programme**

The Code Commission updated its work programme and revised the order of items under ‘Sections 8 to 15’ to reflect the level of prioritisation.

Under the point 4 of the section on Glossary, the Code Commission briefly discussed the use of the terms ‘commodities’, ‘animal products’, ‘products of animal origin’ and ‘animal by-products’ in the *Terrestrial Code* based on a discussion paper prepared by a Commission member. The Code Commission acknowledged the importance of clarifying the use of these terms and whether to develop definitions for some terms. It agreed to continue this work out of session and to discuss further at its next meeting.

The Code Commission received a request to review Chapter 9.4 Infestation with *Aethina Tumida* (Small hive beetle) with regard to the timing of inspection prior to export, and included this item to its work programme. The Code Commission requested the OIE Secretariat seek expert advice on the proposal in order to prioritise this request.

The Code Commission noted that in general few comments are submitted on the work programme, which outlines the work areas undertaken by the Commission. The Code Commission encouraged Members to provide feedback on the proposed topics, as well as their level of prioritisation.

The updated work programme is attached as [Annex 3](#) for Member comments.

## **EU comment**

**The EU welcomes the proposed work programme and would like to stress the need to progress the work on Surra.**

### **6. Texts proposed for adoption in May 2020**

#### **6.1. User's Guide**

Comments were received from the EU.

##### **Background**

Amendments to the User's Guide were circulated to Members in the Code Commission's February 2019 meeting report proposing to replace 'pathogenic agents' with 'diseases, infections and infestations' under point 3 of Section B for consistency with terminology used throughout the *Terrestrial Code*, and to include a reference to Chapter 2.2 on the safety of commodities under point 5 of Section C.

In response to a comment asking why Glossary terms were not italicised in the User's Guide, the Code Commission explained that this is because the Glossary appears after the User's Guide.

The User's Guide is attached as **Annex 4** for Member comments and is proposed for adoption at the 88<sup>th</sup> General Session in May 2020.

## **EU comment**

**The EU supports the proposed change to the User's Guide.**

#### **6.2. Glossary Part A ('epidemiological unit')**

Comments were received from Argentina, USA and the EU.

The Code Commission considered comments received and highlighted that the last four sentences in the definition were provided to describe how epidemiological units may be applied in practice and were not intended to be exhaustive. The Code Commission agreed that these sentences are useful and therefore proposed that this text be moved to point 1(d) of Article 1.4.3 in Chapter 1.4 Animal Health Surveillance. Although Annex 6 presents the whole point 1 of Article 1.4.3 for ease of reference, Member comments are sought specifically for point 1(d) where the proposed amendments are being made.

The Code Commission also noted that the definition for 'epidemiological unit' as described in the first sentence is similar to the definition for 'epidemiological unit' that can be found in reference texts. In agreement with advice from the Scientific Commission, however, the Code Commission considered it appropriate to keep this part as a Glossary definition for the *Terrestrial Code* due to recognised reliance by many Members on the definition.

The Glossary definition for 'epidemiological unit' is attached as **Annex 5** for Member comments, and is proposed for adoption at the 88<sup>th</sup> General Session in May 2020.

## **EU comment**

**The EU in general supports the proposed change to the definition of *epidemiological unit* in the Glossary.**

The revised Article 1.4.3 is attached as [Annex 6](#) for Member comments, and is proposed for adoption at the 88<sup>th</sup> General Session in May 2020.

**EU comment**

**The EU supports the proposed addition in Chapter 1.4. to explain how ‘epidemiological units’ can be applied.**

**6.3. Notification of diseases, infections and infestations, and provision of epidemiological information (Chapter 1.1)**

Comments were received from Australia, Chile, New Zealand, Singapore, USA and the EU.

**General comments**

The Code Commission noted the comments received on the use of the terms ‘disease’, ‘infection’ and ‘infestation’, and clarified that these terms are used throughout the *Terrestrial Code* as follows:

- ‘Disease’ is used when referring to general aspects pertaining to the expression, epidemiology and transmission of pathogenic agents. (The Code Commission reiterated that ‘disease’ is no longer a defined term in the *Terrestrial Code*. In some Glossary definitions such as ‘listed disease’, ‘notifiable disease’ and ‘emerging disease’, the word disease is italicised as it is part of these defined terms.)
- ‘Infection’ and ‘infestation’, as defined in the Glossary, are used in more specific contexts such as cases, outbreaks, incursions, surveillance, control, eradication and free status.
- All terms ‘disease’, ‘infection’ and ‘infestation’ may be used in the context of describing spread.

The Code Commission noted in agreement with the Scientific Commission that as they apply this approach throughout the *Terrestrial Code*, if they find exceptions they will provide a rationale when they propose a change.

**Article 1.1.2**

In response to comments regarding the addition of ‘within 24 hours’ in point 3, the Code Commission reminded Members that this amendment had been made to ensure consistency with Article 1.1.3. In order to address these comments, the Code Commission agreed with one of the comments to replace ‘immediate’ with ‘initial’ and delete ‘within 24 hours’ noting that the sentence describes the events in the time span beginning from initial notification through to the final report.

Given some of the confusion over the use of the term disease, the Code Commission agreed to replace the terms ‘disease, infection or infestation’ by ‘listed disease and emerging disease’, noting that this article refers to notification of listed and emerging diseases.

**Article 1.1.4**

The Code Commission did not agree with a comment to specify that notification for an emerging disease should be made ‘within 24 hours’ because of the difficulties involved in defining within 24 hours, whether the event meets the definition of an emerging disease.

The revised Chapter 1.1 Notification of diseases, infections and infestations, and provision of epidemiological information is attached as [Annex 7](#) for Member comments, and is proposed for adoption at the 88<sup>th</sup> General Session in May 2020.

**EU comment**

## The EU supports the proposed changes to this chapter.

### 6.4. Procedures for self-declaration and for official recognition by the OIE (Chapter 1.6)

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

#### Background

At its September 2018 meeting, the Code Commission had agreed, in coordination with the Scientific Commission to harmonise provisions in disease-specific chapters for official recognition of status (see Item 8.6). Common provisions concerning procedures applicable to the diseases with official status recognition would be addressed in Chapter 1.6 instead of being repeated in each disease-specific chapter.

#### General comment

In response to a comment on standardising the use of the singular form of the term 'Member Country', the Code Commission agreed and applied this throughout the text, where relevant.

#### Title

The Code Commission agreed with a comment to change the order of the three types of status in the title of Chapter 1.6 and amended the title to 'Procedures for official recognition of an animal health status, endorsement of an official control programme, and publication of a self-declaration of animal health status, by the OIE'.

The order of the articles in the chapter were also re-ordered to reflect this sequence. In the Annex, Members should note that the re-ordered text is reflected by the change in the Article numbers.

To ensure consistency with the title, the Code Commission agreed to replace 'disease freedom' by 'animal health status' throughout the text.

#### Article 1.6.1 (Article 1.6.2 in the previous draft)

The Code Commission did not agree with a comment to amend the title of this article to include 'official' before the words 'animal health status' and agreed to keep it as 'official recognition of animal health status' in accordance with the title of the chapter. The Code Commission also noted the comment from OIE Secretariat that when the draft chapter has been adopted, all relevant OIE documents including the Standard Operating Procedure will be harmonised.

Regarding comments questioning the purpose of an official control programme for dog-mediated rabies when there is no official animal health status recognised for rabies, the Code Commission noted that as described in Article 8.14.11, the purpose of an OIE endorsed official control programme is for Members to progressively improve their dog-mediated rabies situation. The Commission highlighted that the endorsement of official control programmes does not necessarily have a link with the procedure for official disease status; the procedure to self-declare freedom from dog-mediated rabies is available. The Commission also emphasised that this mechanism is a useful tool to support and contribute to the Global Strategic Plan for Dog-mediated Human Rabies Elimination. For point 1(e), the Code Commission agreed with a comment to harmonise the wording with terminology used in Chapter 8.8 and replaced 'with or without vaccination' with 'where vaccination is either practised or not practised'.

In response to comments requesting to include a reference to the rabies questionnaire in paragraph 4, the Code Commission clarified that until the questionnaire has been published, a reference cannot be included.

In paragraph 7, the Code Commission agreed to insert 'geographical' before 'boundaries' for clarity, and correspondingly deleted the terms 'describing the geographical boundaries of the zone' at the end of the sentence. The Code Commission agreed with a comment to replace 'susceptible animals and their products' in the last sentence with 'commodities' for consistency with other chapters.

In paragraph 8, in response to a comment that there is no official recognition of animal health status for dog-mediated rabies, the Code Commission proposed amendments to address the possibility of self-declaration for dog-mediated rabies.

**Article 1.6.2** (Article 1.6.3 in the previous draft)

In the first paragraph, the Code Commission agreed with a comment to specify 'list' in the first sentence and amended the sentence accordingly. For consistency with the terms used in Chapter 1.1, the Code Commission replaced the word 'reported' with 'notified'.

In the last indent, the Code Commission agreed with a comment to include 'or distribution' noting that this is an important piece of evidence for the withdrawal of endorsement of an official control programme.

**Article 1.6.3** (Article 1.6.1 in the previous draft)

In the first indent and second indent of the first sentence of Article 1.6.3, the Code Commission proposed to include 'infection or infestation', in line with the agreed approach for these terms (see Item 6.3).

The Code Commission did not agree with a comment to add 'disease-free' before 'status' in this article as it considered the freedom status is being referred to in the text as written. Furthermore, the addition of 'disease' may be confusing as freedom refers to freedom from infection or infestation.

In the last sentence of the first paragraph, the Code Commission did not agree with a comment to amend the text to 'publish the self-declaration to provide information to OIE Member Countries' as it considered the current wording described the procedure more accurately.

The Code Commission noted a comment requesting clarity on the 'Procedure for the application for the publication by the OIE of a self-declaration of disease freedom' (SOP), in particular whether Article 1.4.6 or the disease-specific chapter should be referred to for historical freedom. The Code Commission, in agreement with the Scientific Commission clarified that in the absence of specific requirements or unless otherwise specified in the disease-specific chapter for freedom from a particular disease, compliance with the relevant horizontal chapters of the *Terrestrial Code* should be applied. The requirements of a disease-specific chapter provide the framework for interpretation of compliance by adding specificity to requirements in a horizontal chapter. Notwithstanding, the Commission noted that OIE Secretariat will update the SOP to clarify the guidance regarding self-declarations on the basis of historical freedom.

In the third indent, the Code Commission agreed with a comment to replace 'surveillance and early warning system' with 'surveillance, including an early warning system' agreeing that this was in line with Chapter 1.4 where an early warning system is a component of surveillance.

Regarding a comment seeking clarification on the objective of 'administrative and technical screening', the Code Commission noted the explanation provided by the OIE Secretariat that administrative screening entails checking that the structure of the self-declaration dossier is in accordance with the SOP, whilst technical screening involves the assessment of the dossier to ensure that sufficient information on the provisions of the specific disease or relevant horizontal chapters of the *Terrestrial Code* has been provided and is consistent with the information reported by the Members to OIE WAHIS.

In the fourth paragraph, the Code Commission and Scientific Commission agreed with a comment to include 'except when otherwise provided for in the listed disease specific chapter' at the start of the first sentence, as the occurrence of an outbreak does not automatically change the status of a country or zone for certain diseases, depending on provisions in the disease-specific chapter.

In the fourth paragraph, the Code Commission did not agree with a comment to add more detail on the recovery of a lost self-declared free status by aligning the text with Article 4.4.7 and to make reference to Article 1.4.6, noting that when a self-declared free status is lost, the procedure is to submit a new self-declaration in accordance with the procedures described in this article.

The revised Chapter 1.6 Procedures for official recognition of an animal health status, endorsement of an official control programme, and publication of a self-declaration of animal health status, by the OIE is attached as **Annex 8** for Member comments and is proposed for adoption at the 88<sup>th</sup> General Session in May 2020.

## **EU comment**

### **The EU supports the proposed changes to Annex 8**

#### **6.5. Veterinary legislation (Chapter 3.4)**

Comments were received from Argentina, Australia, Canada, China (People's Republic), Chile, Chinese Taipei, New Zealand, Singapore, USA, the EU, AU-IBAR, and CVP.

##### **Background**

A full review of Chapter 3.4 Veterinary legislation was undertaken by the *ad hoc* Group on Veterinary legislation in January 2018. A draft revised chapter has been circulated for Member comments on two occasions, September 2018 and February 2019.

##### **General comments**

In response to a comment, the Code Commission reviewed the use of the terms 'establishment', 'facility', and 'premise' throughout the chapter and amended the text to ensure consistency. The Commission recalled that 'establishment' is a defined term in the Glossary referring only to the premises in which animals are kept.

### **Article 3.4.2**

Regarding the definition for the ‘veterinary domain’, the Code Commission did not agree with comments requesting to replace ‘veterinary public health’ with ‘public health’ and reiterated the need to refer to ‘veterinary public health’ because not all components of public health pertain to the veterinary domain. The Commission emphasised that this definition refers only to the ‘veterinary’ aspects of the public health sector. In response to a comment to include a definition for ‘veterinary public health’ in the Glossary, the Commission recalled that Chapter 6.1 Introduction to recommendations for veterinary public health provides further details on veterinary public health, taking a ‘one health’ approach, and therefore considered there was no need to add a new specific definition.

### **Article 3.4.3**

In point 2, the Code Commission did not agree with a comment to replace ‘as soon as possible’ with ‘without delay’ noting that the process to develop legislation may encounter unavoidable delays.

In point 4, in response to a comment, the Commission amended the text to ensure that it covered the inclusion of all relevant stakeholders in the consultative processes related to veterinary legislation.

In point 5, the Code Commission did not agree with a comment requesting to add ‘as much as possible’ concerning the protection of citizens, as it considered it unnecessary. However, the Commission did agree with a comment to amend the text to address the protection of the environment.

### **Article 3.4.4**

The Code Commission agreed to include a new point 7 to ensure that the collection, use of, and disclosure of the information is appropriately covered under veterinary legislation.

In point 8, the Code Commission agreed with a comment to replace ‘regulations’ with ‘secondary legislation’ agreeing that depending on the legal system, the terms for legal instruments and their meaning could vary significantly.

### **Article 3.4.5**

In the second paragraph, the Code Commission did not agree with a comment proposing to replace ‘that is effective, as short as possible, and with all responsibilities clearly defined’ by ‘that is effective, efficient and with all responsibilities clearly defined’, as it considered that this change would change the meaning, and highlighted that it was important to have as few steps as possible in the chain of command.

In the second paragraph, the Code Commission agreed with a comment to add the phrase ‘including clarifying the role of each Competent Authority’ to reflect the importance of avoiding overlapping roles and regulatory gaps.

In point 1(b), the Code Commission did not agree with a comment to delete ‘good faith’ as it considered it necessary to specify that actions were not from dishonest or insincere intention. The Commission also noted this was a well understood dictionary term.

In point 1(d)(i), the Code Commission agreed to amend the term ‘vehicles’ to ‘vehicles/vessels’ for alignment with the Glossary definition. This amendment was made throughout the chapter.

In point 1(d)(iii), in response to a comment as to whether the inclusion of ‘establishment of compensation mechanisms’ created an obligation to Members, the Commission emphasised that this article does not prescribe the implementation of any specific compensation mechanisms, but it recommends that veterinary legislation should provide the Veterinary Authority with the power to establish compensation mechanisms. On the same point, the Code Commission did not agree with a comment to delete the list of sanitary measures explaining that the list does not have to be exhaustive and provides useful guidance for Members.

In point 2, in response to a comment regarding the use of the term ‘delegation’, the Code Commission recognised the possibility that different countries use different terminology in their legislation, but considered that the term ‘delegation’ was the most appropriate term to use when referring to the power of a Competent Authority to entrust others to conduct, on its behalf, a task for which it had the primary responsibility.

#### **Article 3.4.6**

In points 1(d)(i), (ii) and (iii), the Code Commission agreed with a comment that these points covered all veterinarians and therefore amended the text to refer to the ‘various professional categories of veterinarians (e.g. specialisations)’.

In point 1(d)(vi), the Code Commission agreed with a comment that it was important to ensure that procedural fairness is facilitated in situations relating to veterinarian conduct and competence, and amended the text accordingly.

In point 1(d)(vii), the Code Commission did not agree with a comment to delete this point noting that in some cases it was not the responsibility of the veterinary statutory body to regulate which persons other than veterinarians could undertake activities that are normally carried out by veterinarians. The Commission referred readers to the rationale that was provided in its February 2019 meeting report for this point and reminded Members that the text had been modified to reflect that the veterinary statutory body may define the conditions, but it is the responsibility of the Competent Authority to decide the situations where this could be allowed.

#### **Article 3.4.7**

In point 1, the Code Commission did not agree with a comment requesting to add ‘reporting’ after ‘obligations’ as it considered reporting was part of obligations.

In point 1(c), the Code Commission did not agree with a comment to replace ‘testing’ with ‘analyses’, noting that ‘testing’ was in line with the relevant terms used in the *Terrestrial Manual* for ‘Testing methods’ and ‘tests’.

In point 1(c), the Code Commission did not agree with a comment to add ‘animal health, veterinary public health’ after ‘for the purposes of’, as it considered that points (a), (b) and (c) clearly define three different types of laboratories.

#### **Article 3.4.8**

In point 2(b), the Code Commission did not agree with comments to add ‘cleaning and’ before ‘disinfection’ because this is already addressed by the Glossary definition for ‘disinfection’.

In point 3, the Code Commission did not agree with a comment to add ‘animal welfare and ethical consideration’, noting that animal welfare is addressed in Article 3.4.10.

The Code Commission agreed to add a new point 4(a) for alignment with point 5(a).

In point 4(b), the Code Commission agreed with a comment to amend the text to include other biological, chemical or physical risks.

In point 5(d), the Code Commission agreed with a comment that the meaning of this point was unclear, and deleted the point, noting that the animal owner’s compliance with rules was not specific to this point.

#### **Article 3.4.9**

In the first paragraph, the Code Commission did not agree with a comment to recommend that legislation should provide for the listing and mandatory reporting of all OIE listed diseases within the country. The Commission emphasised that mandatory reporting within a country should be in accordance with each country’s situation, and some of the OIE listed diseases may not be relevant.

Nevertheless, the Commission amended the text to clarify that veterinary legislation should provide powers for the Veterinary Authority to access information needed to comply with its obligation to notify all listed diseases to the OIE.

In point 2(b)(ii), the Code Commission did not agree with a comment to include the phrase ‘including the capacity to destroy livestock and declare quarantine areas’, noting that this was already addressed in Article 3.4.5.

In point 2, the Code Commission did not agree with a request to add a new point (d) on the provision of the storage for materials for disease prevention and control, noting that this was included in ‘logistic organisation’ in point 2(b)(i).

#### **Article 3.4.10**

In the second paragraph of point 1, the Code Commission agreed with a comment to include the words ‘cruelty or’ before ‘neglect’. The Commission also agreed to remove ‘animal keepers’ because ‘cruelty’ or ‘neglect’ could be related to a variety of actors.

In point 2, the Code Commission agreed with a comment to add ‘domestic’ in the subheading to clarify that this clause was not intended for wildlife.

#### **Article 3.4.11**

In point 1(b), the Code Commission agreed with a comment requesting to take into consideration the disposal of veterinary medicinal products and amended the text accordingly.

In response to a comment requesting to clarify if veterinary medicinal products would include veterinary biologics used for research purposes, the Code Commission clarified that this was covered by the Glossary definition for ‘*veterinary medicinal product*’ i.e. ‘any product with approved claims to having a prophylactic, therapeutic or diagnostic effect or to alter physiological functions when administered or applied to an animal’.

In point 2(b), in response to a comment, the Code Commission clarified that this point does not pertain to proteins contained in a vaccine which do not allow for differentiation between exposure and vaccinal reaction but rather this point refers to substances that could be intentionally added to the formulation.

In point 3, the Code Commission clarified that point 3(b)(i) referred to all types veterinary medicinal products incorporated into feed, while point 3(b)(ii) referred to all products prepared by authorised veterinarians or authorised pharmacists, irrespective of their use. The Commission agreed with a comment proposing to include a new point (v) regarding restrictions of use of veterinary medicinal products for food-producing animals.

In point 4(c), the Code Commission did not agree to add a reference to distribution, noting that it was already addressed in point 1(b) and 5(a).

In point 5(b), the Code Commission agreed with a comment to include ‘appropriate labelling’ agreeing that labelling is critical for the effective use of veterinary medicinal products.

In points 5(f) and 5(g), in response to comments the Code Commission amended the texts to include a reference to a system of surveillance of falsification and a system of surveillance of the quality of veterinary medicinal products marketed.

#### **Article 3.4.12**

In point 2(b), in response to a comment the Code Commission clarified that the ‘visible marks’ referred to visual proof on the products, showing that the product complied with health standards in a broader sense, and not only to ante and post-mortem inspection. The Code Commission also noted that the use of visible marks would apply not only to meat but also to other animal products such as milk and honey, for example.

In the last paragraph of point 2, the Code Commission did not agree with a comment to add more detail, as it considered that the means to prevent the operator from producing and distributing withdrawn products in the future was implicit in the existing text.

In point 3, the Code Commission did not agree with adding a new point on the ‘the recognition of quality assurance systems’ noting that this was out of the scope of the chapter.

The Code Commission noted a comment highlighting the importance of the public-private partnerships (PPP) but did not agree to include a new article as it considered that in Article 3.4.5 point 2 Delegation of powers by the Competent Authority the current text addresses the provision of the necessary basis within the legislation to make these partnerships possible.

The revised Chapter 3.4 Veterinary legislation attached as **Annex 9** for Member comments and is proposed for adoption at the 88<sup>th</sup> General Session in May 2020.

### **EU comment**

**The EU supports changes to Annex 9. The EU has made extensive comments that do not change the content of the text but have the aim of improving it.**

### **6.6. Draft new chapter on official control programmes for listed and emerging diseases (Chapter 4.Y)**

Comments were received from Argentina, Australia, Canada, China (People’s Republic), Chinese Taipei, New Caledonia, New Zealand, Thailand, USA, the EU and AU-IBAR.

#### **Background**

The first draft of this new chapter was circulated for Member comments in the Code Commission’s February 2017 meeting report. Since that time, the Commission has made significant amendments to the content of this chapter having taken into consideration the important feedback received from Members during five rounds of comments. During the development of this new draft chapter the Code Commission has also consulted with the Scientific Commission to address specific comments and text. The latest version was circulated in the Commission’s February 2019 meeting report.

#### **General comments**

In response to a comment requesting to clarify the difference between official control programme and disease contingency plan, the Code Commission reiterated that official control programmes, as defined in the Glossary of the *Terrestrial Code* ‘means a programme which is approved, and managed or supervised by the Veterinary Authority of a Member Country for the purposes of controlling a vector, pathogenic agent or disease by specific measures applied throughout that Member Country, or within a zone or compartment of that Member Country’ whereas disease contingency plans are developed only for emergencies and are part of the official control programme as described in point 3 of Article 4.Y.1. The Code Commission also noted a comment regarding consistency in the use of the terms ‘listed disease’ and ‘emerging disease’, and reviewed the usage of these terms throughout the chapter to ensure the correct use for each specific situation.

The Code Commission clarified that this chapter addressed official control programmes in general, whether or not they are endorsed by the OIE.

In response to a comment that the Glossary term ‘commodity’ was not used in a consistent manner in this chapter, the Code Commission reviewed the text to ensure its consistent use.

#### **Title**

The Code Commission did not agree with a suggestion to add ‘Recommendations on’ at the beginning of the title of the chapter as it is not in line with the current convention for chapter titles used in the

*Terrestrial Code*, except for introductory chapters. The Code Commission noted that all chapters of the *Terrestrial Code* contain recommendations thus it is not necessary to highlight this in the title.

#### **Article 4.Y.1**

The Code Commission agreed with a comment requesting to change the order of the first three paragraphs to provide a more logical flow, and amended the text accordingly.

In the first paragraph, the Code Commission agreed with a comment to move ‘including zoonosis’ in the first sentence to the second sentence for consistency with point 1 of Article 4.Y.2.

In the second paragraph, the Code Commission did not agree with a proposal to delete the entire paragraph because its content focused on management of outbreaks of listed diseases, which was the initial title of the chapter, as it was of the view that the paragraph was still relevant to this chapter, despite the change in focus of the chapter.

The Code Commission did not agree to a comment requesting to include ‘or Veterinary Services’ after ‘Veterinary Authority’ noting that Veterinary Services are under the overall control and direction of the Veterinary Authority, in accordance with the current Glossary definitions. The Code Commission did not agree with a suggestion to add ‘undertake a risk assessment and’ before ‘implement control measures’ agreeing that the text should not be too prescriptive in this general introductory article. Furthermore, risk analysis, including risk assessment, is addressed in point 1 of Article 4.Y.3.

In the fifth paragraph, the Code Commission noted a comment that there were still inconsistencies regarding the use of the terms ‘disease’, ‘infection’ and ‘infestation’ in this chapter. The Commission did not agree with a suggestion to reinstate ‘disease’ after ‘the eradication of a given’ as this was not in line with the agreed approach for the use of these terms (see Item 6.3).

For point 2, the Code Commission did not agree with a comment to replace ‘appropriate’ with ‘relevant’, as it considered that ‘appropriate’ is a better fit for the intent of this point.

For point 3, the Code Commission did not agree with a comment to add ‘as appropriate’ after ‘emergency preparedness plans and emergency response plans’, as official control programmes should include plans for emergencies and endemic diseases since the epidemiological situation may evolve in a way that is not manageable with routine activities.

For point 4, in response to a comment suggesting to add ‘infection and infestation’ after ‘surveillance of the relevant disease’, the Code Commission amended the text to read ‘surveillance of the relevant infection or infestation’ as to align with the agreed approach for the use of these terms (see Item 6.3).

For point 5, the Code Commission did not agree with a comment to add ‘in accordance with Chapter 1.1’ at the end as this point noting that this point is about internal reporting within countries and is different from disease notification to the OIE, which is addressed in Chapter 1.1.

For point 6, in response to a comment to include ‘infection and infestation’ after ‘cases of the relevant disease’, the Code Commission amended the text to read ‘cases of the relevant infection or infestation’ to align with the agreed approach for the use of these terms (see Item 6.3).

For point 7, in response to a comment to add ‘infection and infestation’ after ‘spread of the relevant disease’, the Code Commission amended the text to read ‘spread of the relevant infection or infestation’ to align with the agreed approach for the use of these terms (see Item 6.3).

The Code Commission did not agree with a comment to replace ‘including’ with ‘and’ explaining that movement control is a part of sanitary measures.

In the last paragraph, the Code Commission, in response to comments, included a separate sentence to highlight the importance of evaluation of the programmes at the beginning of the paragraph while emphasising that plans can be tested before the implementation of programme components but the programmes can only be evaluated afterwards.

## **Article 4.Y.2**

For the first indent under point 2, the Code Commission did not agree with a comment to delete ‘with the possibility of obliging owners to assist’ as it considered this statement to be clear as written and noted that in this sentence ‘assist’ means help and participate.

For the fifth indent under point 2, the Code Commission did not agree with a comment to add ‘as part of disease control efforts’ at the end, as it considered this point to be implicit in the current draft.

For the fourth indent under point 3, the Code Commission did not agree with a comment to add ‘animals in contact and potentially infected or contaminated’ before ‘commodities and fomites’ for consistency with Article 4.Y.5, as it considered the current text to be clear as written and noted this point was a general consideration.

For the fifth indent under point 3, the Code Commission did not agree with a comment requesting to cross-reference Chapter 4.4 noting that Article 4.Y.8 specifically addresses zoning and refers to Chapter 4.4.

For the sixth indent under point 3, in response to a suggestion to add ‘and samples collected from fomites if relevant’ at the end for completeness, the Code Commission addressed this by deleting ‘animal’ to clarify that samples may be taken from not just animals.

For the tenth indent under point 3, the Code Commission did not agree with a comment to replace ‘products of animal origin’ with ‘commodities and fomites’, as this text is about commodities and fomites is addressed in the next indented text.

For the thirteenth indent under point 3, the Code Commission did not agree with a comment to add ‘for countries that have established mechanisms for compensation,’ at the beginning in order to take into account some Members may not be able to comply with the provisions for compensation. Indeed, the Code Commission stressed that all recommendations in the *Terrestrial Code* are meant to guide Members in the development of their measures, that compensation mechanisms are an essential component in disease control efforts like other human and financial resources and that this statement is about establishing those mechanisms for compensation.

## **Article 4.Y.3**

For the first paragraph, the Code Commission considered a comment questioning whether there should be an official control programme against all diseases that meet the criteria in the first sentence, and clarified that this was not the case and amended the text accordingly. The Code Commission did not agree with a comment to insert ‘according to an evaluation of the actual or likely impact of the disease or risk analysis’ in the first sentence, as it considered it implicit that such an evaluation is performed by Veterinary Authorities.

In point 2(b), the Code Commission considered that since the article was about emergencies, it was logical to refer to an emergency in the text, rather than to the occurrence of a listed or emerging disease.

For point 3, following advice from the *ad hoc* Group on Veterinary Emergencies, the Code Commission proposed to add a sentence defining simulation exercises. The Code Commission also agreed with a comment that simulation exercises within a country should be encouraged, and amended the text accordingly.

## **Article 4.Y.4**

In the first paragraph, the Code Commission did not agree with a comment to replace ‘and’ with ‘or’ in the text ‘Chapter 1.4 and listed disease-specific chapters’ noting that all chapters were relevant, i.e. Chapter 1.4 provides general recommendations for animal health surveillance and disease-specific chapters complement these recommendations or add specific requirements for each disease, as appropriate.

The Code Commission did not agree with a comment to replace 'detect suspected cases and either rule them out or confirm them' with 'confirm cases', explaining that surveillance first detects suspected cases. The Commission did not agree with a comment to replace 'full sanitary measures' with 'the approved control programme' noting that implementation of full sanitary measures is critical in the control of the disease and this is worth highlighting.

#### **Article 4.Y.5**

For point 1, the Code Commission did not agree with a comment to add ‘and surveillance’ after ‘tracing forward and backward’, noting that an epidemiological investigation is part of surveillance (as described in Chapter 1.4) and inclusion of ‘surveillance’ in this sentence could lead to confusion. The Commission also noted that post-control surveillance was addressed in Article 4.Y.12.

For the first indent under point 2, the Code Commission did not agree with a comment to replace ‘dead animals’ with ‘carcasses’ explaining that carcasses were not in line with the terminology used in Chapter 4.13 Disposal of dead animals. The Commission agreed with a comment to add some examples of fomites and amended the text accordingly.

For point 3, the Code Commission did not agree with a suggestion to insert a new indent on zoning, explaining that as zoning is not a measure *per se*, but rather a framework for the implementation of measures. For the third indent, the Code Commission agreed with a comment that the activities listed are not limited to animals that are at-risk of being infected and amended the text accordingly.

In the second paragraph, the Code Commission considered a comment seeking clarification on ‘partial control’ and replaced this term by ‘prevalence control’. The Code Commission did not agree with a comment to delete the examples in the third sentence of the paragraph as although examples are not usually given in the *Terrestrial Code*, in this case the Commission considered it may be useful for Members to have some examples to refer to with regard to choice of strategy. The Commission amended the text regarding compensation for clarity.

#### **Article 4.Y.6**

In the first paragraph, in response to a comment to replace ‘remain contaminated’ with ‘continue to contaminate the environment’, the Code Commission addressed this concern by amending the text to read ‘remain infective’.

In the fourth paragraph of point 1, the Code Commission considered a comment questioning whether depopulation is the same as killing in the context of wildlife. The Code Commission requested the OIE Secretariat seek advice from the Working Group on Wildlife as to which term is the most appropriate in this context to be discussed at the Code Commission meeting of February 2020.

In the fifth paragraph of point 1, the Code Commission considered a comment requesting to delete ‘rendering plant’ on grounds that slaughtering of animals should not be undertaken at a rendering plant. The Commission did not agree explaining that depending on the country or in specific situations killing or slaughter of animals may take place at rendering plants.

In the last paragraph of point 1, the Code Commission agreed with a comment to include text that notes that when disinfection is not practical, alternate means of elimination of the causal pathogenic agent such as extended following periods or composting should be permitted.

#### **Article 4.Y.8**

The Code Commission agreed with a comment to add ‘biosecurity and communication’ after ‘surveillance’ for completeness.

#### **Article 4.Y.9**

In the second paragraph, the Code Commission did not agree with a comment to replace ‘unwanted animals’ with ‘animals that are capable of transmitting the disease’, explaining that the proposed term could be confusing and mean ‘susceptible animals’, while ‘unwanted animals’ may include more than only those capable of transmitting the disease, e.g. any animals from outside the premises, and this would be a decision made by the owner or operator of the premises.

#### **Article 4.Y.10**

In the second paragraph, the Code Commission did not agree with a comment to add a sentence regarding animal identification and animal traceability, explaining that this was addressed in point 3 of Article 4.Y.2.

In the fourth paragraph, the Code Commission did not agree with a comment to include a sentence regarding a vaccination-to-kill strategy and differentiating infected and vaccinated animals, as it considered this to be too detailed to be included in this article. The Commission reminded Members that Chapter 4.18 addresses vaccination.

#### **Article 4.Y.11**

The Code Commission did not agree with a comment to replace ‘before, during and after outbreaks’ with ‘at all times’, explaining that it wanted to highlight the different stages of intervention on outbreaks.

#### **Article 4.Y.13**

In response to a suggestion to include a sentence highlighting the importance of feedback, the Code Commission amended the text accordingly. However, the Commission did not accept the proposal to include ‘feedback’ in the title of this article.

The revised Chapter 4.Y Official control programmes for listed and emerging diseases is attached as **Annex 10** for Member comments and is proposed for adoption at the 88<sup>th</sup> General Session in May 2019.

#### **EU comment**

**The EU in general supports the proposed changes to Chapter 4.Y.**

### **6.7. Draft new chapter on animal welfare and laying hen production systems (Chapter 7.Z)**

#### **Background**

This new draft chapter was elaborated by the *ad hoc* Group on animal welfare and laying hen production systems in 2016. The draft chapter has been circulated for comments on two occasions in September 2017 and September 2018.

The OIE Secretariat recalled that a significant number of comments had been received on the draft chapter circulated in the Code Commission’s September 2018 report and that the Commission, at its February 2019 meeting, had requested that the *ad hoc* Group on animal welfare and laying hen production systems be reconvened to consider all comments and to amend the draft chapter accordingly.

The Code Commission considered the report of the *ad hoc* Group on Animal welfare and laying hen production systems which met in April 2019 and thanked the *ad hoc* Group for its work noting that they had to consider a very large number of comments often expressing opposing positions with respect to some of the recommendations proposed in the draft chapter.

The Code Commission confirmed that the *ad hoc* Group had considered all comments received and reminded Members that the *ad hoc* Group report provided responses to comments received and proposed amendments to the draft chapter and therefore should be read in conjunction with this report.

The Code Commission highlighted that the revised chapter allowed for the continuous development of country specific animal welfare recommendations and monitoring for implementation. The Commission noted the *ad hoc* Group’s comment that the role of ethics in animal welfare cannot be summarised easily and in a manner that encompasses the belief systems of all Members and because

of this the amended text focused, as much as possible, on the scientific basis for the recommendations presented in the chapter.

The Code Commission considered the *ad hoc* Group report and reviewed the draft chapter and made some minor changes of an editorial nature as well as the following amendments.

### **Preamble**

The Code Commission did not agree with the *ad hoc* Group proposal to include a preamble to consider the social, economic and cultural diversity of OIE Members when developing country-specific recommendations. The Commission considered that this text was generic in terms of the framework of the OIE standard-setting process and not specific to this chapter.

### **Article 7.Z.3**

In point 2(d), the Code Commission deleted the last sentence regarding the reduction of incidence of feather pecking when there are opportunities to forage, given that this wording corresponds to the recommendations section.

In point 2(d), the Code Commission moved the scientific references provided to justify that the provision of foraging and other materials reduces the incidence of injurious feather pecking and cannibalism to Article 7.Z.19. The Code Commission also replaced the word ‘activity’ by ‘behaviour’ in the subtitle, to align this measurable with other behavioural ones such as fear, feeding and drinking or locomotory and comfort.

### **Articles 7.Z.3, 7.Z.4, 7.Z.5, 7.Z.12 and 7.Z.13**

In the third paragraph of Article 7.Z.4, the Code Commission modified the text to highlight that it is also possible to include other criteria or measurables, such as design or management-based measurable criteria, when appropriate.

In Articles 7.Z.3 and 7.Z.7, the Code Commission agreed with the *ad hoc* Group and highlighted that the lists of bullet points in these articles alphabetically ordered and were not a ranking of the listed factors.

Regarding point 2(g), (h) and (i) of Article 7.Z.3, and Articles 7.Z.5, 7.Z.12 and 7.Z.13, the Code Commission deleted the word ‘highly’ when referring to a behavioural aspect, as it considered this to be subjective and without a clear metric.

### **Article 7.Z.24**

The Code Commission modified the text to be consistent with the use of the term ‘euthanasia’ throughout this article and deleted the use of the term ‘humane killing’. The Code Commission also reviewed and modified the first bullet point of the list of reasons in which euthanasia is required to make it clear that euthanasia is part of the disaster management. The Code Commission also deleted the last bullet point noting that this point is included in the previous bullet points.

### **Order for articles**

The Code Commission agreed with the proposal of the *ad hoc* Group to reorder the articles to provide a more logical structure and fluidity to the chapter. The proposal is presented in Annex IV of the Report of the *ad hoc* Group meeting of April 2019. However, to avoid complicating readability of the revised draft chapter, the Code Commission requested that the reordering of articles be undertaken in February 2020.

The revised new draft Chapter 7.Z Animal welfare and laying hen production systems is attached as **Annex 11** (clean version) and **Annex 12** (track-changed version) for Member comments and is proposed for adoption at the 88<sup>th</sup> General Session in May 2020.

**EU comment**

**The EU thanks the OIE for its work on the revision of this new draft chapter.**

**The EU cannot support the adoption of this modified chapter as it considers that some of the revisions made by the Ad-hoc group are not fully consistent.**

The report of the *ad hoc* Group on Animal welfare and laying hen production systems is attached as **Annex 29** for Member information.

## **6.8. Infection with avian influenza viruses (Chapter 10.4)**

### **Background**

At the Code Commission's February 2017 meeting, it agreed to undertake a major revision of Chapter 10.4 Infection with avian influenza viruses. The *ad hoc* Group on Avian Influenza met in December 2017 and June 2018 to undertake a comprehensive review and draft a revised chapter which was circulated for comments in the Code Commission's September 2018 meeting report.

At its February 2019 meeting, the Commission considered all comments received on the draft chapter and referred comments of a technical nature to the *ad hoc* Group on Avian influenza which met in June 2019. The *ad hoc* Group was also tasked with the assessment of H5 and H7 low pathogenicity avian influenza against the listing criteria in Chapter 1.2 of the *Terrestrial Code*.

The Code Commission reviewed the report of the *ad hoc* Group, including the assessment of H5 and H7 low pathogenicity avian influenza against the listing criteria, as well as the revised draft chapter. The Code Commission commended the comprehensive work of the *ad hoc* Group.

The Code Commission noted that the Scientific Commission had agreed, at its September 2019 meeting, with the *ad hoc* Group's recommendation that, taking into account the caveats observed by the experts, H5 and H7 low pathogenicity avian influenza does not meet the criteria for the inclusion in the OIE listed diseases.

The Code Commission agreed with most of the amendments proposed by the *ad hoc* Group and made some additional amendments to improve clarity and alignment with other chapters of the *Terrestrial Code* and the *Terrestrial Manual*, where relevant.

The following text includes the Code Commission's rationale for comments that it addressed at its February 2019 meeting, as well as the rationales for additional amendments proposed at its September 2019 meeting, including one to address the comment from the Scientific Commission.

### **Article 10.4.1**

In point 2(c), the Code Commission noted comments on the rationale for the proposed wording on single households being excluded from the definition of poultry. The Commission explained that although susceptible, birds kept in a single household and that are not traded or exchanged are of negligible epidemiological significance.

In response to a comment requesting the alignment of the definitions for 'poultry' used in this chapter and the one in the Glossary, the Code Commission noted that the definition for 'poultry' as described in point 2(c) of this article is for the purposes of the *Terrestrial Code*, thus once adopted, the Glossary definition will be amended accordingly and be applied throughout the *Terrestrial Code*.

In response to another comment on the definition of poultry requesting to explicitly include 'breeding flocks producing offspring raised for restocking supplies of game', the Code Commission clarified that those birds were included in the current wording 'all birds used for restocking supplies of game' and there was no need to amend the text.

In point 4, the Code Commission agreed with a comment that the Glossary definition of 'commodity' covers live animals and changed the text accordingly. This change was applied throughout this chapter to ensure consistency.

### **Article 10.4.1bis**

The Code Commission did not agree with a comment to delete the article on safe commodities noting that the listed commodities are produced using standardised industry protocols that have been evaluated and considered to meet the criteria in Chapter 2.2 by the *ad hoc* Group and the Code Commission. The Code Commission reminded Members that the definition of safe commodity, as per the Glossary, means 'a commodity that can be traded without the need for risk mitigation measures specifically directed against a particular listed disease, infection or infestation and regardless of the status of the country or zone of origin for that disease, infection or infestation'.

In point 1, the Code Commission agreed with a comment regarding the notation for  $F_0$  value and changed from '3.00' to '3' for consistency with other disease-specific chapters. The Code Commission did not agree to a comment to include 'or pet food containing poultry' after 'heat-treated poultry meat', but included poultry meat products, which can include pet food.

In point 2, the Code Commission did not agree with a comment to include 'containing poultry' after 'extruded dry pet food' but addressed this issue by deleting 'poultry-based' for consistency because it considered there would be no misunderstanding as written now.

In point 4, the Code Commission did not agree with a comment to add a treatment time and temperature requirement given that feathers and down are produced using standardised industry protocols and these products had been included following scientific advice provided by the *ad hoc* Group (See the report of the meeting of the OIE *ad hoc* Group on avian influenza, Paris (France), 25–27 June 2018).

#### **Article 10.4.2**

For the first indent, the Code Commission did not agree with a comment to change from 'viruses' to 'virus' to maintain consistency with the title of this chapter and noted that HPAI may be caused by different viruses.

#### **Article 10.4.2ter**

The Code Commission did not agree with comments to clarify the possibility of the concurrent establishment of more than one containment zone. The Code Commission noted that if the outbreaks are not related, establishment of more than one containment zone is possible and this is sufficiently explained by 'a containment zone, which includes all epidemiologically linked outbreaks may be established...' in Article 4.4.7.

The Code Commission did not agree with a comment to claim that a slight deviation from Article 4.4.7 exists in this article as it could not find any deviation. The Commission noted that this article only adds some specifications regarding the surveillance programme in addition to the provisions in Article 4.4.7.

The Code Commission did not agree with a comment to add a sentence about removal of commodities from containment zone as it is already covered in point 3 of Article 4.4.7.

#### **Article 10.4.2quater**

The Code Commission agreed with a comment to add 'with high pathogenicity avian influenza virus' after 'infection' for clarity.

The Code Commission agreed with a comment to add '(i.e. two flock-level incubation periods)' after '28 days' to explain the basis for the waiting period. This change was applied throughout this chapter to ensure consistency.

In response to comments regarding the start of counting 28 days, the Code Commission reminded Members that this was in line with the Glossary definition for 'stamping-out policy'. With regard to the timeline for surveillance, the Commission clarified that Members should decide when to start the surveillance and that the surveillance could begin prior to the completion of 'stamping-out policy' (i.e. completion of the disinfection mentioned in point c) of the definition), but this would not change the period of 28 days that begins after the stamping-out policy. The Code Commission noted that this would be considered whenever a relevant chapter is revised.

#### **Article 10.4.3**

The Code Commission did not agree with a comment to italicise the word 'poultry' in the subtitle because it is a convention of the *Terrestrial Code* not to italicise defined terms in the title and subtitle of the chapter.

The Code Commission agreed with a comment that poultry traded internationally are usually alive, however sometimes the word 'poultry' is used for meat, therefore the Code Commission considered that 'live poultry' should be used for clarity throughout this chapter.

In point 2, the Code Commission noted a comment that the current wording 'originated from' may allow for commodities to originate in a free country and then move through an infected country, but considered that this issue can be adequately addressed by an appropriate international veterinary certificate. Furthermore, the Code Commission clarified that 'originate' in this context not only means where the animals were born but also where they come from.

The Code Commission did not agree with a comment to add a new point 'the necessary precautions were taken to avoid contact of the commodity with any source of high pathogenicity avian influenza virus', as it considered that this was already addressed in the provisions for importation from free countries or zones.

#### **Article 10.4.4**

In point 1, the Code Commission agreed with a comment to delete 'infection with a virus which would be considered' and 'in poultry' in point 1 as this was not consistent with the new definition of the disease, and modified the text accordingly. This change was applied throughout the chapter to ensure consistency.

In points 2 and 3, the Code Commission modified the text for clarity.

#### **Article 10.4.10**

The Code Commission did not agree with a comment to start point 3 with 'a statistically valid sample of donor birds were tested ...' as each donor bird should be tested because there is no flock of origin for this type of birds.

#### **Article 10.4.11**

The Code Commission agreed with a comment to move the previous articles on eggs for human consumption and egg products, respectively, to after the previous article on semen of birds and changed accordingly to respect the logical order of the chapters of the *Terrestrial Code*.

#### **Article 10.4.15**

The Code Commission did not agree with a comment to add 'post treatment' after 'avoid' in point 3 noting that a 'commodity' in this case refers to the final goods traded and it is implicit that the commodity is well handled post treatment.

#### **Article 10.4.17**

The Code Commission agreed with a comment to add 'not listed in Article 10.4.1bis' to the title and amended it accordingly. The Commission did not agree with a comment to insert 'AND' between points 1 and 2 noting that this is not the convention used in the *Terrestrial Code*. The convention is to put 'AND' only when there is an 'OR'.

#### **Article 10.4.17bis**

Taking into account that the draft chapter includes Article 10.4.19bis 'Procedures for the inactivation of high pathogenicity avian influenza viruses in scientific specimens and in skins and trophies', the Code Commission proposed to add trade provisions for these commodities in a new Article 10.4.17bis 'Recommendations for the importation of scientific specimens, skins and trophies of birds other than poultry'.

#### **Article 10.4.19bis**

The Code Commission did not agree with a comment that virus inactivation procedures in this and other articles should cover all types of avian influenza viruses instead of only those of high pathogenicity, noting that the proposed chapter is focused on the risk management of HPAI, even if low pathogenicity avian influenza viruses are monitored.

#### **Article 10.4.20**

The Code Commission agreed to move specific text on monitoring of low pathogenicity influenza virus in poultry to Article 10.4.22ter which specifically addresses this activity, while keeping in this article the justification for the recommendation of a monitoring system to be in place.

#### **Article 10.4.22**

The Code Commission did not agree with a comment to replace ‘viruses’ with ‘virus’ in point 1 as there are a variety of HPAI viruses. The Code Commission also requested that the OIE Secretariat check that use of this term throughout the chapter is consistent.

The Code Commission considered a comment from the Scientific Commission that based on the opinion of the *ad hoc* Group that ‘the absence of the disease and infection could be effectively demonstrated, even after vaccination if adequate surveillance is in place’, there could be a need for surveillance articles to take into consideration the use of a differentiating infected from vaccinated animals (DIVA) approach.

The Code Commission considered the relevant text of Chapter 3.3.4 Avian influenza in the *Terrestrial Manual* and amended the text in point 2 of Article 10.4.22 to include a reference to the DIVA test to address this comment.

The revised Chapter 10.4 Infection with high pathogenicity avian influenza viruses is attached as [Annex 13](#) (clean version) and [Annex 14](#) (track-changed version) for Member comments and is proposed for adoption at the 88<sup>th</sup> General Session in May 2020.

#### **EU comment**

**The EU thanks the OIE for the effort invested in the revision and the changes made to this chapter. The EU welcomes the revised content and new structure of this chapter and considers that it goes in the right direction. There are relevant comments that we wish the Code Commission to consider.**

The revised Article 1.3.6 is attached as [Annex 15](#) for Member comments and is proposed for adoption at the 88<sup>th</sup> General Session in May 2020.

#### **EU comment**

**The EU in general supports the proposed change to this chapter.**

The report of the *ad hoc* Group on Avian Influenza (June 2019) is attached as [Annex 30](#) for Member information.

#### **6.9. Infection with peste des petits ruminants virus (Articles 14.7.3, 14.7.7, 14.7.24 and 14.7.34)**

Comments were received from Australia, China (People’s Republic), Chinese Taipei, New Zealand, Thailand, USA, the EU and AU-IBAR.

#### **Background**

The Code Commission, at its February 2019 meeting agreed to use Chapter 14.7 Infection with peste des petits ruminants virus (PPR) as the ‘model chapter’ to present amendments regarding harmonisation of requirements for official recognition and maintenance of freedom status to be applied across the five disease-specific chapters with official recognition of status (see Item 8.6). As part of this work, the Code Commission circulated Articles 14.7.3 and 14.7.34 for comment in its February 2019 report.

### **General comments**

The Code Commission did not agree with comments requesting to include a reference to Chapter 1.12 Application for official recognition by the OIE of free status for peste des petits ruminants in Articles 14.7.3 and 14.7.34 given that these articles outline the conditions required for official recognition and maintenance of animal health status and therefore should not include procedural information.

The Code Commission encouraged Members to read these articles in conjunction with Chapter 1.6 and Chapter 14.7 when providing comments.

### **Article 14.7.3**

In point 1, the Code Commission did not agree with a comment to include ‘in all domestic sheep and goats’ as it considered this to be unnecessary given that Article 14.7.1 includes a definition for PPR as an infection of domestic sheep and goats with PPRV. For the same reason, the Code Commission, in agreement with the Scientific Commission, did not accept a comment to specify whether ‘wildlife’ was included in point 2.

In point 3(a), the Code Commission agreed to replace ‘Chapter 1.4’ with ‘Article 1.4.6’ as the latter is a more precise reference.

The Code Commission introduced a new point 4 to reiterate point 2(a)(iii) of Article 1.4.6 given that this is a requirement to demonstrate and maintain freedom from PPRV. This amendment also addressed a comment to include an additional point that the ‘importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with this chapter’.

Under point 6 (previous point 5), the Code Commission discussed a comment seeking clarification on whether the importation of vaccinated animals results in a loss of PPR-free status, given that point 3(b) of Article 14.7.10 recommends that animals imported from countries or zones considered infected should be vaccinated against PPR. Whilst noting that alternative provisions to vaccination are available in Article 14.7.10, the Code Commission acknowledged this discrepancy and requested the OIE Secretariat to seek expert opinion on the impact of importing vaccinated animals on status recognition.

The Code Commission included a new paragraph (second paragraph) stating that ‘the country or the zone will be included in the list of countries or zones free from PPR in accordance with Chapter 1.6’. This is to ensure alignment with other disease-specific chapters with official status recognition (see Items 6.10 and 8.6), and would address comments requesting elaboration on what the list refers to.

In response to a comment on the last paragraph, the Code Commission agreed with the Scientific Commission to distinguish notification obligations from documented evidence to be submitted for annual reconfirmation and modified the text accordingly. The Commission also deleted the reference to point 4(d) of Article 1.4.6 as this is already included in point 3.

### **Article 14.7.7**

The Code Commission proposed amendments to the structure of Article 14.7.7 as part of the harmonisation work.

### **Article 14.7.24**

The Code Commission agreed with a comment that the reference to Chapter 8.8 is incorrect and proposed to delete this reference and to add the text of relevant provisions from Articles 8.8.32 and 8.8.34.

### **Article 14.7.34**

In point 2(b), the Code Commission together with the Scientific Commission accepted a comment to replace 'diagnosis' with 'diagnostic testing'.

In point 3, the Code Commission agreed with a comment to rename the subheading as 'vaccination', and to split the previous point 3(a) into two parts, now 3(a) and 3(b) for clarity.

In point 3(b)(vi), the Code Commission in agreement with the Scientific Commission, agreed with a comment to remove 'if relevant' noting that vaccines used should always be compliant with the Terrestrial Manual for an official control programme to be endorsed. The Code Commission deleted 'proposed timeline for the transition to the' given that there is no official PPR free status where vaccination is practised.

The Code Commission together with the Scientific Commission, did not agree with a comment to delete point 5 on an emergency preparedness plan and emergency response plan given that this is not the same as measures to prevent the introduction of and rapid detection of the pathogenic agent included in point 4.

In response to a comment asking whether the actual emergency preparedness and response plans need to be submitted for the endorsement of an official control programme, the Code Commission noted the clarification from the OIE Secretariat that provision of evidence that such plans exist, for example a summary of these plans would be considered sufficient.

In point 6, in response to a comment questioning what is meant by ‘defined work plan’, the Code Commission agreed that ‘defined’ was an ambiguous term and proposed to delete it. The Code Commission reiterated that the work plan should address all control activities for PPR with the objective of achieving an official recognition of PPR free status in at least one zone in the country.

In point 8, in response to a comment asking what is meant by ‘assessment of evolution’, the Code Commission proposed to replace ‘assessment of the evolution and implementation’ with ‘monitoring, evaluation and review’ noting that this was aligned with wording in draft Chapter 4.Y.

To ensure consistency with Article 14.7.3, the Code Commission proposed a new paragraph stating that ‘the country will be included in the list of countries having an OIE endorsed official control programme for PPR in accordance with Chapter 1.6.’ This is also to ensure alignment with other disease-specific chapters with official status recognition (see Items 6.10 and 8.6) and addresses comments requesting elaboration on what the list mentioned in the last paragraph refers to.

The Code Commission did not agree with a comment to reinstate the paragraph on withdrawal of endorsement of the official control programme noting that these provisions have been moved to the revised draft Chapter 1.6 as part of the harmonisation work (see Item 8.6).

Articles 14.7.3, 14.7.7, 14.7.24 and 14.7.34 are attached as **Annex 16** for Member comments and are proposed for adoption at the 88th General Session in May 2020.

## **EU comment**

**The EU in general supports the proposed changes to this chapter.**

### **6.10. Infection with classical swine fever virus (Chapter 15.2)**

Comments were received from Argentina, Australia, Canada, Chile, Chinese Taipei, Japan, Mexico, New Zealand, USA and the EU.

#### **Background**

The revision to Chapter 15.2 Infection with classical swine fever virus was undertaken in response to comments submitted by Members, experts, the *ad hoc* Group on classical swine fever, as well as to ensure alignment with the most recent amendments to Chapter 15.1 Infection with African swine fever virus (ASF) adopted in 2019. The draft revised Chapter 15.2 was last circulated for comments in the Code Commission’s September 2018 report.

In February 2019 meeting, the Code Commission requested the OIE Secretariat to incorporate the relevant amendments as part of the harmonisation work and to present the amended draft, along with previous amendments for its consideration at its September 2019 meeting.

#### **General comments**

The Code Commission did not agree with a general comment that the terms ‘suid’ and ‘pig’ are inconsistently used in this chapter and the chapter on ASF as the case definitions for both chapters are different and these two terms are used appropriately in each chapter. In the CSF chapter, CSF is

defined as an infection in pigs only while for ASF, infection is also defined in African wild suids, which are not pigs.

Additional changes have been proposed to this chapter as part of harmonisation with other disease-specific chapters with official status recognition, under Articles 15.2.2, 15.2.3 and 15.2.6. (see Item 8.6).

#### **Article 15.2.1**

The Code Commission agreed with a comment requesting to match the first indent of this article with the same statement in the chapter on ASF for consistency, and changed the text accordingly.

The Code Commission did not agree with the Scientific Commission to delete the sentence 'Pigs exposed to CSFV prenatally may not show clinical signs at birth and be persistently infected throughout life' as it considered these points relevant to the epidemiology of CSF and the interpretation of the text in this chapter. However, for clarity, the Code Commission moved the sentence 'Pigs exposed to CSFV postnatally have an *infective period* of up to three months' up, and made it a separate paragraph from the statement on incubation period.

#### **Article 15.2.1bis**

The Code Commission did not agree with a comment to delete the last sentence of this article as the sentence provides the better guidance and understanding for Members.

#### **Previous Article 15.2.2 (deleted)**

The Code Commission agreed to delete the previous Article 15.2.2 as part of harmonisation with other disease-specific chapters with official status recognition, and to move the relevant contents of this article to Article 15.2.3 which was renumbered 15.2.2 (subsequent articles were also renumbered accordingly).

#### **Article 15.2.2**

Amendments have been made to the text as part of harmonisation mentioned under General Comments.

For point 5, the Code Commission agreed with a comment that 'pigs and' should be deleted and modified the associated text to indicate that the importation or movements of commodities into a country or zone have been carried out in accordance with this chapter, without specifying the type of commodities and specific articles to refer to.

For point 7, the Code Commission also agreed with comments requesting the better alignment between this chapter and the chapter on ASF and changed the texts accordingly.

In the last paragraph, the Code Commission proposed to amend the reference to the points in this article so that documented evidence should be resubmitted annually for 'points 1) to 5)', thereby addressing comments on the incorrectly cited points.

#### **Article 15.2.3**

The Code Commission agreed with a comment to delete the second sentence of this article to align with the chapter on ASF.

#### **Article 15.2.4**

The Code Commission agreed with a comment to add 'previously' to the title for clarity and consistency with the first sentence of this article.

The Code Commission made further amendments to the text for clarity and consistency with Article 4.4.7.

In the last sentence of the fourth paragraph, in response to a comment to include a specific mention that the provisions did not apply to safe commodities in Article 15.2.1bis, the Code Commission explained that Article 15.2.1bis already states that Veterinary Authorities should not require any CSF-related conditions for safe commodities, therefore it is redundant to add a specific exclusion for safe commodities in this paragraph. Nonetheless, the Code Commission deleted this last sentence to avoid duplication with Article 4.4.7.

#### **Article 15.2.5**

For points 1, 2 and 3, the Code Commission agreed as part of the work of harmonisation to replace ‘the disposal of the last case’ with ‘the disinfection of the last affected establishment’ and modified the text accordingly.

#### **Article 15.2.5bis**

The Code Commission noted a comment asking the reason why the provisions in this article and Article 15.2.5ter were added to this draft chapter but not to the chapter on ASF. The Commission clarified that the *ad hoc* Group had proposed the inclusion of these articles to facilitate the OIE official recognition of disease status, which does not apply to ASF.

For points 1 through 3, the Code Commission did not agree with a comment to restructure these points for clarity as it considered the current structure is adequately clear.

For point 4, the Code Commission agreed with a comment to replace ‘Veterinary Services’ with ‘Veterinary Authority’ for alignment with Chapter 8.8. The Commission noted a comment suggesting to add a sentence on minimising the risk of virus spread during the transport and proposing adding ‘under biosecure conditions’ to the first sentence.

For point 5, the Code Commission noted a comment proposing to add a sentence on precautions to prevent the cross-contamination, but considered it is unnecessary to include such a sentence in this point.

For point 6, the Code Commission did not agree with a comment to add ‘under the supervision of the Veterinary Authority’ at the beginning as it is implicit.

In response to a comment requesting to delete this article and Article 15.2.5ter on the basis that the current draft articles recommend that the meat be eventually treated in accordance with Article 15.2.18 on the inactivation of the CSFV, the Code Commission considered the advice from the Scientific Commission. The Scientific Commission had advised that these two articles not only address the inactivation of the virus in meat, but also related to the safe transport of commodities in a free zone. The Code Commission added that the conditions in 15.2.5bis and 15.2.5ter are to provide the possibility for slaughter to take place in free zones. As the conditions in these articles are less stringent than the importation of live animals, meat or meat products from countries or zones not free from CSF, some additional measures have been included to minimise the risk of transmission or contamination.

#### **Article 15.2.6**

For point 3, the Code Commission did not agree with a comment that the phrase ‘unless there are means, validated in accordance with Chapter 3.8.3 of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.’ should be deleted, with the provided rationale that vaccinated animals can represent a significant risk. The Commission stated that this is not the case if any reactor can be demonstrated to not be infected with CSFV and other relevant conditions have been met.

#### **Article 15.2.7**

For point 3, in response to the same comment made to Article 15.2.6, the Code Commission did not agree as per the same rationale.

#### **Previous Article 15.2.9 (deleted)**

The Code Commission did not agree with a comment requesting to reinstate this article on recommendations for the importation of wild and feral pigs as, while recognising the importance of a risk presented by countries where CSF is present in their wild and feral pig populations, fit for all mitigation measures cannot be drafted, and such importations should not be covered by the *Terrestrial*

*Code*, but should be agreed between countries on a bilateral basis. The Commission stressed that in the absence of a specific recommendation in the *Terrestrial Code*, a country can take necessary measures in accordance with the WTO Sanitary and Phytosanitary Measures Agreement via bilateral trade agreements.

### **Article 15.2.9**

The Code Commission did not agree with a comment to add ‘prior to the collection’ at the end of point 1(a) as it considered it was obvious and did not improve clarity.

The Code Commission agreed with a comment to replace ‘caused’ with ‘elicited’ in point 1(c)(iii) for consistency with Article 15.2.13.

In response to a comment requesting to delete points 1(c)(ii) and 1(c)(iii) altogether, the Code Commission reiterated its justification previously made for Article 15.2.7 above that the recommendation in this article was a set of requirements ensuring risk mitigation.

### **Article 15.2.11**

The Code Commission agreed with a comment proposing to add point 2 of the Article 15.2.10 to this article as it considered that the provision is also relevant to this article.

### **Article 15.2.12bis**

In response to comments querying whether or not ‘official control programme’ in this article refers to an OIE endorsed official control programme, the Code Commission concurred with the Scientific Commission that OIE does not endorse official control programme for CSF and the term used here means an official control programme as defined in the Glossary.

For point 1, the Code Commission agreed with a comment to replace ‘comes’ with ‘derives’ and changed the text accordingly.

### **Previous Article 15.2.15 (deleted)**

The Code Commission agreed with a comment that this article on recommendations for the importation of fresh meat of wild and feral pigs should be deleted entirely, based on the same justification as the decision to delete previous Article 15.2.9 on recommendations for the importation of wild and feral pigs.

### **Article 15.2.13**

The Code Commission did not agree with a comment proposing to delete ‘, 15.2.12bis’ from point 1(b)(ii) as Article 15.2.12bis was not about just ‘endemic countries or zones’ as said in the comment but about ‘countries or zones not free from CSF, where an official control programme exists’ and effective risk mitigation measures are possible in such countries and zones.

### **Article 15.2.15**

The Code Commission did not agree with a comment that this article should be deleted due to a high risk of dissemination of CSFV relating to litter and manure as it considered litter and manure can be traded as long as the appropriate risk mitigation measures are in place.

### **Article 15.2.16bis**

The Code Commission agreed with a comment proposing to change the text in point 2 for consistency with other articles and modified the text accordingly.

### **Article 15.2.17**

In response to a comment querying discrepancies regarding heat treatment requirements for some commodities and swill, the Code Commission reiterated its view expressed at its report of February 2018 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. The Commission in agreement with the Scientific Commission considered that meat and swill cannot be compared

because their water/fat content is very different and the diverse material that can be present in swill could potentially protect the virus, hence the thermal inactivation procedure for swill should be more stringent than that for meat. The Commission also noted that the term 'swill' is not defined in the Glossary, although in this context, purely vegetal swill is not of concern. The main transmission pathway is kitchen swill and all swill containing meat or meat products.

Furthermore, the Code Commission took this opportunity to encourage the scientific community to continue the relevant research on this important issue of thermal inactivation processes in different commodities and field environments, which would also help with the future development of a new chapter on biosecurity.

#### **Article 15.2.18**

In response to some comments to request reviewing the minimum curing period for dry cured pig meat, the Code Commission noted that the proposed changes aimed to align with Chapter 15.1 on African swine fever since the same conditions applied for both diseases. The Commission reminded Members that the current text of Article 15.1.23 had been adopted after years of discussion in the Code Commission and Scientific Commission and consultations with Members. Since then, the Code Commission has not acknowledged any major trade issues that arouse due to the existing provision nor recognised any global epidemiological changes pertaining to this product. More importantly, there is no new scientific evidence that justifies the review of the current provision.

#### **Article 15.2.19**

In response to a comment seeking clarity on the procedures for the inactivation of CSFV in casings in pigs, the Code Commission proposed some changes to the text.

#### **Article 15.2.19ter**

The Code Commission added the point 3 to be consistent with other disease-specific chapters.

In response to the same comment as made in Article 15.2.15 requesting the deletion of this article, the Code Commission highlighted that these inactivation procedures had been effective in the field and in the absence of scientific evidence to the contrary the recommendations were valid.

#### **Article 15.2.22**

The Code Commission did not agree with a comment to replace 'live pigs or products' with 'pig commodities other than those listed in Article 15.2.1bis' as this is a general statement and does not need to be specific.

#### **Article 15.2.23**

For point 1, the Code Commission agreed with a comment to clarify the populations to be covered by surveillance and amended the text accordingly. The Commission however did not agree with a comment to replace 'survey design' with 'design of the randomised survey' in the second last paragraph as this should be consistent with Chapter 1.4. The Commission did not agree with a comment to include 'false negative' in the first sentence of the last paragraph as this paragraph specifically deals with false positive reactions found in CSF surveillance.

For point 4, the Code Commission did not agree with a comment requesting to modify the text in the second paragraph as it considered the current wording is clear enough.

The revised Chapter 15.2 Infection with classical swine fever virus is attached as [Annex 17](#) for Member comments and is proposed for adoption at the 88<sup>th</sup> General Session in May 2020.

### **EU comment**

**The EU in general supports the proposed changes to this chapter.**



## 7. Texts for comments

### 7.1. Glossary Part B ('captive wild [animal]', 'feral [animal]', 'wild [animal]', 'slaughter', 'euthanasia', 'stunning', 'death', 'pain', 'distress' and 'suffering')

'Captive wild [animal]', 'feral [animal]', and 'wild [animal]'

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

#### Background

The Code Commission recalled that at its September 2018 meeting it proposed a revision to the Glossary definition for 'captive wild [animal]' in response to a comment submitted for Chapter 15.1 Infection with African swine fever that was under revision at that time. At its February 2019 meeting, the Code Commission reviewed the comments received and recognised the different views expressed by Members and the complexity posed by the diversity of species and scenarios covered under this definition. The Code Commission requested comments from the OIE Working Group on Wildlife (Working Group) for its review. The Working Group conducted an electronic consultation during the summer of 2019 to address this request, and the Commission thanked the Working Group for its contribution.

#### Definitions

The Code Commission agreed with the Working Group proposal to delete 'population management', 'regular contacts' and 'harvesting' from the examples. The Commission agreed with some comments that stated that these examples created confusion and replaced 'feeding' with 'regular feeding' to clarify that this does not include 'occasional' feeding for luring and hunting animals. The Commission also concurred with the Working Group's suggestion to include 'protection from predators' as another example and to delete 'direct' before 'human supervision' for clarity.

The Working Group did not agree with a comment to delete 'a phenotype' from the definition for captive wild [animal] on the grounds that not all domestic animals are phenotypically manipulated by humans, such as llamas and alpacas as it considered that a phenotype is an easily observable trait that distinguishes domesticated animals from their wild conspecifics. Furthermore, both llamas and alpacas were domesticated from their wild guanaco and vicuña conspecifics by humans, changing their phenotypes, and neither exist naturally in the wild. The Code Commission concurred with the Working Group's opinion.

In response to a comment that pets should not be emphasised since all pets do not fall into this category, the Working Group agreed that the current definition as written does not imply that all pets are captive wild animals. The Code Commission concurred and did not amend the text regarding this point.

The Code Commission also agreed with the Working Group's recommendation to make minor amendments to the Glossary definitions for 'feral [animal]' and 'wild [animal]' for alignment with the proposed definition for 'captive wild [animal]'.

The revised Glossary definitions for 'captive wild [animal]', 'feral [animal]' and 'wild [animal]' are attached as **Annex 18** for Member comments.

#### EU comment

**The EU in general supports the proposed changes to the Glossary. The EU has provided suggestions with the aim of improving the proposed changes to the definitions.**

Furthermore, the Code Commission proposed new or revised Glossary definitions for 'slaughter', 'euthanasia', 'stunning', 'death', 'distress', 'pain' and 'suffering' which arose from the ongoing revision of Chapter 7.5 Slaughter of animals (see Item 7.4).

## 7.2. Diseases, infections and infestations listed by the OIE (Articles 1.3.1, 1.3.2 and 1.3.9)

Comments were received from Australia, USA and the EU.

The OIE Secretariat reminded the Code Commission that Article 1.3.1 had been circulated for comments in the Commission's February 2019 report as a consequence of the proposal to delist *M.tuberculosis* in Chapter 8.11 (see Item 7.6).

Regarding comments on the lack of alignment in the species-categorisation in Chapter 1.3 vis a vis the species-categorisation in Volume II of the *Terrestrial Code*, after consultation with the Scientific Commission, the Code Commission requested the OIE Secretariat to look into the rationale behind the discrepancies in the categorisation and to report back to the Commission.

In addition, the Code Commission proposed further amendments to Articles 1.3.1, 1.3.2 and 1.3.9 based on the assessments of a number of pathogenic agents against the listing criteria (see Items 7.5 and 8.7).

The revised Articles 1.3.1, 1.3.2 and 1.3.9 are attached as **Annex 19** for Member comments.

### **EU comment**

**The EU in general supports the proposed changes to this chapter and welcomes the decision to put on hold the delisting of *M. tuberculosis* until new evidence are obtained.**

## 7.3. Quality of Veterinary Services, Evaluation of Veterinary Services and draft new chapter on Veterinary Services (Chapters 3.1, 3.2, 3.X)

The OIE Secretariat informed the Code Commission that as recommended at its February 2019 meeting, the Director General agreed to convene a new *ad hoc* Group on Veterinary Services to continue the work to revise Chapters 3.1 and 3.2 noting that although this work was linked to the PVS Tool, it required a broader profile and competencies in its membership. The Group met in July 2019 to draft revised Chapters 3.1 and 3.2. They were also requested to consider comments received on the proposed revised Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'.

The Code Commission reviewed the report of the *ad hoc* Group and wished to acknowledge the excellent work undertaken to develop these draft chapters. The Commission agreed with the proposed new structure for Chapters 3.1 and 3.2. The Commission agreed with the proposal to change the title of Chapter 3.1 to 'Quality of Veterinary Services' noting that this better reflected the content of the chapter.

The Code Commission also agreed with the *ad hoc* Group's proposal for a new Chapter 3.X. Introduction to recommendations for Veterinary Services to be included as an introductory chapter to Section 3. In addition, the Commission agreed to change the title of Section 3 to 'Veterinary Services' to better reflect the chapters in this section. This amendment will be made once the new chapter is adopted. The Commission noted this was consistent with the approach taken in other sections of the *Terrestrial Code*.

The Commission amended draft Chapters 3.1 and 3.2, and the new Chapter 3.X, for clarity and alignment with other chapters of the *Terrestrial Code*.

The revised Chapters 3.1 and 3.2, and the new Chapter 3.X are attached as **Annexes 20, 21** and **22** for Member comments.

### **EU comment**

## The EU in general supports the proposed structure and content of these three annexes.

The report of the *ad hoc* Group on Veterinary Services is attached as **Annex 31** for Member information.

### 7.4. Slaughter of animals (Chapter 7.5)

The OIE Secretariat informed the Code Commission that the *ad hoc* Group on Chapter 7.5 Slaughter of animals and Chapter 7.6 Killing of animals for disease control purposes had met for the fourth time in June 2019 to progress its work on the revision of Chapter 7.5. The *ad hoc* Group made significant progress on this revision and will start work on the revision of Chapter 7.6 once this work is completed.

The Code Commission thanked the *ad hoc* Group for its ongoing work acknowledging the significant work that the revision of these two chapters represented.

The Code Commission considered the *ad hoc* Group report and reviewed the draft chapter and made some minor changes of an editorial nature. As noted in its February 2019 meeting report, the Code Commission, agreed with the proposed new title for Chapter 7.5 ‘Animal welfare during slaughter’ and the new proposed structure.

The Code Commission agreed with the proposal to limit the scope of the revision of Chapter 7.5 to cattle, buffalo, bison, sheep, goats, horses, pigs, rabbits and poultry and not include camelids, deer or ratites given that there is not enough scientific information to develop robust recommendations for the slaughter of these species.

In Article 7.5.18, the Code Commission considered that it was important to maintain some existing text from the current chapter concerning the transportation of pregnant animals to the slaughterhouse.

Even though the draft chapter was not yet complete and still needed articles to address the welfare of animals arriving in containers to the slaughterhouse, the Code Commission agreed to annex the revised draft chapter and requested Members to provide their views as to whether the new proposed structure is appropriate as well as comments on the draft text.

Given the very extensive amount of amendments to this chapter, the Code Commission agreed to only provide this draft revised chapter as clean text.

#### Definitions related to this revision

##### Definitions for ‘slaughter’, ‘euthanasia’, ‘stunning’ and ‘death’

The OIE Secretariat informed the Code Commission that as agreed at its February 2019 meeting, the *ad hoc* Group continued its work to amend the existing definitions for *slaughter*, *euthanasia*, *stunning* and *death* to ensure that they are harmonised with their use in the proposed new Chapter 7.5 as well as ensuring consistency with other uses of these defined terms throughout the *Terrestrial Code*.

The Code Commission reviewed the proposed amendments and made the following additional amendments for (i) ‘slaughter’ - to include the concept of a product that is primarily suitable for human consumption; (ii) ‘euthanasia’ - to simplify the definition so it can be used in different contexts, such as on-farm or in a natural disaster setting; (iii) ‘stunning’ - to focus on the outcomes rather the specific methods; (iv) ‘death’ - added some aspect in relation to the indicators to confirm the permanent loss of vital function.

##### Defined terms for ‘distress’, ‘pain’ and ‘suffering’

The Code Commission agreed with the *ad hoc* Group proposal to move the definitions for pain, suffering and distress from Chapter 7.8 Use of animals in research and education to the Glossary of

the *Terrestrial Code* given that these terms are extensively used throughout the *Terrestrial Code* and not only in other chapters of Section 7 Animal Welfare.

The Code Commission made some editorial amendments to these three definitions.

The revised proposed definitions for ‘slaughter’, ‘euthanasia’, ‘stunning’, ‘death’, ‘distress’, ‘pain’ and ‘suffering’ are provided in the Glossary attached as **Annex 18** for Member comments.

**EU comment**

**The EU in general supports the proposed changes to the Glossary. The EU has provided suggestions with the aim of improving the proposed changes to the definitions.**

The revised version of Chapter 7.5 Animal welfare during slaughter (free-moving animals) is attached as **Annex 23** for Member comments.

**EU comment**

**The EU supports the approach taken to revise this chapter. The EU includes a few preliminary comments for consideration in the further drafting and reserves its rights to provide detailed comments when the whole chapter is completed.**

The report of the *ad hoc* Group on the revision of Chapter 7.5 Slaughter of animals and 7.6 Killing for disease control purposes is attached as **Annex 32** for Member information.

## 7.5. Draft new chapter on infection with animal trypanosomes of African origin (Chapter 8.Y)

Following requests from Members, the OIE Director General convened an *ad hoc* Group that met in March 2018 and January 2019 to evaluate the most relevant species of trypanosomes of African origin against the criteria for the inclusion of diseases, infections and infestations in the OIE list as described in Chapter 1.2 of the *Terrestrial Code* and to draft a new chapter for animal African trypanosomoses.

The Code Commission considered both reports of the *ad hoc* Group, which had been endorsed by the Scientific Commission in February 2019.

The Code Commission reviewed the assessments conducted for the relevant species of trypanosomes of African origin against the criteria in Chapter 1.2 and agreed with the Scientific Commission to propose the inclusion of *T. vivax*, *T. congolense*, *T. simiae* and *T. brucei* in Chapter 1.3 Diseases, infections and infestations listed by the OIE. Consequently, the Code Commission amended Chapter 1.3 to include these in the OIE list, as ‘Infection with animal trypanosomes of African origin (*T. vivax*, *T. congolense*, *T. simiae* and *T. brucei*)’ within the category of multiple species in Article 1.3.1, and to delete the current ‘Trypanosomosis (tsetse-transmitted)’ from Article 1.3.2 (see Item 7.2).

The Code Commission noted that the definition of Infection with animal trypanosomes of African origin in Chapter 8.Y explicitly excluded *T. brucei*, *T. evansi* and *T. equiperdum* that are dealt with in other chapters and listed elsewhere in Chapter 1.3. Thus, it did not consider necessary to repeat this exclusion in the name of the listed disease in Article 1.3.1.

The Code Commission reviewed the draft new Chapter 8.Y Infection with animal trypanosomes of African origin and made some additional amendments to improve clarity and alignment with other chapters of the *Terrestrial Code*.

The Code Commission concurred with the opinion of the Scientific Commission, as presented in their February 2019 report, that an article on importation of live susceptible animals from infected countries or zones should not be included in the draft chapter given that, currently there is insufficient scientific information to define effective sanitary measures. However, the Code Commission emphasised that, if sanitary measures are applied to prevent the spread of the disease through international trade of live animals, they should be supported by a risk analysis in accordance with Chapter 2.1. The Code Commission amended the draft new chapter to reflect this principle.

The reports of the *ad hoc* Group on Animal African Trypanosomoses can be found as Annex 14 to the [Scientific Commission report of February 2019](#).

The draft new Chapter 8.Y Infection with animal trypanosomes of African origin is attached as **Annex 24** for Member Country comments.

### **EU comment**

**The EU in general supports the proposed chapter.**

## 7.6. Infection with *Mycobacterium tuberculosis* complex (Chapter 8.11)

Comments were received from China (People’s Republic), Chile, New Caledonia, South Africa and the EU.

In light of comments requesting to reinstate *Mycobacterium tuberculosis* as part of the *Mycobacterium tuberculosis* complex, the Code Commission agreed with the Scientific Commission that available scientific evidence may have led to contradictory opinions on the possibility of transmission of *M.tuberculosis* from animals to humans or animals to animals and therefore agreed to defer the delisting until new scientific information is available.

The Code Commission addressed other comments received and will keep these on hold pending resolution on the above.

### **EU comment**

**We endorse the decision to keep this Chapter 8.11 on hold until further evidence are available.**

## **7.7. Infection with Rift Valley fever virus (Chapter 8.15)**

Comments received from Australia, China (People's Republic), Chile, Mexico, New Zealand, South Africa, USA, the EU and AU-IBAR.

### **Background**

Proposed amendments to Chapter 8.15 were first circulated in the Code Commission's February 2019 meeting report to clarify the obligations of Members to notify when there is an epizootic of Rift Valley fever (RVF) in an endemic country or zone. This amendment was in response to the observation that human cases are often notified to the World Health Organisation without corresponding notifications of animal cases to the OIE despite epidemiological knowledge that the occurrence of indigenous human cases would imply virus circulation in the animal population.

### **General comments**

In response to a comment that Chapter 8.15 focused only on notification from endemic countries and not the first occurrence of RVF in a free country, the Code Commission reaffirmed that in accordance with Chapter 1.1, Members must notify the first occurrence of RVF as with other listed diseases to the OIE. However, considering the epidemiological characteristics of RVF and the difficulties associated with achieving freedom from infection, this chapter emphasises the requirement to notify the transition from an inter-epizootic to an epizootic period.

### **Article 8.15.1**

The Code Commission proposed to move the definitions 'for the purposes of this chapter' (previously in point 6) to point 2 to ensure alignment with other disease-specific chapters.

In point 2(a), the Code Commission replaced the defined term 'area' with 'epizootic area' for improved readability of Articles 8.15.7, 8.15.8, 8.15.9 where the term 'epizootic area' is used.

In point 2(b), the Code Commission noted comments that disagreed with the inclusion of indigenous human cases as a definition of an epizootic of RVF. The Code Commission concurred with the Scientific Commission that human cases of RVF are usually preceded by or at least accompanied by cases in animals. However, the Code Commission was of the view that the notification of indigenous human cases does not fall within the scope of the *Terrestrial Code*. Therefore, the Code Commission removed 'occurrence of indigenous human cases' in the definition of 'epizootic of RVF'.

Notwithstanding, the Code Commission agreed with the Scientific Commission that further guidance on surveillance, especially during the inter-epizootic period, was required in Article 8.15.13 in order to facilitate an early warning system indicating the start of an epizootic period. The detection of indigenous human cases could serve as a trigger in an early warning system and the Veterinary Authorities are encouraged to take appropriate actions to detect animal cases.

Under the same point, the Code Commission agreed with the Scientific Commission's proposed changes to improve the definition of 'epizootic of RVF' and modified the definition to 'sudden and unexpected change in the distribution or increase in incidence of, or morbidity or mortality of RVF', in line with point 1(d) of Article 1.1.3.

In point 2(c), the Code Commission agreed with the Scientific Commission's proposed changes to the definition of 'inter-epizootic period' and modified the definition to 'a period with low levels of vector activity and low rates of RVFV transmission'. This also addressed a comment that the definition of inter-epizootic was not scientific.

The Code Commission and the Scientific Commission agreed with a comment that it was inappropriate to consider dromedary camels as 'ruminants' in this chapter and made changes throughout the text to refer to 'susceptible animals' instead of ruminants. In point 2(d), 'susceptible animal' has been defined as ruminants and dromedary camels for the purpose of the chapter.

Regarding a comment questioning the exclusion of New World Camelids, the Code Commission explained that in the absence of evidence on the contrary, only dromedary camels are of epidemiological significance in the transmission of RVF.

In the last sentence of point 6, the Code Commission did not agree with a comment to include compliance with Articles 8.15.9 to 8.15.12 for importations in the event of transition from an inter-epizootic to epizootic period, as when the animal health status changes, it is understood that Members should observe the relevant trade provisions corresponding to that status. The Commission explained that notification was highlighted because the transition to an epizootic of RVF is a significant epidemiological event that should be shared with other countries, despite the disease being endemic, in order to take risk mitigation measures relevant to the new situation.

In response to a comment that disagreed with the requirement to notify a transition from an inter-epizootic to epizootic period because all outbreaks should be immediately notified, the Code Commission explained that cases could also occur during the inter-epizootic periods which would not correspond to point 1(d) of Article 1.1.3 and consequently such cases are not usually notified to the OIE.

The Code Commission agreed with a comment to delete point 7 on the general description of the historical, temporal and spatial distribution of RVF agreeing that such a description does not normally feature in other disease-specific chapters.

### **Article 8.15.3**

In point 2(a), in response to a comment that a minimum of ten years seemed excessive to demonstrate freedom, the Code Commission agreed with the Scientific Commission that the ten-year time period referred to the duration of the inter-epizootic period, which is highly variable and could last several years.

In point 2(b), in response to a comment asking why the animal health status of a country or zone should depend on the absence of indigenous human cases, the Code Commission explained that the epidemiology of RVF is such that when there is an indigenous human case it implies virus circulation in the animal population. In response to a comment that reference to human cases was not mentioned in other disease-specific chapters, the Commission gave the example of Article 8.14.2 of Chapter 8.14 Infection with rabies virus where it is stated that ‘an imported human case of rabies does not affect the free status’, implying that an indigenous case would.

### **Article 8.15.4**

The Code Commission agreed with a comment that the definition of a country or zone infected with RVF virus (RVFV) during the inter-epizootic period may be unclear. Given that relevant definitions are already outlined in point 2 of Article 8.15.1, the Code Commission simplified this article to refer to ‘country or zone infected with RVFV’. In line with this amendment, the Code Commission deleted the previous Article 8.15.5 on country or zone infected with RVFV during an epizootic as it is not needed.

### **Article 8.15.5**

In the first sentence, the Code Commission agreed with a comment to include ‘potential insecticide resistance’ but not ‘bionomics’ as local ecology is already addressed.

In point 1, the Code Commission agreed with a comment to include ‘vehicles’ and ‘insecticides’. The Commission also included ‘vessels’ for completeness.

In point 3, the Code Commission did not agree with a comment to replace ‘en route’ with ‘on the way’ as it considered the meaning to be clear as written.

### **Article 8.15.7**

In point 2(a), the Code Commission deleted ‘modified live virus vaccine’, in response to a comment asking why this was specifically mentioned in this article and not in other articles. Indeed, the Code Commission agreed that the types of vaccines are recommended in the *Terrestrial Manual*.

In point 3, given that ‘epizootic area’ has been defined in point 2(a) of Article 8.15.1, ‘area experiencing an epizootic’ was replaced with ‘epizootic area’. This was applied throughout the chapter, where relevant.

#### **Article 8.15.8**

In point 1, the Code Commission agreed with a comment to replace ‘sign’ with ‘clinical signs’ for consistency with other disease-specific chapters. This was applied throughout the chapter, where relevant.

#### **Article 8.15.9**

The Code Commission did not accept a comment to delete point 2(b) as it did not agree with the rationale provided and clarified that this point refers to the seropositivity of donors, which confers safety to the semen or embryos.

#### **Article 8.15.10**

The Code Commission noted that despite the title for this article i.e. ‘fresh meat and meat products’, the provisions only refer to meat. Therefore, the title was amended to delete ‘meat products’, and a new Article 8.15.10bis was proposed to address meat products.

In point 2, the Code Commission did not accept a comment to add ‘findings not consistent with RVFV infection’, noting that findings in *ante* and *post-mortem* inspections may not be disease-specific.

The Code Commission agreed with a comment to include a new point 4 that necessary precautions were taken to avoid contact of the products with any potential source of RVFV, for consistency with other disease-specific chapters.

The revised Chapter 8.15 Infection with Rift Valley fever virus is attached as **Annex 25** for Member comments.

### **EU comment**

**The EU supports the proposed changes to this chapter.**

## **7.8. Bovine spongiform encephalopathy (Chapter 11.4)**

### **Background**

In February 2018, The Code Commission and the Scientific Commission had agreed on an in-depth review of Chapter 11.4 Bovine spongiform encephalopathy (BSE), in particular regarding the provisions for categorisation of official BSE risk status and the corresponding surveillance. The OIE convened two *ad hoc* Groups on BSE risk assessment and surveillance, respectively, and a total of four meetings have been held (from July 2018 to March 2019).

The Code Commission reviewed the reports of the four *ad hoc* Groups on BSE risk assessment and surveillance that met between July 2018 and March 2019, and the opinion of the Scientific Commission regarding the revised draft chapter.

The Code Commission made some additional amendments to improve clarity and ensure alignment with other chapters of the *Terrestrial Code*, where relevant. Where amendments were of an editorial nature no explanatory text has been provided.

The rationale for significant amendments made by the Code Commission are described in the following text.

#### **Article 11.4.1**

The Code Commission agreed with a proposal from the *ad hoc* Group to include a new definition for 'protein meal', which will replace the terms 'meat-and-bone meal (MBM)' and 'greaves'. The Code Commission stated that once the chapter is adopted it will review the use of terms MBM and greaves in other disease-specific chapters and consider deleting these terms and replacing them with 'protein meal', where relevant.

#### **Article 11.4.1bis**

The Code Commission reviewed recommendations of the *ad hoc* Groups as to whether gelatin and collagen prepared from bones could meet the criteria for safe commodities in accordance with Article 2.2.2. Given that point (2)(a) of the current Article 11.4.15 was considered unjustifiable and that point (2)(b) describes industrial practices that are not specifically directed against BSE, the Code Commission agreed to include 'gelatin and collagen' in Article 11.4.1bis and to delete the draft article on recommendations for importation of gelatin and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices.

Similarly, the Code Commission reviewed recommendations of the *ad hoc* Groups as to whether tallow derivatives can be considered safe commodities and concluded that tallow derivatives complied with the criteria in Article 2.2.2. Therefore, the Code Commission added 'tallow derivatives' to point 6 of Article 11.4.1bis and deleted the draft article on recommendations on importation of tallow derivatives intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices.

The Code Commission agreed with the *ad hoc* Groups and Scientific Commission that deboned skeletal meat, as well as blood and blood products, as defined in points 1(g) and 1(h) of current article 11.4.1, do not comply with the criteria in Chapter 2.2 to be considered as safe commodities because they include process conditions specifically directed to address BSE risks. Therefore, the Code Commission proposed their removal from the list of safe commodities, and the drafting of new articles on recommendations for trade of these products.

#### **Article 11.4.3**

The Code Commission noted that the conditions to be met to be considered of negligible BSE risk were the same as the ones for controlled BSE risk, and the only difference was whether all conditions have been met for at least 8 years. Taking this into account, the Code Commission proposed modifications to the conditions to ensure that they are applicable to both BSE risk status.

The Code Commission agreed with the Scientific Commission on the need to include the required information for the retention on the list of countries or zones posing a negligible risk for BSE, and amended the text to be in line with disease-specific chapters with official status recognition.

#### **Article 11.4.3bis**

The Code Commission separated out the relevant provisions regarding the recovery of negligible BSE risk from Article 11.4.3 and introduced a new Article 11.4.3bis to include these provisions. The Code Commission also highlighted that the current maximum 2-year period given to regain negligible BSE risk status as described in the relevant Standard Operating Procedures should be modified to a 1-year period to align with the conditions for annual re-confirmation of status.

#### **Article 11.4.4**

The Code Commission amended the text in the last two paragraphs for alignment with the amendments it made to Article 11.4.3, and for consistency with disease-specific chapters with official status recognition.

#### **Articles 11.4.6 to 11.4.11**

In Article 11.4.6 the Code Commission deleted the proposed condition ‘the cattle selected for export were born in the country, zone or compartment during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible’ explaining that the negligible BSE risk should have been determined for the whole cattle population in accordance with Article 11.4.3 thus ‘the cattle selected for export came from a country, zone or compartment posing a negligible BSE risk’ is sufficient. This principle was applied to other relevant draft articles and the text was amended accordingly.

For Articles 11.4.6 to 11.4.11, taking into consideration that the change in BSE risk status (from negligible to controlled to undetermined risk) should correspond to a gradation in risk mitigation measures that are proportionate to the BSE risk posed by live animals or animal products, the Code Commission revised the provisions accordingly.

#### **Article 11.4.14**

The Code Commission agreed that the draft chapter should consider two populations in countries or zones with a controlled BSE risk. The first would be cattle populations consisting of animals that were born during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible, and the second would be cattle populations consisting of animals that were not born during this time period. The Code Commission stressed that the risk posed by these two populations are different and should be distinguished. Therefore, the Commission added a paragraph at the end of this article to clarify that the provisions do not apply to the first cattle population aforementioned.

#### **Article 11.4.18**

The Code Commission agreed that BSE surveillance should include the reporting of animals with clinical signs suggestive of BSE and amended the text accordingly.

#### **Consequential amendments to Chapter 1.8**

In view of the linkages between Chapter 11.4 Bovine spongiform encephalopathy and Chapter 1.8 Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy, the Code Commission requested the Status Department to prepare an amended version of Chapter 1.8 that aligns with the amendments being proposed in the revised draft Chapter 11.4.

Given that the revised draft Chapter 11.4 will be circulated for the first time in this meeting report and that further changes are expected, and that Chapter 1.8 always reflects provisions provided in Chapter 11.4, the Code Commission requested that the revised draft Chapter 1.8 be provided for Member information only (not for comments) so Members can see the consequential amendments. Once the revised draft Chapter 11.4 is closer to final version the revised Chapter 1.8 will be circulated for comment.

Therefore, Chapter 1.8 is attached as [Annex 33](#) (clean version) and [Annex 34](#) (track-changed version) for Member information.

The revised Chapter 11.4 Bovine spongiform encephalopathy is attached as [Annex 26](#) (clean version) and [Annex 27](#) (track-changed version) for Member comments.

#### **EU comment**

**The EU thanks the OIE for the very significant effort invested in the revision of this chapter. We welcome some of the changes proposed. We are also including important comments that we would like to see them addressed before the revised chapter is presented for adoption.**

A document summarising the rationale for the changes proposed by the *ad hoc* Groups during four meetings is attached as [Annex 35](#) for Member information.

#### **7.9. Infection with equine influenza (Article 12.6.6)**

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

At the Code Commission’s February 2019 meeting it had proposed amendments to Article 12.6.6 ‘Recommendations for the importation of domestic equids for unrestricted movement’ arising from

the results of a clinical trial coordinated by an OIE Reference Laboratory for equine influenza. The revised article was circulated for comment in its February 2019 meeting report.

**Article 12.6.6**

In response to a comment requesting to add a new point that the domestic equids were tested with negative results on two occasions during the pre-export isolation period by use of the validated type A influenza pan-reactive assay targeting the matrix gene, the Code Commission considered the advice provided by the Biological Standards Commission to accept this addition. The Code Commission did not agree to include a new point that would create a requirement for all countries, but agreed to include the provision in the last paragraph, so that it would only be applicable to countries that are free from equine influenza or undertaking an eradication programme.

For point 3, the Code Commission in agreement with the Biological Standards Commission, concurred with a comment to state that vaccines used are effective against the virus lineages that are in circulation, and amended the text accordingly.

In point 3(a), the Code Commission considered a comment whether it should be stated that in young horses or horses that are undergoing the vaccination for the first time, the booster should be considered valid only if it was a booster to complete a primary course as in some cases different vaccines are used from the first dose. The Code Commission agreed with the advice of the Biological Standards Commission that receiving a mix of equine influenza vaccines during the primary vaccination schedule does not have a detrimental impact on the antibody response that correlates with the protection<sup>1,2</sup>. In line with this, the Code Commission deleted the words 'the same' from point (3)(b), which addressed a comment from another Member claiming that it is uncommon for horses to receive the same influenza vaccine repeatedly.

#### References

<sup>1</sup> Dilai M, Piro M, El Harrak M, Fougerolle S, Dehhaoui M, Dikrallah A, Legrand L, Paillot R, Fassi Fihri O: Impact of Mixed Equine Influenza Vaccination on Correlate of Protection in Horses. *Vaccines* (Basel). 2018 Oct 4;6(4)

<sup>2</sup> Ryan M, Gildea S, Walsh C, Cullinane A: The impact of different equine influenza vaccine products and other factors on equine influenza antibody levels in Thoroughbred racehorses. *Equine Vet J*. 2015 Nov;47(6):662-6

In point 3(b), in response to a comment to replace '180 days' with '201 days' on the grounds that equine federations may exercise some flexibility around the 6-month interval, the Code Commission noted the opinion of the Biological Standards Commission that there is no published data to support this change. Therefore, the Code Commission agreed to maintain 180 days and to review the figure again should new supporting evidence be published.

In this respect, the Code Commission was informed that a scientific publication on work done by the Irish Equine Center, the OIE Reference Laboratory for equine influenza, is underway and will be published in a peer-reviewed journal. The Commission will review this paper once published.

The revised Article 12.6.6 is attached as **Annex 28** for Member comments.

#### **EU comment**

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

### **8. Other topics for information**

#### **8.1. Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'**

Following the request of the Code Commission at its February 2019 meeting, the *ad hoc* Group on Veterinary Services, who met in July 2019, considered comments received on the proposed amendments of the Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'. The Code Commission considered the proposed amendments and provided its comments to the OIE Secretariat.

The OIE Secretariat informed the Code Commission that the opinion of all the Specialist Commissions will be sought on the proposed amendments to these definitions which will be considered by an internal OIE group, including a representative from each Commission. This group will ensure that any cross-Commission issues are addressed, and any consequences of these amendments on other OIE work can be considered before presenting draft revised definitions to the Specialist Commissions at their February 2020 meetings.

## **8.2. General hygiene in semen collection and processing centres and collection and processing of bovine, small ruminant and porcine semen (Chapters 4.6 and 4.7)**

The Code Commission reviewed a discussion paper that had been developed by the OIE Secretariat following the request from the Code Commission in February 2019, which outlined current issues of gaps and inconsistencies in the *Terrestrial Code* pertaining to sanitary measures applicable to the collection and processing of semen of animals, in particular Chapter 4.6 General hygiene in semen collection and processing centres and Chapter 4.7 Collection and processing of bovine, small ruminant and porcine semen and provisions in some disease-specific chapters, with the objective of defining future work to improve the chapters concerned.

The Commission noted the issues and discussed possible approaches for the revision of these chapters considering the complexity of some matters. The Commission agreed that Chapter 4.6 should provide overarching general guidance for hygienic production of semen without any cross-references to disease-specific chapters and that Chapter 4.7 should provide provisions for ensuring animals entering the artificial insemination centre are free of relevant OIE listed diseases, including equine diseases, and to remove cross-references to disease-specific chapters.

The Code Commission requested that an *ad hoc* Group be convened to undertake a revision of Chapter 4.6 and would work with the Secretariat to develop the Terms of Reference. In parallel, noting that the proposed approach for a revised Chapter 4.7 would require significant work, the Code Commission requested the OIE Secretariat to explore the availability of internationally recognised information on safe processing or production of semen and testing protocols for semen production in order to scope the work required and to report back to the Commission at its next meeting.

## **8.3. Revision of collection and processing of oocytes and in vitro produced embryos from livestock and horses (Chapter 4.9) to include bovine viral diarrhoea**

The Code Commission, at its February 2019 meeting, requested the OIE Secretariat to prepare a draft text for the Commission's review to amend Chapter 4.9. Collection and processing of oocytes and in vitro produced embryos from livestock and horses to include provisions regarding risk mitigation measures for bovine viral diarrhoea (BVD) for in vitro produced embryos based on the proposal from the International Embryo Technology Society (IETS).

The Commission wished to thank the IETS for its proposal and the detailed supporting rationale. However, the Code Commission considered that further information was needed regarding the process to demonstrate that the bovine granulosa cells or co-culture cells used for in vitro culture were free from BVD virus in order to develop appropriate risk mitigation measures regardless of disease status of a country or zone (as there is no provision in the *Terrestrial Code* for BVD free countries or zones). Therefore, the Code Commission requested the OIE Secretariat to seek expert advice on this point before amending Chapter 4.9.

## **8.4. Infection with rinderpest virus (Chapter 8.16)**

The Code Commission reviewed a discussion paper developed by the OIE Secretariat on a proposed approach to the revision of Chapter 8.16 Infection with rinderpest virus. It agreed with the proposal to undertake a thorough review of the chapter and provided comments on the Terms of Reference of the *ad hoc* Group. The Code Commission also requested that a member from each of the Specialist Commissions (Code Commission, Scientific Commission and Biological Standards Commission) and an expert from the FAO working on the dossier for the Global Rinderpest Action Plan be invited to participate in the *ad hoc* Group meeting.

## **8.5. Contagious equine metritis and equine piroplasmiasis (Chapters 12.2 and 12.7)**

At its February 2019 meeting, the Code Commission, agreed to amend Chapter 12.2 Contagious equine metritis and Chapter 12.7 Equine piroplasmiasis to include requirements for the temporary movement of horses. In addition, given that these chapters had not been reviewed for many years the Commission also requested the OIE Secretariat to evaluate the need for a comprehensive revision of these two chapters.

The OIE Secretariat reported that two electronic consultations with subject matter experts were held to undertake a comprehensive review of both chapters.

The Code Commission was informed that the revised draft chapters will be provided to the Scientific Commission and the Code Commission for their February 2020 meetings.

#### **8.6. Harmonisation of *Terrestrial Code* chapters for diseases with OIE official status recognition**

At its September 2018 meeting, the Code Commission agreed with the proposal presented by the OIE Secretariat and endorsed by the Scientific Commission, to harmonise the requirements for official recognition and maintenance of free status, and endorsement and maintenance of official control programmes in Chapters 8.8 Infection with foot and mouth disease virus, 11.5 Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia), 12.1 Infection with African horse sickness virus, 14.7 Infection with peste des petits ruminants virus, and 15.2 Infection with classical swine fever virus.

The Code Commission also agreed that common provisions applicable to the five diseases with official recognition of status, in particular those regarding procedural aspects, be addressed in Chapter 1.6 instead of repeating them in each disease-specific chapter.

In February 2019, proposed amendments for harmonisation were introduced into Chapter 14.7 as a 'model chapter' and Member comments were received and addressed (see Item 6.9). During this September meeting, the Code Commission continued the work of harmonisation by applying relevant amendments to Chapter 15.2 (see Item 6.10). Both Chapters 14.7 and 15.2 will be proposed for adoption in 2020. The remaining chapters will be amended progressively.

#### **8.7. The Scientific Commission's recommendation on the evaluation of pathogenic agents against the listing criteria**

The Code Commission considered the Scientific Commission's conclusion on the assessments of pathogenic agents against the listing criteria together with the assessments undertaken by *ad hoc* Groups or subject experts for (a) Middle East Respiratory Syndrome Coronavirus (MERS-CoV), (b) Animal trypanosomes of African origin, (c) Porcine epidemic diarrhoea, (d) Chronic wasting disease and (e) *Theileria lestoquardi*, *T. luwenshuni*, *T. uilenbergi* and *T. orientalis*. The Commission noted that this information had been included in the February 2019 report of the Scientific Commission.

In line with the assessments, the Code Commission proposed the following amendments to Chapter 1.3 (see Item 7.2):

- Article 1.3.1 to add 'Infection with animal trypanosomes of African origin (*T. vivax*, *T. congolense*, *T. simiae* and *T. brucei*)' (see Item 7.5) and
- Article 1.3.9 to add 'Infection of dromedary camels with Middle East Respiratory Syndrome Coronavirus'.

The Code Commission concurred with the listing of *Theileria lestoquardi*, *T. luwenshuni*, *T. uilenbergi* and *T. orientalis*. Nevertheless, taking into consideration that this assessment is linked to previous work of the Code Commission on related disease-specific chapters (refer to its February 2018 meeting report), it will not propose changes to Chapter 1.3 until it reassesses previous work and circulates the corresponding chapters for comments.

The Code Commission reminded Members that each time a new disease is listed, there should be a corresponding new disease-specific chapter. However, for MERS-CoV, the Code Commission concurred with the Scientific Commission that there was a need to better understand the transmission dynamics in animal populations and mechanisms of zoonotic transmission to humans before recommending risk mitigation measures in the *Terrestrial Code*. The report of the *ad hoc* Group on MERS-CoV may be found as Annex 3 to the [Biological Standard Commission report of February 2019](#). The Commission was also pleased to note that a draft chapter for the *Terrestrial Manual* is being drafted.

Regarding the assessment for chronic wasting disease (CWD), the Code Commission reviewed the Scientific Commission's assessment and the subject experts' assessment for CWD, as well as the justification provided. The Code Commission noted that there was not a consensus of opinion between the 2 subject experts for criteria 2 and 4b and that the Scientific Commission did not recommend the listing of CWD. The Code Commission also noted that in the October 2018 report of the OIE *ad hoc* Group on Bovine Spongiform Encephalopathy Risk Status Evaluation of Members, the *ad hoc* Group had noted that the impact of CWD on wild cervid populations was significant. Considering the divergence of opinions, the Code Commission requested the OIE Secretariat seek further clarification from the Scientific Commission on its recommendation.

**9. Date of next meeting**

The next meeting will be held from 4–13 February 2020.

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../Annexes

**WORK PROGRAMME FOR  
THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

**EU Comment**

The EU welcomes the work programme and accepts that it is not easy to manage conflicting priorities.

While the EU in general supports a Chapter on animal trypanosomes of African origin, subject to taking into account the few comments made during the consultation, it would have welcomed more progress in the development of the chapters on Surra and dourine prepared by the OIE several years ago.

In the EU, following the exercise of listing and categorisation of transmissible animal diseases in accordance with the obligations arising from the Animal Health Law, both Surra and dourine have been listed as diseases for which trade measures should be applied in case of movement of susceptible animals.

The EU would like to suggest that decisive progress is made on the chapters related to Surra and dourine

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
<b>Horizontal chapters</b>		
<b>Restructuring of the Code</b>	1) Work with AAHSC towards harmonisation, as appropriate, of the horizontal parts of the <i>Codes</i> , notably Glossary, User's Guide, Section 4 on Disease prevention and control and Section 5 on Trade measures, import/export procedures and veterinary certification	Ongoing
	2) Work with BSC for accurate disease description and diagnostic in the <i>Manual</i> and case definitions in the <i>Code</i> and names of diseases and country and zone disease status	Ongoing
	3) Revision and formatting of chapters (articles numbering, tables and figures)	Ongoing
	4) Revision of the Users' Guide	Sent for comments and proposed for adoption May 2020
<b>Glossary</b>	1) 'epidemiological unit'	Revised definition sent for comments and proposed for adoption May 2020 (Sep 2018/3 <sup>rd</sup> )
	2) 'Competent Authority', 'Veterinary Authority'. 'Veterinary Services'	Ongoing
	3) Captive wild [animal]', 'feral' and 'wild'	Revised definitions sent for comments (Sep 2018/2 <sup>nd</sup> )
	4) Review animal welfare terms 'slaughter', 'euthanasia', 'stunning', 'death', 'pain', 'distress' and 'suffering'	Revised and new definitions sent for comments (Sep 2019/1 <sup>st</sup> )

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
	5) New definitions for 'animal product', 'product of animal origin' and 'animal by-product'	Preliminary discussion
	6) Review the terms 'notify', 'notifiable disease', 'report' and 'reportable disease'	Preliminary discussion
<b>Horizontal issues not yet in the Code</b>		
<b>Section 3. Veterinary Services</b>	1) New introductory CH in Section 3	Sent for comments (Sep 2019/1 <sup>st</sup> )
<b>Section 4. Disease control</b>	1) New CH on official control programmes for listed and emerging diseases	Sent for comments and proposed for adoption May 2020 (Feb 2017/ 6 <sup>th</sup> )
	2) New CH on biosecurity	Preliminary discussion
	3) New CH on application of zoning	Preliminary discussion
<b>Section 6. Veterinary public health</b>	1) Control of Shiga toxin-producing <i>E. coli</i> (STEC) in food-producing animals	Preliminary discussion pending FAO/WHO expert consultation
<b>Section 7. Animal welfare</b>	1) New CH on AW and laying hen production systems	Sent for comments and proposed for adoption May 2020 (Sep 2017/3 <sup>rd</sup> )
<b>Horizontal chapters in need of revision</b>		
<b>Section 1. Animal disease diagnosis, surveillance and notification</b>	1) CH 1.6 on procedures for publication of a self-declaration of disease freedom, recognition of an official animal health status and endorsement of an official control programme by the OIE	Sent for comments and proposed for adoption May 2020 (Feb 2018/4 <sup>th</sup> )
	2) CH 1.1 on notification of diseases	Sent for comments and proposed for adoption May 2020 (Sep 2018/3 <sup>rd</sup> )
	3) CH 1.3 on listed diseases: <ul style="list-style-type: none"> <li>• <i>T. lestoquardi</i>, <i>T. luwenshuni</i>, <i>T. uilenbergi</i> and <i>T. orientalis</i></li> <li>• Chronic wasting disease</li> <li>• MERS-CoV</li> </ul>	Sent for comments (Sep 2019/1 <sup>st</sup> )
	4) CH 1.3 on listed diseases: <ul style="list-style-type: none"> <li>• Theileriosis</li> <li>• West Nile fever</li> <li>• <i>M. paratuberculosis</i></li> </ul>	Preliminary discussions
<b>Section 3. Veterinary Services</b>	1) CH 3.4 on veterinary legislation	Revised CH sent for comments and proposed for adoption May 2020 (Sep 2018/3 <sup>rd</sup> )
	2) CHs 3.1 and 3.2 on Veterinary Services	Revised CHs sent for comments (Sep 2019/1 <sup>st</sup> )
<b>Section 4. Disease control</b>	1) CH 4.6 on general hygiene in semen collection and processing centres	Ongoing
	2) CH 4.7 on collection and processing of semen	Ongoing
	3) CH 4.4 on zoning and compartmentalisation	Ongoing discussions on protection zone

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
	4) BVD in collection and processing of <i>in vivo</i> derived embryos	Ongoing
	5) CH 4.14 on disinfection	Preliminary discussion
	6) CH 4.8 on collection and processing of <i>in vivo</i> derived embryos	Preliminary discussion
	7) CH 4.9 on collection and processing of oocytes and <i>in vitro</i> produced embryos from livestock and horses	Preliminary discussion
<b>Section 5. Trade measures</b>	1) CHs 5.4 to 5.7 on measures applicable at departure and on arrival	Preliminary discussions
	2) CH 5.12 on model certificates for competition horses	Preliminary discussion and pending revision of CHs on horse diseases
<b>Section 6. Veterinary public health</b>	1) CH 6.3 on meat inspection	Preliminary discussion pending AHG
	2) CH 6.10 on responsible and prudent use of antimicrobial agents in veterinary medicine	Pending expert advice
<b>Section 7. Animal welfare</b>	1) CH 7.5 on slaughter and CH 7.6 on killing of animals	Ongoing and CH7.5 sent for comments (Sep 2019/1 <sup>st</sup> )
	2) CH 7.7 on stray dog population control	Pending report of AHG
<b>Diseases not yet in the Code</b>		
<b>Disease-specific chapters</b>	1) New CH on animal trypanosomoses of African origin	Sent for comments (Sep 2019/1 <sup>st</sup> )
	2) New CH on surra (and revision of CH on Dourine)	Pending expert advice
	3) New CH on Crimean Congo hemorrhagic fever (MCs comments, listed disease without chapter)	Preliminary discussion
<b>Listed disease chapters/articles in need of revision</b>		
<b>Sections 8 to 15</b>	1) CH 10.4 on avian influenza	Sent for comments and proposed for adoption May 2020 (Sep 2018/2 <sup>nd</sup> )
	2) CH 11.4 on bovine spongiform encephalopathy and CH 1.8 Questionnaire	Sent for comments (Feb 2015/2 <sup>nd</sup> )
	3) CH 8.8 on foot and mouth disease	Pending outcome of discussion on protection zone (CH 4.4) and of expert advice (Sep 2015/2 <sup>nd</sup> )
	4) CH 14.7 on peste des petits ruminants (Harmonisation of articles regarding official status recognition by the OIE)	Sent for comments and proposed for adoption May 2020 (Feb 2019/2 <sup>nd</sup> )
	5) CH 15.2 on classical swine fever	Sent for comments and proposed for adoption May 2020 (Feb 2017/3 <sup>rd</sup> )

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
	6) CH 8.15 on Rift Valley fever virus	Sent for comments (Feb 2019/2 <sup>nd</sup> )
	7) CH 8.16 on rinderpest	Pending work AHG
	8) Revision of safe commodities list to add lactose	Ongoing
	9) CH 12.2 on contagious equine metritis	Pending work of HQs and expert advice
	10) CH12.7 on equine piroplasmiasis	Pending work of HQs and expert advice
	11) CH 12.6 on equine influenza	Sent for comments (Sep 2019/1 <sup>st</sup> )
	12) CH 11.10 on Theileriosis and new CH 14.X. on infection with <i>Theileria</i> in small ruminants	Ongoing (Sep 2017/1 <sup>st</sup> )
	13) CH 8.11 on Mycobacterium tuberculosis complex	Ongoing
	14) CH 12.3 on dourine	Pending expert advice
	15) Revision of Article 15.3.9 on import of semen from countries not free from PRRS	Pending expert advice
	16) CH 14.8 on scrapie	Pending expert advice
	17) CH 10.5 on avian mycoplasmosis	Pending expert advice
	18) CH 9.4 on <i>Aethina Tumida</i> (Smallhive beetle)	Preliminary discussion
	19) Pet food (for certification or safe commodities)	Pending expert advice
<b>Follow-up revision of chapters recently adopted</b>		
<b>Recently adopted chapters</b>	1) CH 8.14 on rabies	Pending expert advice
	2) CH 6.2 on the role of Veterinary Services in food safety systems	Pending discussion on definitions of VS, VA and CA

List of abbreviations	
AAHSC	Aquatic Animal Health Standards Commission
AHG	<i>ad hoc</i> Group
AMR	Antimicrobial resistance
AW	Animal Welfare
BSC	Biological Standards Commission
CH	Chapter
HQs	Headquarters
MERS-CoV	Middle East Respiratory Syndrome Coronavirus

## USER'S GUIDE

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[...]

### EU comment

**The EU supports the proposed changes to the User's Guide.**

**Specific comments are included within the text of the User's Guide**

### B. *Terrestrial Code* content

[...]

- 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~~ diseases, infections and infestations. 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.

### EU Comment

**Because the ‘diagnosis (of diseases, infection and infestation)’ and ‘tests for international trade’ are found in the Manual and not in the chapters of Section 1 of TAHC, we suggest deleting the words ‘diagnosis’ and ‘tests for international trade’ from the above paragraph.**

**The standards in the chapters of Section 1 are designed for the implementation of measures for the ~~diagnosis~~, surveillance and notification of ~~pathogenic agents~~ diseases, infections and infestations. 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.**

[...]

### C. Specific issues

[...]

#### 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. Chapter 2.2. describes the criteria used to assess the safety of commodities.

[...]

## GLOSSARY

### EU comment

The EU in general supports the proposed change to the definition of *epidemiological unit* in the Glossary.

We suggest a small modification in the text of the definition below.

### EPIDEMIOLOGICAL UNIT

means a group of *animals* with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogenic agent. This may be because they share a common environment (e.g. *animals* in a pen), or because of common management practices. Usually, this ~~an epidemiological unit is a herd or a flock.~~ However, an *epidemiological unit* it may also refer to be groups such as a group of *animals* in a pen or a group of *animals* belonging to residents of a village, or a group of *animals* sharing a communal animal handling facility or, in some circumstances, to a single *animal*. The epidemiological relationship may differ from disease to disease, or even strain to strain of the pathogenic agent.

### EU Comments

In the definition, the EU would like:

- to delete the word 'approximately' as this will makes the text clearer; and
- not to delete and to retain the phrase 'Usually, an *epidemiological unit* is a *herd* or a *flock*'.

An epidemiological unit is not only used in relation to surveillance, but it is an essential part of the Glossary definition of 'outbreak'. Keeping the phrase that refers to a herd or a flock helps to understands that an outbreak is usually a herd or a flock with one or more cases.

CHAPTER 1.4.

**ANIMAL HEALTH SURVEILLANCE**

[ ... ]

**EU comment**

**The EU supports the proposed addition in Chapter 1.4. to explain in practice how ‘epidemiological units’ can be applied.**

Article 1.4.3.

**Surveillance systems**

In designing, implementing and assessing a *surveillance* system, the following components should be addressed in addition to the quality of *Veterinary Services*.

1. Design of surveillance system

a) Populations

*Surveillance* should take into account all animal species susceptible to the *infection* or *infestation* in a country, *zone* or *compartment*. The *surveillance* activity may cover all individuals in the *population* or only some of them. When *surveillance* is conducted only on a *subpopulation*, inferences to the target *population* should be justified based on the epidemiology of the disease and the degree to which the *subpopulation* is representative of the target *population* stated.

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

b) Timing and temporal validity of surveillance data

The timing, duration and frequency of *surveillance* should be determined taking into consideration factors such as:

- objectives of the *surveillance*;
- biology and epidemiology (e.g. pathogenesis, *vectors*, transmission pathways, seasonality);
- *risk* of introduction and spread;
- husbandry practices and production systems;
- disease prevention and control measures (e.g. *vaccination*, restocking after *disinfection*);
- accessibility of target *population*;

- geographical factors;
- environmental factors, including climate conditions.

c) Case definition

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

## Annex 6 (contd)

### d) Epidemiological unit

The relevant epidemiological unit for the *surveillance* system should be defined to ensure that it is appropriate to meet the objectives of *surveillance*.

A group of *animals* may be considered an *epidemiological unit* because they share a common environment or because of common management. Usually, an *epidemiological unit* is a *herd* or a *flock*. However, it may also be a group of *animals* in a pen or a group of *animals* belonging to residents of a village, or a group of *animals* sharing a communal animal handling facility or, in some circumstances, a single *animal*. The epidemiological relationship may differ from disease to disease, or even strain to strain of the pathogenic agent.

### e) Clustering

*Infection* or *infestation* in a country, *zone* or *compartment* usually clusters rather than being uniformly or randomly distributed through a *population*. Clustering may occur at a number of different levels (e.g. a cluster of infected *animals* within a *herd* or *flock*, a cluster of pens in a building, or a cluster of farms in a *compartment*). Clustering should be taken into account in the design of *surveillance* activities and considered in the statistical analysis of *surveillance* data.

### f) Diagnostic tests

*Surveillance* involves the use of tests for detection of *infection* or *infestation* according to appropriate case definitions. Tests used in *surveillance* may range from clinical observations and the analysis of production records to rapid field and detailed laboratory assays.

The performance of a test at the *population* level (including field observations) may be described in terms of its sensitivity, specificity and predictive values. These values together with prevalence will have an impact on the conclusions drawn from *surveillance* and should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.

Laboratory tests should be chosen in accordance with the relevant chapters of the *Terrestrial Manual*.

### g) Analytical methodologies

*Surveillance* data should be analysed using appropriate methodologies and at the appropriate organisational level to facilitate effective decision-making, whether it be for planning disease control interventions or demonstrating health status.

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

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

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

### h) Scope of the surveillance system

When designing the *surveillance* system consideration should be given to the purposes of *surveillance* and how the information it generates will be used, the limitations of the information it will generate, including representativeness of the study *population* and potential sources of bias as well as the availability of financial, technical and human resources.

i) Follow up actions

The design of the *surveillance* system should include consideration of what actions will be taken on the basis of the information generated.

[...]

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CHAPTER 1.1.

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

**EU comment**

**The EU in general supports the proposed changes to this chapter.**

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

Article 1.1.1.

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

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

Article 1.1.2.

- 1) Member Countries shall make available to other Member Countries, through the OIE, whatever information is necessary to minimise the spread of important animal diseases, and their pathogenic agents, and to assist in achieving better worldwide control of these diseases.
- 2) To achieve this, Member Countries shall comply with the *notification* requirements specified in Articles 1.1.3. and 1.1.4.
- 3) For the purposes of this chapter, an 'event' means a single *outbreak* or a group of epidemiologically related *outbreaks* of a given ~~disease, disease, infection or infestation~~ *listed disease or emerging disease* that is the subject of a *notification*. An event is specific to a pathogenic agent and strain, when appropriate, and includes all related *outbreaks* reported from the time of the ~~immediate~~ *initial notification within 24 hours* through to the final report. Reports of an event include susceptible species, number and geographical distribution of affected animals and *epidemiological units*.

**EU comment**

**We would like to suggest that this change where ‘immediate notification within 24 hours’ is replaced by ‘initial notification’ is also reflected in WAHIS, including the guidelines, to avoid any confusion. This comment is relevant for all changes in the Code that affects WAHIS.**

- 4) To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the OIE disease reporting format.
- 5) The detection of the pathogenic agent of a *listed disease* in an *animal* should be reported, even in the absence of clinical signs. Recognising that scientific knowledge concerning the relationship between diseases and their pathogenic agents is constantly developing and that the presence of a pathogenic agent does not necessarily imply the presence of a disease, Member Countries shall ensure, through their reports, that they comply with the spirit and intention of point 1) above.

- 6) In addition to notifying new findings in accordance with Articles 1.1.3. and 1.1.4., Member Countries shall also provide information on the measures taken to prevent the spread of diseases, ~~infections and infestations~~. Information shall include biosecurity and quarantine sanitary measures and including restrictions applied to the movement of *animals*, animal products, biological products and other miscellaneous objects which could by their nature be responsible for the transmission of diseases, ~~infections or infestations~~. In the case of diseases transmitted by *vectors*, the measures taken against such *vectors* shall also be specified.

Article 1.1.3.

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

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

Annex 7 (contd)

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

Article 1.1.4.

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

- 1) a *notification* through WAHIS or by fax or email, when an *emerging disease* has been detected in a country, a *zone* or a *compartment*;
- 2) periodic reports subsequent to a *notification* of an *emerging disease*:
- a) for the time necessary to have reasonable certainty that:
- the ~~disease, infection or infestation~~ has been eradicated; or
  - the situation has become stable;
- OR
- b) until sufficient scientific information is available to determine whether it meets the criteria for inclusion in the OIE list as described in Chapter 1.2.;

- 3) a final report once point 2) a) or 2) b) above is complied with.

~~Article 1.1.5.~~

- 1) ~~The *Veterinary Authority* of a country in which an *infected zone* is located shall inform the *Headquarters* when this zone or the entire country becomes free from the disease, *infection* or *infestation*.~~
- 2) ~~A country or *zone* may be considered to have regained freedom from a specific disease, *infection* or *infestation* when all relevant conditions given in the *Terrestrial Code* have been fulfilled.~~

- 3) ~~The Veterinary Authority of a Member Country which establishes one or several free zones shall inform the Headquarters giving necessary details, including the criteria on which the free status is based, the requirements for maintaining the status and indicating clearly the location of the zones on a map of the territory of the Member Country.~~

Article 1.1.~~65~~.

- 1) Although Member Countries are only required to notify *listed diseases*, ~~infections and infestations~~ and *emerging diseases*, they are encouraged to provide the OIE with other important animal health information.
  - 2) The *Headquarters* shall communicate by email or through the interface of WAHIS to *Veterinary Authorities* all *notifications* received as provided in Articles 1.1.2. to 1.1.~~54~~ and other relevant information.
-

## CHAPTER 1.6.

**PROCEDURES FOR PUBLICATION OF A SELF-DECLARATION OF DISEASE FREEDOM, RECOGNITION OF AN OFFICIAL RECOGNITION OF AN DISEASE ANIMAL HEALTH STATUS, AND FOR ENDORSEMENT OF AN OFFICIAL CONTROL PROGRAMME, AND PUBLICATION OF A SELF-DECLARATION OF ANIMAL HEALTH STATUS, RECOGNITION BY THE OIE**

**EU comment**

**The EU in general supports the proposed changes to Chapter 1.6.**

Article ~~1.6.2~~<sup>1.6.1bis</sup> 1.6.1.

**Application for Official recognition of animal health status and endorsement of an official control programme by the OIE**

A Member Countries may request:

- 1) official recognition of *animal health status* by the OIE of as to:
    - a) freedom of a country or zone from African horse sickness (AHS);
    - b) risk status of a country or zone with regard to bovine spongiform encephalopathy (BSE);
    - c) freedom of a country or zone from classical swine fever (CSF);
    - d) freedom of a country or zone from contagious bovine pleuropneumonia (CBPP);
    - e) freedom of a country or zone from foot and mouth disease (FMD), with or without where vaccination is either practised or not practised;
    - f) freedom of a country or zone from peste des petits ruminants (PPR);
  - 2) endorsement by the OIE of:
    - a) an official control programme for contagious bovine pleuropneumonia;
    - b) an official control programme for foot and mouth disease;
    - c) an official control programme for peste des petits ruminants;
    - d) an official control programme for dog-mediated rabies.
- 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.

## Annex 8 (contd)

The OIE does not grant official recognition of animal health status or endorsement of an official control programme for other diseases other than those listed under points 1) and 2) above.

~~In these cases, The Member Countries Country~~ should present documentation setting out the compliance of their Veterinary Services with the applicant country or zone with the provisions of Chapters 1.1., 1.4., 3.1., and 3.2. and 4.34. of the Terrestrial Code, when relevant, and with the provisions of the relevant disease-specific chapters in the Terrestrial Code and the Terrestrial Manual.

When requesting official recognition of disease animal health status or endorsement by the OIE of an official control programme, the Member Country should follow the Standard Operating Procedures (available on the OIE website) and submit to the OIE Status Department a dossier providing the information requested 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 animal health status, the endorsement of official control programmes, and their maintenance is described in relevant Resolutions No. XV (administrative procedures) and Resolution No. XVI (financial obligations) adopted during the 83rd General Session in May 2015, as well as in the Standard Operating Procedures (available on the OIE website)<sup>1</sup> adopted by the World Assembly of OIE Delegates.

The country or the zone, or the country having its official control programme endorsed will be included in the relevant lists of official animal health status or endorsed official control programmes only after the evidence submitted, based on the provisions of Chapters 1.7. to 1.12., has been adopted by the World Assembly of OIE Delegates.

When a Member Country requests official recognition of animal health status for a zone, the geographical boundaries of the proposed zone should be clearly defined describing the geographical boundaries of the zone. When applying for a free zone being adjacent to another zone of the same status, it should be stated if the new zone is being merged or kept separate. If the proposed zone remains separate, details should be provided on the control of the movement of susceptible animals and their products relevant commodities between the zones in accordance with Chapter 4.34.

The overall objective of the OIE endorsed official control programmes is for Member Countries to progressively improve their animal health situation and eventually attain official recognition of animal health status or in the case of dog-mediated rabies to make a self-declaration as a free country or zone. The official control programme should be applicable to the entire country even if certain measures are directed towards defined zones.

### Article 1.6.2. 1-6.3.

#### Maintenance of official recognition of animal health status and endorsement of an official control programme by the OIE

Retention on the lists of countries and zones having an official animal health status or of countries having an endorsed official control programme requires that the information in relevant chapters be re-submitted annually and that changes in the epidemiological situation or other significant events should be reported notified to the OIE in accordance with the requirements in Chapter 1.1.

Non-compliance with the requirements for the maintenance of an animal health status results in the suspension of that status. A Member Country/ies may apply for the recovery of a previously recognised status, following the provisions of the relevant disease-specific chapter, within 24 months after suspension. When the status has not been recovered within 24 months of its suspension, it is withdrawn and the Member Country/ies should reapply following the procedure for the application for official recognition of animal health status.

<sup>1</sup> <http://www.oie.int/en/animal-health-in-the-world/official-disease-status/official-recognition-policy-and-procedures/>

The OIE may withdraw the endorsement of an official control programme if there is evidence of:

- = non-compliance with the timelines or performance indicators of the programme; or
- = significant problems with the quality of the Veterinary Services as described in Section 3 of the Terrestrial Code; or
- = an increase in the incidence or distribution of the disease that cannot be addressed by the programme.

Article ~~1.6.1.~~ 1.6.3.

**General principles Publication by the OIE of a self-declaration of an animal health status disease freedom by a Member Country**

A Member Countries may wish to make a self-declaration as to of the freedom of a country, zone or compartment from an OIE listed disease or another animal disease, infection or infestation. The Member Country may inform the OIE of the its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim. and request that the OIE publish the self-declaration for information of OIE Member Countries.

A Member Country requesting the publication of a self-declaration should follow the Standard Operating Procedure (available on the OIE website)<sup>2</sup> for submission of a self-declaration of disease freedom an animal health status and provide documented information on its compliance with the relevant chapters of the Terrestrial Code, including:

- = evidence that the infection or infestation disease is a notifiable disease in the entire country;
- = history of absence or eradication of the infection or infestation disease in the country, zone or compartment.
- = surveillance and including an early warning system for all relevant species in the country, zone or compartment;
- = measures implemented to maintain freedom in the country, zone or compartment.

The self-declaration may be published only after all the information provided has been received and an administrative and technical screening has been performed by the OIE. Publication does not imply endorsement of the claim of freedom by the OIE and does not reflect the official opinion of the OIE. Responsibility for the accuracy of the information contained in a self-declaration lies entirely with the OIE Delegate of the Member Country concerned.

Except when otherwise provided for in the listed disease-specific chapter, aAn outbreak in a Member Country, a zone or a compartment having a self-declared free status results in the loss of the self-declared free status. A Member Countries wishing to reclaim a lost free status should submit a new self-declaration following the procedure described in this article.

The OIE does not publish self-declarations for of freedom 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), listed diseases listed under in point 1) of Article ~~1.6.21bis.~~ 1.6.1.

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## CHAPTER 3.4.

## VETERINARY LEGISLATION

**EU comment**

**The EU in general supports the proposed changes to this chapter.**

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

## Article 3.4.1.

**Introduction and objective**

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

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

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

The objective of this chapter is to provide advice and assistance to Member Countries **for use** when formulating or modernising *veterinary legislation* so as to comply with OIE standards and other relevant international standards and instruments, thus ensuring good governance of the entire veterinary domain.

## Article 3.4.2.

**Definitions**

For the purposes of this chapter the following definitions apply:

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

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

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

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

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

**Veterinary domain:** means all the activities that are directly or indirectly related to *animals*, their products and by-products which help to protect, maintain and improve ~~the~~ animal health, **and** animal welfare

~~and veterinary public health of humans, including by means of the protection of animal health and animal welfare, and food safety consistent with a One Health approach.~~

**EU comment**

**During recent years, a great effort has been made worldwide to explain and reintroduce the ‘one health’ approach. To reinforce this message of considering human and animal health as intrinsically linked, we suggest keeping the final text ‘consistent with a One Health approach’.**

**General principles**

1. Respect for the hierarchy of legislation

*Veterinary legislation* should ~~scrupulously~~ respect the hierarchy between primary legislation and secondary legislation, to ensure that the primary legislation provides the legal basis for the application and enforcement of the secondary legislation.

2. Legal basis

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

When primary legislation requires that secondary legislation be made to implement the legislative scheme, or to provide details to the legislative scheme, the relevant secondary legislation should be developed and enacted as soon as possible.

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

**EU comment**

**We believe "regional law" refers to legislation of a region or territory, which is part of a country that also has national legislation.**

**We recommend that ‘supranational law’ belonging to organisations (like the EU in Europe or the Regional Economic Communities in Africa) is also included as it can be directly enforceable in a country (and its regions) that is part of an organisation like the EU. We would therefore suggest inserting the term "supranational" after “regional”.**

3. Transparency

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

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

4. Consultation

The drafting of new and revised legislation relevant to the veterinary domain should be a consultative process involving *Competent Authorities*, and legal experts and other relevant stakeholders to ensure that the resulting legislation has been evaluated through an impact analysis, as appropriate, and is scientifically, technically and legally sound. The resulting draft legislation should be evaluated through an impact analysis as appropriate.

**EU comment**

**The point above mentions that legislation should be ‘scientifically, technically and legally sound’. In that respect, the consultation should be in place with legal experts, Competent Authorities and other relevant stakeholders. However, there is no reference to the (reference) laboratories and / or other scientific institutions, which would be**

**necessary to ensure scientifically sound legislation.**

**We suggest making explicit reference to laboratories and/or other scientific institutions unless this is covered by ‘other relevant stakeholders’.**

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

5. Quality of legislation and legal certainty

*Veterinary legislation* should be clear, ~~and coherent, and stable and transparent~~ should provide legal certainty and protect citizens and the environment against unintended adverse side effects of legal instruments. ~~The legislation~~ should be stable but regularly evaluated and updated as appropriate to be ensure that it is technically relevant, acceptable to society, able to be effectively implemented effectively and sustainable in technical, financial and administrative terms. A high quality of legislation is essential for achieving legal certainty.

**EU comment**

**We suggest including ‘animals’ as another group that should be given legal certainty. i.e. ‘...and protect citizens, animals and the environment...’**

Article 3.4.4.

**The drafting of veterinary legislation**

*Veterinary legislation* should:

- 1) be drafted in a manner that establishes clear authorities, rights, responsibilities and obligations (i.e. ‘normative’);

**EU comment**

**We suggest the use of the word ‘mandates’ to replace ‘authorities’.**

**We believe the term ‘authorities’ does not refer to ‘competent authorities’ but to an obligation. Using the term ‘mandates’ will avoid any confusion.**

Annex 9 (contd)

- 2) ~~be unambiguous, with clear and consistent syntax and vocabulary;~~
- 3) ~~be precise, accurate and consistent in the repeated use of the terminology;~~ be accurate, clear, precise and unambiguous, and use consistent terminology;
- 3) include only definitions that are sufficient, necessary and relevant to the country;
- 4) contain no definitions or provisions that create any ~~duplication or contradiction or unnecessary duplication or ambiguity;~~
- 5) include a clear statement of scope and objectives;
- 6) provide for the application of penalties and sanctions, either criminal or administrative, as appropriate to the situation; ~~and~~

**EU comment**

**It is important to stress that penalties and sanctions are effective in achieving their objectives. We suggest including the terms ‘proportionate and dissuasive’ after ‘provide for the application of’ to read:**

**6) provide for the application of proportionate and dissuasive penalties and sanctions, either criminal or administrative, as appropriate to the situation; and**

7) when relevant, make provision for the collection, use and disclosure of information gathered under the veterinary legislation;

~~78) make provision for the financing needed for the execution of all activities of *Competent Authorities*; or these activities the financing should be ensured~~ should be supported by appropriate financing in accordance with the national funding system; and

~~89) indicate when the legislation comes into effect and its impact on similar pre-existing legislation, in particular regulations secondary legislation.~~

Article 3.4.5.

### Competent Authorities

*Competent Authorities* should be legally mandated, ~~capacitated~~ have the necessary technical, administrative and infrastructure capacity and be organised to ensure that all necessary actions are taken quickly in a timely, and coherently to and effectively manner to address animal health, animal welfare and veterinary public health and animal welfare matters of concern emergencies effectively.

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

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

#### 1. Necessary powers of the Competent Authority

The *veterinary legislation* should also ensure that:

- a) ~~officials have the legal authority to intervene in accordance with the legislation and the penal procedures in force; the *Competent Authority* has all the necessary legal authorities to achieve the purposes of the legislation, including the powers to enforce the legislation;~~
- b) while executing their legal mandate, officials are protected against legal action and physical harm for actions carried out in good faith and in accordance with professional standards;
- c) the powers and functions of officials are explicitly and thoroughly listed to protect the rights of stakeholders and the general public against any abuse of authority. This includes respecting confidentiality and transparency, as appropriate; and
- d) at least the following powers are available through the primary legislation:
  - i) access to premises and ~~vehicles~~ vessels for carrying out inspections;
  - ii) access to documents;

Annex 9 (contd)

iii) ~~taking samples; application of specific *sanitary measures* such as:~~

~~= taking samples;~~

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

~~v) = seizure and destruction of *animals, products and food of animal origin* commodities and fomites;~~

**EU comment**

**We suggest adding ‘where necessary’ before destruction. Destruction is not always needed for example if there is a treatment or process to transform the product into a safe commodity.**

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

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

~~viii) = suspension or withdrawal of authorisations or approvals; and~~

~~= restrictions on the movement of *commodities, vehicles/vessels* and, if required, other fomites and people;~~

**EU comment**

**To ensure that any type of transport is covered and can be subject to restrictions, we suggest deleting vehicles/vessels and replacing them by a more generic term such as ‘means of transport’**

~~= establishment of compensation mechanisms;~~

~~= listing disease for mandatory reporting; and~~

**EU comment**

**We suggest adding ‘notification and’ before reporting in line with Chapter 1.1.**

~~= ordering of *disinfection, disinfection or pest control*;~~

iv) establishment of compensation mechanisms.

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

2. Delegation of powers by the Competent Authority

The *veterinary legislation* should provide the possibility for *Competent Authorities* to delegate specific powers and tasks related to official activities. The specific powers and tasks delegated, the competencies required, the bodies or officers to which the powers and tasks are delegated, and the conditions of supervision by the *Competent Authority* and the conditions of withdrawals of delegations should be defined.

~~For this purpose, the *veterinary legislation* should:~~

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

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

- ~~c) define the procedures for making delegation;~~
- ~~d) define the competencies to be held by persons receiving delegation; and~~
- ~~e) define the conditions of withdrawals of delegations.~~

Article 3.4.6.

#### **Veterinarians and veterinary paraprofessionals**

##### **4. Veterinary medicine/science**

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

- ~~a) define the prerogatives of *veterinarians* and of the various categories of *veterinary paraprofessionals* that are recognised by the Member Country;~~
- ~~b) define the minimum initial and continuous educational requirements and competencies for *veterinarians* and *veterinary paraprofessionals*;~~

- ~~e) prescribe the conditions for recognition of the qualifications for *veterinarians* and *veterinary paraprofessionals*;~~
- ~~d) define the conditions to perform the activities of veterinary medicine/science; and~~
- ~~e) identify the exceptional situations, such as epizootics, under which persons other than *veterinarians* can undertake activities that are normally carried out by *veterinarians*.~~

2. The control of veterinarians and veterinary paraprofessionals

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

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

1. The regulation of veterinarians and veterinary paraprofessionals

~~*Veterinary legislation* should provide a basis for the regulation of *veterinarians* and *veterinary paraprofessionals* in the interests of the public. To this end, the legislation should:~~

- ~~a) provide for the creation of a *veterinary statutory body*;~~
- ~~b) describe the prerogatives, **the** functioning and responsibilities of the *veterinary statutory body*;~~
- ~~c) describe the general structure and system of regulation of *veterinarians* and *veterinary paraprofessionals* by the *veterinary statutory body*; and~~
- ~~d) give authority to the *veterinary statutory body* to ~~make secondary legislation or otherwise deal with~~ provide **basic** principles for or regulate the following matters:
  - ~~i) describe the various categories **professional categories specialisations** of *veterinarians* (e.g. **specialisations**) and categories of *veterinary paraprofessionals* recognised in the country in accordance with its needs, notably in animal health, animal welfare and food safety;~~
  - ~~ii) define the prerogatives of the various categories **professional categories specialisations** of *veterinarians* (e.g. **specialisations**) and categories of *veterinary paraprofessionals* that are recognised in the country;~~
  - ~~iii) define the minimum initial and continuous educational requirements and competencies for the various categories **professional categories specialisations** of *veterinarians* (e.g. **specialisations**) and categories of *veterinary paraprofessionals*;~~
  - ~~iv) **prescribe the** conditions for recognition of the qualifications for *veterinarians* and *veterinary paraprofessionals*;~~~~

Annex 9 (contd)

- v) define the conditions to for performing the activities of veterinary medicine/science, including the extent of supervision for each category of *veterinary paraprofessionals*;
- vi) prescribe the powers to deal with issues of conduct and competence issues, including licensing requirements and mechanisms to appeal, that apply to *veterinarians* and *veterinary paraprofessionals*;
- vii) identify the exceptional situations, such as epizootics, define the conditions (except those that are under the responsibilities responsibility of the *Competent Authority*) under which persons other than *veterinarians* can undertake activities that are normally carried out by *veterinarians*.

2. If the *veterinary legislation* does not create a *veterinary statutory body* for the regulation of *veterinarians* and *veterinary paraprofessionals*, the legislation should at least address all the elements listed in paragraphs 1(d)(i) to (vii) to ensure quality in the conduct of veterinary medicine/science.

Article 3.4.7.

**Laboratories in the veterinary domain**

1. Facilities

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

- a) reference *laboratories*, which are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods;
- b) *laboratories* designated by the *Competent Authority* for carrying out the analysis of official samples; and
- c) *laboratories* recognised by the *Competent Authority* to that conduct analyses in-house testing required under the legislation e.g. for the purposes of safety and quality control, e.g. bacteriological testing for pathogenic agents in milk at a dairy processing plant.

**EU comment**

**We would like some clarification in relation to the above paragraph. We believe that it could be interpreted that any laboratory carrying out laboratory tests for a business operator owns' checks has to be 'recognised' by the Competent Authority.**

**We would also like to understand what 'recognised' means in this context, does the laboratory needs to be registered? Or authorised?**

*Veterinary legislation* should define the conditions for the classification, approval, operations and supervision of each of these types of *laboratories* *laboratory*, including conditions for laboratory biosafety and biosecurity.

2. Reagents, diagnostic kits and biological agents and products

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

- a) procedures for authorising the use and transfer of reagents, diagnostic kits and biological agents and products that are used to perform official analyses and other purposes approved by the *Competent Authority*;
- b) quality assurance by manufacturers and providers of reagents used in official analyses and for other purposes approved by the *Competent Authority*; and
- c) surveillance oversight of marketing of reagents, diagnostic kits and biological agents and products

where these can affect the quality of analyses required by the *veterinary legislation*.

3. Laboratory containment and control of biological agents and products

*Veterinary legislation should make provisions for the effective containment and control of biological agents and products into, within and out of the laboratory, including their disposal when applicable, as described in Chapter 5.8. of the Terrestrial Code and Chapter 1.1.4. of the Terrestrial Manual.*

Article 3.4.8.

**Health provisions relating to animal production**

1. Identification and traceability

*Veterinary legislation* should provide a basis for actions to address all the elements in point 6) of Article ~~4.2.3.~~ 4.3.3.

2. Animal markets and other gatherings

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

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

3. Animal reproduction

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

4. Animal feed

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

- a) definition of the animal feed subject to the legislation;
- b) standards for the production, composition and quality control of animal feed in relation to the biological, chemical and physical risks of disease transmission;
- ~~b)~~ c) registration and, if necessary, approval of establishments facilities and the provision of health requirements for relevant operations; ~~and~~
- ~~d)~~ d) distribution and use of animal feed in relation to the biological, chemical and physical risks; and
- ~~e)~~ e) recall from the market of any product likely to present a hazard to human health or animal health.

5. Animal by-products

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

- a) definition of the animal by-products subject to the legislation;
- b) rules for sourcing, collection, transport, processing, use and disposal of animal by-products;
- c) registration and, if necessary, approval of establishments facilities and the provision of health requirements for relevant operations; ~~and~~
- ~~d)~~ d) rules to be followed by animal owners.

6. Disinfection

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

## Annex 9 (contd)

### Article 3.4.9.

#### **Animal diseases**

*Veterinary legislation* should provide a basis for ~~the~~ *Competent Authorities* to manage diseases of importance to the country, ~~present or not, and to list those diseases, guided by the recommendations in Chapters 1.1 and 1.2, as well as emerging diseases, using a risk-based approach. The legislation should also provide for the listing and mandatory reporting of diseases of importance to the country. It should also provide powers for the Veterinary Authority to access information needed to comply with its notification obligations to the OIE.~~

#### 1. Surveillance

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

#### 2. Disease prevention and control

- a) *Veterinary legislation* should include general animal health measures applicable to all diseases and, if necessary, additional or specific measures such as *surveillance*, establishment of a regulatory programme or emergency response for particular diseases listed ~~in the country~~ by the *Competent Authority*.
- b) The legislation should also provide a basis for contingency emergency response plans for use in responding to disease, to include the following ~~for use in disease responses~~:
  - i) the administrative administration and logistics organization necessary to activate, implement and coordinate activities;
  - ii) exceptional powers of the *Competent Authority*; and
  - iii) ~~special and temporary~~ measures to address all identified *risks* to human or animal health including accidental or deliberate introduction of biological agents or products.
- c) *Veterinary legislation* should provide for the financing of animal disease control measures, such as operational expenses and, as appropriate, owners' compensation in the event of *killing or slaughtering of animals* and seizure or destruction of carcasses, *meat*, animal feed or other things, or alternatively, the financing of these measures should be ensured in accordance with the national funding system.

#### 3. Emerging diseases

*Veterinary legislation* should provide for measures to investigate and respond to *emerging diseases including those due to natural, accidental or deliberate introduction of biological agents or products*, using a risk-based approach.

### Article 3.4.10.

#### **Animal welfare**

#### 1. General provisions

*Veterinary legislation* should provide a basis for actions to address the *animal welfare* related requirements in Section 7.

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

2. Stray dogs and other free-roaming domestic animals

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

Article 3.4.11.

**Veterinary medicines and biological medicinal products**

*Veterinary legislation* should provide a basis for assuring the quality of *veterinary medicines and biological medicinal products* and minimising the *risk* to human, animal and environmental health associated with their use, including the development of antimicrobial resistance.

1. General measures

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

- a) definition of *veterinary medicines and biological medicinal products*, including any specific exclusions; and
- b) regulation of the authorisation, importation, manufacture, safety, efficacy, distribution and usage of, and commerce in, and disposal of safe and effective *veterinary medicines and biological medicinal products*, including laboratory biosafety and biosecurity measures.

**EU comment**

**We would like to suggest that the term ‘distribution’ is replaced and split into ‘wholesale and retail’ as these two activities have their own different particularities, to read:**

**‘...importation, manufacture, distribution wholesale, retail and usage of...’**

2. Raw materials for use in veterinary medicines and biological medicinal products

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

- a) quality standards for raw materials used in the manufacture or composition of *veterinary medicines and biological medicinal products* and arrangements for checking quality;
- b) establishment of the ~~withdrawal periods and maximum residue limits for veterinary medicines and biologicals, as appropriate; and~~
- e**b**) requirements for restrictions on substances in *veterinary medicines and biological medicinal products* that may, through their effects, interfere with the interpretation of veterinary diagnostic test results or the conduct of other veterinary checks.

3. Authorisation of veterinary medicinal products medicines and biologicals

- a) *Veterinary legislation* should ensure that only authorised *veterinary medicines and biological medicinal products* may be placed on the market.
- b) Special provisions should be made for:
  - i) veterinary medicinal products incorporated into medicated feed;
  - ii) products prepared by authorised *veterinarians* or authorised pharmacists; ~~and~~

- iii) emergencies and temporary situations; and
- iv) establishment of maximum residue limits for active substances and withdrawal periods for relevant veterinary medicinal products containing these substances and maximum residue limits for the active substance contained in each such product; and
- v) restrictions of use of veterinary medicinal products for food-producing animals.

Annex 9 (contd)

- c) *Veterinary legislation* should address the technical, administrative and financial conditions associated with the granting, **suspension**, renewal, refusal and withdrawal of authorisations.
- d) In defining the procedures for seeking and granting, **or refusing**, authorisations, the legislation should:
  - i) describe the ~~role~~ responsibilities of the relevant *Competent Authorities*; and
  - ii) establish rules providing for **the** transparency in decision-making.
- e) *Veterinary legislation* may provide for the possibility of recognition of the equivalence of authorisations made by other countries.

4. Quality of veterinary medicines and biologicals

~~*Veterinary legislation* should address the following elements:~~

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

54. **Establishments Facilities** producing, storing and wholesaling veterinary medicines and biologicals medicinal products

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

- a) registration or authorisation of all operators manufacturing importing, **exporting**, storing, processing, wholesaling or otherwise distributing ~~veterinary medicines and biologicals~~ medicinal products or raw materials for use in making ~~veterinary medicines and biologicals~~ medicinal products;
- b) definition of the responsibilities of operators;
- c) good manufacturing practices **as** appropriate;

**EU comment**

**We suggest adding ‘and good distribution practices’ after ‘good manufacturing practices’ to make sure that good distribution practices are also considered.**

- d) reporting on adverse effects to the *Competent Authority*; and
- e) mechanisms for traceability and recall.

65. Retailing, use and traceability of veterinary medicines and biologicals medicinal products

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

- a) control over the distribution of ~~veterinary medicines and biologicals~~ medicinal products and arrangements for traceability, recall and conditions of use;
- b) establishment of rules for the prescription and provision of ~~veterinary medicines and biologicals~~ medicinal products to end users, **including appropriate labelling**;
- c) restriction to veterinarians or other authorised professionals and, as appropriate, authorised *veterinary paraprofessionals*, of commerce in ~~veterinary medicines and biologicals~~ medicinal products that are subject to prescription;

- d) obligation of *veterinarians*, other authorised professionals or authorised *veterinary paraprofessionals* to inform end users of the withdrawal periods of relevant *veterinary medicinal products* and the obligation of end users to observe those withdrawal periods when using those products;

- ~~e)~~ the supervision by an authorised professional of organisations approved for **the** holding and use of ~~veterinary medicines and biologicals~~ medicinal products;
- ~~f)~~ the regulation of advertising claims and other marketing and promotional activities **including a system of surveillance for falsification**; and

**EU comment**

**We suggest deleting ‘including a system of surveillance for falsification from bullet point f) because these activities are not part of advertising but should be part of a system of surveillance.**

- ~~g)~~ **a system of surveillance of the quality of veterinary medicinal products marketed in the country and the reporting on adverse effects to the Competent Authority.**

**EU comment**

**Following the comment above, we suggest the inclusion in bullet point g) above the ‘system of surveillance for falsifications’ and to mention in a separate bullet point that the reporting of adverse effects should be part of a pharmacovigilance system, to read:**

**g) a system of surveillance of the quality of veterinary medicinal products marketed in the country, including a system, of surveillance for falsification; and the reporting on adverse effects to the Competent Authority;**

**f) a system for reporting on adverse effects to the Competent Authority included in a pharmacovigilance system.**

Article 3.4.12.

**Human food production chain**

*Veterinary legislation* should provide a basis for actions to safeguard the human food production chain through controls at all critical steps, consistent with national food safety standards and taking into account the risk of accidental and deliberate contamination. The role of the *Veterinary Services* in food safety is described in Chapter 6.2.

1. General provisions

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

- a) the conduct of veterinary ante- and post-mortem inspections at slaughterhouses/abattoirs in accordance with Chapter 6.3;
- ~~a)~~ controls over all stages of the production, processing and distribution of food of animal origin;
- ~~b)~~ recording all significant animal and public health events that occur during primary production including slaughter;

**EU comment**

**Because slaughter is not part of primary production, we suggest deleting the word ‘including’ and replacing it with the word ‘and’ to read:**

**c) recording all significant animal and public health events that occur during primary production including and slaughter;**

- ~~e~~d) giving operators of food production **premises facilities** the primary responsibility for compliance with food safety requirements, including traceability established by the *Competent Authority*;
- ~~e~~e) inspection for compliance with food standards, where this is relevant to health or safety;
- ~~e~~f) inspection and audit of **premises facilities**;
- ~~f~~g) prohibition of the marketing of products not fit for human consumption; and
- ~~g~~h) provisions for recall from the marketplace of all products likely to be hazardous for human or animal health.

2. Products of animal origin intended for human consumption

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

- ~~a)~~ ~~arrangements for inspection and audit~~;
- ~~b)~~ ~~the conduct of inspection and audit~~;
- ~~e~~a) health standards including measures to control diseases, and monitoring and enforcement of maximum residue levels (MRL); and
- ~~e~~b) the application use of health identification marks that are visible to the intermediary or and final user visible marks that indicate the product **has been inspected complies with the health standards**.

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

Annex 9 (contd)

3. Operators responsible for **premises facilities** and establishments pertaining to the food chain

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

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

Article 3.4.13.

**Import and export procedures and veterinary certification**

*Veterinary legislation* should provide a basis for actions to address the elements ~~relating to import and export procedures and veterinary certification~~ referred to in Section 2 Risk Analysis and Section 5 Trade measures, import/export procedures and veterinary certification.

## CHAPTER 4.Y.

**OFFICIAL CONTROL PROGRAMMES MANAGEMENT OF**  
**OUTBREAKS OF FOR LISTED AND EMERGING AND**  
**LISTED DISEASES**

**EU comment**

**The EU in general supports the proposed changes to this chapter.**

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

*Article 4.Y.1.***Introduction**

When a *listed disease or emerging disease*, including a zoonosis, occurs in a Member Country, the *Veterinary Services Authority* should implement a response control measures proportionate to the likely impact of the disease and as a result of a *risk analysis*, in order to minimise its spread and consequences and, if possible, eradicate it. These measures can vary from rapid response (e.g. the first occurrence to of a new *hazard disease*) and management of *outbreaks*, to long-term control (e.g. of an endemic disease) *infection or infestation*.

The purposes of this chapter is to provide recommendations to for the prepare preparation, develop development and implement implementation of official control programmes for plans in response to outbreaks occurrence outbreaks of listed and emerging or listed diseases, including zoonoses. It is not aimed at giving providing ready-made fit-for-all solutions, but rather at outlining principles to follow when combating transmissible animal diseases, including zoonoses through organised control programmes plans. Although this chapter focuses primarily on *listed and emerging diseases*, the recommendations may also be used by the *Veterinary Authorities* for any *notifiable diseases* or diseases against which they have established *official control programmes*.

The *Veterinary Authority* should determine which the diseases to establish against which official control programmes against and at which regulatory level are implemented, according to an evaluation of the actual or likely impact of the disease. *Official control programmes* plans should be prepared in-advance by the *Veterinary Authority* and *Veterinary Services* in close collaboration with the relevant stakeholders and other authorities, as appropriate disposing of the necessary regulatory, technical and financial tools.

When a *listed disease or emerging disease* occurs in a Member Country, the *Veterinary Authority* should implement control measures proportionate to the likely impact of the disease in order to minimise its spread and consequences and, if possible, eradicate it. These measures can vary from a rapid response (e.g. to the first occurrence of a disease) to long-term control (e.g. of an endemic disease).

Control-plans They *Official control programmes* should be justified by rationales developed through based on the basis of risk analyses and considering taking into account animal health, public health, and socio-economic, animal welfare and environmental aspects. They should preferably be supported by relevant cost-benefit analysis when possible and should include the necessary regulatory, technical and financial tools.

*Official control programmes* Control-plans should be developed with the aim of achieving defined measurable objectives, in response to a situation in which purely private action alone is not sufficient. Depending on the prevailing epidemiological, environmental and socio-economic situations, the goal may vary from the reduction of impact to the eradication of a given disease *infection or infestation*.

The general components of an *official control programme* should include:

- 1) a plan of the programme to control or eradicate the relevant disease *infection or infestation* in the country or zone;
- 2) regular and prompt animal disease reporting appropriate *veterinary legislation*;

- 3) emergency preparedness plans and emergency response plans;
- 4) surveillance of the relevant **disease infection or infestation** in accordance with Chapter 1.4.;
- 45) regular and prompt animal disease reporting;

Annex 10 (contd)

- 6) rapid detection and management of, and response to, cases of the relevant **disease infection or infestation**, to reduce the *incidence* and the *prevalence* to by ~~eliminating~~ **minimising** transmission;
- 57) measures implemented to prevent introduction or spread of the relevant **disease infection or infestation**, including *biosecurity* and *sanitary measures* **including such as** movement control;
- 68) a vaccination programme, **as if** relevant appropriate;
- 79) ~~preparedness and contingency plans~~ measures to protect public health, **as if** appropriate;
- 810) communication and collaboration ~~with other~~ among all relevant *Competent Authorities*.

In any case, the critical components of *official control programmes* plans for management of *outbreaks* for diseases that are not present in the ~~Member Country~~ country or zone are measures to prevent the introduction of the disease, an early *detection* warning system (including a warning procedure), and a plan for rapid response and quick and effective action, possibly followed by long-term measures. Such ~~Plans~~ programmes should always include an exit strategy options.

**Official control programmes and the application of their components should be regularly evaluated.** Learning from past *outbreaks*, and reviewing the response sequence and revising the methods are critical for adaptation to evolving epidemiological situations circumstances and for better future performance in future situations. Experiences of the *Veterinary Services* of other Member Countries may also provide useful lessons. Plans should be tested regularly to ensure that they are fit-for-purpose, practical, feasible and well understood, and that field staff are trained and other stakeholders are fully aware of their respective roles and responsibilities in implementing the response. This is especially important for diseases that are not present in the Member Country.

Article 4.Y.2.

**Legal framework and regulatory environment**

- 1) In order to be able to **effectively** control *listed diseases* and *emerging diseases* ~~and listed diseases~~ **effectively**, the *Veterinary Authority* should ensure that:
  - the *Veterinary Services* comply with the principles of Chapter 3.1., especially the services dealing with the prevention and control of ~~contagious~~ **infectious transmissible** animal diseases, including zoonoses;
  - the *veterinary legislation* complies with the principles of Chapter 3.4.
- 2) In particular, in order for the *Veterinary Services* to be the most effective **when combatting animal disease outbreaks**, the following should be addressed in the *veterinary legislation* or other relevant legal framework:
  - legal powers and structure of command and responsibilities, including responsible officials with defined powers authority, especially **those with** a right of entry to *establishments* or other related enterprises such as live *animal* markets, *slaughterhouses/abattoirs* and **processing plants for** animal products ~~processing plants~~, for regulated purposes of *surveillance* and disease control actions, with the possibility of obliging owners **or operators** to assist;
  - sources of **financing finance** for dedicated staff and additional supporting staff when needed;
  - sources of **financing finance** for epidemiological enquiries, laboratory **diagnostic diagnosis**, disinfectants, insecticides, vaccines and other critical supplies;
  - sources of **financing finance** for communication and awareness campaigns;

- sources of financing finance and a compensation policy for livestock commodities and property that may be lost or destroyed as part of disease control programmes, or for direct losses incurred due to movement restrictions imposed by the control programme;
- coordination with other authorities, especially law enforcement and public health authorities.

- 3) Furthermore, the specific regulations, policies, or guidance on disease control activities ~~policies~~ should include the following:
- *risk analysis to identify assess and prioritise potential disease risks*, including a regularly updated list of *notifiable diseases*;
  - definitions and procedures for the reporting and management of a suspected *case, or confirmed case, of an listed disease or an emerging disease or a listed disease*;
  - procedures for the management of infected establishments, directly or indirectly affected by the disease infected establishment, contact establishment;
  - ≡ procedures for epidemiological investigations of outbreaks including forward and backward tracing of animals and animal products commodities and fomites;
  - definitions and procedures for the declaration and management of *infected zones* and other zones, such as *free zones, protection zones, containment zones*, or less specific ~~ones~~ **zones** such as zones of intensified *surveillance*;

#### EU comment

**We suggest adding ‘if relevant’ after ‘management of infected zone’ as the implementation of a zone is not needed for all diseases.**

- procedures for the collection, transport and testing of **animal** samples;
- procedures for *animal identification and the management of animal identification systems* ~~the identification of animals~~;
- procedures for the restriction<sup>s</sup> of movements, including possible standstill or compulsory veterinary certification, of relevant *animals, and animal products commodities and fomites* within, to, or from given *zones or establishments* or other related enterprises;
- procedures for the destruction or *slaughter* and safe disposal or processing of infected or potentially infected *animals*, including relevant *wildlife*; ~~and~~
- ≡ procedures for the destruction and collection, treatment or safe disposal or processing of contaminated or potentially contaminated animal products of animal origin and other materials;
- ≡ procedures for collection, treatment or safe disposal of contaminated or potentially contaminated fomites such as fodder and effluents such as fodder, bedding, and litter, manure and waste water;
- ≡ procedures for **cleaning**, disinfection and disinsection of establishments and related premises, vehicles/vessels or equipment;

#### EU comment

**We do not see ‘cleaning’ mentioned in any other bullet point of this list. It could be assumed that no effective disinfection could take place without prior cleaning but we consider that there is no harm in not deleting and keeping ‘cleaning’ to reinforce this key activity for disease control.**

- procedures ~~for of~~ compensation for the owners of *animals or animal products commodities*, including defined standards and means of implementing such ~~a~~ compensation;

- procedures for cleaning, *disinfection* and disinsection of *establishments* and related premises, *vehicles* or equipment;
- procedures for the compulsory emergency implementation of vaccination programmes or treatment of *animals*, as relevant, and for any other necessary disease control actions;
- = procedures for post-control *surveillance* and possible *gaining* or recovery of status, as relevant.

Article 4.Y.3.

### Emergency Preparedness

Rapid and effective response to animal health emergencies, such as *In case of* occurrence of an *emerging disease* or a *listed disease* that was not present in the country or zone, or of a sudden increase of *in the incidence of a listed disease* that is *already* present, Rapid and effective response to a new occurrence or emergence of contagious infectious diseases is dependent on the level of preparedness.

### **EU comment**

**The need for a contingency plan is a complex exercise and often it is the result of an evaluation of the likely impact of the disease as described below in the risk analysis section.**

**For this reason, we suggest adding ‘...is dependent on a risk analysis or an evaluation of the actual or likely impact of the disease and on the level of preparedness’**

### Annex 10 (contd)

The *Veterinary Authority* should define emergencies and integrate emergency preparedness planning, and practice equipping, training and *exercising exercises* within the official control programmes against for these diseases as one of its core functions. Rapid, effective response to a new occurrence or emergence of contagious diseases is dependent on the level of preparedness.

Emergency Preparedness should be justified supported by risk analysis, should be planned in advance, and should include training, capacity building and simulation exercises.

#### 1. Risk analysis

*Risk analysis*, including import *risk analysis*, in accordance with Chapter 2.1., should be used to determine which a list of *notifiable diseases* that require *emergency* preparedness planning, and to what extent.

A *risk analysis* identifies the pathogenic agents that present the greatest *risk* and for which preparedness is most important, and therefore helps to prioritise the range of disease threats and categorise define the consequent actions. It also helps to define the best strategies and control options.

The *risk analysis* should be reviewed updated regularly to detect changes (e.g. new pathogenic agents, or changes in distribution and virulence of pathogenic agents previously identified as presenting the major *risk* and or changes in possible pathways) and be updated accordingly, taking into account the latest scientific findings.

#### 2. Planning

Four kinds of plans, Emergency planning consists of describing the following in advance of an emergency:

- what governmental or national and local authorities, and all relevant stakeholders should do; comprise any comprehensive preparedness and response system
- how they should be trained, equipped and exercised to be ready to do it;
- how their actions should be activated and coordinated.

This implies the development of:

- a) a preparedness plan, which outlines what should be done before an outbreak of a notifiable listed disease or an emerging disease or a notifiable disease occurs an emergency;
  - b) a response or contingency plan, which details what should be done in the event of an occurrence of a notifiable listed disease or an emerging disease or notifiable disease an emergency, beginning from the triggering point when a suspected case is reported;
  - c) a comprehensive set of instructions for field staff and other stakeholders on how to undertake specific tasks required by the response or contingency plan;
  - d) a recovery plan for the safe restoration of normal activities, including food supply, possibly including procedures and practices modified in light of the experience gained during the management of the outbreak notifiable listed disease or the emerging disease emergency.
3. Simulation exercises

A simulation exercise is a controlled activity where a situation, that could exist in reality, is imitated for training or assessment of capabilities and plans. The *Veterinary Services* and all stakeholders should be made aware of the sequence of measures to be taken in the framework of a contingency plan, through the organisation of simulation exercises, mobilising a sufficient number of staff and stakeholders to evaluate the level of preparedness and fill possible gaps in the plan or in staff capacity. Simulation exercises may be organised between within a country or among the Veterinary Services of neighbouring several countries and with other relevant agencies.

#### **EU comment**

**We suggest alternative wording for explaining better the objectives of a simulation exercise. We also consider that the sequence of measures should be known by the veterinary services and stakeholder before the simulation exercise is played. Indeed, the simulation exercise should also assess if the responsibilities of the different players are well understood and if this is not the case, the simulation exercise should help to identify areas for improvement.**

**For these reasons we suggest rewording the above paragraph as follows:**

**‘A simulation exercise is a controlled activity where a situation, that could exist in reality, is imitated tested for training or the assessment of capabilities or for assessing that plans are fit for purpose. The *Veterinary Services* and all stakeholders should be made aware of the sequence of measures to be taken in the framework of a contingency plan, ~~through the organisation of simulation exercises~~, mobilising a sufficient number of staff and stakeholders to evaluate the level of preparedness and fill possible gaps in the plan or in staff capacity. Simulation exercises may be organised between within a country or among the *Veterinary Services* of neighbouring several countries and with other relevant agencies’.**

## Article 4.Y.4.

Surveillance and early warning detection systems

- 4) Depending on the priorities identified by the *Veterinary Authority*, *Veterinary Services* should implement adequate *surveillance* for *listed diseases* in accordance with Chapter 1.4. ~~or and *listed disease*~~ specific chapters, in order to detect suspected cases and either rule ~~them~~ out or confirm them. The *surveillance* should be adapted to the ~~specific~~ epidemiological and environmental situation. Early warning systems are an integral component of emergency preparedness management. They should be in place for diseases *infections or infestations* for which a rapid response is desired, and should comply with the relevant articles of Chapter 1.4. When used, *vector surveillance* should be conducted in accordance with Chapter 1.5.

~~All suspected case investigations should provide a result, either positive or negative. Criteria should be established in advance for a case definition. Confirmation can be made on clinical and post-mortem grounds, epidemiological information, laboratory test results or a combination of these, in accordance with relevant articles of the *Terrestrial Code* or *Terrestrial Manual*. Strong suspicion of a *listed disease* or an *emerging disease* based on supportive, but not definitive, findings should lead to at least the implementation of local pre-emptive control measures as a precaution. When Once a case is confirmed, full sanitary measures should be implemented as planned.~~

- 2) In order to implement adequate *surveillance*, the *Veterinary Authority* should have access to good diagnostic capacity. This means that the *veterinarians* and other relevant personnel of the *Veterinary Services* have adequate knowledge of the *disease*, its clinical and pathological manifestation and its epidemiology, and that laboratories approved for the testing of animal samples for the relevant *diseases* are available.
- 3) Suspected cases of *notifiable diseases* should be reported without delay to the *Veterinary Authority*, ideally with the following information:
- the *disease* or pathogenic agent suspected, with brief descriptions of clinical signs or lesions observed, or laboratory test results as relevant;
  - the date when the signs were first noticed at the initial site and any subsequent sites;
  - the names and addresses or geographical locations of suspected infected *establishments* or premises;
  - the animal species affected, including possible human cases, and the approximate numbers of sick and dead *animals*;
  - initial actions taken, including *biosecurity* and precautionary movement restrictions of *animals*, products, staff, vehicles and equipment;
- 4) Immediately following the report of a suspected case, investigation should be conducted by the *Veterinary Services*, taking into account the following:
- *biosecurity* to be observed when entering and leaving the *establishment*, premises or locality;
  - clinical examinations to be undertaken (number and types of *animals*);
  - samples to be taken from *animals* showing signs or not (number and types of *animals*), with specified sampling and sample handling equipment and sample handling procedures, including for the safety of the investigator and animal owners;
  - procedure for submitting samples for testing;
  - size of the affected *establishment*, premises or locality and possible entry pathways;
  - investigation of the approximate numbers of similar or possibly susceptible *animals* in the *establishment* and its surroundings;

Annex 10 (contd)

- details of any recent movements of possibly susceptible *animals or vehicles* or people to or from the affected *establishments, premises or locality*;
- any other relevant epidemiological information, such as presence of the suspected *disease in wildlife or abnormal vector activity*;

A procedure should be in place for reporting findings to the *Veterinary Authority* and for record keeping.

- 5) All suspected case investigations should provide a result, either positive or negative. Criteria should be established in advance for a case definition. Confirmation can be made on clinical and post-mortem grounds, epidemiological information, laboratory test results or a combination of these, in accordance with relevant articles of the *Terrestrial Code* or *Terrestrial Manual*. Strong suspicion based on supportive, but not definitive, findings should lead to the implementation of local control measures as a precaution. When a case is confirmed, full *sanitary measures* should be implemented as planned.
- 6) When a case of a *listed disease* is detected, *notification* shall be made to the OIE in accordance with Chapter 1.1.

Article 4.Y.5.

**General considerations ~~when managing an~~ for outbreak management**

Upon confirmation of ~~Once an outbreak of a notifiable listed disease or an emerging disease or a notifiable disease that is subject to an official control programme, is confirmed~~ effective risk management should be applied. ~~This depends on the application implementation of a combination of measures that are operating at the same time or consecutively, These measures should aimed at:~~

- 1) ~~epidemiological investigation to tracing back and forward and backward animals in contact and potentially infected or contaminated products commodities or fomites through epidemiological investigation;~~
- 2) eliminating the source of ~~the~~ pathogenic agent, ~~through by:~~
  - the *killing or slaughter of animals* infected or suspected of being infected, *as appropriate*, and safe disposal of dead *animals* and *other* potentially contaminated *products commodities and fomites, such as beddings and single use clothing and equipment*;

**EU comment**

**Should other activities as described in Article 4.Y.2. (3) be also included in this article related to outbreak management?**

We suggest include here the following extra bullet points, for example:

**= procedures for the destruction and collection, treatment or safe disposal or processing of contaminated or potentially contaminated animal products of animal origin and other materials;**

**= procedures for collection, treatment or safe disposal of contaminated or potentially contaminated fomites such as fodder and effluents such as fodder, bedding, and litter, manure and waste water;**

- the cleaning, *disinfection* and, if relevant, *disinsection* of premises and *other fomites such as vehicles, clothing and* equipment;

- 23) ~~stopping preventing~~ the spread of *disease, infection, or infestation* through:

**EU comment**

**We believe it will help to add that these requirements refer to premises and/or restricted zone.**

**We suggest adding ‘...or infestation in premises and/or restricted zones through:’**

- movement restrictions on animals commodities and fomites, vehicles, and equipment and people, as appropriate;
- biosecurity;
- vaccination, treatment or culling of animals at risk;
- control of vectors;
- communication and public awareness.

Different strategies may be chosen depending on the objective and expected outcome of the official control programme (i.e. eradication, containment or partial prevalence control) and the epidemiological, environmental, economic and social situation. The *Veterinary Authority* should assess the situation beforehand and at the time of the outbreak detection. For example, the wider the spread of the disease and the more locations affected at the beginning of the implementation of the measures, the less likely it will be that culling will be effective as a the main eradication tool will be effective, and the more likely it will be that other control tools such as *vaccination* or treatment, either in conjunction with culling or alone, will be needed. The involvement of *vectors* or *wildlife* will also have a major influence on the control strategy and different options chosen. The strategies chosen will, in turn, influence the final objective outcome of the official control programme.

In any case, the management plan response measures should consider the costs of the response measures, including the compensation of owners for losses incurred by the measures as described in regulations, policies or guidance, should be considered in relation to the benefits expected, and should at least integrate the compensation of owners for losses incurred by the measures, as described in regulations, policies or guidance.

In case of highly contagious transmissible or high impact disease events, the management plan response measures should be closely coordinated through an inter-sectoral mechanism such as an incident command system.

#### Article 4.Y.6.

#### Culling of animals and disposal of dead animals and animal products other potentially contaminated commodities

Living infected *animals* can be are the greatest most significant source of pathogenic agents. These *animals* may directly transmit the pathogenic agent to other *animals*. They may and also cause lead to indirect infection transmission of pathogenic agents through live living organisms (vectors, people) or through the contamination of fomites, including breeding and handling equipment, bedding, feed, vehicles/vessels, and people's clothing and footwear, or the contamination of the environment. Although in some cases carcasses may remain contaminated infective for a period after death, active shedding of the pathogenic agent effectively ceases when the *animal* is killed or slaughtered. Thus, culling of *animals* is often a the preferred strategy for the control of contagious transmissible diseases.

Veterinary Services should adapt any strategy for culling of animals, killing or disposal of dead animals and their products other potentially contaminated commodities strategy to the transmission pathways of the pathogenic agent. A stamping-out policy is should be the preferred strategy for highly contagious transmissible diseases and for situations where the country or zone was formerly previously free or freedom was impending, while eOther strategies, such as test and cull, are better suited to less contagious transmissible diseases and situations where the disease is endemic.

For control measures, including destruction of *animals* or products other commodities, to be most effective, *animal identification* and *animal traceability* should be in place, in accordance with Chapters 4.1. and 4.2.

The *slaughter* or *killing* of *animals* should be performed in accordance with Chapter 7.5. or Chapter 7.6., respectively.

The disposal of dead *animals* and their other related potentially contaminated products commodities should be performed in accordance with Chapter 4.12.

#### 1. Stamping-out policy

A stamping-out policy consists primarily in of the killing of all the animals affected infected or suspected of being affected infected, including those which that have been directly or indirectly exposed to the causal pathogenic agent. This strategy is used for the most contagious transmissible diseases.

A stamping-out policy can be limited to the affected establishments and, where appropriate, other establishments found to be epidemiologically linked with an affected establishment, or be broadened to include all establishments of a defined zone, when pre-emptive depopulation can be used to stop the transmission of a fast rapidly spreading pathogenic agent.

A stamping-out policy can be applied to all the animal species present on an affected establishment, or to all susceptible species, or only to the same species as the infected animals, based on the assessment of associated risks.

Depopulation and carcass disposal can be applied to wildlife within a defined zone, based on the assessment of associated risks.

## Annex 10 (contd)

*Killing* should preferably be performed on site, and the carcasses either disposed of on site or transported directly and safely to a rendering plant or other dedicated site for destruction. If they are to be killed outside of the establishment or slaughtered, the *animals* should be transported directly to a dedicated *approved* rendering plant or *slaughterhouse/abattoir*, respectively, without avoiding any possible direct or indirect contacts with other *animals*. These slaughtered animals and their products should be processed separately from others.

### EU comment

To improve clarity we suggest adding 'susceptible' in the following sentence of the above paragraph:

'..avoiding any possible direct or indirect contacts with other susceptible animals.'

~~Stamping-out can be applied to all the animal species present on affected premises, or to all susceptible species, or only to the same species as the affected animals.~~

Products originating from killed or slaughtered *animals*, (ranging from carcasses, *meat*, *milk*, *eggs* or genetic material to hair, wool, feathers or manure, slurry) should be destroyed or processed in a way that inactivates the pathogenic agent. The inactivating process should be carried out in accordance with the relevant articles of the listed disease-specific chapters.

Stamping-out policy procedures systematically include the cleaning and *disinfection* of *establishments* and *vehicles/vessels* used for the transport of *animals*, carcasses or products, as well as of any equipment and material that has been in direct or indirect contact with the *animals*. The procedures may include *disinsection* or *disinfestation* in the case of *vector-borne* disease or parasitic *infestation*. These procedures should be conducted in accordance with the relevant articles of Chapter 4.13.14. Where premises cannot be practically disinfected, alternate means of elimination of the causal pathogenic agent, such as extended fallowing periods or composting, may be considered.

## 2. Test and cull

This strategy consists primarily of finding the ~~proven~~ infected *animals* in order to remove them from the population and either *slaughter* or kill and dispose of them. This strategy is ~~it should be used~~ more suitable for less contagious transmissible or slow-spreading diseases. Veterinary Services may apply different test and cull strategies based on the epidemiology of the infection or infestation or on the characteristics of available diagnostic tests. In particular, the design of the test and cull strategy will depend on the sensitivity and specificity of the tests. Veterinary Services may adjust test and cull strategies in response to the changes of in the prevalence.

Apart from the selection of *animals* to be culled, the same principles apply as for a *stamping-out policy* in terms of processing, treatment and disposal of dead or slaughtered *animals* and their products.

Article 4.Y.7.

## Movement control

Disease spread due to the movement of live *animals*, ~~animal products~~ and contaminated material commodities and fomites should be controlled by movement restrictions that are adequately enforced.

These restrictions can be applied to one or more animal species and their associated products commodities, and to different types of fomites (e.g. people, clothing, vehicles/vessels and equipment). They may vary from pre-movement certification to total standstill, and be limited to one ~~or more~~ establishment only or multiple establishments, or cover specific zones, or the entire country. The restrictions can include the complete isolation

of individual *animals* or groups of *animals*, and specific rules may be applied to movements, such as protection from *vectors*.

Specific rules covering movement controls should apply to each of any defined *zones*. Physical barriers should may be installed as needed, to ensure the effective application of movement restrictions.

Movement controls should be in place until the end of other disease control operations, e.g. such as a stamping-out policy, and after surveillance and a revised risk assessment ~~has~~ have demonstrated that they are no longer needed.

When implementing movement control operations, *Veterinary Services* should coordinate their movement control actions with other relevant authorities such as local authorities, and law enforcement agencies, and with communication media, as well as with the Veterinary Services of neighbouring countries in the case of transboundary animal diseases.

Annex 10 (contd)

#### Article 4.Y.8.

##### Zoning

The Veterinary Authority should use the tool of zoning in official control programmes, in accordance with Chapter 4.34.

The use of zoning for disease control and eradication is inherently linked with measures of killing or slaughter, movement control, vaccination, and surveillance, biosecurity and communication, which apply differently according to the zones. In particular, efforts should be concentrated on those parts of a territory affected by the disease, to prevent the spread of the pathogenic agent and to preserve the status of the parts of the territory not affected by the disease.

Zones established in response to outbreaks of listed diseases or emerging diseases are usually infected zones, containment zones and protection zones. However, other types of zones, such as zones where specific surveillance, vaccination or other activities are conducted, can also be used.

#### Article 4.Y.89.

##### Biosecurity

In order to avoid the spread of the pathogenic agent outside of the affected *establishments* or *infected zones*, and in addition to the management measures described in Articles 4.Y.5. to 4.Y.7., *biosecurity* should be applied. In particular measures should be taken to avoid the contamination of people's clothes clothing and shoes, of equipment, of vehicles/vessels, and of the environment or anything capable of acting as a fomite.

Disinfection and disinsection should be applied in accordance with Chapter 4.13. When disinfection is applied, specific disinfectant solutions should be used for footbaths or disinfectant baths for vehicles' wheels. Single-use material and clothes, or material and clothes that can be effectively cleaned and disinfected, should be used for the handling of animals and animal products other commodities. Protection of premises from wildlife and other unwanted animals should be ensured. Wastes, waste-water and other effluents should be collected and treated appropriately.

#### Article 4.Y.910.

##### Vaccination and treatment and treatment

Vaccination as part of an official control programme in response to a contagious disease outbreak should be conducted in accordance with Chapter 4.4718.

Vaccination programmes, especially in response to an outbreak, require previous planning to identify potential sources of vaccine, including vaccine or antigen banks, and to plan determine the possible strategies for application, such as emergency barrier, blanket, vaccination or ring or targeted vaccination.

The properties of the vaccines should be well understood, especially the level of protection against *infection* or disease and the possibility to of differentiate differentiating the immune response produced by the vaccine from

that ~~produced~~ induced by *infection* with the pathogenic agent, or to differentiate differentiating live vaccine strains from field strains.

Although *vaccination* may hide ongoing *infection* or agent transmission of pathogenic agents, it can be used to decrease the shedding of the pathogenic agent, hence reduce reducing the reproductive rate of the *infection*. In particular, when stamping-out is not feasible, *vaccination* can be used to reduce the circulation prevalence of the *infection* until its levels are is low enough for the implementation of another strategies such as a test and cull strategy.

Vaccination can also be used to minimise the impact of an infection by reducing clinical signs or economic losses.

## EU comment

**In the sentence above, when discussing vaccination to reduce economic losses, this should be balanced with the losses due to the impact of vaccination on trade, costs of vaccination, etc. Indeed, while this is addressed in Chapter 4.17., it would be worth stating it also here. The EU therefore suggests amending the sentence as follows:**

**“Vaccination can also be used to minimise the impact of an infection by reducing clinical signs or economic losses, however a cost benefit analysis taking into account other factors, for example those related to trade, cost of vaccination and public health, should be considered.”.**

Whenever *vaccination* is to be used as a tool to control *outbreaks* or spread of disease, the official control programme ~~plan~~ should ~~include~~ consider a cost-benefit analysis with regard to trade and public health and an exit strategy, i.e. when and how to stop the *vaccination* or whether *vaccination* should become systematic routine.

Annex 10 (contd)

Treatment can also be used as part of an official control programme. It would require planning to identify potential sources of veterinary medicinal products, and to plan determine the possible strategies for application and an exit strategy.

Article 4.Y.10.

## Zoning

~~The Veterinary Authority should use the tool of zoning in official control programmes, in accordance with Chapter 4.3.~~

~~The use of zoning for disease control and eradication is inherently linked with measures of killing or slaughter, movement control, vaccination and surveillance, which apply differently according to the zones. In particular, efforts should be concentrated on those parts of a territory affected by the disease, to prevent the spread of the pathogenic agent and to preserve the status of the parts of the territory not affected by the disease.~~

~~Zones established defined in response to outbreaks of notifiable diseases or emerging diseases or listed diseases may be are usually infected zones, containment zones and protection zones, and containment zones. However, or other types of zones, e.g. such as zones of intensified surveillance, or zones of intensified vaccination can also be used.~~

Article 4.Y.11.

## Communication in outbreak management

For the best implementation of disease control measures, *Veterinary Services* should ensure good communication with all concerned stakeholders, including the general public. This should be part of the official control programme and be carried out, among others, through awareness campaigns targeted at breeders animal owners or keepers, veterinarians, veterinary paraprofessionals, local authorities, the media, consumers and the general public.

*Veterinary Services* should communicate before, during and after *outbreaks*, in accordance with Chapter 3.3.

Article 4.Y.12.

#### **Specific post-control surveillance**

Specific *surveillance* should be applied in order to monitor the effectiveness of the official control programme plan, and to assess the status of the ~~remaining~~ *animal populations* in the different *zones* established by the *Veterinary Services*.

The results of this *surveillance* should be used to reassess the measures applied, including reshaping of the *zones* and re-evaluation of the culling or *vaccination* strategies, and for the eventual recovery of free status if possible.

This *surveillance* should be conducted in accordance with Chapter 1.4. and with the relevant articles of the listed *disease-specific* chapters.

Article 4.Y.13.

#### **Further outbreak investigation, monitoring, evaluation and review**

In order to gather information required for any management information system, *Veterinary Services* should conduct an in-depth epidemiological investigation of each *outbreak* to build up a detailed first-hand, field-based knowledge of how the disease is transmitted, and to inform further disease control plans. This requires staff who have been trained in ~~the way to conduct it~~ appropriate methods and in the use of the standardised data collection forms.

Furthermore, feedback from persons involved in the organisation and implementation of official control programmes should be gathered.

The information information gathered and experience gained should be used to monitor, evaluate and review disease the official control programmes plans.

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DRAFT CHAPTER 7.Z.

**ANIMAL WELFARE AND LAYING HEN PRODUCTION  
SYSTEMS**

**EU position**

**The EU thanks the OIE for its work on the revision of this new draft chapter.**

**The EU considers that some of the revisions made by the Ad-hoc group are not fully consistent. The EU finds that there is a need for better correspondence between the indicators and the recommendations in order to ensure good level of animal welfare in line with the guiding principles for animal welfare as described in Article 7.1.2.**

**The EU cannot support the adoption of this modified chapter unless the comments inserted in the text below have been addressed.**

Article 7.Z.1.

**Definitions**

For the purposes of this chapter:

**Laying hens** means sexually mature female birds of the species *Gallus gallus domesticus* kept for the commercial production of eggs for human consumption. Breeding hens are not included.

**End-of-lay hens** means laying hens at the end of their productive lives.

**Layer pullets** means female birds of the species *Gallus gallus domesticus* raised for commercial layer production purposes from hatch until the onset of sexual maturity.

Article 7.Z.2.

**Scope**

This chapter provides recommendations for the animal welfare aspects of commercial laying hen production systems. It covers the production period from the arrival of *day-old birds* onto the pullet-rearing farm through to the removal of end-of-lay hens from the laying production facilities. Laying hens kept in village or backyard flocks and used to produce eggs for personal consumption are not included.

Commercial laying hen production systems involve the confinement of layer pullets and laying hens, the application of *biosecurity* and trade in eggs or pullets.

These recommendations address the welfare aspects of layer pullets or laying hens kept in cage or non-cage systems, whether indoors or outdoors.

Commercial layer pullet or laying hen production systems include:

1. Completely housed systems

Layer pullets or laying hens are completely confined in a poultry house, with or without mechanical environmental control.

2. Partially housed systems

Layer pullets or laying hens are kept in a poultry house with access to a designated outdoor area.

3. Completely outdoor systems

Layer pullets or laying hens are not confined inside a poultry house during the day but are confined in a designated outdoor area.

This chapter should be read in conjunction with Chapters 6.5., 7.1., 7.2., 7.3., 7.4., 7.5. and 7.6. Article 7.Z.3.

**Outcome-based criteria (or measurables) for the welfare of layer pullets and laying hens**

The welfare of layer pullets and laying hens should be assessed using outcome-based criteria or measurables, preferably animal-based measurables, as described in Article 7.1.4. Outcome-based criteria or measurables are particularly useful for evaluating compliance and improving animal welfare. Animal-based outcomes are usually the most sensitive measurables (e.g. mortality rate). However, resource and management-based outcomes can also have important applications (e.g. interpretation of mortality rate data may be informed by decisions made to euthanise). There is no one single measurable that addresses all aspects of animal welfare. The use of measurables and the appropriate thresholds should be adapted to the different situations in which layer pullets and laying hens are kept, also taking into account the genetics used, resources provided, and the design and management of the system. Animal-based criteria or measurables can be considered as tools to monitor and refine these factors.

**EU comment**

**The EU propose the following revision:**

**“Outcome-based criteria or measurables are particularly useful for evaluating compliance and improving animal welfare. Animal-based outcomes are usually the most sensitive measurables (e.g. mortality rate, body condition and plumage condition).”**

**Justification**

**Mortality rate does not have always a direct link only with animal welfare while body condition and plumage condition can also serve as good examples.**

**EU comment**

**The EU would like to ask the OIE to clarify the following sentence:**

**“However, resource and management-based outcomes can also have important applications (e.g. interpretation of mortality rate data may be informed by decisions made to euthanise).”**

**Justification**

**The example doesn't seem to fit with the previous sentence.**

Criteria (or measurables) that can be used at farm level include conditions such as skeletal and foot problems, disease and *infection* or *infestation* that can be assessed during routine or targeted *monitoring*, or at depopulation. It is recommended that target values or thresholds for animal welfare measurables be determined by taking into account current scientific knowledge and appropriate national, sectorial or regional recommendations for layer pullets or laying hens. Determining the age and stage of production at which problems are detected may help to determine the cause.

The following animal-based and outcome-based measurables, in alphabetical order, may be useful indicators of layer pullet or laying hen welfare:

**EU comment**

**The EU proposes to modify the above sentence as follows:**

**“The following animal-based and outcome-based measurables, in alphabetical order, may be considered as useful indicators to ensure that of layer pullet or laying hen experience good welfare as described in Article 7.1.4:”**

**Justification**

**The proposed revision puts more emphasis on the need and usefulness of indicators to ensure good level of welfare for layer pullet or laying hen. Concrete scientific references are available directly in the text after each of the indicators listed below.**

1. Beak condition

Evaluation of beak condition provides useful information about the extent to which layer pullets and laying hens are able to engage in normal behaviour, such as foraging, feeding, drinking and preening [Dennis and Cheng, 2012; Vezzoli *et al.*, 2015]. Tools for assessing beak condition have been developed and implemented in animal welfare assessment programmes [e.g. Kajlich *et al.*, 2016].

**EU comment**

**The EU proposes to add the following additional reference:**

**“Tools for assessing beak condition have been developed and implemented in animal welfare assessment programmes [e.g. Kajlich *et al.*, 2016 and the Welfare Quality assessment protocol for laying hens].”**

**Reference**

<https://library.wur.nl/WebQuery/wurpubs/fulltext/235525>

2. Behaviour

The presence or absence of certain behaviours may indicate either good *animal welfare* or an *animal welfare* problem, such as fear, pain or sickness. Some behaviours may not be uniquely indicative of one type of problem; they may be exhibited for a variety of reasons. *Gallus gallus domesticus* has evolved behaviours that they are motivated to perform and, a good understanding of their normal behaviour [Nicol, 2015], including their social interactions [Estevez *et al.*, 2007; Rodríguez-Aurrekoetxea A. and Estevez I., 2014], is required for appropriate management and decision-making. Opportunities to display these behaviours are influenced by the physical and social environment [Widowski *et al.*, 2016; Lay *et al.*, 2011; O'Connor *et al.*, 2011].

a) Dust bathing

Dust bathing is a complex behaviour providing body maintenance benefits. During dust bathing, layer pullets and laying hens remove loose substrate material, such as litter, through their feathers. This behaviour helps remove stale lipids [van Liere and Bokma, 1987]; which contributes to the maintenance of plumage condition; This helps to regulate body temperature and protect against skin injury. Reduced dust bathing behaviour in the *flock* may indicate problems with substrate or range quality, such as the-substrate or ground being wet or not friable [Olson and Keeling, 2005; Van Liere and Bokma, 1987]. The demonstration of complete sequences of dust bathing may be associated with positive affect [Widowski and Duncan, 2000].

b) Fear behaviour

Fearful layer pullets and laying hens show high reactivity to various stimuli [Jones, 1987; Zeltner and Hirt, 2008] and this may result in traumatic injuries or suffocation if the layer pullets or laying hens pile on top of one another. Fearful layer pullets and laying hens may be less productive [Barnett *et al.*, 1992] and more prone to injurious feather pecking behaviour [de Haas *et al.*, 2014]. Methods have been developed for evaluating fearfulness [Forkman *et al.*, 2007], for example by observing layer pullet and laying hen behaviour when people, including *animal handlers*, walk through the pullet and hen area of the poultry house [Jones, 1996; Waiblinger *et al.* 2006].

## c) Feeding and drinking behaviour

Changes in feeding or drinking behaviour can indicate management problems, including inadequate spaces for, or inappropriate placement of, feeders or drinkers, dietary imbalances, poor feed or water quality, or feed contamination [Garner *et al.*, 2012; Thogerson *et al.*, 2009a; Thogerson *et al.*, 2009b]. Feed and water intake often reduce when pullets or hens are ill. Feed or water intake may also change as a result of heat [Lara L. J. & Rostagno M. H., 2013; Lin H. *et al.*, 2006] or cold [Alves *et al.*, 2012] stress.

## d) Foraging behaviour

Foraging is a motivated behaviour [de Jong *et al.*, 2007, Nicol *et al.*, 2011]. Foraging is the act of searching for food, typically by pecking or scratching the substrate. Reduced foraging activity may suggest problems with substrate quality or the presence of conditions that decrease foraging ability [Appleby *et al.*, 2004; Lay *et al.*, 2011; Weeks and Nicol, 2006]. When in the presence of an adequate substrate, laying hens spend a large amount of time foraging even when food is readily accessible [Weeks and Nicol, 2006].

**EU comment**

**The EU proposes the following revision:**

**“Foraging is a motivated behaviour [de Jong *et al.*, 2007, Nicol *et al.*, 2011]. Foraging is the act of searching for food, typically by alternately scratching and pecking ~~or scratching~~ the substrate. Reduced foraging activity may suggest problems with substrate quality or the presence of conditions that decrease foraging ability [Appleby *et al.*, 2004; Lay *et al.*, 2011; Weeks and Nicol, 2006]. When in the presence of an adequate substrate, laying hens spend a large amount of time foraging even when ~~food~~ feed is readily accessible [Weeks and Nicol, 2006].”**

**Justification**

**Scratching and pecking is considered as normal behaviour.**

**Replacing “food” with “feed” will align the text to the terminology used in other chapters on animal welfare.**

## e) Injurious feather pecking and cannibalism

Injurious feather pecking can result in significant feather loss and lead to cannibalism. Cannibalism is the tearing of the flesh of another layer pullet or lying hen, and can result in severe injury or death. These behaviours can have multifactorial causes and be difficult to control [Nicol, 2018; Hartcher, 2016; Estevez, 2015; Nicol *et al.*, 2013; Rodenburg, 2013; Lambton, 2013; Newberry, 2004].

**EU comment**

**The EU proposes the following revision:**

**“e) Injurious ~~feather~~ pecking and cannibalism**

**Injurious ~~feather~~ pecking can result in significant feather loss and lead to cannibalism. Cannibalism is the tearing of the flesh of another layer pullet or**

**lying hen, and can result in severe injury or death. These behaviours can have multifactorial causes and be difficult to control.”**

### **Justification**

**Feather pecking is not the same, as injurious pecking, as pecking at the feathers is not causing any real harm to the animal. Severe feather pecking can lead to naked areas and subsequently to wounds. In that stage, it is injurious pecking.**

**In science either the wording, ‘feather pecking’ or ‘injurious pecking’ is used.**

#### f) Locomotory and comfort behaviours

Layer pullets and laying hens may display a variety of locomotory and comfort behaviours, including walking, running, leaping, turning, stretching legs and wings, wing flapping, feather ruffling, tail wagging, and preening [Bracke and Hopster, 2006; Harthcher and Jones, 2017; Dawkins and Hardie, 1989; Shipov *et al.*, 2010; Norgaard, 1990]. Some of these behaviours have been shown to be important for skeletal, body and plumage development and maintenance. For example, walking and wing movements contribute to improved leg and wing bone strength [Knowles and Broom, 1990], and preening helps remove stale lipids from the skin [Vezzoli *et al.*, 2015] and keeps the feathers flexible and intact [Shawkey *et al.*, 2003].

#### g) Nesting

Nesting is a motivated behaviour that includes nest site selection, nest formation and egg laying [Cooper and Albentosa, 2003; Weeks and Nicol, 2006; Cronin *et al.*, 2012; Yue and Duncan, 2003]. Uneven nest box utilisation, delayed oviposition, increased pacing and egg laying outside the nest may be indicative of problems with environmental or social behavioural factors [Cronin *et al.*, 2012; Cooper and Appleby, 1996; Gunnarsson *et al.*, 1999; Yue and Duncan, 2003; Widowski *et al.*, 2013].

## EU comment

The EU proposes the following revision:

“Nesting is a highly motivated natural behaviour that includes nest site selection, nest formation and egg laying”

### Justification

Although the Code Commission considered the word *highly* to be ‘subjective and without a clear metric’, in fact, scientific studies demonstrate that nesting is indeed *highly* motivated; it is a *priority behaviour* for laying hens.

Removal of the word *highly* does not accurately reflect the scientific evidence.

It is the fact that nesting is such a *highly* motivated behaviour, that makes it important to include in the code. By simply saying it is a motivated behaviour, the importance is lost, which undermines the reason for its inclusion.

### References

Opinion of the Scientific Panel on Animal Health and Welfare on a request from the Commission related to the welfare aspects of various systems of keeping laying hens. *The EFSA Journal* (2005) 197, 1-23, The welfare aspects of various systems of keeping laying hens. The EFSA report states: “*laying hens have a high behavioural priority to lay their eggs in a nest site that is suitable to them and to perform nest building behaviour.*”

LAYWEL, 2006. Welfare implications of changes in production systems for laying hens. Deliverable 7.1: Overall strengths and weaknesses of each defined housing system for laying hens, and detailing the overall welfare impact of each housing system  
The above *LayWel* report, produced for the European Commission states “*normal nesting is a behavioural priority essential for good laying hen welfare*”.

Weeks, C.A. and Nicol, C.J., 2006. Behavioural needs, priorities and preferences of laying hens. *World's Poultry Science Journal*, 62(2), pp.296-307. This review of multiple studies concluded: “*Access to a nest site is a high-ranking priority for laying hens, preferred over food at this time*”

h) Perching

Perching is a motivated behaviour. Layer pullets and laying hens may seek elevation during the day; however, the motivation to seek elevation is particularly strong at night when pullets and hens select a site for resting or sleeping [EFSA, 2015]. Reduced perching behaviour in the *flock* may indicate problems with environmental factors, injuries or pullet rearing experience [Janczak and Riber, 2015;

### **EU comment**

**The EU proposes the following revision:**

**“Perching is a highly motivated natural behaviour.”**

### **Justification**

**Perching is also a highly motivated behaviour for hens, as demonstrated through scientific research. Removal of the word highly does not accurately reflect the scientific evidence.**

### **References**

**LAYWEL, 2006. Welfare implications of changes in production systems for laying hens.**

**Deliverable 7.1: Overall strengths and weaknesses of each defined housing system for laying hens, and detailing the overall welfare impact of each housing system.**

**The same LayWel report, produced for the European Commission stated that: “perching, dustbathing and foraging are also very important parts of the normal behavioural repertoire.”**

**Olsson, I.A.S. and Keeling, L.J., 2002. The push-door for measuring motivation in hens: laying hens are motivated to perch at night. *Animal welfare*, 11(1), pp.11-19.**

Gunnarsson *et al.*, 1999].

*i)* Resting and sleeping

Sleep is an adaptive state that allows animals to recover from daily stress, conserve energy and consolidate memory [Siegel, 2009]. Layer pullets and laying hens display synchronised resting and sleeping behaviours, which can be disrupted by light intensity, photoperiod, environmental or social factors [Malleau *et al.*, 2007; Alvino *et al.*, 2009].

## Annex 12 (contd)

### j) Social behaviour

Pullets and hens are social and engage in synchronised behaviour [Olsson *et al.*, 2002; Olsson and Keeling, 2005]. Social behaviour may differ according to the characteristics of the social environment [Estevez *et al.*, 2002; 2007]. Problems in social behaviour can be assessed using scoring systems for measuring the degree of damage caused by aggression and competition for resources [Estevez *et al.*, 2002; Blatchford *et al.*, 2016].

### k) Spatial distribution

Uneven spatial distribution of layer pullets and laying hens may indicate fear reactions, thermal discomfort or, uneven availability or use of resources such as light, feed or water, shelter, nesting areas or comfortable resting locations [Rodríguez-Aurrekoetxea and Estevez, 2016; Bright and Johnson, 2011].

### l) Thermoregulatory behaviour

Prolonged or excessive panting and wing spreading are observed during heat stress [Mack, 2013; Lara and Rostagno, 2013]. Indicators of cold stress include feather ruffling, rigid posture, trembling, huddling and distress vocalisations.

### m) Vocalisation

Vocalisation can indicate emotional states, both positive and negative. A good understanding of *flock* vocalisations and their causes is useful for good *animal welfare* [Zimmerman *et al.*, 2000; Bright, 2008; Koshiha *et al.*, 2013].

## 3. Body condition

Poor body condition is reflective of *animal welfare* problems for individual layer pullet and laying hens. At *flock* level, uneven body condition may be an indicator of poor *animal welfare*. Body condition can be evaluated using on-farm sampling methods for body weight or body condition scores [Gregory and Robins, 1998; Craig and Muir, 1996, Elson and Croxall, 2006; Keeling *et al.*, 2003]. The choice of sampling methods should take into account the fact that feather cover can mask actual body condition.

### **EU comment**

#### **The EU proposes the following revision:**

**“Poor body condition is reflective of *animal welfare* problems for individual layer pullet and laying hens. At *flock* level, uneven body condition may be an indicator of poor *animal health and welfare*.”**

#### **Justification**

**Body condition can vary due to health issues such as gastrointestinal or parasitic diseases as well as welfare. Both are interconnected but it is best to mention both to highlight this interconnection.**

## 4. Eye conditions

Conjunctivitis can indicate disease or the presence of irritants such as dust and ammonia. High ammonia levels can also cause corneal burns and eventual blindness. Abnormal eye development can be associated with very low light intensity (<5 lux) [Jenkins *et al.*, 1979; Lewis and Gous, 2009; Prescott *et al.*, 2003].

## 5. Foot problems

Hyperkeratosis, bumblefoot, contact dermatitis, excessive claw growth, broken claws and toe injuries are painful conditions associated with, amongst other things, inappropriate flooring, poorly designed perches,

poorly maintained substrate [EFSA, 2005; Lay *et al.*, 2011; Abrahamsson and Tauson, 1995; Tauson and Abrahamson, 1996; Abrahamsson and Tauson, 1997] and inadequate maintenance of aspects of the production system.

If severe, the foot and hock problems may contribute to locomotion problems and lead to secondary *infections*. Scoring systems for foot problems have been developed [Blatchford *et al.*, 2016].

6. Incidence of diseases, infections, metabolic disorders and infestations

Ill-health, regardless of the cause, is an *animal welfare* concern, and may be exacerbated by poor environmental or husbandry management.

7. Injury rate and severity

Injuries are associated with pain and risk of infection. They can be a consequence of the actions of other pullets and hens (e.g. scratches, feather loss or wounding), management (e.g. nutritional deficits leading to skeletal problems), environmental conditions, (e.g. fractures and keel bone deformation), genetics used or human intervention (e.g. during handling and catching). It is important to assess both the rate and severity of injuries.

8. Mortality, culling and morbidity rates

Daily, weekly and cumulative mortality, culling and morbidity rates should be within expected ranges. Any unforeseen increase in these rates may reflect an *animal welfare* problem. Recording and evaluating causes of morbidity and mortality can be useful aids in diagnosing and remediating *animal welfare* problems.

**EU comment**

**The EU proposes the following revision:**

**“Daily, weekly and cumulative mortality, culling and morbidity rates should be within expected ranges. Any unforeseen increase in these rates may reflect an *animal health and welfare problem.*”**

**Justification**

**Increase in mortality can be the result of health issues, such as infectious disease, as well as welfare. Both are interconnected but it is best to mention both to highlight this interconnection.**

9. Performance indicators

Daily, weekly and cumulative performance should be within expected ranges. Any unforeseen reduction in these rates may reflect an *animal welfare* problem. Types of measures that can be used include:

- a) pullet growth rate, which measures average daily mass gain per pullet and *flock* uniformity;
- b) pullet feed conversion, which measures the quantity of feed consumed by a *flock* relative to the total live mass produced, expressed as the mass of feed consumed per unit of body mass;
- c) hen feed conversion, which measures quantity of feed consumed by a *flock* relative to the unit of egg production;
- d) egg production, which measures the number and size of eggs per hen housed;
- e) egg quality and downgrades, which can be measured by, for example, grade percentage, shell strength, Haugh units, abnormalities and mis-laid or floor eggs;

10. Plumage condition

Evaluation of plumage condition provides useful information about aspects of *animal welfare* in terms of feather pecking and cannibalism, ability to thermoregulate, illness, and protection from injury [Rodriguez-Aurrekoetxea and Estevez, 2016; Drake *et al.*, 2010]. Dirty plumage may be associated with illness, environmental conditions or the layer pullet and laying hen housing system.-Plumage cover and cleanliness scoring systems have been developed for these purposes [Blokhuys, 2007; Blatchford *et al.*, 2016].

11. Water and feed consumption

Monitoring and evaluating daily water and feed consumption is a useful tool which may indicate thermal stress, disease, *infection* or *infestation* and other welfare conditions, taking into consideration ambient

temperature, relative humidity and other related factors. Changes in intake, crowding at feeders and drinkers and wet substrate may be associated with problems with the quality or supply of water, or feed.

Article 7.Z.4.

#### **Recommendations for layer pullets and laying hens**

Ensuring good welfare of layer pullets and laying hens is contingent upon several management factors, such as system design, environmental management practices, and animal management practices including responsible husbandry and provision of appropriate care, and the genetics used. Serious problems can arise in any system if one or more of these elements are lacking. Although pullets and hens 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.

Articles 7.Z.5. to 7.Z.29. provide recommendations for layer pullets and laying hens.

Each recommendation includes a list of relevant outcome-based criteria or measurables derived from Article 7.Z.3. and when appropriate other criteria or measurables. The suitability of some of these criteria or measurables should be determined in accordance with the system in which the pullets and hens are housed.

Annex 12 (contd)

Article 7.Z.5.

#### **Location, design, construction and equipment of establishments**

The location of layer pullet and laying hen *establishments* should be safe from the effects of fires and floods and other natural disasters to the extent practicable. In addition, *establishments* should be located or designed to avoid or minimise disease risks and exposure of layer pullets and laying hens to chemical and physical contaminants, noise and adverse climatic conditions.

Good welfare outcomes for layer pullets and laying hens can be achieved in a range of housing systems. Houses, outdoor areas and accessible equipment should be designed after considering the opportunities for layer pullets and laying hens to perform motivated behaviours as well as health, environmental factors, and animal management capability.

#### **EU comment**

**The EU proposes to modify the above sentence as follows:**

**“In any case, hHouses, outdoor areas and accessible equipment should be designed after considering the opportunities for layer pullets and laying hens to perform motivated behaviours as described in Article 7.Z.3.2. as well as health, environmental factors, and animal management capability.”**

#### **Justification**

**Including a reference will make more concrete which behaviours are meant.**

**Housing systems for hens differ in the possibilities for hens to show species specific behaviors such as foraging, dust-bathing, perching and building or selecting a suitable nest. If hens cannot perform such priority behaviors, this may result in significant frustration, or deprivation or injury, which is detrimental to their welfare.**

#### **References**

**Point 8.5.1. Cage Systems (p. 69) of EFSA Scientific Opinion on the welfare aspects of various systems of keeping laying hens**

**<http://www.efsa.europa.eu/en/efsajournal/pub/197>**

**“Within FCs, increased spatial allowance, from 750cm<sup>2</sup> to 3000cm<sup>2</sup> per bird, allows increased performance of comfort activities such as tail-wagging and wing/leg stretching, and also increased locomotion.” (Albentosa and Cooper, 2004)**

They should also be maintained to avoid injury or discomfort. Pullet and hen houses should be constructed with materials, electrical and fuel installations that minimise the risk of fire and other hazards, and are easy to clean and maintain. Producers should have a maintenance programme in place, including record-keeping for all equipment and contingency plans to address failures that could jeopardise layer pullets and laying hens welfare.

Outcome-based measurables include: body condition, culling and morbidity rates, fear behaviour, feeding and drinking behaviour, foot problems, foraging behaviour, incidence of diseases, *infections* and *infestations*, injury rates and severity, locomotory and comfort behaviours, mortality rates, performance indicators, plumage condition, resting and sleeping, social behaviour and spatial distribution, thermoregulatory behaviour and vocalisations.

### **EU comment**

**The EU proposes to add “dustbathing, nesting and perching” to this list of outcome-based measurables.**

### **Justification**

**For consistent with other sections of the chapter.**

**These behaviours are rightly included in the list of outcome-based measurables in Article 7.Z.3.2, and are described as motivated behaviours, which are referred to as considerations in the second para of 7.Z.5. They are therefore highly relevant for inclusion here and it is strange to omit them.**

Article 7.Z.6.

### **Matching the layer pullets and laying hens with the housing and production system**

*Animal welfare* and health considerations should balance any decisions on performance when choosing the genetics to be used for a particular location, housing and production system. The pullet rearing system should pre-adapt the bird for the intended production system [Aerni *et al.*, 2005].

Outcome-based measurables include: dust bathing, feeding, and drinking behaviours, foraging behaviour, incidence of diseases, *infections* and *infestations*, injurious feather pecking and cannibalism, injury rate and severity, locomotory and comfort behaviours, mortality rate, nesting, perching, performance indicators, plumage condition, resting and sleeping, social behaviour, and spatial distribution.

Article 7.Z.7.

### **Space allowance**

Layer pullets and laying hens should be housed with a space allowance that allows them to have adequate access to resources and to adopt normal postures. Providing sufficient space for the expression of locomotory and comfort behaviours that contribute to good musculoskeletal health and plumage condition is desirable.

### **EU comment**

**The EU would like to reiterate once again the key issue of space allowance and to ask the OIE to take into account the following revision:**

**"Layer pullets and laying hens should be housed with a space allowance that allows them to have adequate access to resources, and to adopt normal postures and to express locomotory and comfort behaviours. Providing sufficient space for the expression of locomotory and comfort behaviours, contributing that contribute to good**

**musculoskeletal health and plumage condition is desirable important.”**

#### **Justification**

**Considering the substantive scientific evidence, supporting that insufficient space allowance impairs hens to express priority behaviours the EU proposes to replace “desirable” with “important”. It is always necessary to provide sufficient space for the expression of (species specific) locomotory and comfort behaviours and this should not be restricted to behaviours that contribute to good musculoskeletal health and plumage condition. (The behaviours may however contribute to good musculoskeletal health and plumage condition).**

#### **References**

**Opinion of the scientific panel on animal health and welfare on a request from the Commission related to the welfare aspects of various systems of keeping laying hens" (Question N EFSA-Q-2003-092) EFSA Journal (2005) 197, 1-23,**

**Report of the Scientific Veterinary Committee, Animal Welfare Section on the Welfare of Laying Hens, Brussels, 30 October 1996.**

Problems with space allowance may increase stress and the occurrence of injuries.

#### **EU comment**

**The EU propose the following revision:**

**“Problems with space allowance may increase stress and the occurrence of injuries injurious pecking.”**

#### **Justification**

**Less available space may not lead to increase of occurrence of injuries like bone fractures, but may surely increase injurious pecking if there is too little space.**

#### **Reference**

**Jung, L. and U. Knierim (2018). “Are practice recommendations for the prevention of feather pecking in laying hens in non-cage systems in line with the results of experimental and epidemiological studies?” Applied Animal Behaviour Science 200: 1-12.**

**This paper sums up all references that found relations between feather pecking and management factors. For rearing there are a number of references proofing that lower stocking density reduces the incidence of injurious pecking (although for the laying period there actually are only papers advising lower stocking densities, but without hard proof).**

**Bestman, M., et al. (2009). "Influence of farm factors on the occurrence of feather pecking in organic reared hens and their predictability for feather pecking in the laying period." Applied Animal Behaviour Science 121(2): 120-125 found a strong relation between injurious pecking during rear with injurious pecking in the laying period, so if**

**lower stocking density in rear would reduce injurious pecking, it should be beneficial for lower levels of injurious pecking in the laying period as well.**

**Cooper, J. J. and M. J. Albentosa (2004). Social space for laying hens. Welfare of the Laying Hen. G. Perry, CABI Publishing. 27: 191-202. Indicate that lower stocking densities are beneficial for the welfare of hens in cages/colony systems**

The following factors, in alphabetical order, should be considered when determining space allowance:

- age and mass of layer pullets and laying hens,
- ambient conditions,
- *biosecurity* strategy,
- equipment selection,
- feed and watering systems,

- flooring substrate,
- genetics,
- housing design,
- management capabilities,
- production system,
- usable space,
- ventilation.

Outcome-based measurables include: dust bathing, feeding and drinking behaviour, foraging behaviour, incidence of diseases, *infections* and *infestations*, injury rate and severity, locomotory and comfort behaviours, mortality rate, nesting, perching, performance indicators, plumage condition, resting and sleeping, social behaviour, and spatial distribution.

Article 7.Z.8.

**Nutrition**

Layer pullets and laying hens should always be fed a diet appropriate to their age, production stage and genetics. The form of the feed should be acceptable to the layer pullets and laying hens and contain adequate nutrients to meet requirements for good *animal welfare* and health. Feed and water should be free from contaminants, debris and microorganisms or other potential *hazards*.

The feeding and watering systems should be inspected regularly and cleaned as needed, to prevent the growth of hazardous microorganisms.

Layer pullets and laying hens should be provided with adequate access to feed on a daily basis. Water should be continuously available except under veterinary advice. Special provisions should be made to enable newly hatched pullets to access appropriate feed and water.

Outcome-based measurables include: body condition, foraging behaviour, incidence of disease, *infections* and *infestations*, injurious feather pecking, injury rate and severity, metabolic disorders, mortality rate, performance, plumage condition, vocalisations and water and feed consumption.

Article 7.Z.9.

**Flooring**

The slope, design and construction of the floors should provide adequate support for the locomotion of layer pullets and laying hens, prevent injuries, and entrapments, ensure good health and allow the performance of normal behaviour. Changes of flooring types from pullet to hen housing should be avoided. Manure contamination from other layer pullets and laying hens within the house should be minimised through appropriate floor design and other elements of system design. The flooring should be easy to clean and disinfect.

**EU comment**

**The EU proposes the following revision:**

**“The slope, design and construction of the floors should provide adequate support for the locomotion of layer pullets and laying hens, prevent injuries, and entrapments, ensure good health and allow the performance of normal behaviours. Changes of flooring types from pullet to hen housing should be avoided. Manure contamination**

from other layer pullets and laying hens within the house should be minimised through appropriate floor design and other elements of system design as well as management.”

#### Justification

Not only design of the floor/system can be important for reducing the contamination with manure, also sufficient loose and dry litter can fulfil an important role in limiting the contact with manure (on the floor).

From practical experience, it is clear that if there is too little litter (at start of lay), there will be too little litter to absorb the moist from the manure.

When litter is provided, it should be managed to remain dry and friable, and adequately treated or replaced when required to prevent *diseases* and minimise any detrimental effects on *animal welfare*.

#### EU comment

The EU proposes to add a new sentence and then to modify the above sentence as follows:

**“Litter should be provided to enable the expression of behaviours as described in Article 7.Z.3.2.**

**~~When The litter is provided,~~ it should be managed to remain dry and friable, and adequately treated or replaced when required to prevent *diseases* and minimise any detrimental effects on *animal health and welfare*”.**

#### Justification

The litter allow dust bathing and some other motivated behaviours such as foraging, pecking and scratching as already described in Article 7.Z.3.2. Litter can cause gastrointestinal issues as well as act as a fomite and have an impact on both health and welfare. Both are interconnected but it is best to mention both to highlight this interconnection.

#### References

EFSA Journal (2005) 197, 1-23. The welfare aspects of various systems of keeping laying hens

De Jong, I.C. and Blokhuis, H.J. The welfare of laying hens, Proceedings of the XII European Poultry Conference, Verona, Italy, 12-14 sept 2006

Hens are highly motivated to access litter for dust bathing, and showed very strong preference of hens for dust bathing in peat moss (there was no preference to stay on a certain substrate in general, but the efforts and the total expenditure to take a dust bath in peat moss were high).

De Jong *et al.* (2007), Applied Animal Behaviour Science 104 (2007) 24-36.

Matthews, L.R., Temple, W., Foster, T.M., Walker, A.W., McAdie, T.M., 1995. Comparison of the demand for dustbathing substrates by layer hens. In: Rutter, S.M., Rushen, J., Randle, H.D., Eddison, J.C. (Eds.), Proceedings of the 29<sup>th</sup> International Congress of the ISAE, Conference Universities' Federation of Animal Welfare, Exeter, pp. 11–12.

“Hens have been found to work for access to a range of additional resources including pecking, scratching and dust bathing substrates, perches (particularly prior to

nightfall), additional space and nestboxes.” And: “Modified or enriched cages allow for these activities, as well as perching, and, potentially dust bathing, but do not allow full expression of exploratory or comfort behaviours. Free-range systems, percherics and other types of colony housing provide opportunities for all of the above, although at high stocking densities social competition and limited space may restrict performance of these behaviours for certain birds.”

**Cooper, J.J., Albentosa, M.J., 2003. Behavioural priorities of laying hens. Avian Poultry Biol. Rev. 14, 127–149.**

Outcome-based measurables include: dust bathing, foot problems, foraging behaviour, incidence of diseases, *infections* and *infestations*, injury rate and severity, locomotory and comfort behaviours, performance, plumage condition and, resting and sleeping.

Article 7.Z.10.

**Dust bathing areas**

Access to friable, dry substrate to encourage dust bathing is desirable. When provided, dust bathing areas should be designed and positioned to encourage dust bathing, allow synchronised behaviour, prevent undue competition and not cause damage or injuries.

Dust bathing areas should be easy to inspect and maintain [Weeks and Nicol, 2006].

Outcome-based measurables include: dust bathing, incidence of diseases, *infections* and *infestations*, injury rate and severity, plumage condition and spatial distribution.

Article 7.Z.11.

**Foraging areas**

Access to substrate that encourages foraging behaviour activity is desirable. When provided, foraging areas should be designed and positioned to encourage synchronised behaviour, prevent undue competition and not cause damage or injuries.

**EU comment**

**The EU proposes to modify the above sentence as follows:**

**“Access to substrate that encourages foraging behaviour activity ~~is desirable~~ should be provided as it allows freedom to express normal patterns of behaviour as described in Chapter 7.1., Article 7.1.2. ~~When provided,~~ Foraging areas should be designed and positioned to encourage synchronised behaviour, prevent undue competition and not cause damage or injuries.”**

**Justification and reference as above:**

**DAWKINS, M. S. 1989. TIME BUDGETS IN RED JUNGLEFOWL AS A BASELINE FOR THE ASSESSMENT OF WELFARE IN DOMESTIC-FOWL. Applied Animal Behaviour Science, 24, 77-80**

Foraging areas should be easy to inspect and maintain.

Outcome-based measurables include: foraging behaviour, incidence of diseases, *infections* and *infestations*, injurious feather pecking and cannibalism, injury rate and severity and spatial distribution.

Article 7.Z.12.

**Nesting areas**

nesting areas is desirable. When provided nesting areas should be built of suitable materials, and designed and positioned to encourage nesting, prevent undue competition and not cause damage or injuries.

**EU comment**

**The EU proposes to modify the above sentence as follows:**

**“~~Nesting areas is desirable~~ should be provided as they allow freedom to express normal patterns of behaviour as described in Chapter 7.1., Article 7.1.2. ~~When provided~~ Nesting areas should be built of suitable materials, and designed and positioned to encourage**

nesting, prevent undue competition and not cause damage or injuries.”

#### Justification

Hens deprived of nests show higher levels of corticosterone and signs of stress than hens with access. Therefore, providing adequate numbers of nesting areas is deemed relevant in that context.

#### References

EFSA Scientific Opinion on the welfare aspects of various systems of keeping laying hens <http://www.efsa.europa.eu/en/efsajournal/pub/197>

Cooper, J. J., & Appleby, M. C. (1995). Nesting behaviour of hens: effects of experience on motivation. *Applied Animal Behaviour Science*, 42(4), 283-295.

Kruschwitz, A., Zupan, M., Buchwalder, T., & Huber-Eicher, B. (2008). Nest preference of laying hens (*Gallus gallus domesticus*) and their motivation to exert themselves to gain nest access. *Applied animal behaviour science*, 112(3), 321-330.

Alm, M., Tauson, R., Holm, L., Wichman, A., Kalliokoski, O., & Wall, H. (2016). Welfare indicators in laying hens in relation to nest exclusion. *Poultry science*, 95(6), 1238-1247.

COOPER, J. J. & APPLEBY, M. C. 2003. The value of environmental resources to domestic hens: A comparison of the work-rate for food and for nests as a function of time. *Animal Welfare*, 12, 39-52.

Nesting areas should be easy to inspect, clean and maintain.

Outcome-based measurables include: incidence of diseases, *infections* and *infestations*, injurious feather pecking and cannibalism, injury rate and severity, nesting, performance (mis-laid or floor eggs), and spatial distribution.

Article 7.Z.13.

#### Perches

Access to perches is desirable. When provided perches should be built of suitable materials, designed, elevated and positioned to encourage perching by all layer pullets and laying hens, prevent undue competition, minimise keel bone deformation, foot problems or other injuries, and to ensure stability during perching. In the absence of designated perches, other structures such as platforms, grids or slats that are perceived by the pullets and hens as elevated and that do not cause damage or injuries, may be a suitable alternative. When provided, perches or their alternatives should be made available from an early age, be easy to clean and maintain, and be positioned to minimise faecal fouling [Hester, 2014; EFSA, 2015].

#### EU comment

The EU proposes to modify the above sentence as follows:

**“Access to perches is ~~desirable~~. should be provided as they allow freedom to express normal patterns of behaviour as described in Chapter 7.1., Article 7.1.2. ~~When provided~~ Perches should be built of suitable materials, designed, elevated and positioned to encourage perching by all layer pullets and laying hens, prevent undue competition, minimise keel bone deformation, foot problems or other injuries, and to ensure stability during perching. In the absence of designated perches, other structures such as platforms, grids or slats that are perceived by the pullets and hens as elevated and that do not cause damage or injuries, may be a suitable alternative. ~~When provided,~~ Perches or their alternatives should be made available from an early age, be easy to clean and**

maintain, and be positioned to minimise faecal fouling [Hester, 2014; EFSA, 2015]”.

#### **Justification**

Resting and perching are important aspects of pullet and hen welfare. Perch design and hygiene are important to avoid damage to the foot pad. All pullets and hens should be able to perch at the same time.

Scientific evidence exist demonstrating work how perches should be positioned to reduce the risk of keel bone problems, pecking and aid navigation.

Further, the change to ‘desirable’ is inconsistent with other guidance in the Chapter: Art 7.Z.5 recognises that “Houses, outdoor areas and accessible equipment should be designed after considering the opportunities for layer pullets and laying hens to perform motivated behaviours”

Nesting and perching are recognised as motivated behaviours. It is therefore appropriate that the Chapter maintains the wording that they should be provided.

#### **References**

EFSA Scientific Opinion on the welfare aspects of various systems of keeping laying hens <http://www.efsa.europa.eu/en/efsajournal/pub/197>

The EFSA report states: “laying hens have a high behavioural priority to lay their eggs in a nest site that is suitable to them and to perform nest building behaviour.”

The report’s recommendations reflect the importance they attach to certain key behaviours. The recommendations include:

“Housing systems should provide the possibility for hens to carry out activities which are behavioural priorities.

An adequate number of discrete enclosed individual or group nests should be provided.

They should be placed so that birds can easily gain access to them.

Litter appropriate for foraging and dust-bathing should be provided in all systems and should be managed in such a way that it is friable and is readily accessible to all birds.

Perch material, design and position should be an important consideration when selecting a housing system for laying hens. Perches should be raised above the level of the floor.”

EFSA Scientific Opinion Scientific Opinion on welfare aspects of the use of perches for laying hens <https://www.efsa.europa.eu/en/efsajournal/pub/4131>

Appleby, Michael C., and Barry O. Hughes. “Welfare of laying hens in cages and alternative systems: environmental, physical and behavioural aspects.” *World’s Poultry Science Journal* 47.2 (1991): 109-128. This paper states “Foot and claw damage are often a major problem in cages, with lesions, fissures and hyperkeratosis on the feet and with twisted, broken or overgrown claws (Tauson, 1980). These problems are affected by the thickness of the floor wire [...]”.

**LAYWEL, 2006. Welfare implications of changes in production systems for laying hens. Deliverable 7.1: Overall strengths and weaknesses of each defined housing system for laying hens, and detailing the overall welfare impact of each housing system**  
The above LayWel report, produced for the European Commission states “normal nesting is a behavioural priority essential for good laying hen welfare”.

The same LayWel report, produced for the European Commission states that: “perching, dustbathing and foraging are also very important parts of the normal behavioural repertoire.”

Weeks, C.A. and Nicol, C.J., 2006. Behavioural needs, priorities and preferences of laying hens. *World's Poultry Science Journal*, 62(2), pp.296-307. This review of multiple studies concluded: “Access to a nest site is a high-ranking priority for laying hens, preferred over food at this time.”

OLSSON, I. A. S. & KEELING, L. J. 2000. Night-time roosting in laying hens and the effect of thwarting access to perches. *Applied Animal Behaviour Science*, 68, 243-256.

Donaldson, C. J. and N. E. O’Connell (2012). "The influence of access to aerial perches on fearfulness, social behaviour and production parameters in free-range laying hens." *Applied Animal Behaviour Science* 142(1-2): 51-60.

Outcome-based measurables include: foot problems, injurious feather pecking and cannibalism, injury rate and severity, perching, plumage condition, resting and sleeping and spatial distribution.

## **EU comment**

**EU to add the following:**

“Outcome-based measurables include: foot problems, injurious feather pecking and cannibalism, injury rate and severity (e.g. keel bone damages), perching, plumage condition, resting and sleeping and spatial distribution.”

## **References:**

(Riber et al., 2018) Riber, A.B., Casey-Trott, T.M., Herskin, M.S., 2018. The Influence of Keel Bone Damage on Welfare of Laying Hens. *Front. Vet. Sci.* 5. <https://doi.org/10.3389/fvets.2018.00006>

(Djukic-Stojcic et al., 2017) Djukic-Stojcic, M., Peric, L., Relic, R., Bozickovic, I., Rodic, V., Rezar, V., 2017. Keel bone damage in laying hens reared in different production systems in Serbia. *Biotechnol. Anim. Husband.* 33, 487–492. <https://doi.org/10.2298/BAH1704487D>

(Harlander-Matauschek et al., 2015) Harlander-Matauschek, A., Rodenburg, T.B., Sandilands, V., Tobalske, B.W., Toscano, M.J., 2015. Causes of keel bone damage and their solutions in laying hens. *Worlds Poult. Sci. J.* 71, 461–472. <https://doi.org/10.1017/S0043933915002135>

### Outdoor areas

Layer pullets and laying hens may be given access to outdoor areas when they have sufficient feather cover and can range safely. Where pullets and hens are partially housed, there should be sufficient appropriately designed openings to allow them to leave and re-enter the poultry house freely.

Management of outdoor areas is important. Land and pasture management measures should be taken to reduce the risk of layer pullets and laying hens becoming infected by pathogenic agents or infested by parasites or being injured. This may include limiting the stocking density or using several pieces of land consecutively in rotation.

Annex 12 (contd)

Outdoor areas should be located on well-drained ground and managed to minimise stagnant water and mud. The outdoor area should be able to contain the layer pullets and laying hens and prevent them from escaping. Outdoor areas should be designed, built and maintained to allow layer pullets and laying hens to feel safe outdoors and to encourage them to utilise the range optimally, while mitigating predation, disease risks, and adverse climatic conditions [Gilani *et al.*, 2014; Hegelund *et al.*, 2005; Nagle and Glatz, 2012].

### EU comment

**The EU proposes the following revision:**

**“Outdoor areas should be located on well-drained ground and managed to minimise stagnant water and mud. The outdoor area should be able to contain the layer pullets and laying hens and prevent them from escaping. Outdoor areas should be designed, built and maintained to allow layer pullets and laying hens to feel safe outdoors via sufficient cover for the birds and to encourage them to utilise the range optimally, while mitigating predation, disease risks, and adverse climatic conditions.”**

### Justification

**Gilani, A. M., et al. (2014). "Factors affecting ranging behaviour in young and adult laying hens." British Poultry Science 55(2): 127-135.**

**More birds ranged away from the house when cover and more artificial structures were present on the range.**

Pullets and hens should be habituated early to the outdoor area [Rodriguez–Aurrekoetxea and Estevez, 2016]. Outdoor areas should be free from harmful plants and contaminants.

Outcome-based measurables include: fear behaviour, foot problems, foraging behaviour, incidence of diseases, *infections* and *infestations*, injury rate and severity, locomotory and comfort behaviours, morbidity and mortality rates, performance, plumage condition, social behaviour, spatial distribution, thermoregulatory behaviour, and vocalisation.

### EU comment

**The EU would like to ask the OIE to further clarify or specify the meaning of “performance” as Article 7.z.16 refers to performance indicators. Clarity on whether these mean the same or different things would be helpful.**

### **Justification**

**As this is a chapter focused on laying hens some might interpret this as egg laying performance, however it would be best to clarify if this is the case or whether other performance indicators are included.**

Article 7.Z.15.

### **Thermal environment**

Thermal conditions for layer pullets and laying hens should be maintained within a range that is appropriate for their stage of life and the genetics used; extremes heat, humidity and cold should be avoided. A heat index can assist in identifying the thermal comfort zones for layer pullets and laying hens at varying temperatures, air velocities and relative humidity levels [Xin and Harmon, 1998], and can be found in management guidelines provided by laying hen genetics companies.

When environmental conditions move outside of these zones, strategies should be used to mitigate the adverse effects on the layer pullets and laying hens. These may include adjusting air speed, provision of heat or evaporative cooling [Yahav, 2009].

The thermal environment should be monitored regularly so that failure of the system can be detected and corrected before they cause *animal welfare* problem.

Outcome-based measurables include: morbidity rate, mortality rate, performance, spatial distribution, temperature and humidity, thermoregulatory behaviours and water and feed consumption.

Article 7.Z.16.

### **Air quality**

Ventilation, housing, space allowance and manure management can affect air quality.

### **AT comment**

Actions are required to maintain air quality at levels required for good *animal welfare*, including the removal or mitigation of noxious gases such as carbon dioxide and ammonia, dust and excess moisture in the environment.

Ammonia concentrations should not routinely exceed 25 ppm at layer pullet and laying hen level [David *et al.*, 2015; Miles *et al.*, 2006; Olanrewaiu, 2007].

Dust levels should be kept to a minimum [David *et al.*, 2015].

Outcome-based measurables include: ammonia level, carbon dioxide level, dust level, eye conditions, incidence of diseases, *infections*, metabolic disorders and *infestations*, morbidity and mortality rates, plumage condition, performance indicators, temperature and humidity and thermoregulatory behaviours.

Article 7.Z.17.

### **Lighting**

There should be an adequate period of continuous light. The light intensity during the light period should be sufficient and homogeneously distributed to promote normal development, allow layer pullets and laying hens to find feed and water, to stimulate activity, to stimulate onset of lay, minimise the likelihood of feather pecking and

cannibalism, and to allow adequate inspection [Prescott *et al.*, 2003; Prescott and Wathes, 1999; Green *et al.*, 2000].

#### **EU comment**

**The EU proposes to the following revision:**

**“There should be an adequate period of continuous light. The light intensity during the light period should be sufficient and homogeneously distributed to promote normal development, allow layer pullets and laying hens to find feed and water, to stimulate activity, to stimulate onset of lay, minimise the likelihood of injurious feather pecking and cannibalism, and to allow adequate inspection.”**

#### **Justification**

**Consistency with terminology across the rest of the chapter and previous comments.**

#### Annex 12 (contd)

There should also be an adequate period of ~~light and~~ darkness during each 24-hour cycle to allow layer pullets and laying hens to rest and sleep, to reduce stress and promote circadian rhythms [Malleau *et al.*, 2007].

Changes in lighting should occur gradually or in a step-wise fashion, as needed, except during induced moulting when rapid adjustments to lighting should be considered [Tanaka and Hurnik, 1990; Kristenson, 2008].

Outcome-based measurables include: eye conditions, injurious feather pecking and cannibalism, injury rate and severity, locomotory behaviour, nesting, perching, performance, plumage condition, resting and sleeping and spatial distribution.

Article 7.Z.18.

#### **Noise**

Although layer pullets and laying hens can adapt to different levels and types of noise, exposure of layer pullets and laying hens to unfamiliar noises, particularly those that are sudden or loud, should be minimised to prevent stress and fear reactions, such as piling up [Bright and Johnson, 2001]. Ventilation fans, machinery and other indoor or outdoor equipment should be constructed, placed, operated and maintained in such a way as to causes the least possible amount of noise [Chloupek *et al.*, 2009].

Location of *establishments* should, where possible, consider existing local sources of noise. Strategies should be implemented to acclimatise the layer pullets and laying hens to the conditions [Candland *et al.*, 1963; Morris, 2009].

Outcome-based measurables include: fear behaviours, injury rate and severity, mortality rate, performance indicators, resting and sleeping, and vocalisation.

Article 7.Z.19.

#### **Prevention and control of injurious feather pecking and cannibalism**

Injurious feather pecking and cannibalism are challenges in pullet and hen production systems.

Management methods that may reduce the risk of occurrence include:

- adapting the diet and form of feed during rearing and lay [Lambton *et al.*, 2010],

#### **EU comment**

**The EU proposes the following revision:**

**“adapting the diet and form of feed during rearing and lay, but avoiding abrupt changes in composition,”**

### **Justification**

**Each change in food composition is a risk for injurious pecking.**

### **References**

**Gilani, A.-M., et al. (2013). "The effect of rearing environment on feather pecking in young and adult laying hens." *Applied Animal Behaviour Science* 148(1–2): 54-63**

**Conclusions (part): The analysis further indicated that ... feather pecking increased with an increasing number of diet changes during rear.**

- choosing genetics with a low propensity for injurious feather pecking [Craig and Muir, 1996; Kjaer and Hocking, 2004],
- increasing age at onset of lay [Pöttsch, 2001],
- increasing space allowance during rearing [Jung and Knierim, 2018],
- managing light during rearing and lay [Nicol *et al.*, 2013; van Niekerk *et al.*, 2013],
- minimising fear-related stimuli [Uitdehaag K. A. *et al.*, 2009],
- providing elevated perches during rearing and lay [Green *et al.*, 2000],
- providing foraging or other manipulable materials during rearing and lay [Huber-Eicher and Wechsler, 1998; de Jong *et al.*, 2010; Daigle *et al.*, 2014; Dixon *et al.*, 2010; Nicol, 2018],
- reducing group size during rearing and lay [Bilcik and Keeling, 1999].

### **EU comment**

**The EU proposes to add the following:**

**“- managing the transition from rearing to laying house by matching conditions as far as possible.”**

### **Justification**

**This is a high risk period for stress and the onset of feather pecking behaviour and the transition should be kept as smooth as possible.**

**It also noted letting them out to the range as early as possible. As the section notes perches i.e. indoor housing, it would be appropriate to mention outdoor measures.**

### **References**

**Christine Nicols looked at all the management strategies to aid the prevention of IP. <https://www.researchgate.net/publication/265641215> The prevention and control of feather pecking Application to commercial systems**

Management methods should be implemented, where applicable, and in the event of injury affected layer pullets and laying hens should be promptly removed and treated or euthanased.

If these management methods are unsuccessful, partial beak removal [Gentle *et al.*, 1997], may be considered as a final course of action.

Outcome-based measurables include: injurious feather pecking and cannibalism, injury rate and severity, mortality and culling rate, plumage condition, and vocalisation.

### **EU comment**

**The EU proposes to add “foraging behaviour” to the outcome-based measurables.**

### **Justification**

**As this article is on the prevention and control of injurious feather pecking, it is logical to include monitoring of foraging behaviour as it is such a key prevention strategy (and is listed as one of the management strategies).**

## Article 7.Z.20.

**Moulting**

Induced moulting can lead to *animal welfare* problems if not well managed [Nicol *et al.*, 2017; Sariozkan *et al.*, 2016; Holt, 2003, Ricke, 2003, Webster, 2003]. When induced moulting is practised, methods that do not involve withdrawal of feed and are consistent with Article 7.Z.8. should be used. Laying hens should have access to light and to water at all times [Anderson, 2015]. Only laying hens in good body condition and health should be moulted. During the moulting period, loss of body mass should not compromise the laying hen welfare, including welfare during the subsequent laying period. Total mortality and culling rates during the moult period should not exceed normal variations in *flock* mortality and culling rate.

**EU comment**

**The EU proposes the following revision:**

**“Laying hens should have access to light and to water at all times.”**

**Justification****Grammatical correction.**

Outcome-based measurables include: body condition, feeding and drinking, foraging behaviour [Biggs *et al.*, 2004; Saiozkan *et al.*, 2016; Petek and Alpaly, 2008], injurious feather pecking and cannibalism, injury rate and severity, morbidity rate, mortality and culling rate, performance, plumage condition, and social behaviour.

## Article 7.Z.21.

**Painful procedures**

Painful procedures should not be practised unless necessary and should be performed in such a way as to minimise any pain, distress and suffering. If used, partial beak removal should be carried out at the earliest age possible and care should be taken to remove the minimum amount of beak necessary using a method that minimises pain and controls bleeding. If management methods to control injurious feather pecking and cannibalism are not successful, therapeutic partial beak removal may be considered as a final course of action [Gentle *et al.*, 1991; Marchand-Forde *et al.*, 2008; Marchand-Forde *et al.*, 2010; McKeegan and Philbey, 2012; Freire *et al.*, 2011; Glatz *et al.*, 1998]. Partial beak removal at a mature age can cause chronic pain. Dubbing, toe trimming and other mutilations should not be performed in layer pullets and laying hens.

Potential options for improving *animal welfare* in relation to these procedures include: ceasing the procedure, reducing or eliminating the need for the painful procedures through management strategies, using genetics that do not require the painful procedures, or replacing the current procedures with less painful or invasive alternatives.

**EU comment**

**The EU proposes the following revision:**

**“Potential options for improving *animal welfare* in relation to these procedures include: ceasing the procedure, reducing or eliminating the need for the painful procedures through management strategies, using genetics that do not require the painful procedures; without compromising functionality and/or normal behaviour of the layer pullets and laying hens or replacing the current procedures with less painful or invasive alternatives.”**

**Justification**

The sentence “using genetics that do not require the painful procedures” if referred to partial beak removal may encourage the use of genetically modified beak shapes without a proper assessment of the risks related to loss of function and/or impact on natural behaviour. There is a growing interest in commercial layer breeding on the possibility to adjust the shape of the beak in order to reduce the risk of severe cannibalism; however there is a lack of evidence related to the potential impact on pullets and laying hens’ behaviour.

### References

Preisinger, R., 2018. Innovative layer genetics to handle global challenges in egg production. *British poultry science*, 59(1), pp.1-6.

Bhullar, B. S., Morris, Z. S., Sefton, E. M., Tok, A., Tokita, M., Namkoong, B., et al. (2015). A molecular mechanism for the origin of a key evolutionary innovation, the bird beak and palate, revealed by an integrative approach to major transitions in vertebrate history. *Evolution*, 69(7), 1665–1677. [https:// doi.org/10.1111/evo.12684](https://doi.org/10.1111/evo.12684).

Outcome-based measurables include: beak condition, body condition, feeding and drinking behaviour, foraging behaviour, injurious feather pecking and cannibalism, locomotory and comfort behaviours, mortality rate, morbidity rate, performance, plumage condition; and vocalisations.

### **EU comment**

**The EU proposes the following revision:**

**Outcome-based measurables include: beak condition, body condition, feeding and drinking behaviour, foraging behaviour, injurious feather pecking and cannibalism, locomotory and comfort behaviours, mortality rate, morbidity rate, performance, plumage condition, and vocalisations.**

### **Justification**

**Feather pecking is not the same as injurious pecking as pecking at the feathers is not causing any real harm to the animal. Severe feather pecking can lead to naked areas and subsequently to wounds. In that stage, it is injurious pecking.**

Article 7.Z.22.

### **Animal health management, preventive medicine and veterinary treatment**

*Animal handlers* responsible for the care of pullets and hens should have knowledge of normal layer pullet and laying hen behaviour, and be able to detect signs of ill-health or distress, such as a change in feed or water intake, reduced production, changes in behaviour and abnormalities in plumage condition faeces or other physical features.

If *animal handlers* are unable to identify the cause of disease, ill-health or distress, or are unable to correct these, or if they suspect the presence of a *notifiable disease*, they should seek advice from a *veterinarian* or other qualified advisers. Veterinary treatments should be prescribed by a *veterinarian*.

There should be an effective programme for the prevention of diseases that is consistent with the programmes established by *Veterinary Services* as appropriate, and which includes record-keeping.

*Vaccinations* and treatments should be administered by personnel skilled in the procedures and with consideration for the welfare of the layer pullets and laying hens.

Sick or injured pullets and hens should be placed in a hospital area for observation and treatment, or euthanised in accordance with Chapter 7.6. as soon as possible.

## Annex 12 (contd)

Outcome-based measurables include: body condition, incidence of diseases, *infections*, metabolic disorders and *infestations*, injury rate and severity, morbidity rate, mortality rate and performance.

Article 7.Z.23.

### **Biosecurity plans**

*Biosecurity plans* should be designed, implemented, and reviewed regularly, commensurate with the best possible layer pullet and laying hen health status. The *biosecurity plan* should be sufficiently robust to be effective in addressing the current disease *risks* that are specific to each epidemiological group of layer pullets and laying hens and in accordance with relevant recommendations in the *Terrestrial Code*.

These programmes should address the control of the major routes for *infection* and *infestation* such as:

- aerosols,
- direct transmission from other *poultry*, domestic *animals* and *wildlife* and humans,
- feed,
- fomites, such as equipment, facilities and vehicles,
- *vectors* (e.g. arthropods and rodents),
- water supply.

Partially restocking (back filling), in a response to catastrophe or incomplete flock placement, should only be practised with due consideration to biosecurity and in a manner that prevents co-mingling of flocks.

Outcome-based measurables include: culling and morbidity rates, incidence of diseases, mortality rate and performance.

Article 7.Z.24.

### **Euthanasia of individual layer pullets or laying hens**

Individual layer pullets or laying hens may be euthanised. Techniques used should be performed, in accordance with Chapter 7.6.

Reasons for euthanasia may include:

- disaster management,
- diagnostic purposes,
- rapid deterioration of a medical condition for which treatment has been unsuccessful,
- bone fractures or other injuries,
- emaciation,
- severe pain that cannot be alleviated.

The decision to euthanise an animal and the procedure itself should be undertaken by a competent person. The *establishment* should have documented procedures and appropriate equipment.

Outcome-based measurables include: injury rate and severity.

Article 7.Z.25.

### **Depopulation of pullet and hen facilities**

This article refers to the removal of flocks of layer pullets and laying hens from facilities for whatever reason and should be read in conjunction with Article 7.Z.24.

The period of feed withdrawal prior to depopulation of layer pullets and laying hens should be minimised.

Water should be available up to the time of depopulation.

Layer pullets and laying hens that are not fit for *loading* or transport should be euthanised. Hens with poor plumage condition are at risk of thermal stress and injury during transport [Broom, 1990; Fleming *et al.*, 2006; Gregory and Wilkins 1989; Newberry *et al.*, 1999; Webster, 2004; Whitehead and Fleming, 2000]. On-farm killing should be performed in accordance with Chapter 7.6.

Catching should be carried out by competent *animal handlers* in accordance with Article 7.Z.28. and every attempt should be made to minimise stress, fear reactions and injuries. If a layer pullet or laying hen is injured during catching, it should be euthanised.

Layer pullets and laying hens should be handled and placed into the transport *container* in accordance with Chapter 7.3.

Catching should preferably be carried out under dim or blue light to calm the layer pullets and laying hens.

Catching should be scheduled to minimise the transport time as well as climatic stress during catching, transport and holding.

The stocking density in transport *containers* should be in accordance with Chapters 7.2., 7.3. and 7.4.

Outcome-based measurables include: fear behaviour, injury rate and severity, mortality rate, spatial distribution, and vocalisation.

#### Article 7.Z.26.

##### **Contingency plans**

Layer pullet and laying hen producers should have contingency plans to minimise and mitigate the consequences of natural disasters, disease *outbreaks* and the failure of mechanical equipment. Planning should include a fire safety plan and, where relevant, include the provision, maintenance and testing of backup generators and fail-safe alarm devices to detect malfunctions, access to maintenance providers, alternative heating or cooling arrangements, ability to store water on farm, access to water cartage services, adequate on-farm storage of feed and an alternative feed supply and a plan for managing ventilation emergencies.

The contingency plans should be consistent with national programmes established or recommended by *Veterinary Services*. Humane emergency *killing* procedures should be a part of the plan and be in accordance with the methods recommended in Chapter 7.6.

Outcome-based measurables include: culling, morbidity and mortality rates.

#### Article 7.Z.27.

##### **Competencies of personnel**

*Animal handlers* should have the ability, knowledge and competencies necessary to maintain the welfare and health of the layer pullets and laying hens.

All people responsible for layer pullets and laying hens should have received appropriate training, and be able to demonstrate that they are competent to carry out their responsibilities, which should include the assessment of pullet and hen behaviour, handling techniques, *euthanasia* and *killing* procedures, implementation of *biosecurity*, and the detection of general signs of diseases, and indicators of poor *animal welfare* and procedures for their alleviation.

Outcome-based measurables include: body condition, culling and morbidity rate, fear behaviour, incidence of diseases, locomotory and comfort behaviours, performance, mortality rate, spatial distribution and vocalisation.

#### Article 7.Z.28.

##### **Inspection and handling**

Layer pullets and laying hens, and the facilities and equipment within their poultry house should be inspected at least daily. Inspection should have the following objectives

Annex 12 (contd)

- to collect and remove dead layer pullets and laying hens, and dispose of them in accordance with Chapter 4.12.;
- to identify sick or injured layer pullets and laying hens, and treat or euthanised them in accordance with Article 7.Z.24.;
- to detect and correct any *animal welfare* or health problems in the *flock*; and
- to detect and correct malfunctioning equipment and other problems with the facility.

Inspections should be done in such a way that layer pullets and laying hens are not unnecessarily disturbed, for example *animal handlers* should move quietly and slowly through the *flock*.

When layer pullets and laying hens are handled, particularly when placed into or removed from the poultry house, they should not be injured, and should be held in a manner that minimises fear and stress [Gregory & Wilkins, 1989; Gross & Siegel, 2007; Kannan & Mench, 1996]. The distance over which layer pullets and laying hens are carried should be minimised. Laying hens are prone to bone fractures when not handled properly.

Outcome based measurables include: culling and morbidity rates, fear behaviour, injury rate and severity, mortality, performance, spatial distribution, and vocalisation.

**EU comment**

**The EU proposes to include hyphen to “Outcome-based measurable...”**

**Justification**

**For consistency with spelling across the rest of the chapter**

Article 7.Z.29.

**Protection from predators**

Layer pullets and laying hens should be protected from predators in indoor and outdoor areas. All production systems should be designed and maintained to prevent access by predators and wild *birds*.

Outcome based measurables include: culling and morbidity rates, fear behaviour, injury rate and severity, locomotory and comfort behaviours, mortality rate, performance, spatial distribution and vocalisation.

**EU comment**

**The EU proposes to include hyphen to “Outcome-based measurable...”**

**Justification**

**For consistency with spelling across the rest of the chapter**



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## CHAPTER 10.4.

## INFECTION WITH HIGH PATHOGENICITY AVIAN INFLUENZA VIRUSES

**EU position**

The EU thanks the OIE for the effort invested in the revision and the changes made to this chapter 10.4 on Infection with high pathogenicity avian influenza viruses.

The EU supports the new proposal, which clearly differentiates between Member Countries' obligation to notify the infection with high pathogenicity viruses in poultry and other birds. The EU also appreciates that infection with low pathogenicity viruses does not affect the status of a country or zone. However, we wish to submit important comments inserted in the text below that we would like to see them addressed.

We consider that the content and new structure of this chapter goes in the right direction. There are important aspects that we wish the Code Commission to consider.

## Article 10.4.1.

**General provisions**

1) The objective of this chapter is to mitigate animal and public health risks posed by avian influenza viruses, and prevent their international spread. The chapter focuses on high pathogenicity avian influenza viruses, which cause the *listed disease* of concern. However, since they have the ability to mutate into high pathogenicity viruses, low pathogenicity avian influenza viruses of H5 and H7 subtypes should be included in any surveillance and control programmes for high pathogenicity viruses. 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.

This chapter deals with the *listed disease*, *infection* with high pathogenicity avian influenza viruses.

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.

2) For the purposes of the *Terrestrial Code*:

**EU comment**

The title of point 2) above is "For the purposes of the *Terrestrial Code*".

We understand that, once this chapter is adopted, the intention is to amend the

definition of ‘poultry’ in the Glossary according to the definition proposed for this chapter .

However, until the Glossary is amended and because this point includes more definitions than ‘poultry’, we suggest that the title is amended to **‘For the purpose of this Chapter’**.

Furthermore, we have included specific comments related to the definition of ‘poultry’ below.

a) High pathogenicity avian influenza means an infection of poultry by any influenza A virus with an intravenous that has been determined as high pathogenicity index (IVPI) in accordance with the Terrestrial Manual.

in six week old chickens greater than 1.2 or, as an alternative, causes at least 75% mortality in four to eight week old chickens infected intravenously. Viruses of H5 and H7 subtypes that 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 a high pathogenicity avian influenza virus.

b) The following defines the An occurrence of infection with a high pathogenicity avian influenza virus: is defined by the isolation and identificaton of the virus has been isolated and identified as such or the detection of specific viral ribonucleic acid has been detected, in one or more samples from poultry or a product derived from poultry.

#### EU comment

In the track-changed version the phrase **‘has been isolated and identified’** remains, while in the clean version this phrase has been deleted.

We understand that the intention is to delete it.

#### Annex 14 (contd)

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.

c) Poultry means all domesticated birds used for the production of meat or eggs for human consumption, for the production of other commercial products, or for breeding of these categories of birds, as well as fighting cocks used for any purpose. All birds used for restocking supplies of game are considered poultry. If birds are kept in a single household and their products are only used in the same household, these birds are not considered poultry.

Birds that are kept in captivity for any reason other than those referred to in the preceding paragraph, including those that are kept for shows, races racing, exhibitions, zoological collections, competitions or for breeding or selling these categories of birds, as well as pet birds, are not considered poultry.

#### EU comment

We have several concerns in relation to the definition of ‘poultry’.

First of all, the word ‘domesticated’ is understood differently and to avoid any confusion we propose to be replaced by the word ‘kept’. For these reasons we suggest that the first sentence is amended to read **‘Poultry means all domesticated birds reared or kept in captivity used for the production of...’**

We understand that ‘breeding for the purposes of restocking supplies of game birds’ is not explicitly mentioned in the definition of ‘poultry’ because you consider that the wording ‘all birds used for restocking supplies of game’ includes also ‘breeding poultry’. However, the first sentence of the definition reads ‘poultry means all domesticated birds used for ...’ and it also explicitly mentions ‘or for breeding of these categories of birds’. For clarity and consistency, we would suggest to explicitly include breeding birds for this category.

Moreover, we suggest it is made clear that those birds are considered poultry until the time they are released. We suggest to amend this sentence as follows: ‘All birds used for restocking supplies of game, or for breeding for this purpose, are considered poultry until they are released from captivity.’

In addition, in the proposed definition of ‘poultry’ birds kept in a single household for own consumption are not considered ‘poultry’.

The Code Commission acknowledges that these birds are also susceptible to the disease and because they are isolated in households and not involved in commercial trade they are considered of negligible epidemiological significance. We acknowledge that last year the EU, through our comments, supported this change in the definition. However, after further reflection and discussion, we consider that the birds excluded from the definition, in certain circumstances, can play a role in the introduction and spread of the disease, for example, when these households keeping birds are not sufficiently separated from poultry kept for production, located in the proximity of commercial premises or there is other epidemiological link with commercial premises. For this reason and in order to mitigate such risks, we recommend that the following sentence is amended as follows:

‘If birds are kept in a single household and their products are only used in the same household, these birds are not considered poultry, provided that they have no direct or indirect contact with poultry or poultry facilities.’

d) ~~the~~ **The** *incubation period* at the *flock* level for high pathogenicity avian influenza ~~shall be~~ is 14 days.

3) ~~In accordance with Chapter 1.1., a sudden and unexpected change in the distribution, host range, or increase in incidence or virulence of, or morbidity or mortality caused by avian influenza viruses is notifiable to the OIE, as well as zoonotic avian influenza viruses. Occurrences of influenza A viruses of high pathogenicity in birds other than poultry, including wild birds, are notifiable. Six-monthly reports on the presence of avian influenza viruses in a country or zone should include low pathogenicity viruses of H5 and H7 subtypes.~~

~~Although the objective of this chapter is to mitigate animal and public health risks posed by *infection* with high pathogenicity avian influenza viruses, other influenza A viruses of avian host origin (i.e. low pathogenicity avian influenza viruses) may have the potential to exert a negative impact on animal and public health. A sudden and unexpected increase in virulence of low pathogenicity avian influenza viruses in *poultry* is notifiable as an *emerging disease* in accordance with Article 1.1.4. *Infection* of domestic and *captive wild* birds with low pathogenicity avian influenza viruses having proven natural transmission to humans associated with severe consequences is also notifiable as an *emerging disease* with public health impact in accordance with Article 1.1.4. Occurrences of *infection* with avian influenza viruses of high pathogenicity in birds other than *poultry*, including *wild* birds, are notifiable in accordance with Article 1.3.6.~~

#### EU comment

We would like to suggest that more clarity is needed early in the text and in other relevant parts of the Chapter, to make it clear:

- the purpose of the requirements for surveillance of avian influenza (Article 10.4.20); and
- the purpose of monitoring low pathogenicity avian influenza (Article 10.4.22ter)

And why those are linked to the management of high pathogenicity avian influenza throughout the chapter.

In this context, we suggest that further thinking is dedicated to improve the layout of the chapter, for example, providing specific and separate sections at the end of the chapter for aspects not related to HPAI (e.g. LPAI). This could help to avoid misinterpretations.

4) A notification of infection with avian influenza A viruses of high pathogenicity in birds other than poultry, including wild birds, or of low pathogenicity avian influenza viruses in poultry (as described in point 2) c) does not affect the high pathogenicity avian influenza status of the country or zone. A Member Country should not impose bans on the trade in poultry and of poultry commodities in response to such notifications, or to other information on the presence of any influenza A virus in birds other than poultry, including wild birds.

#### EU comment

It should be clearer in the above paragraph that trade barriers must not be imposed on a Member Country when there is an outbreak of low pathogenicity avian influenza or when there is an outbreak of HPAI in birds other than poultry. The EU suggests the following changes to the last sentence above:

**‘A Member Country should not impose bans on the trade of poultry commodities, including live poultry, or on the trade of birds other than poultry, in response to such notifications, or to other information on the presence of any influenza A virus in birds other than poultry, including wild birds.**

~~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.~~

5) This chapter includes monitoring considerations for low pathogenicity avian influenza viruses because some, especially H5 and H7 subtypes, have the potential to mutate into high pathogenicity avian influenza viruses.

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.

46) The use of vaccination against high pathogenicity avian influenza in *poultry* may be recommended under specified specific conditions, while not affecting the status of a free country or zone, if the Any vaccine complies used should comply with the standards described in the *Terrestrial Manual*. Vaccination will not affect the high pathogenicity avian influenza status of a free country or zone if surveillance supports the absence of *infection*, in accordance with Article 10.4.22., in particular point 2. Vaccination is an effective complementary control tool that can be used when a stamping-out policy alone is not sufficient. The decision whether Whether to vaccinate or not is to should be made decided by the Veterinary Authorities Authority based on on the basis of the avian influenza situation as well as the ability of the Veterinary Services to execute implement the proper vaccination strategy, as described in Chapter 4.1718. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

#### EU comment

We suggest that in the sentence 'Vaccination is an effective complementary control too...' The verb is replaced by 'may be' to read: 'Vaccination is may be an effective complementary control too...'

Vaccination could induce the selection of mutant viruses and when it is not well controlled, the circulation of virulent viruses could start, which compromises the initial objective of vaccination in controlling the disease.

597) Standards for diagnostic tests and vaccines, including pathogenicity testing, are described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

#### Article 10.4.1bis.

##### Safe commodities

When authorising import importation or transit of the following commodities, *Veterinary Authorities* should not require any conditions related to high pathogenicity avian influenza-related conditions, regardless of the high pathogenicity avian influenza status of the exporting country or zone:

- 1) heat-treated poultry meat products in a hermetically sealed container with a an F<sub>0</sub>-value of 3.00 or above;
- 2) extruded dry pet food and poultry-based coated ingredients after extrusion;
- 3) rendered meat and bone meal, blood meal, feather meal, and poultry oil;
- 4) washed and steam-dried feathers and down from poultry and other birds processed by washing and steam-drying.

Other commodities of poultry and other birds can be traded safely if in accordance with the relevant articles of this chapter.

Article 10.4.2.

**Determination of the avian influenza status of a country, zone or compartment**

The avian influenza status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1) ~~avian influenza is notifiable in the whole country, an ongoing avian influenza awareness programme is in place, and all notified suspect occurrences of avian influenza are subjected to field and, where applicable, laboratory investigations;~~

Annex 14 (contd)

2) ~~appropriate surveillance is in place to demonstrate the presence of infection in the absence of clinical signs in poultry, and the risk posed by birds other than poultry; this may be achieved through an avian influenza surveillance programme in accordance with Articles 10.4.27. to 10.4.33.;~~

3) ~~consideration of all epidemiological factors for avian influenza occurrence and their historical perspective.~~

Article 10.4.3.

**Country, zone or compartment free from avian influenza**

A country, *zone* or *compartment* may be considered free from avian influenza when it has been shown that infection with avian influenza viruses in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, based on surveillance in accordance with Articles 10.4.27. to 10.4.33.

If infection has occurred in *poultry* in a previously free country, *zone* or *compartment*, avian influenza free status can be regained:

1) ~~In the case of infections with high pathogenicity avian influenza viruses, three months after a stamping-out policy (including disinfection of all affected establishments) is applied, providing that surveillance in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.~~

2) ~~In the case of infections with low pathogenicity avian influenza viruses, poultry may be kept for slaughter for human consumption subject to conditions specified in Article 10.4.19. or a stamping-out policy may be applied; in either case, three months after the disinfection of all affected establishments, providing that surveillance in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.~~

Article 10.4.234.

**Country, or zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry**

A country, or *zone* or *compartment* may be considered free from infection with high pathogenicity avian influenza viruses in *poultry* when:

= infection with high pathogenicity avian influenza viruses in poultry is a notifiable disease in the entire country;

= an ongoing avian influenza surveillance is implemented to monitor the general situation of H5 and H7 low pathogenicity avian influenza viruses in poultry and an awareness programme is in place related to biosecurity and management of H5 and H7 low pathogenicity avian influenza viruses;

absence of infection with high pathogenicity avian influenza viruses, based on surveillance, in accordance with Chapter 1.4. and Articles 10.4.20. to 10.4.22ter., has been demonstrated in the country or zone for the past 12 months;

=1) based on surveillance in accordance with Chapter 1.4. and Articles 10.4.27. to 10.4.33., it has been shown demonstrated that infection with high pathogenicity avian influenza viruses in poultry as defined in Article 10.4.1. has not been present occurred in the country, or zone or compartment for the past 12 months; Although its status with respect to low pathogenicity avian influenza viruses may be unknown; or

an awareness programme is in place related to biosecurity and management of avian influenza viruses;

**EU comment**

**When above it is mentioned that ‘an awareness programme is in place related to biosecurity and management of avian influenza viruses’, we would like clarification on**

this sentence and if the purpose here is different to that of similar sentences in the Code to encourage reporting (e.g. in the case of CSF ‘an ongoing awareness programme is in place to encourage reporting of all cases suggestive of CSF’).

We also understand that the awareness programme in relation to biosecurity would be relevant for farmers. However, we consider that limiting the awareness programme to biosecurity is a missed opportunity to raise awareness for other aspects of the control of this disease. For this reason we would suggest to read ‘including the importance of biosecurity’.

We would also think that the meaning of an awareness programme related to “management of avian influenza viruses” is not clear and it will be helpful to clarify its purpose and also to whom those programmes should be targeted.

= bird commodities are imported in accordance with Articles 10.4.53. to 10.4.2317.

The surveillance should may need to be adapted to parts of the country or existing zones or compartment depending on historical or geographical factors, industry structure, population data, or and proximity to recent outbreaks or the use of vaccination.

If infection has occurred in poultry in a previously free country, zone or compartment, the free status can be regained three months after a stamping-out policy (including disinfection of all affected establishments) is applied, providing that surveillance in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

Annex 14 (contd)

Article 10.4.32bis.

#### Compartment free from high pathogenicity avian influenza

The establishment of a compartment free from high pathogenicity avian influenza should follow be in accordance with the relevant requirements of this chapter and the principles described in Chapters 4.34. and 4.45.

Article 10.4.32ter.

#### Establishment of a containment zone within a country or zone free from high pathogenicity avian influenza

In the event of an outbreaks of high pathogenicity avian influenza within a previously free country or zone, a containment zone, which includes all epidemiologically linked outbreaks, may be established for the purposes of minimising the impact on the rest of the country or zone.

In addition to the requirements for the establishment of a containment zone outlined in Article 4.34.7., the surveillance programme should take into account the density of poultry production, types of poultry, local management practices (including inter-premises movement patterns of poultry, people and equipment), relevant biosecurity, and the presence and potential role of birds other than poultry, including wild birds, and the proximity of poultry establishments to perennial permanent and seasonal water bodies.

The free status of the areas outside the containment zone is suspended while the containment zone is being established. It may be reinstated, irrespective of the provisions of Article 10.4.32quater., once the containment zone is clearly established. It should be demonstrated that commodities for international trade either have originated from outside the containment zone or comply with the relevant articles of this chapter.

Article 10.4.32quater.

#### Recovery of free status

If infection with high pathogenicity avian influenza virus has occurred in poultry in a previously free country or zone, the free status can may be regained after a minimum period of 28 days (i.e. two flock-level incubation periods) after a stamping-out policy has been completed, provided that surveillance in accordance with Articles 10.4.2720. to 10.4.3322ter., in particular point 3 of Article 10.4.3022., has been carried out during that period and has demonstrated the absence of infection.

If a stamping-out policy is not implemented, Article 10.4.32. applies.

## EU comment

**Although cleaning and disinfection is part of the definition of ‘stamping out’, to make it clear that this period only starts once the disinfection has been satisfactorily completed and to avoid any uncertainty, we propose to amend the sentence inserting a parenthesis as follows:**

**‘...after a stamping-out policy has been completed (starting after the disinfection of all affected establishments and the elimination or treatment of all potentially contaminated materials), provided that surveillance...’**

Article 10.4.53.

Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza

For live poultry (other than day-old poultry)

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

- 1) the *poultry* showed no clinical signs of avian influenza on the day of shipment;
- 2) a) the *poultry* ~~were kept in~~ originated from an avian influenza free a country, zone or compartment free from high pathogenicity avian influenza ~~since they were hatched or for at least the past 24 days;~~

b3) the *poultry* originated from a flock free from infection with any H5 or H7 that was monitored for avian influenza A viruses and was found to be negative;

## EU comment

**The above point requires attesting that ‘the poultry originated from a flock that was monitored for avian influenza viruses and was found to be negative’.**

**We would like clarification about this requirement. It is not clear to which type of flock this is referring to or which type of test is expected to be negative.**

**There is no mention of the type of test (clinical, laboratory, other?), the frequency (continuous, regular, occasional?) or who is responsible for it (the farmer, the veterinarian?).**

**It could be misinterpreted as a requirement for pre-movement test. This would be a much stricter requirement than the present standard and quite disproportionate. We consider that a pre-movement test should not be required when poultry is coming from a free country or zone.**

**We will welcome clarification of the above points, also because this comment is relevant for other articles where this sentence is included.**

**In any case, we consider that any requirements should only apply to influenza A viruses of H5 or H7 subtypes.**

**These comments are also relevant for other parts of the chapter, such as Article 10.4.5**

## 1)a) and Article 10.4.7 2)a).

Annex 14 (contd)

34) the *poultry* are transported in new or appropriately ~~sanitized~~ ~~sanitised~~ *containers*.

If the *poultry* have been vaccinated against avian influenza ~~viruses~~, the nature of the vaccine used and the date of vaccination should be ~~attached to~~ ~~mentioned stated~~ in the *international veterinary certificate*.

Article 10.4.64.

### Recommendations for the importation of live birds other than poultry

Regardless of the ~~avian influenza~~ ~~high pathogenicity avian influenza~~ status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) on the day of shipment, the birds showed no clinical signs of ~~infection with a virus which would be considered~~ avian influenza ~~in poultry~~;

2) the birds ~~were~~ ~~had been~~ kept in isolation ~~in facilities~~ approved by the *Veterinary Services* since they were hatched or for at least 24 ~~28~~ days (~~i.e. two flock-level incubation periods~~) prior to shipment and showed no clinical signs of ~~infection with a virus which would be considered~~ avian influenza ~~in poultry~~ during the isolation period;

3) a statistically ~~valid~~ ~~appropriate~~ sample of the birds, ~~selected in accordance with the provisions of Article 10.4.29.~~, was subjected to a diagnostic test ~~for avian influenza A viruses, in accordance with the Terrestrial Manual,~~ within 14 days prior to shipment, ~~with negative results for H5 and H7 to demonstrate freedom from infection with a virus which would be considered avian influenza in poultry;~~

### EU comment

**[Editorial note: we have noticed that the sentence in paragraph 3 above is different in the clean and tracked-change version]**

**The phrase ‘a diagnostic test for avian influenza, in accordance with the *Terrestrial Manual*’ seems to imply that the choice of the test (serological or virological) is left open to the importing country. We would like clarification on the meaning of the above phrase and whether the minimum 14-day period of isolation prior to testing is time enough for antibodies to become detectable and justify a testing strategy based on serological methods alone.**

**Furthermore, we question whether this recommendation is relevant and proportionate as it covers all avian influenza viruses and this article is not related to poultry.**

**This comment also applies to article 10.4.6 3), article 10.4.8 1), and article 10.4.10 3). For these articles in particular, serological testing alone could miss a recent active infection occurring in the parent flock or the animals producing semen.**

4) the birds are transported in new or appropriately ~~sanitized~~ ~~sanitised~~ *containers*.

If the birds have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination

Article 10.4.7.

**Recommendations for importation from a country, zone or compartment free from avian influenza**

For day-old live poultry

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

- ~~1) the *poultry* were kept in an avian influenza free country, *zone* or *compartment* since they were hatched;~~
- ~~2) the *poultry* were derived from parent *flocks* which had been kept in an avian influenza free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;~~
- ~~3) the *poultry* are transported in new or appropriately sanitized *containers*.~~

~~If the *poultry* or the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be attached to the *certificate*.~~

Article 10.4.85.

**Recommendations for importation from a country, zone or compartment free from ~~infection with~~ high pathogenicity avian influenza ~~viruses in poultry~~**

For day-old live poultry

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

1) the day-old live poultry ~~were had been~~ kept in a country, zone or compartment free from ~~infection with~~ high pathogenicity avian influenza since they were hatched;

2) and

a) the day-old live poultry were derived from parent flocks free from infection with any H5 or H7 that were monitored for avian influenza A viruses and were found to be negative which had been kept in an avian influenza free establishment for at least 21 days prior to and at the time of the collection of the eggs from which the day-old poultry hatched; or

b) the day-old live poultry that hatched from eggs that have had had their surfaces sanitized sanitised in accordance with point 4 d) of Article 6.5.5.:

AND

23) the day-old live poultry ~~are were~~ transported in new or appropriately sanitized sanitised containers.

If the day-old live poultry or the parent flocks have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination should be attached to mentioned stated in the international veterinary certificate.

Article 10.4.96.

#### **Recommendations for the importation of day-old live birds other than poultry**

Regardless of the ~~avian influenza~~ high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) on the day of shipment, the birds showed no clinical signs of infection with a virus which would be considered avian influenza in poultry;

2) the birds were hatched and kept in isolation facilities approved by the *Veterinary Services*;

3) a statistically appropriate sample of the parent flock birds were subjected to a diagnostic test for avian influenza A viruses at the time of the collection of the eggs, with negative results for H5 and H7 to demonstrate freedom from infection with a virus which would be considered avian influenza in poultry;

4) the birds ~~are were~~ transported in new or appropriately sanitized sanitised containers.

If the birds or parent flocks have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination should be attached to mentioned stated in the international veterinary certificate.

Article 10.4.10.

#### **Recommendations for importation from a country, zone or compartment free from avian influenza**

##### For hatching eggs of poultry

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

1) the eggs came from an avian influenza free country, zone or compartment;

2) the eggs were derived from parent flocks which had been kept in an avian influenza free country, zone or compartment for at least 21 days prior to and at the time of the collection of the eggs;

3) the eggs are transported in new or appropriately sanitized packaging materials.

Annex 14 (contd)

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination should be attached to the *certificate*.

Article 10.4.117.

**Recommendations for importation from a country, zone or compartment free from ~~infection with high pathogenicity avian influenza viruses in poultry~~**

For hatching eggs of poultry

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

1) the hatching eggs came from a country, zone or *compartment* free from ~~infection with high pathogenicity avian influenza viruses in poultry~~;

2) a) the hatching eggs were derived from parent *flocks* ~~free from infection with any H5 or H7 that were monitored for avian influenza A viruses and were found to be negative~~ which had been kept in an avian influenza free *establishment* for at least 21 days prior to and at the time of ~~the~~ collection of the hatching eggs; ~~or~~

b) the hatching eggs have had their surfaces sanitized sanitised (in accordance with ~~Chapter 6.5. point 4 d) of Article 6.5.5.~~);

3) the hatching eggs are transported in new or appropriately sanitized sanitised packaging materials and containers.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination should be attached to mentioned stated in the *international veterinary certificate*.

Article 10.4.128.

**Recommendations for the importation of hatching eggs from birds other than poultry**

Regardless of the ~~avian influenza~~ high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) a statistically valid appropriate sample of birds from the parent *flock* ~~birds were~~ was subjected to a diagnostic test for avian influenza A viruses ~~seven 14 days prior to and at the time of the collection of the hatching eggs, with negative results for H5 and H7 to demonstrate freedom from infection with a virus which would be considered avian influenza in poultry~~;

2) the hatching eggs have had their surfaces sanitized sanitised (in accordance with point 4 d) of Article 6.5.5. Chapter 6.5.);

3) the hatching eggs are transported in new or appropriately sanitized sanitised packaging materials and containers.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination should be attached to mentioned stated in the *international veterinary certificate*.

Article 10.4.9.

**Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza**

For poultry semen

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

- 1) showed no clinical signs of avian influenza on the day of semen collection;
- 2) were kept in a country, zone or compartment free from high pathogenicity avian influenza.

Article 10.4.10.

**Recommendations for the importation of semen from birds other than poultry**

Regardless of the high pathogenicity avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the donor birds:

- 1) were kept in isolation facilities approved by the Veterinary Services for at least 28 days (i.e. two flock-level incubation periods) prior to semen collection;
- 2) showed no clinical signs of avian influenza during the isolation period;
- 3) were subjected to a diagnostic test for avian influenza, within 14 days prior to semen collection with negative results.

Article 10.4.13.

**Recommendations for importation from a country, zone or compartment free from avian influenza**

For eggs for human consumption

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

- 1) the eggs were produced and packed in an avian influenza free country, zone or compartment;
- 2) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.14.11.

**Recommendations for importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry**

For eggs for human consumption

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

- 1) the eggs for human consumption were produced and packed in a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry;
- 2) the eggs have had their surfaces sanitized (in accordance with Chapter 6.5.);
- 23) the eggs for human consumption are were transported in new or appropriately sanitized sanitised packaging materials and containers.

Article 10.4.15.12.

**Recommendations for the importation of egg products of from poultry**

Regardless of the avian influenza high pathogenicity avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

Annex 14 (contd)

1) the commodity egg products ~~is~~ are derived from eggs which meet the requirements of Articles ~~10.4.13-~~ ~~er~~ 10.4. ~~1411~~ ; or

2) the commodity egg products ~~has~~ have been processed to ensure the ~~destruction~~ inactivation of high pathogenicity avian influenza viruses, in accordance with Article 10.4. ~~2518~~ ;

AND

3) the necessary precautions were taken to avoid contact of the commodity egg products with any source of high pathogenicity avian influenza viruses.

Article 10.4.16.

**~~Recommendations for importation from a country, zone or compartment free from avian influenza~~**

~~For poultry semen~~

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

1) ~~showed no clinical sign of avian influenza on the day of semen collection;~~

2) ~~were kept in an avian influenza free country, zone or compartment for at least 21 days prior to and at the time of semen collection.~~

Article 10.4.17.

**~~Recommendations for the importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry~~**

~~For poultry semen~~

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

1) ~~showed no clinical signs of infection with high pathogenicity avian influenza viruses in poultry on the day of semen collection;~~

2) ~~were kept in a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry for at least 21 days prior to and at the time of semen collection.~~

Article 10.4.18.

**~~Recommendations for the importation of semen of birds other than poultry~~**

~~Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the donor birds:~~

1) ~~were kept in isolation approved by the Veterinary Services for at least 24 28 days prior to semen collection;~~

2) ~~showed no clinical signs of infection with a virus which would be considered avian influenza in poultry during the isolation period;~~

3) ~~were tested within 14 days prior to semen collection and shown to be free from infection with a virus which would be considered avian influenza in poultry;~~

Article 10.4.1913.

**Recommendations for importation from a country, zone or compartment ~~free from avian influenza or free from infection with high pathogenicity avian influenza viruses in poultry~~**

For fresh meat of poultry

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

- 1) which ~~have been kept in~~ originated from a country, zone or *compartment* free from ~~infection with high pathogenicity avian influenza viruses in poultry since they were hatched or for at least the past 21 days;~~
- 2) which ~~have been~~ were slaughtered in an approved slaughterhouse/abattoir in a country, zone or *compartment* free from ~~infection with high pathogenicity avian influenza viruses in poultry~~ and ~~have been~~ were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3. ~~and have been found free of any signs suggestive of avian influenza with favorable favourable results.~~

Article 10.4.2014.

**Recommendations for the importation of meat products ~~of from~~ poultry**

Regardless of the ~~avian influenza~~ high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the commodity meat products from poultry ~~is are~~ derived from *fresh meat* which meets the requirements of Article 10.4.1913.; or
- 2) the commodity meat products from poultry ~~has have~~ been processed to ensure the ~~destruction~~ inactivation of high pathogenicity avian influenza viruses in accordance with Article 10.4.2619.;

AND

- 3) the necessary precautions were taken to avoid contact of the commodity meat products from poultry with any source of high pathogenicity avian influenza viruses.

Article 10.4.2115.

**Recommendations for the importation of poultry products not listed in Article 10.4.1bis. and intended for use in animal feeding, or for agricultural or industrial use**

Regardless of the high pathogenicity avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- 1) these commodities were processed in a country, zone or compartment free from high pathogenicity avian influenza and were obtained from poultry which originated in a country, zone or compartment free from high pathogenicity avian influenza:

**EU comment**

**Bullet point 1) above requires that poultry products for feeding are obtained from a free country and are processed in a free country.**

**We consider that both requirements may not be necessary. If the commodities are obtained from poultry from a free country and processed in an infected country BUT they are kept separate and processed in a way as to avoid contact with any source of viral contamination, these commodities could be considered safe.**

OR

2) these commodities have been processed to ensure the inactivation of high pathogenicity avian influenza viruses using:

a) moist heat treatment for 30 minutes at 56 °C; or

b) heat treatment where the internal temperature throughout the product reaches reached at least 74 °C; or

c) any equivalent treatment that has been demonstrated to inactivate avian influenza viruses:

Annex 14 (contd)

AND

3) the necessary precautions were taken to avoid contact of the commodity with any source of high pathogenicity avian influenza viruses.

Article 10.4.21.

**~~Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use~~**

~~Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:~~

~~1) these commodities were processed in an avian influenza free country, zone or compartment from poultry which were kept in an avian influenza free country, zone or compartment from the time they were hatched until the time of slaughter or for at least the 21 days preceding slaughter; or~~

~~2) these commodities have been processed to ensure the destruction of avian influenza virus using;~~

~~a) moist heat treatment for 30 minutes at 56°C; or~~

~~b) any equivalent treatment which has been demonstrated to inactivate avian influenza virus;~~

AND

~~3) the necessary precautions were taken to avoid contact of the commodity with any source of avian influenza virus.~~

Article 10.4.22~~16~~.

**Recommendations for the importation of feathers and down ~~of from~~ poultry not listed in Article 10.4.1bis.**

~~Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:~~

~~1) these commodities originated from poultry as described in Article 10.4.19~~13~~, and were processed in an avian influenza free a country, zone or compartment free from high pathogenicity avian influenza; or~~

~~2) these commodities have been processed to ensure the inactivation of high pathogenicity avian influenza viruses using one of the following:~~

~~a) washed and steam dried at 100°C for 30 minutes;~~

**EU comment**

**We consider that ‘washed and steam dried at 100°C for 30 minutes’ is a safe treatment and should continue as a possible treatment to place feathers safely on the market.**

**The same applies to article 10.4.17**

~~b)~~ fumigation with formalin (10% formaldehyde) for 8 hours;

**EU comment**

**The above treatment is not permitted in the EU. If no other Member Country of the OIE uses it, we would like to propose that this treatment is deleted.**

**This comment also applies to article 10.4.17**

~~b~~e) irradiation with a dose of 20 kGy;

~~c~~d) any equivalent treatment which has been demonstrated to inactivate avian influenza virus~~es~~;

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of high pathogenicity avian influenza virus~~es~~.

Article 10.4.23.17.

**Recommendations for the importation of feathers and down of birds other than poultry not listed in Article 10.4.1bis.**

Regardless of the ~~avian influenza~~ high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) these *commodities* have been processed to ensure the ~~destruction~~ inactivation of any virus which would be considered high pathogenicity avian influenza viruses in poultry using one of the following:

a) ~~washed and steam dried at 100°C for 30 minutes;~~

**EU comment**

**We consider that ‘washed and steam dried at 100°C for 30 minutes’ is a safe treatment and should continue as a possible treatment to place feathers safely on the market.**

**The same applies to article 10.4.16**

~~b)~~ fumigation with formalin (10% formaldehyde) for 8 hours;

**EU comment**

**The above treatment is not permitted in the EU. If no other Member Country of the OIE uses it, we would like to propose that this treatment is deleted.**

**This comment also applies to article 10.4.16**

~~c)~~ irradiation with a dose of 20 kGy;

~~d)~~ any equivalent treatment which has been demonstrated to inactivate avian influenza viruses;

2) the necessary precautions were taken to avoid contact of the *commodity* with any source of viruses which would be considered high pathogenicity avian influenza viruses in poultry.

Article 10.4.17bis.

**Recommendations for the importation of scientific specimens, skins and trophies of birds other than poultry**

**EU comment**

**The inclusion of ‘scientific specimens’ in the title and the conditions required in this article may prevent the exchange of samples containing an active virus between scientific laboratories. For this reason, you may wish to consider deleting ‘scientific specimens’ from the title.**

Regardless of the high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) these *commodities* have been processed to ensure the inactivation of high pathogenicity avian influenza viruses in accordance with Article 10.4.19bis.;

**AND**

2) the necessary precautions were taken to avoid contact of the commodity with any source of high pathogenicity avian influenza viruses.

Article 10.4.24.

**Recommendations for the importation of feather meal and poultry meal**

Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- 1) these commodities were processed in an avian influenza free country, zone or compartment from poultry which were kept in an avian influenza free country, zone or compartment from the time they were hatched until the time of slaughter or for at least the 21 days preceding slaughter; or
- 2) these commodities have been processed either:
  - a) with moist heat at a minimum temperature of 118°C for minimum of 40 minutes; or
  - b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122°C for a minimum of 15 minutes; or
  - c) with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74°C;

AND

Annex 14 (contd)

- 3) the necessary precautions were taken to avoid contact of the commodity with any source of avian influenza viruses.

Article 10.4.25-18.

**Procedures for the inactivation of high pathogenicity avian influenza viruses in eggs and egg products from poultry**

The following times for industry standard temperatures time/temperature combinations are suitable for the inactivation of high pathogenicity avian influenza viruses present in eggs and egg products:

	Core temperature (°C)	Time
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	870 seconds
Liquid egg white	56.7	232 seconds
Plain or pure egg yolk	60	288 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	20 hours
Dried egg white	54.4	50.4 hours
Dried egg white	51.7	73.2 hours

The listed temperatures These time/temperature combinations are indicative of a range that achieves a 7-log<sub>10</sub> kill reduction of avian influenza virus infectivity. These are listed as examples in for a variety of egg products, but, when supported by scientifically documented scientific evidence, variances variations from of these times and temperatures time/temperature combinations may be used, and they may be used for additional other egg products, may also be suitable when if they achieve equivalent inactivation of the virus.

Article 10.4.26-19.

### Procedures for the inactivation of high pathogenicity avian influenza viruses in meat products from poultry

The following times for industry standard temperatures time/temperature combinations are suitable for the inactivation of high pathogenicity avian influenza viruses in meat products.

	Core temperature (°C)	Time
Poultry meat Meat products from poultry	60.0	507 seconds
	65.0	42 seconds
	70.0	3.5 seconds
	73.9	0.51 second

The listed temperatures These time/temperature combinations are indicative of a range that achieves a 7-log<sub>10</sub> kill reduction of avian influenza virus infectivity. Where scientifically documented When supported by scientific evidence, variances from variations of these times and temperatures time/temperature combinations may also be suitable used when if they achieve the equivalent inactivation of the virus.

Annex 14 (contd)

#### Article 10.4.2619bis.

### Procedures for the inactivation of high pathogenicity avian influenza viruses in scientific specimens and in skins and trophies

For the inactivation of high pathogenicity avian influenza viruses in scientific specimens and in skins and trophies, one of the following procedures should be used:

- 1) boiling in water for an appropriate time so as to ensure that any matter material other than bone, claws or beaks is removed; or
- 2) soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate-Na<sub>2</sub>CO<sub>3</sub>) maintained at pH 11.5 or above for at least 48 hours; or
- 3) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained below pH 3.0 for at least 48 hours; wetting and dressing agents may be added; or
- 4) in the case of raw hides, treating treatment for at least 28 days with salt (NaCl) containing 2% washing soda (sodium carbonate-Na<sub>2</sub>CO<sub>3</sub>); or
- 5) treatment with 1% formalin for a minimum of six days; or
- 6) any equivalent treatment which has been demonstrated to inactivate the virus.

#### Article 10.4.2720.

### Introduction to Principles of surveillance of high pathogenicity for avian influenza

Articles 10.4.27. to 10.4.33. define the principles and provide a guide on the surveillance for avian influenza complementary to Chapter 1.4., Article 10.4.20. defines the principles and Articles 10.4.21., 10.4.22., 10.4.22bis. and 10.4.22ter. provide guidance on avian influenza surveillance for the entire country, zone or compartment and are complementary to Chapter 1.4. applicable to These principles should be applied by Member Countries seeking to determine their high pathogenicity avian influenza status.; Surveillance is they are also necessary to support vaccination programmes, to monitor general situation of H5 and H7 low pathogenicity avian influenza viruses, especially H5 and H7, in poultry and for to monitoring monitor avian influenza in wild birds. This may be for the entire country, zone or compartment. Guidance for Member Countries seeking free status following an outbreak and for the maintenance of avian influenza status is also provided.

The presence of influenza A viruses in *wild* birds creates a particular problem. In essence, no Member Country can declare itself free from influenza A in *wild* birds. However, the definition of avian influenza in this chapter refers to the *infection* in *poultry* only, and Articles 10.4.27. to 10.4.33. were developed under this definition.

The impact and epidemiology of avian influenza differ widely in among different regions of the world and therefore it is impossible to provide specific detailed recommendations for all situations. Surveillance strategies employed for demonstrating freedom from avian influenza at an acceptable level of confidence should be adapted to the local situation. Variables such as the frequency of contacts of between poultry with and wild birds, different biosecurity levels and production systems, and the commingling of different susceptible species including domestic waterfowl, may require specific different surveillance strategies to address each specific situation. Furthermore, domestic waterfowls typically do not show clinical signs and have longer infective periods than gallinaceous poultry. It is therefore incumbent upon the Member Country to provide scientific data that explains the epidemiology of avian influenza in the region concerned of concern and also demonstrates to demonstrate how all the risk factors are managed have been taken into account. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that absence of *infection* with avian influenza viruses is assured at an acceptable level of confidence. Member Countries have flexibility to provide a science-based approach to demonstrate absence of infection with avian influenza viruses at an appropriate level of confidence, as described in Chapter 1.4.

There is an increased recognition of the value of the application of sequencing technologies and phylogenetic analyses to determine routes of introduction, transmission pathways and epidemiological patterns of *infection*. When avian influenza viruses are detected, Member Countries should apply these technologies, when possible, to enhance the evidence used to develop specific surveillance strategies and control activities.

A monitoring system for low pathogenicity avian influenza viruses in *poultry* should be in place for the following reasons:

### EU comment

As we have expressed in previous comments, we suggest that surveillance requirements other than those for HPAI are grouped in a separate section of this chapter. This will avoid misinterpretation or confusion and will improve clarity.

1) Surveillance of Some H5 and H7 low pathogenicity avian influenza viruses in *poultry* is relevant as they might have the potential to mutate into high pathogenicity avian influenza viruses. There is and currently no scientific evidence it is not possible to predict if whether and when this mutation might will occur. Outbreaks of low pathogenicity viruses can be managed at establishment level however spread to other *poultry* establishments increases the risk of virus mutation, if it is not detected and managed. Therefore, a system should be in place to detect clusters of infected *poultry* establishments where H5 and H7 low pathogenicity viruses spread between *poultry* establishments.

2) The detection of sudden and unexpected increases in virulence of low pathogenicity avian influenza viruses in *poultry*, in order to fulfil notification obligations of an emerging disease in accordance with Article 1.1.4.

3) The detection, in domestic and *captive wild* birds, of low pathogenicity avian influenza viruses that have been proven to be transmitted naturally to humans with severe consequences, as in order to fulfil notification obligations of an emerging disease in accordance with Article 1.1.4.

Surveillance for avian influenza should be in the form of a continuing programme designed to establish that the country, zone or compartment, for which application is made, is free from *infection* with avian influenza viruses.

In cases where potential public health implications are suspected, reporting to the appropriate public health authorities is essential.

Article 10.4.2821.

### General conditions and methods for surveillance-Surveillance for early warning of high pathogenicity avian influenza

1) An ongoing surveillance programme for avian influenza should be in the form of a continuing programme place and be designed to detect the presence of *infection* with high pathogenicity avian influenza viruses in the country or zone in a timely manner. A surveillance system in accordance with Chapter 1.4. should be under the responsibility of the Veterinary Authority. In particular:

a) a formal and ongoing system for detecting and investigating outbreaks of disease or *infection* with avian influenza viruses should be in place;

b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of avian influenza to a laboratory for avian influenza diagnosis;

e) a system for recording, managing and analysing diagnostic and surveillance data should be in place.

2) The high pathogenicity avian influenza surveillance programme should include the following:

a) include an An early warning system for reporting suspected cases, in accordance with Article 1.4.5. throughout the production, marketing and processing chain for reporting suspicious suspected cases. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of high pathogenicity avian influenza to the Veterinary Authority. They should be supported directly or indirectly (e.g. through private veterinarians or veterinary para-professionals) by government information programmes and the Veterinary Authority. All suspected cases of high pathogenicity avian influenza should be investigated immediately. As Given that suspicion cannot always be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a laboratory for appropriate tests. This requires

that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in avian influenza diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;

## EU comment

The last sentence indicates that ‘Given that suspicion cannot always be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a laboratory for appropriate tests’.

This could be interpreted both ways, that in all suspicious cases, sampling and lab testing has to be carried out, or only in some circumstances, as appropriate.

We believe that the intention is to do this only when the suspicion cannot be rule out by other means and therefore, we suggest that the wording is amended as follows: ‘When suspicion cannot be resolved by epidemiological and clinical investigation, samples ~~should~~ shall be taken and submitted to a laboratory for appropriate tests’.

Annex 14 (contd)

b) ~~implement~~ Implementation, when as relevant, ~~of~~ regular and frequent clinical inspection, ~~and or~~ serological and virological testing, of high-risk groups of *animals*, such as those adjacent to an country or zone infected with high pathogenicity avian influenza ~~infected country or zone~~, places where birds and *poultry* of different origins are mixed, such as live bird markets, ~~and~~ *poultry* in close proximity to waterfowl or other potential sources of influenza A viruses. This activity is particularly applicable to domestic waterfowl, where detection of high pathogenicity avian influenza via clinical suspicion can be of low sensitivity.

c) ~~ensure that~~ Immediate investigation of the presence of antibodies against influenza A viruses, which that have been detected in *poultry* and are not a consequence of vaccination, be immediately investigated. In the case of single or isolated serological positive results, infection with high pathogenicity 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.

~~An effective surveillance system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is influenza A viruses. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Documentation for freedom from infection with avian influenza viruses should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).~~

Article 10.4.29.

## Surveillance strategies

### 4. Introduction

~~The target population for surveillance aimed at identification of disease and infection should cover all the susceptible *poultry* species within the country, zone or compartment. Active and passive surveillance for avian influenza should be ongoing with the frequency of active surveillance being appropriate to the epidemiological situation in the country. Surveillance should be composed of random and targeted approaches using molecular, virological, serological and clinical methods.~~

~~The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of infection with avian influenza viruses at an acceptable level of confidence. Random surveillance is conducted using serological tests. Positive serological results should be followed up with molecular or virological methods.~~

~~Targeted surveillance (e.g. based on the increased likelihood of infection in particular localities or species) may be an appropriate strategy. Virological and serological methods should be used concurrently to define the avian influenza status of high risk populations.~~

A Member Country should justify the *surveillance* strategy chosen as adequate to detect the presence of *infection* with avian influenza viruses in accordance with Chapter 1.4. and the prevailing epidemiological situation, including cases of high pathogenicity influenza A detected in any birds. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

If a Member Country wishes to declare freedom from *infection* with avian influenza viruses in a specific zone or compartment, the design of the survey and the basis for the sampling process would need to be aimed at the population within the zone or compartment.

For random surveys, the design of the sampling strategy should incorporate epidemiologically appropriate design prevalence. The sample size selected for testing should be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The Member Country should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular should be clearly based on the prevailing or historical epidemiological situation.

#### Annex 14 (contd)

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 positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *flocks* which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease* and *infection* are technically well defined. The design of *surveillance* programmes to prove the absence of *infection* with, or circulation of, avian influenza viruses should be carefully followed to avoid producing results that are either insufficiently reliable, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

#### 2- Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of avian influenza at the *flock* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory *disease* or a drop in egg production, is important for the early detection of *infection* with avian influenza viruses. In some cases, the only indication of *infection* with low pathogenicity avian influenza virus may be a drop in feed consumption or egg production.

Clinical *surveillance* and laboratory testing should always be applied in series to clarify the status of avian influenza suspects detected by either of these complementary diagnostic approaches. Laboratory testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should have restrictions imposed upon it until avian influenza *infection* is ruled out.

Identification of suspect *flocks* is vital to the identification of sources of avian influenza viruses and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that avian influenza virus isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterisation.

#### 3- Virological surveillance

Virological *surveillance* should be conducted:

- a) to monitor at risk populations;

- b) to confirm clinically suspect cases;
- c) to follow up positive serological results;
- d) ~~to test 'normal' daily mortality, to ensure early detection of infection in the face of vaccination or in establishments epidemiologically linked to an outbreak.~~

#### 4. Serological surveillance

Serological *surveillance* aims at the detection of antibodies against avian influenza virus. Positive avian influenza viruses antibody test results can have four possible causes:

- a) natural *infection* with avian influenza viruses;
- b) *vaccination* against avian influenza;

Annex 14 (contd)

- c) ~~maternal antibodies derived from a vaccinated or infected parent flock are usually found in the yolk and can persist in progeny for up to four weeks;~~
- d) ~~lack of specificity of the test.~~

~~It may be possible to use serum collected for other survey purposes for avian influenza *surveillance*. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of avian influenza viruses should not be compromised.~~

~~The discovery of clusters of seropositive flocks may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or *infection*. As clustering may signal *infection*, the investigation of all instances should be incorporated in the survey design. Clustering of positive flocks is always epidemiologically significant and therefore should be investigated.~~

~~If *vaccination* cannot be excluded as the cause of positive serological reactions, diagnostic methods to differentiate antibodies due to *infection* or *vaccination* should be employed.~~

~~The results of random or targeted serological surveys are important in providing reliable evidence that no *infection* with avian influenza viruses is present in a country, zone or compartment. It is therefore essential that the survey be thoroughly documented.~~

#### 5. Virological and serological surveillance in vaccinated populations

~~The *surveillance* strategy is dependent on the type of vaccine used. The protection against influenza A virus is haemagglutinin subtype specific. Therefore, two broad *vaccination* strategies exist: 1) inactivated whole viruses, and 2) haemagglutinin expression-based vaccines.~~

~~In the case of vaccinated populations, the *surveillance* strategy should be based on virological or serological methods and clinical *surveillance*. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, virus antibody free birds and clearly and permanently identified. Sentinel birds should be used only if no appropriate *laboratory* procedures are available. The interpretation of serological results in the presence of *vaccination* is described in Article 10.4.33.~~

Article 10.4. **3922**.

Surveillance for demonstrating ~~Documentation of freedom from avian influenza or freedom from infection with high pathogenicity avian influenza viruses in poultry~~

#### **EU comment**

**We welcome the efforts to improve the structure of this article, however, we still find it too long and too academic.**

**We suggest specific changes below.**

1. ~~Additional surveillance requirements for Member Countries declaring freedom of the country, zone or compartment from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry~~

~~In addition to the general conditions described in above mentioned articles, a Member Country declaring freedom of the entire country, or a zone or a compartment from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry should provide evidence for the existence of an effective surveillance programme.~~

Transparency in the application of different methodologies is essential to ensure consistency in decision-making, ease of understanding, fairness and rationality. The assumptions made, the uncertainties, and the effect of these on the interpretation of the results, should be documented.

The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and it should be planned and implemented according to general conditions and methods described in accordance with this chapter and in Article 1.4.6, to demonstrate absence of *infection* with avian influenza viruses or with high pathogenicity avian influenza viruses, during the preceding 12 months in susceptible *poultry* populations (vaccinated and non-vaccinated). This requires the availability of demographic data on the poultry population and the support of a *laboratory* able to undertake identification of *infection* with avian influenza viruses through virus detection and antibody tests.

The surveillance programme should demonstrate absence of infection with high pathogenicity avian influenza viruses during the preceding 12 months in susceptible poultry populations (vaccinated and non-vaccinated).

Annex 14 (contd)

The design of the sampling strategy should include an epidemiologically appropriate design prevalence. The design prevalence and desired level of confidence in the results will determine the sample size. The Member Country should justify the choice of design prevalence and confidence level used on the basis of the stated objectives of the surveillance and the epidemiological situation.

This surveillance may be targeted to poultry population at the holding establishment and poor biosecurity measures in place. It should include the monitoring of high pathogenicity avian influenza virus in wild birds and of H5 and H7 low pathogenicity avian influenza virus in poultry, in order to adapt the biosecurity and possible control measures.

Data from different surveillance activities can be included to increase the sensitivity of the surveillance estimates and hence the confidence in freedom from disease. If this is to be done, a probabilistic approach is required to combine data from structured (e.g. surveys and active surveillance) and non-structured (e.g. passive surveillance) sources. It is necessary to quantify the sensitivity of each activity, in order to be able to quantify the sensitivity of the overall surveillance system and estimate the probability of disease freedom.

#### **EU comment**

**The above paragraph seems to be too academic and confusing. For example, the phrase ‘probability of disease freedom’ is difficult to define. Actually, either a country is free from a disease or it is not: there is no probability involved.**

**We consider that the understanding of the above paragraph could be improved with the following suggestions:**

**‘Data from different surveillance activities can be included to increase the sensitivity of the surveillance estimates and hence the confidence in freedom from disease. If this is to be done, a probabilistic approach it is required to combine data from structured (e.g. surveys and active surveillance) and non-structured (e.g. passive surveillance) sources. It is necessary and to quantify the sensitivity of each activity, in order to be able to quantify the sensitivity of the overall surveillance system and estimate the probability of disease freedom.’**

The surveillance programme should include surveillance for high pathogenicity avian influenza viruses in wild birds and monitoring of low pathogenicity avian influenza viruses in poultry, in order to ensure that biosecurity and control measures are fit for purpose.

Documentation for of freedom from infection with high pathogenicity avian influenza should provide details of the poultry population, the occurrence of suspected cases and how they were investigated and dealt with. This should include the results of laboratory testing and the biosecurity and control measures to which the animals concerned were subjected during the investigation.

2. Additional requirements for countries, zones or compartments that practice practise vaccination

Vaccination to prevent the transmission of high pathogenicity avian influenza virus may be part of a disease control programme. The level of flock immunity required to prevent transmission depends on the flock size, composition (e.g. species) and density of the susceptible poultry population. It is therefore impossible to be prescriptive. Based on the epidemiology of avian influenza in the country, zone or compartment, it may be that a decision is may be reached to vaccinate only certain species or other poultry subpopulations.

In all vaccinated flocks there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel poultry may provide further confidence of in the absence of virus circulation. The tests have to should be repeated at least every six months or at shorter intervals at a frequency, according to the risk in the country, zone or compartment.

**EU comment**

**We struggle to identify the purpose of sentinel birds. We understand that the test mentioned relate to the vaccinated animals. If our understanding is correct, the third sentence (The tests ~~have to~~ should be repeated at least every six months or at shorter intervals at a frequency, according to the risk in the country, zone or compartment) should follow the first one (In all vaccinated flocks there is a need to perform virological and serological tests to ensure the absence of virus circulation) to ensure that the test do not refer to sentinel poultry.**

**Furthermore, we don't see the need for testing all vaccinated epidemiological units (e.g. flocks), but we propose a more proportionate measure to require testing at establishment level, i.e. in 'all establishments vaccinating against avian influenza'.**

Evidence to show the effectiveness of the vaccination programme should also be provided.

Member Countries seeking the demonstration of freedom from high pathogenicity avian influenza in vaccinated population should refer to Chapter 2.3.4, paragraph C.4 on Avian Influenza (infection with avian influenza viruses) of the Terrestrial Manual, including virus or serological DIVA approaches.

**EU comment**

**To improve clarity and understanding, we propose to refer to the relevant paragraph (C.4.) of the corresponding Chapter in the Terrestrial Manual.**

Evidence to show the effectiveness of the vaccination programme should also be provided.

3. Additional requirements for recovery of free status

In addition to the conditions described in the point above, a Member Country declaring that it has regained country, zone or compartment freedom after an outbreak of high pathogenicity avian influenza in poultry should show evidence of an active surveillance programme, depending on the epidemiological circumstances of the outbreak, to demonstrate the absence of the infection. This will require surveillance incorporating virus detection and antibody tests. The use of sentinel birds may facilitate the interpretation of surveillance results. The Member Country should report the results of an active surveillance programme in which the susceptible poultry population undergoes regular clinical examination and active surveillance planned and implemented according to the general conditions and methods described in these recommendations. The surveillance samples should be representative of poultry populations at risk.

**EU comment**

**Similar comment in relation to sentinel birds as above**

Populations under this surveillance programme should include:

- 1a) establishments in the proximity of the outbreaks;
- 2b) establishments epidemiologically linked to the outbreaks;
- 3c) animals moved from or poultry used to re-populate affected establishments;
- 4d) any establishments where contiguous culling preventive depopulation has been carried out.

Article 10.4.3922bis.

#### Surveillance of wild bird populations

The presence of high pathogenicity avian influenza viruses in wild birds creates a particular problem. In essence, no Member Country can declare itself free from influenza A viruses in wild birds. However, the definition of high pathogenicity avian influenza in this chapter refers to the infection in poultry only, and Articles 10.4.27. to 10.4.33. were developed under this definition.

Passive surveillance (i.e. sampling of birds found dead) is an appropriate method of surveillance in wild birds as because infection with high pathogenicity avian influenza is usually can be associated with mortality in some species. Mortality events, or clusters of birds found dead should be reported to the local Veterinary Authorities and investigated.

#### **EU comment**

**We would like clarification on what the investigation should include for the requirement in the paragraph above about mortality events, or clusters, found dead that should be ‘investigated’.**

**We suggest to re-word the sentence: Mortality events, or clusters of birds found dead, should be reported to the local *Veterinary Authorities*, sampled and tested for identification of avian influenza viruses. We also consider that other birds such as sick or hunted birds found with clinical signs or injured, or sick wild birds, should also be sampled and tested.**

Active surveillance in wild birds usually has lower sensitivity for detection of high pathogenicity avian influenza, but may be necessary for detection of some strains of high pathogenicity avian influenza viruses that produce infection without mortality in wild birds. Furthermore, it increases knowledge of the ecology and evolution of avian influenza viruses.

#### **EU comment**

**We suggest defining the term *active surveillance* or at least specify what provisions it includes.**

**We would like to propose the following wording: ‘Active surveillance, which includes sampling and testing, in wild birds may be necessary for detection of some strains of high pathogenicity avian influenza viruses that produce *infection* without mortality in wild birds’.**

**It may also be useful to include provisions that in order to develop a surveillance programme for wild birds, data and information from fields such as ornithology, virology and epidemiology may be taken into account.**

Surveillance in wild birds should be targeted towards times of year, species, and locations and times of year in which infection is more likely.

Surveillance in wild birds should be enhanced by raising awareness, raising and by active searching and monitoring for dead or moribund wild birds when high pathogenicity avian influenza has been detected in the region. The movements of migratory water birds, in particular ducks, geese and swans, should be taken into account as a potential pathway for introduction of virus to uninfected areas.

Article 10.4.3022ter.

Monitoring of H5 and H7 low pathogenicity avian influenza in poultry populations

#### **EU comment**

**We consider that the title of this article should refer to H5 and H7 LPAI in poultry i.e. ‘Monitoring of H5 and H7 low pathogenicity avian influenza in poultry’. We believe that provisions for serotypes other than H5 and H7 should not be included in this Chapter.**

**We would like to repeat our comment in relation to the need for the clarification of the purpose of monitoring low pathogenicity avian influenza made in article 10.4.1.**

Outbreaks of low pathogenicity avian influenza viruses can be managed at the establishment level; however, spread to other poultry establishments increases the risk of virus mutation, particularly if it is not detected and managed. Therefore, a monitoring system that includes awareness and reporting should be in place.

#### **EU comment**

**As already mentioned in article 10.4.1. we do not understand the link of this article to the management of high pathogenicity avian influenza.**

**We consider that the last sentence of the paragraph above ‘Therefore, a monitoring system that includes awareness and reporting should be in place’ is quite prescriptive and it does not relate to HPAI.**

**We also consider that requirements for LPAI do not fit well here. LPAI is not notifiable independently of HPAI and therefore “minimum” requirements such as monitoring, awareness, etc. (like any other disease) should be in place without the need to include the reference here.**

Monitoring the presence of H5 and H7 low pathogenicity avian influenza viruses can be achieved through the a combination of clinical investigations where when infection is suspected through because of changes in production indicators parameters, such as reductions in egg production or feed and water intake, and active serological and virological surveillance.

Serological and virological monitoring should aim at detecting clusters of infected flocks to identify spread between establishments. Epidemiological follow-up (tracing forward and back) of serologically positive flocks should be carried out to determine if whether there is clustering of infected flocks regardless of whether the seropositive birds are still present on at the establishment or whether active virus infection has been detected.

## Annex 14 (contd)

### Article 10.4.31.

#### **Additional surveillance requirements for countries, zones or compartments declaring that they have regained freedom from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry following an outbreak**

In addition to the general conditions described in the above-mentioned articles, a Member Country declaring that it has regained country, zone or compartment freedom from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry should show evidence of an active surveillance programme depending on the epidemiological circumstances of the outbreak to demonstrate the absence of the infection. This will require surveillance incorporating virus detection and antibody tests. The use of sentinel birds may facilitate the interpretation of surveillance results.

A Member Country declaring freedom of country, zone or compartment after an outbreak of avian influenza should report the results of an active surveillance programme in which the susceptible poultry population undergoes regular clinical examination and active surveillance planned and implemented according to the general conditions and methods described in these recommendations. The surveillance should at least give the confidence that can be given by a randomised representative sample of the populations at risk.

### Article 10.4.32.

#### **Additional surveillance requirements for the avian influenza free establishments**

The declaration of avian influenza free establishments requires the demonstration of absence of infection with avian influenza viruses. Birds in these establishments should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these recommendations. The frequency of testing should be based on the risk of infection and at a maximum interval of 21 28 days.

### Article 10.4.33.

#### **The use and interpretation of serological and virus detection tests**

Poultry infected with avian influenza virus produce antibodies against haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins is not covered in this chapter. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct and blocking ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI), ELISA and neutralisation (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies against the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype influenza A viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of influenza A viruses.

Poultry can be vaccinated with a variety of influenza A vaccines including inactivated whole virus vaccines, and haemagglutinin expression-based vaccines. Antibodies against the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

Influenza A virus infection of unvaccinated birds including sentinels is detected by antibodies against the NP/M, subtype specific HA or NA proteins, or NSP. Poultry vaccinated with inactivated whole virus vaccines containing a virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies against the NA of the field virus. For example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies against NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In poultry vaccinated with haemagglutinin expression-based vaccines, antibodies are detected against the specific HA, but not any of the other viral proteins. Infection is evident by antibodies against the NP/M or NSP, or the specific NA protein of the field virus.

All flocks with seropositive results should be investigated. Epidemiological and supplementary laboratory investigation results should document the status of avian influenza infection for each positive flock.

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

#### 1. Procedure in case of positive test results if vaccination is used

In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from surveillance conducted on vaccinated poultry. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated animals.

a) Inactivated whole virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If poultry in the population have antibodies against NP/M and were vaccinated with inactivated whole virus vaccine, the following strategies should be applied:

i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating influenza A virus infection, specific HI tests should be performed to identify H5 or H7 virus infection;

ii) if vaccinated with inactivated whole virus vaccine containing homologous NA to field virus, the presence of antibodies against NSP could be indicative of infection. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins;

iii) if vaccinated with inactivated whole virus vaccine containing heterologous NA to field virus, presence of antibodies against the field virus NA or NSP would be indicative of infection. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins.

b) Haemagglutinin expression based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect avian influenza infection. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of infection. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins.

#### 2. Procedure in case of test results indicative of infection with avian influenza viruses

The detection of antibodies indicative of an infection with avian influenza virus in unvaccinated poultry should result in the initiation of epidemiological and virological investigations to determine if the infections are due to low and high pathogenicity viruses.

Virological testing should be initiated in all antibody positive and at risk populations. The samples should be evaluated for the presence of avian influenza virus, by virus isolation and identification, or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting infection by avian influenza virus. All influenza A virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as high or low pathogenicity avian influenza viruses or other influenza A viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as high or low pathogenicity avian influenza viruses. The use of antigen detection systems, because of low sensitivity, should be limited to screening clinical field cases for infection by influenza A virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

Annex 14 (contd)

~~Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:~~

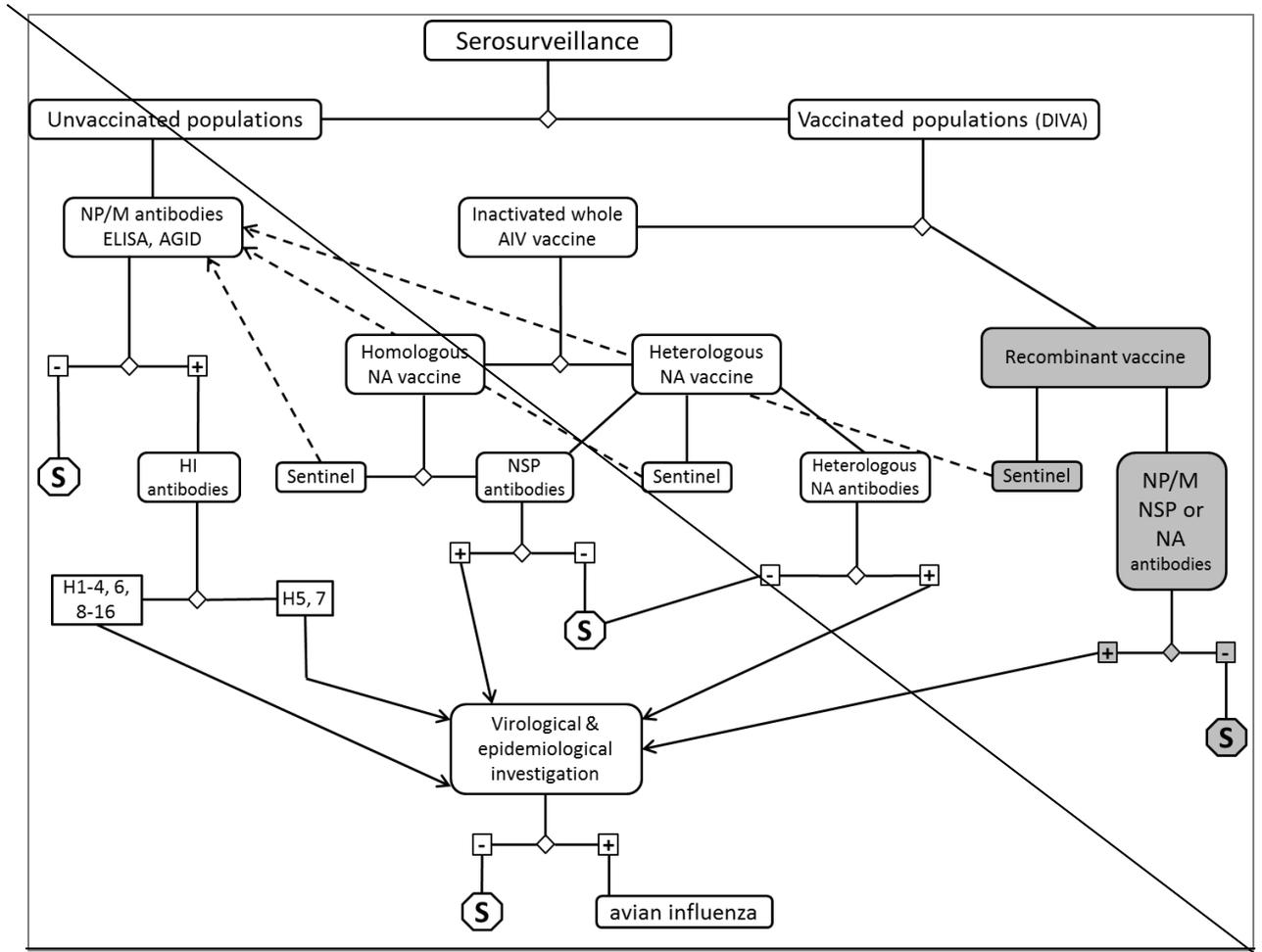
- ~~a) characterisation of the existing production systems;~~
- ~~b) results of clinical *surveillance* of the suspects and their cohorts;~~
- ~~c) quantification of *vaccinations* performed on the affected sites;~~
- ~~d) sanitary protocol and history of the affected *establishments*;~~
- ~~e) control of animal identification and movements;~~
- ~~f) other parameters of regional significance in historic avian influenza virus transmission.~~

~~The entire investigative process should be documented as standard operating procedure within the epidemiological *surveillance* programme.~~

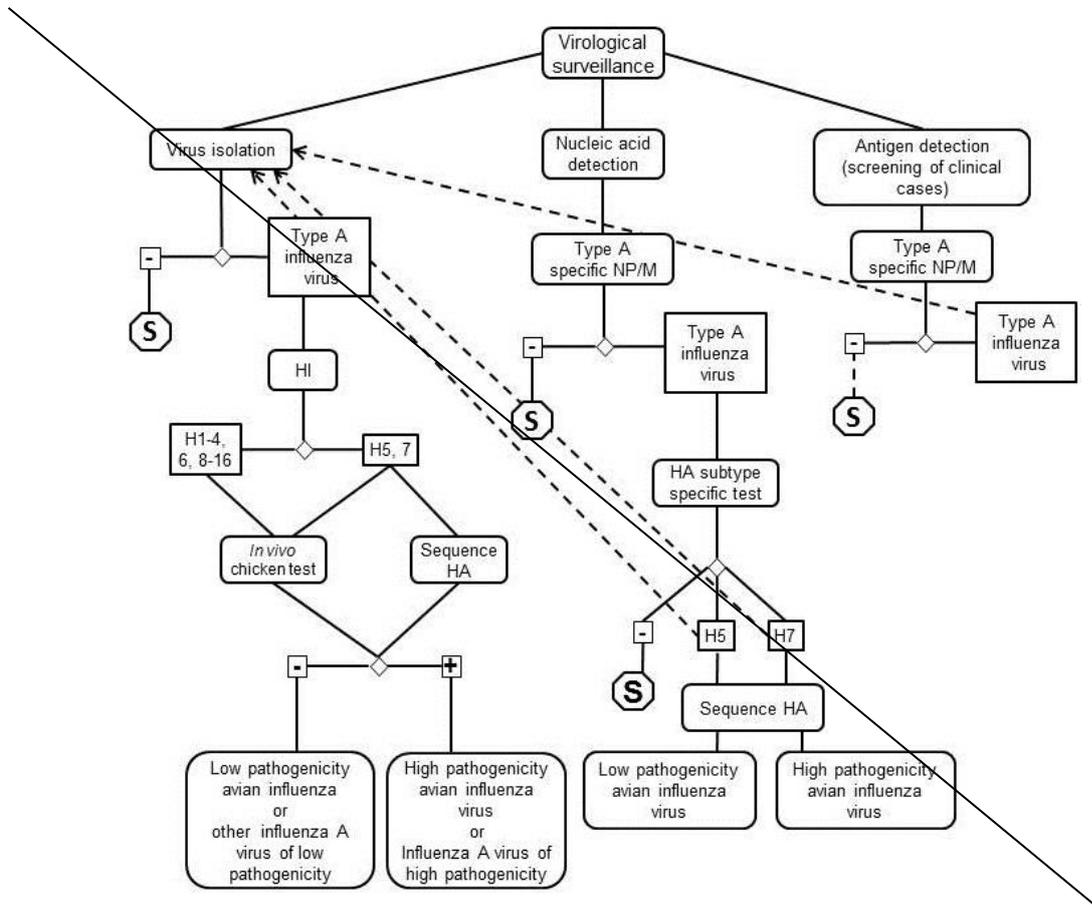
Figures 1 and 2 indicate the tests which are recommended for use in the investigation of *poultry flocks*.

Key abbreviations and acronyms:	
AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbent assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence of avian influenza virus

**Fig. 1.** Schematic representation of laboratory tests for determining evidence of avian influenza infection through or following serological surveys



**Fig. 2.** Schematic representation of laboratory tests for determining evidence of avian influenza infection using virological methods



CHAPTER 1.3.

**DISEASES, INFECTIONS AND INFESTATIONS LISTED BY  
THE OIE**

**EU comment**

**The EU in general supports the proposed change to this chapter.**

[...]

Article 1.3.6.

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

- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Avian mycoplasmosis (*Mycoplasma gallisepticum*)
- Avian mycoplasmosis (*Mycoplasma synoviae*)
- Duck virus hepatitis
- Fowl typhoid
- Infection with high pathogenicity avian influenza viruses
- Infection with influenza A viruses of high pathogenicity in birds other than *poultry* including wild birds
- Infection with Newcastle disease virus
- Infectious bursal disease (Gumboro disease)
- Pullorum disease
- Turkey rhinotracheitis.

[...]

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CHAPTER 14.7.

INFECTION WITH  
PESTE DES PETITS RUMINANTS VIRUS

**EU comment**

**The EU in general supports the proposed changes to this chapter.**

**Specific comments are inserted within the text of this annex.**

[...]

Article 14.7.3.

**~~PPR-free~~ Country or zone free from PPR**

A country or zone may be considered free from PPR when the relevant provisions **of in point 2 of Article 1.4.6. and Chapter 1.6.** have been complied with, and when within the proposed free country or zone for at least the past 24 months:

- 1) there has been no *case of infection* with PPRV;
- 2) the *Veterinary Authority* has current knowledge of, and authority over, all domestic sheep and goats in the country or zone;
- 3) appropriate *surveillance* has been implemented in accordance with:
  - a) **Chapter Article 1.4.6.** where historical freedom can be demonstrated; or
  - b) Articles 14.7.27. to 14.7.33. where historical freedom cannot be demonstrated;
- 4) measures to prevent the introduction of the *infection* have been in place: in particular, the importations or movements of *commodities* into the country or zone have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*;
- 5) no *vaccination* against PPR has been carried out;
- 56) no animals vaccinated against PPR have been introduced since the cessation of *vaccination*. **[under study]**
- 1) ~~The PPR status of a country or zone should be determined on the basis of the following criteria, as applicable:~~
  - a) ~~PPR is notifiable in the whole territory, and all clinical signs suggestive of PPR should be subjected to appropriate field or *laboratory* investigations;~~
  - b) ~~an ongoing awareness programme is in place to encourage reporting of all cases suggestive of PPR;~~
  - c) ~~systematic *vaccination* against PPR is prohibited;~~
  - d) ~~importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with this chapter;~~
  - e) ~~the *Veterinary Authority* has current knowledge of, and authority over, all domestic sheep and goats in the country or zone;~~

- f) appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs, is in place; this may be achieved through a *surveillance* programme in accordance with Articles 14.7.27. to 14.7.33.

Annex 16 (contd)

- 2) To qualify for inclusion in the list of PPR free countries or zones, a Member Country should either:
- a) apply for recognition of historical freedom as described in point 1) of Article 1.4.6.; or
  - b) apply for recognition of freedom and submit to the OIE:
    - i) a record of regular and prompt animal disease reporting;
    - ii) a declaration stating that:
      - there has been no *outbreak* of PPR during the past 24 months;
      - no evidence of PPRV *infection* has been found during the past 24 months;
      - no *vaccination* against PPR has been carried out during the past 24 months;
      - importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with this chapter;
    - iii) supply documented evidence that *surveillance* in accordance with Chapter 1.4. is in operation and that regulatory measures for the prevention and control of PPR have been implemented;
    - iv) evidence that no animals vaccinated against PPR have been imported since the cessation of *vaccination*.

The Member Country will be included in the list only after the application and submitted evidence has been accepted by the OIE. Changes in the epidemiological situation or other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

The country or the zone will be included in the list of countries or zones free from PPR in accordance with Chapter 1.6.

Retention on the list requires ~~annual reconfirmation of point 2) above~~ annual reconfirmation of all points above and relevant points under point 4 of Article 1.4.6. Documented evidence should be resubmitted annually for that information in point 4 d) of Article 1.4.6. and points 1) to 3d) above. ~~above be re-submitted annually and Any changes in the epidemiological situation or other significant events including those relevant to points 4 a) to 4 c) of Article 1.4.6. and points 4) and 5) above should be reported notified to the OIE in accordance with Chapter 1.1.~~

**EU comment**

**In the paragraph above we suggest inserting the words ‘compliance with’ after ‘annual reconfirmation of’ to make it clear that compliance is what is required.**

**In relation to the documented evidence that have to be resubmitted annually for points 1) to 4). On one hand, we find it difficult to know what level of documented evidence is needed for point 1. On the other hand, documenting evidence for compliance with point 4 is quite burdensome and until now it has been sufficient to state the compliance with this requirement (i.e. without documented evidence).**

[...]

Article 14.7.7.

**Recovery of free status**

When ~~Should an~~ a PPR outbreak of PPR or PPRV infection occurs in a ~~previously~~ PPR free country or zone, ~~its~~ status may be restored and when a ~~stamping-out policy~~ is practised, the recovery period shall be six months after the ~~slaughter~~ of the last case ~~disinfection of the last affected establishment~~, provided that: ~~Article 14.7.32. has been complied with~~

1) a stamping-out policy has been implemented;

2) surveillance in accordance with Article 14.7.32. has been carried out with negative results.

~~If a stamping-out policy is not applied~~ Otherwise, Article 14.7.3. applies.

The country or zone will regain PPR free status only after the submitted evidence has been accepted by the OIE.

[...]

Article 14.7.24.

#### Recommendations for importation from countries or zones considered infected with PPRV

For wool, hair, raw hides and skins from sheep and goats

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the products were adequately processed in accordance with one of the following procedures referred to in Article 8.8.34, in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.

##### 1. For wool and hair:

- a) industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);
- b) chemical depilation by means of slaked lime or sodium sulphide;
- c) fumigation with formaldehyde in a hermetically sealed chamber for at least 24 hours;
- d) industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60-70°C;
- e) storage of wool at 4°C for four months, 18°C for four weeks or 37°C for eight days;
- f) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of PPRV.

##### 2. For raw hides and skins:

- a) treatment for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na<sub>2</sub>CO<sub>3</sub>);
- b) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of PPRV.

[...]

Article 14.7.34.

#### OIE endorsed official control programme for PPR

~~The objective of an OIE endorsed official control programme for PPR is for Member Countries to progressively improve the situation in their territories and eventually attain free status for PPR.~~

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for PPR in accordance with Chapter 1.6., when they have implemented measures in accordance with this article.

For a Member Country's *official control programme* for PPR to be endorsed by the OIE, the Member Country should provide a detailed official control programme for the control and eventual eradication of PPR in the country or zone. This document should address and provide documented edary evidence on the following:

##### 1) epidemiology:

- a) the detailed epidemiological situation of PPR in the country, highlighting the current knowledge and gaps;
- b) the main livestock production systems and movement patterns of sheep and goats and their products within and into the country and, where applicable, the specific zone;

Annex 16 (contd)

2) surveillance and diagnostic capabilities:

- a) PPR surveillance in place, in accordance with Chapter 1.4. and Articles 14.7.27. to 14.7.33.:
- b) diagnostic capability and procedures, including regular submission of samples to a laboratory that carries out diagnosis diagnostic testing and further characterisation of strains:
- c) serosurveillance conducted in susceptible species, including wildlife, to serve as sentinels for PPRV circulation in the country:

3) vaccination strategies to reach the objectives:

- a) where vaccination is practised as a part of the official control programme for PPR, documented evidence (such as copies of national legislation, regulations and Veterinary Authority directives) that vaccination of selected populations is compulsory.:
- b) and detailed information on vaccination campaigns, in particular on:
  - i) the strategy that is adopted for the vaccination campaign;
  - ii) target populations for vaccination;
  - iii) target geographical area for vaccination;
  - iv) monitoring of vaccination coverage, including serological monitoring of population immunity;
  - v) technical specification of the vaccines used and description of the vaccine licensing procedures in place;
  - vi) if relevant, proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the Terrestrial Manual;
  - vii) the proposed strategy and work plan including the timeline for the transition to the cessation of the use of vaccination;

4) the measures implemented to prevent the introduction of the pathogenic agent, and to ensure the rapid detection of, and response to, all PPR outbreaks in order to reduce outbreaks and to eliminate PPRV circulation in domestic sheep and goats in at least one zone in the country:

5) existence of an emergency preparedness plan and an emergency response plan to be implemented in case of PPR outbreaks:

46) the defined work plan and timelines of the official control programme:

57) performance indicators for assessing the effectiveness of the control measures to be implemented:

68) monitoring, evaluation and review assessment of the evolution and implementation of the official control programme to demonstrate the effectiveness of the strategies.:

7) existence of an emergency preparedness plan and of an emergency response plan to be implemented in case of PPR outbreaks.

- 1) submit documented evidence on the capacity of its Veterinary Services to control PPR; this evidence can be provided by countries following the OIE PVS Pathway;
- 2) submit documentation indicating that the official control programme for PPR is applicable to the entire territory (even if it is on a zonal basis);
- 3) have a record of regular and prompt animal disease reporting in accordance with the requirements in Chapter 1.1.;

- 4) submit a dossier on the status of PPR in the country describing the following:
  - a) the general epidemiology of PPR in the country highlighting the current knowledge and gaps;
  - b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all PPR *outbreaks* in order to reduce the incidence of *outbreaks* and to eliminate virus circulation in domestic sheep and goats in at least one *zone* in the country;
  - c) the main livestock production systems and movement patterns of sheep and goats and their products within and into the country and, where applicable, the specific *zone(s)*;
- 5) submit a detailed plan of the programme to control and eventually eradicate PPR in the country or *zone* including:
  - a) the timeline for the programme;
  - b) the performance indicators that will be used to assess the efficacy of the control measures;
- 6) submit evidence that PPR *surveillance* is in place, taking into account the provisions in Chapter 1.4. and the provisions on *surveillance* in this chapter;
- 7) have diagnostic capability and procedures in place, including regular submission of samples to a *laboratory*;
- 8) where *vaccination* is practised as a part of the *official control programme* for PPR, provide evidence (such as copies of legislation) that *vaccination* of sheep and goats in the country or *zone* is compulsory;
- 9) if applicable, provide detailed information on *vaccination* campaigns, in particular on:
  - a) the strategy that is adopted for the *vaccination* campaign;
  - b) monitoring of *vaccination* coverage, including serological monitoring of population immunity;
  - c) serosurveillance in other susceptible species, including *wildlife* to serve as sentinels for PPRV circulation in the country;
  - d) disease *surveillance* in sheep and goat populations;
  - e) the proposed timeline for the transition to the cessation of the use of *vaccination* in order to enable demonstration of absence of virus circulation;
- 10) provide an emergency preparedness and contingency response plan to be implemented in case of PPR *outbreak(s)*.

The Member Country's *official control programme* for PPR will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE.

The country will be included in the list of countries having an OIE endorsed *official control programme* for PPR in accordance with Chapter 1.6.

Retention on the list of endorsed *official control programmes* for PPR requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above.

Changes in the epidemiological situation and other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

Annex 16 (contd)

The OIE may withdraw the endorsement of the *official control programme* if there is evidence of:

- non-compliance with the timelines or performance indicators of the programme; or
  - significant problems with the performance of the *Veterinary Services*; or
  - an increase in the incidence of PPR that cannot be addressed by the programme.
-

## CHAPTER 15.2.

## INFECTION WITH CLASSICAL SWINE FEVER VIRUS

**EU comment**

**The EU in general supports the proposed changes to this chapter.**

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

## Article 15.2.1.

**General provisions**

The pig (*Sus scrofa*, both domestic and wild) is the only natural host for classical swine fever virus (CSFV). For the purposes of this chapter, a distinction is made between:

- = domestic and captive wild pigs, whether permanently housed captive or farmed free ranging, used for the production of meat, or other commercial products or purposes use use, or for breeding; and
- = wild and feral pigs.

For the purposes of the *Terrestrial Code*, classical swine fever (CSF) is defined as an *infection* of pigs with classical swine fever virus (CSFV).

The following defines the occurrence of infection with CSFV:

- 1) a strain of CSFV (excluding vaccine strains) has been isolated from samples from a pig;

OR

- 2) ~~viral antigen or nucleic acid specific to CSFV~~ (excluding vaccine strains) has been identified detected, or ~~viral ribonucleic acid (RNA) specific to a strain of CSFV has been demonstrated to be present~~, in samples from ~~one or more a pigs showing clinical signs or pathological lesions suggestive of CSF, or epidemiologically linked to a suspected or confirmed or suspected outbreak case~~ of CSF, or giving cause for suspicion of previous association or contact with CSFV, ~~with or without clinical signs consistent with CSF;~~

OR

- 3) ~~virus specific~~ antibodies specific to CSFV that are not a consequence of *vaccination* or *infection* with other pestiviruses, have been identified detected in samples from ~~one or more a pigs in a herd~~ showing clinical signs or pathological lesions consistent with CSF, or epidemiologically linked to a suspected or confirmed or suspected outbreak case of CSF, or giving cause for suspicion of previous association or contact with CSFV.

~~The pig is the only natural host for CSFV. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild. For the purposes of this chapter, a distinction is made between:~~

- ~~– domestic and captive wild pigs, permanently captive or farmed free range, used for the production of meat, or other commercial products or use, or for breeding these categories of pigs;~~
- ~~– wild and feral pigs.~~

For the purposes of the *Terrestrial Code*, the incubation period shall be 14 days.

Pigs exposed to CSFV postnatally have an *infective period* of up to three months. Pigs exposed to CSFV prenatally may not show clinical signs at birth and be persistently infected throughout life and may have an *incubation period* of several months before showing signs of disease. Pigs exposed postnatally have an *incubation period* of 2-14 days, and are usually infective between post-infection days 5 and 14, but up to 3 months in cases of chronic *infections*. Pigs exposed to CSFV postnatally have an *infective period* of up to three months.

A Member Country should not impose bans on the trade in *commodities* of domestic and captive wild pigs in response to a *notification of infection* with CSFV in wild and feral pigs provided that Article 15.2.2. is implemented.

Annex 17 (contd)

Commodities of domestic or captive wild pigs can be traded safely in accordance with the relevant articles of this chapter from countries complying with the provisions of Article 15.2.2, even if they notify infection with CSFV in wild or feral pigs.

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

Article 15.2.1bis.

Safe commodities

When authorising import or transit of the following commodities, Veterinary Authorities should not require any CSF-related conditions, regardless of the CSF status of the exporting country or zone:

- 1) meat in a hermetically sealed container with a F-value of 3 or above;
- 2) gelatine.

Other pig commodities can be traded safely if in accordance with the relevant articles of this chapter.

Article 15.2.2.

**General criteria for the determination of the classical swine fever CSF status of a country, zone or compartment**

- 1) CSF should be ~~is~~ notifiable in the whole territory, and all pigs showing clinical signs or pathological lesions suggestive of CSF should be ~~are~~ subjected to appropriate field or laboratory investigations;
- 2) ~~an on-going awareness programme should be~~ ~~is~~ in place to encourage reporting of all cases ~~pigs showing signs~~ suggestive of CSF;
- 3) the Veterinary Authority should have ~~has~~ current knowledge of, and authority over, all domestic and ~~captive wild pig herds~~ in the country, zone or compartment;
- 4) the Veterinary Authority should have ~~has~~ current knowledge about ~~of~~ the population ~~distribution~~ and habitat of ~~wild and feral~~ pigs in the country or zone;
- 5) for domestic and ~~captive wild~~ pigs, appropriate ~~surveillance~~ in accordance with Articles 15.2.26. to 15.2.32. ~~is~~ in place;
- 6) for ~~wild and feral~~ pigs, if present in the country or zone, a ~~surveillance~~ programme is in place according to Article 15.2.31., taking into account the presence of natural and artificial boundaries, the ecology of the ~~wild and feral~~ pig population, and an assessment of the ~~risks~~ of disease spread;
- 7) based on the assessed ~~risk~~ of spread within the ~~wild and feral~~ pig population, and according to Article 15.2.29., the domestic and ~~captive wild~~ pig population should be ~~is~~ separated from the ~~wild and feral~~ pig population by appropriate measures.

Article 15.2.32.

**Country or zone free from CSF Classical swine fever free country or zone**

A country or zone may be considered free from CSF when ~~the relevant provisions in point 2 of Article 1.4.6. have been~~ ~~Article 15.2.2. is~~ complied with, and when ~~within the proposed CSF free country or zone for at least the past 12 months:~~

- 1) ~~surveillance~~ in accordance with Articles 15.2.26. to 15.2.32. has been in place for at least 12 months;
- 2) ~~there has been no outbreak~~ of CSF in domestic and ~~captive wild~~ pigs during the past 12 months;

- 13) there has been no evidence case of infection with CSFV has been found in domestic and captive wild pigs during the past 12 months;
- 2) the Veterinary Authority has current knowledge of, and authority over, all domestic and captive wild pig herds in the country or zone;
- 3) the Veterinary Authority has current knowledge of the distribution, habitat and indication of disease occurrence through passive surveillance of wild and feral pigs in the country or zone;
- 4) appropriate surveillance has been implemented in accordance with:
  - a) Article 1.4.6. where historical freedom can be demonstrated; or
  - b) Articles 15.2.21. to 15.2.26. where historical freedom cannot be demonstrated;
- 5) measures to prevent the introduction of the infection have been in place: in particular, the importations or movements of commodities into the country or zone have been carried out in accordance with this chapter and other relevant chapters of the Terrestrial Code;
- 6) no vaccination against CSF has been carried out in domestic and captive wild pigs during the past 12 months unless there are means, validated according to Chapter 3.8.3. of the Terrestrial Manual, of distinguishing between vaccinated and infected pigs;
- 5) imported pigs and pig commodities comply with the requirements in Articles 15.2.7. to 15.2.
- 7) the domestic and captive wild pig populations are separated by appropriate biosecurity, effectively implemented and supervised, from the wild and feral pig populations, based on the assessed likelihood of spread within the wild and feral pig populations, and surveillance in accordance with Article 15.2.26.

The proposed free country or the proposed free zone will be included in the list of CSF free countries or zones only after the submitted evidence, based on the provisions of Article 1.6.9-10. Chapter 1.9., has been accepted by the OIE.

The country or the zone will be included in the list of countries or zones free from CSF in accordance with Chapter 1.6.

Retention on the list requires annual reconfirmation of all points above and relevant points under point 4 of Article 1.4.6. Documented evidence should be resubmitted annually for that the information in points 1) to 5)3), 2) to or 53) above be re-submitted annually and, Any changes in the epidemiological situation or other significant events above should be reported notified to the OIE according to the requirements in in accordance with Chapter 1.1.

Article 15.2.43.

#### **Compartment free from CSF Classical swine fever free compartment**

The establishment and bilateral recognition of a compartment free from CSF free compartment should follow the relevant requirements of this chapter and the principles laid down in Chapters 4.4. and 4.5. Pigs in a the compartment free from CSF should be separated from any other pigs by the application of effective biosecurity

Article 15.2.54.

#### **Establishment of a containment zone within a classical swine fever free country or zone previously free from CSF**

In the event of limited outbreaks or cases of CSF within a CSF free country or zone previously free from CSF, including within a protection zone, a containment zone, which includes all epidemiologically linked outbreaks, can be established, in accordance with Article 4.4.7. for the purpose of to minimising the impact on the entire rest of the country or zone.

Annex 17 (contd)

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE.

~~In addition to the requirements for the establishment of a containment zone outlined in Article 4.3.7, point 3 of Article 4.3.3., the~~ The *surveillance* programme should take into consideration the involvement of *wild* and *feral* pigs and measures to avoid their dispersion.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of these areas may be reinstated irrespective of the provisions of Article 15.2.65., once the *containment zone* is clearly established. ~~It should be demonstrated that commodities for international trade have originated outside the containment zone.~~

## EU comment

Given that the “containment zone” is not an obligation, para 4 should reflect that.

We suggest the inclusion of this sentence at the beginning of the phrase:

**‘In case a containment zone has been established’, the free status of the areas outside the containment zone is suspended while the containment zone is being established. The free status of these areas may be reinstated irrespective of the provisions of Article 15.2.65., once the containment zone is clearly established.**

**Otherwise any country would lose entirely its status while setting up its containment zone.**

In the event of the recurrence of CSF in the *containment zone*, the approval of the *containment zone* is withdrawn, and the free status of the country or zone is suspended until the relevant requirements of Article 15.2.365. have been fulfilled.

The recovery of the CSF free status of the *containment zone* should follow the provisions of Article 15.2.65 and be achieved within 12 months of its approval.

Article 15.2.65.

## Recovery of free status

Should ~~an outbreak~~ of CSF occur in a previously ~~a CSF outbreak occur in a~~ free country or *zone*, ~~the free its~~ status may be ~~restored~~ recovered ~~when where surveillance~~ in accordance with Articles 15.2.263025 ~~to 15.2.32.~~ has been carried out with negative results ~~either, and three months after:~~

- 1) ~~three months after the disinfection of the last affected establishment, provided that~~ a *stamping-out policy* without *vaccination* ~~is practised has been implemented;~~ **OR**
- 2) ~~when where a stamping-out policy with emergency vaccination is practised:~~
- 2) ~~a) three months after and the disinfection of the last affected establishment or and~~ the *slaughter* of all vaccinated *animals*, ~~whichever occurred last;~~ provided that a stamping-out policy with emergency vaccination and slaughter of vaccinated animals has been implemented; or
- 3) ~~b) three months after the disinfection of the last affected establishment provided that a stamping-out policy with emergency vaccination~~ without the *slaughter* of vaccinated *animals* ~~when where~~ there are means, validated according to Chapter 3.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs; **OR**
- 3) ~~when where a stamping-out policy is not practised, the provisions of Article 15.2.3. should be followed.~~

The country or *zone* will regain CSF free status only after the submitted evidence, based on the provisions of Article 1.6.9. Chapter 1.9. has been accepted by the OIE.

The country or zone will regain CSF free status only after the submitted evidence, based on the provisions of Article 1.6.10., has been accepted by the OIE.

Article 15.2.65bis.

**Direct transfer of pigs within a country from an infected zone to a free zone for slaughter**

In order not to jeopardise the status of a free zone, pigs should only leave the infected zone if transported by mechanised vehicle directly for slaughter in the nearest designated slaughterhouse/abattoir under the following conditions:

- 1) no pig has been introduced into the establishment of origin and no pig in the establishment of origin has shown clinical signs of CSF for at least 30 days prior to slaughter.

**EU comment**

**We would suggest adding a bullet point on the need to have biosecurity on the holding of origin of the pigs.**

**Suggested wording:**

**‘1bis) the holding implements biosecurity measures approved by the Veterinary Authority’**

- 2) the pigs were kept in the establishment of origin for at least three months prior to movement for slaughter.
- 3) CSF has not occurred within a 10-kilometre radius of the establishment of origin for at least three months prior to movement;
- 4) the pigs should be transported under biosecure conditions under the supervision of the Veterinary Services Authority in a vehicle, which was cleaned and disinfected before loading, directly from the establishment of origin to the slaughterhouse/abattoir without coming into contact with other pigs;
- 5) such a slaughterhouse/abattoir is not approved for the export of fresh meat during from the time the pigs arrived from the infected zone until it is handling the meat of those pigs have left the premises from the infected zone;
- 6) vehicles and the slaughterhouse/abattoir should be subjected to disinfection immediately after use.

The pigs should be subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results and the meat should be treated according to in accordance with Article 15.2.2318. The fresh meat from those pigs should be identified and kept separate from other pig products until treated.

Any other products obtained from the pigs, and any products coming into contact with them, should be considered contaminated and treated in accordance with Article 15.2.2217, or Articles 15.2.2419, to 15.2.2419ter, to destroy any residual virus CSFV potentially present.

Article 15.2.65ter.

**Direct transfer of pigs within a country from a containment zone to a free zone for slaughter**

In order not to jeopardise the status of a free zone, pigs should only leave the containment zone if transported by mechanised vehicle directly for slaughter in the nearest designated slaughterhouse/abattoir under the following conditions:

- 1) the containment zone has been officially established according to the requirements in Article 15.2.54;
- 2) the pigs should be transported under the supervision of the Veterinary Services in a vehicle, which was cleaned and disinfected before loading, directly from the establishment of origin to the slaughterhouse/abattoir without coming into contact with other pigs;

3) such a slaughterhouse/abattoir is not approved for the export of fresh meat during from the time the pigs arrived from the containment zone until the meat of those pigs have left the premises the time it is handling the meat of pigs from the containment zone;

4) vehicles and the slaughterhouse/abattoir should be subjected to disinfection immediately after use.

The pigs should be subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results and the meat should be treated according to in accordance with Article 15.2.23-18. The fresh meat from those pigs should be identified and kept separate from other pig products until treated.

Any other products obtained from the pigs, and any products coming into contact with them, should be considered contaminated and treated in accordance with Article 15.2.22-17 or Articles 15.2.24-19. to 15.2.24-19ter. to destroy any residual virus CSFV potentially present.

Article 15.2.76.

#### **Recommendations for importation from countries, zones or compartments free from ~~classical swine fever~~ CSF**

For domestic and captive wild pigs

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

Annex 17 (contd)

- 1) showed no clinical sign of CSF on the day of shipment;
- 2) ~~were kept in a country, zone or compartment free from CSF since birth or for at least the past three months in a country, zone or compartment free from CSF;~~
- 3) ~~have were~~ not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated according to in accordance with Chapter 3.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

Article 15.2.87.

#### **Recommendations for importation from countries or zones ~~considered infected with classical swine fever virus~~ not free from CSF**

For domestic and captive wild pigs

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

- 1) showed no clinical sign of CSF on the day of shipment;
- 2) and either:
  - a) were kept since birth or for the past three months in a CSF free compartment, or
  - b) were isolated for 28 days prior to shipment in a quarantine station, and were subjected to a virological test and a serological test performed on a sample collected at least 21 days after entry into the quarantine station, with negative results;
- 3) ~~have were~~ not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated according to in accordance with Chapter 3.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

Article 15.2.9.

#### **Recommendations for the importation of wild and feral pigs**

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *animals/pigs*:

- 1) showed no clinical sign of CSF on the day of shipment;
- 2) were kept ~~isolated~~ in a ~~quarantine station~~ for ~~40-28~~ days prior to shipment, and were subjected to a virological test and a serological test performed ~~on a sample collected~~ at least 21 days after entry into the ~~quarantine station~~, with negative results;
- 3) have ~~were~~ not been vaccinated against CSF, unless there are means, validated according to Chapter 3.8.3. of the *Torrestrial Manual*, of distinguishing between vaccinated and infected pigs.

Article 15.2.108.

**Recommendations for importation from countries, zones or compartments free from ~~classical swine fever~~ CSF**

For semen of domestic and captive wild pigs

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

- 1) the donor ~~animals~~ males:
  - a) were kept ~~in a country, zone or compartment free from CSF~~ since birth or for at least three months prior to collection in a country, zone or compartment free from CSF;
  - b) showed no clinical sign of CSF on the day of collection of the semen;
- 2) the semen was collected, processed and stored in ~~conformity~~ accordance with the provisions of Chapters 4.5. and 4.6.

Article 15.2. 119.

**Recommendations for importation from countries or zones ~~considered infected with classical swine fever virus~~ not free from CSF**

For semen of domestic and captive wild pigs

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

- 1) the donor ~~animals~~ males:
  - a) were kept ~~in a compartment free from CSF~~ since birth or for at least three months prior to collection in an establishment in which surveillance, in accordance with Articles 15.2. 2621 to 15.2. 3226, demonstrated that no case of CSF occurred in the past 12 months;
  - b) showed no clinical sign of CSF on the day of collection of the semen ~~and for the following 40 days~~;
  - c) met one of the following conditions:
    - i) were subjected to a virological test performed on a blood sample taken on the day of collection, with negative results; or
    - ii) ~~were~~ were not ~~been~~ vaccinated against CSF and were subjected to a serological test performed on a sample taken at least 21 days after collection, with negative results; or
    - iii) have been vaccinated against CSF and were subjected to a serological test performed on a sample taken at least 21 days after collection, ~~which and it has been conclusively demonstrated that any antibody is due to was~~ caused elicited by the vaccine; or
    - iiii) ~~have been vaccinated against CSF and were subjected to a virological test performed on a sample taken on the day of collection and it has been conclusively demonstrated that the bear is negative for virus genome~~;
- 2) the semen was collected, processed and stored in ~~conformity~~ accordance with the provisions of Chapters 4.5. and 4.6.

Article 15.2. 1210.

**Recommendations for importation from countries, zones or compartments free from ~~classical swine fever~~ CSF**

For in vivo derived embryos of domestic pigs

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

- 1) the donor females; ~~showed no clinical sign of CSF on the day of collection of the embryos~~;
  - a) were kept since birth or for at least three months prior to collection in a country, zone or compartment free from CSF;
  - b) showed no clinical sign of CSF on the day of collection of the embryos;

Annex 17 (contd)

- 2) the semen used to fertilise the oocytes complied with the conditions in Articles 15.2.108. or Article 15.2.119., as relevant;
- 3) the embryos were collected, processed and stored in accordance with Chapters 4.7. and 4.9., as relevant.

Article 15.2.131.

**Recommendations for importation from countries or zones ~~considered infected with classical swine fever virus~~ not free from CSF**

For *in vivo* derived embryos of domestic pigs

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

- 1) the donor females:
  - a) were kept in a compartment free from CSF since birth or for at least three months prior to collection in an establishment in which surveillance, in accordance with Articles 15.2.2621. to 15.2.3226., demonstrated that no case of CSF occurred in the past three months;
  - b) showed no clinical sign of CSF on the day of collection of the embryos ~~and for the following 40 days;~~
  - c) and either met one of the following conditions:
    - i) were subjected to a virological test performed on a blood sample taken on the day of collection, with negative results; or
    - ii) have ~~were not been~~ vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection; or
    - iii) have ~~been~~ were vaccinated against CSF and were subjected to a serological test performed on a sample taken at least 21 days after collection, which ~~and it has been conclusively demonstrated by means, validated according to Chapter 3.8.3. of the Terrestrial Manual,~~ that any antibody is due to ~~was caused~~ elicited by the vaccine;
- 2) the semen used to fertilise the oocytes complied with the conditions in Article 15.2.8. or Article 15.2.9., as relevant;
- 3) the embryos were collected, processed and stored in accordance with Chapters 4.7. and 4.9., as relevant.

Article 15.2.1412.

**Recommendations for importation from countries, zones or compartments free from ~~classical swine fever~~ CSF**

For *fresh meat* of domestic and *captive wild pigs*

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

- 1) have been kept in a country, *zone* or *compartment* free from CSF, or which have been imported in accordance with Article 15.2.76. or Article 15.2.87.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir*, where they have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results ~~and have been found free from any sign suggestive of CSF.~~

Article 15.2.1412bis.

**Recommendations for importation from countries or zones not free from CSF, where an official control programme exists**

For fresh meat of domestic pigs and captive wild pigs

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

- 1) the meat comes from pigs from which the meat comes derives complying complied complying with Article 15.2.87.;
- 2) the pigs were transported under the supervision of the Veterinary Services, in a vehicle which was cleaned and disinfected before the pigs were loaded;
- 3) the pigs were transported directly to the approved slaughterhouse/abattoir without coming into contact either during transport or at the slaughterhouse/abattoir with other pigs which do not fulfil the conditions of Article 15.2.87 required for export;
- 4) the pigs were slaughtered in an approved slaughterhouse/abattoir.
  - a) which is officially approved designated for export by the Veterinary Authority;
  - b) in which no case of CSF was detected during the period between the last disinfection carried out before slaughter and the shipment for export has been dispatched from the slaughterhouse/abattoir;
- 5) the pigs were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results;
- 6) appropriate precautions have been taken after slaughter to avoid contact cross-contamination of the fresh meat with any source of CSFV.

Article 15.2.15.

**Recommendations for the importation of fresh meat of wild and feral pigs**

Regardless of the CSF status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the entire consignment of fresh meat comes from animals pigs:

- 1) that were killed in a country or zone free from CSF in accordance with point 1) or point 2) of Article 15.2.3.;
- 12) that which have been were subjected with favourable results to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre facility approved by the Veterinary Authority for export purposes, with favourable results and have been found free from any sign suggestive of CSF.;
- 2) from each of which a sample has been was collected and has been subjected to a virological test and a serological test for CSF, with negative results.

Article 15.2.1613.

**Recommendations for the importation of meat and meat products of pigs intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use**

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the meat products:

- 1) have been were prepared:
  - a) exclusively from fresh meat meeting the conditions laid down in Articles 15.2.1412, or 15.2.1412bis, or 15.2.15.;

Annex 17 (contd)

- b) in a processing establishment facility that, at the time of processing:
- i) is approved for export by the *Veterinary Authority* ~~for export purposes;~~
  - ii) ~~processing processes only meat of pigs meeting satisfying~~ the conditions laid down in Articles 15.2. ~~1412, or 15.2. 1412bis, or 15.2.15;~~

OR

- 2) ~~have been were~~ processed in accordance with one of the processes in Article 15.2. ~~2318~~, in an establishment a facility approved by the *Veterinary Authority* for export purposes ~~so as to ensure the destruction of the CSFV in conformity with one of the procedures referred to in Article 15.2.23.~~, and that the necessary appropriate precautions were taken after processing to avoid contact cross-contamination of the product with any source of CSFV.

Article 15.2.17.

**~~Recommendations for the importation of pig products not derived from fresh meat intended for use in animal feeding~~**

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

- 1) ~~originated from domestic and captive wild pigs in a CSF free country, zone or compartment and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or~~
- 2) ~~have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSFV in accordance with Article 15.2.22., and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.~~

Article 15.2.18.

**~~Recommendations for the importation of pig products not derived from fresh meat intended for agricultural or industrial use~~**

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

- 1) ~~originated from domestic and captive wild pigs in a CSF free country, zone or compartment and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or~~
- 2) ~~have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.~~

Article 15.2. ~~1914~~.

**Recommendations for the importation of bristles**

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

- 1) originated from domestic ~~and or~~ captive wild pigs in a CSF free country, zone or compartment free from CSF and have been were prepared processed in a processing establishment facility approved by the *Veterinary Authority* for export purposes; or
- 2) ~~have been were~~ processed in accordance with one of the processes in Article 15.2. ~~2419bis~~, in an establishment a facility approved by the *Veterinary Authority* for export purposes ~~so as to ensure the destruction of the CSFV~~, and that the necessary appropriate precautions were taken after processing to avoid contact cross-contamination of the product with any source of CSFV.

Article 15.2.2015.

**Recommendations for the importation of litter and manure from pigs**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the litter or manure products:

- 1) originated from domestic ~~and or~~ captive wild pigs in a CSF free country, zone or compartment free from CSF and ~~have been prepared~~ were processed in a ~~processing establishment~~ facility approved by the *Veterinary Authority* for export purposes; or
- 2) ~~have been~~ were processed in accordance with one of the procedures in Article 15.2.2419 ~~ter.~~ in an establishment a facility approved by the *Veterinary Authority* for export purposes ~~so as to ensure the destruction of the CSFV, and that the necessary~~ appropriate precautions were taken after processing to avoid ~~contact~~ cross-contamination of the product with any source of CSFV.

Article 15.2.2416.

**Recommendations for the importation of skins and trophies from pigs**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the skins or trophies products:

- 1) originated from domestic ~~and or~~ captive wild pigs in a CSF free country, zone or compartment free from CSF and ~~have been prepared~~ were processed in a ~~processing establishment~~ facility approved by the *Veterinary Authority* for export purposes; or
- 2) ~~have been~~ were processed in accordance with one of the procedures in Article 15.2.2520 in an establishment a facility approved by the *Veterinary Authority* for export purposes ~~so as to ensure the destruction of the CSFV in conformity with one of the procedures referred to in Article 15.2.25., and that the necessary~~ appropriate precautions were taken after processing to avoid ~~contact~~ cross-contamination of the product with any source of CSFV.

Article 15.2.2416bis.

**Recommendations for the importation of other pig products commodities**

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

- 1) originated from domestic or captive wild pigs in a country, zone or compartment free from CSF and were processed in a facility approved by the Veterinary Authority for export purposes; or
- 2) were processed in a manner to ensure the destruction of that has been demonstrated inactivate CSFV in a facility approved by the Veterinary Authority for export purposes, and that appropriate precautions were taken after processing to avoid contact cross-contamination of the product with any source of CSFV.

Article 15.2.2217.

**Procedures for the inactivation of the classical swine fever virus CSFV in swill**

For the inactivation of CSFV in swill, one of the following procedures should be used:

- 1) the swill ~~should be~~ is maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or
- 2) the swill ~~should be~~ is maintained at a temperature of at least 121°C for at least 10 minutes at an absolute pressure of 3 bar; or
- 3) the swill is subjected to an equivalent treatment that has been demonstrated to inactivate CSFV.

Article 15.2. ~~2318~~.

Procedures for the inactivation of ~~the classical swine fever virus~~ CSFV in meat

For the inactivation of CSFV in *meat*, one of the following procedures should be used:

1. Heat treatment

*Meat* should be subjected to one of ~~the following treatments~~:

- a) ~~heat treatment in a hermetically sealed container with a F0 value of 3.00 or more;~~
- b) a heat treatment for at least 30 minutes at a minimum temperature of 70°C, which should be reached throughout the *meat*.

**EU comment**

**To avoid any confusion and to ensure an effective heat treatment we suggest rewording the above paragraph as follows:**

**'a heat treatment to be reached throughout the *meat* for at least 30 minutes at a minimum temperature of 70°C, which should be reached throughout the *meat*.'**

2. Natural fermentation and maturation

The *meat* should be subjected to a treatment consisting of natural fermentation and maturation ~~having resulting in~~ the following characteristics:

- a) an  $A_w$   ~~$a_w$~~  value of not more than 0.93, or
- b) a pH value of not more than 6.0.

~~Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.~~

3. Dry cured ~~pork pig~~ meat

- a) ~~Italian style hams with bone-in should be cured with salt and dried for a minimum of 313 days.~~
- b) ~~Spanish style *pork meat* with bone-in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.~~

*Meat* should be cured with salt and dried for a minimum of six months.

Article 15.2. ~~2419~~.

Procedures for the inactivation of ~~the classical swine fever virus~~ CSFV in casings of pigs

For the inactivation of CSFV in casings of pigs, the following procedures ~~should be used: salting treating~~ for at least 30 days ~~either~~ with ~~phosphate supplemented dry salt~~ or saturated brine ( $A_w$   ~~$a_w$~~  < 0.80) containing 86.5% NaCl, 10.7% Na<sub>2</sub>HPO<sub>4</sub> and 2.8% Na<sub>3</sub>PO<sub>4</sub> (weight/weight/weight), ~~and kept either dry, or as or saturated brine ( $a_w$  < 0.80),~~ and at a temperature of ~~greater than 20°C or above~~ during this entire period.

Article 15.2. ~~2419~~bis.

**Procedures for the inactivation of CSFV in bristles**

For the inactivation of CSFV in bristles for industrial use, they should be boiled for at least 30 minutes.

Article 15.2.2419ter.

**Procedures for the inactivation of CSFV in litter and manure from pigs**

For the inactivation of CSFV in litter and manure from pigs, one of the following procedures should be used:

1) moist heat treatment for at least one hour at a minimum temperature of 55°C; or

Annex 17 (contd)

2) moist heat treatment for at least 30 minutes at a minimum temperature of 70°C;

**EU comment**

**We suggest reviewing the treatment time in bullet point 2) above and increasing it for at least 60 minutes.**

**i.e. ‘2) moist heat treatment for at least ~~30~~ 60 minutes at a minimum temperature of 70°C’**

**We make this comment considering the treatment required for swill, where even at a higher temperature of at least 90°C, the time required is 60 minutes. We believe that the swill treatment is empirical and requires further evidence, and because of this, the OIE will review this treatment in the future. However, until this exercise is carried out we consider prudent to maintain for litter and manure a minimum time of 60 minutes .**

3) any equivalent treatment that has been demonstrated to inactivate CSFV.

Article 15.2.2520.

**Procedures for the inactivation of ~~the classical swine fever virus~~ CSFV in skins and trophies**

For the inactivation of CSFV in skins and trophies, one of the following procedures should be used:

- 1) boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed;
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);
- 3) soaking, with agitation, in a 4 percent % (w/v) solution of washing soda (sodium carbonate [Na<sub>2</sub>CO<sub>3</sub>]) maintained at pH 11.5 or above for at least 48 hours;
- 4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;
- 5) in the case of raw hides, salting for at least 28 days with sea salt containing 2 percent % washing soda (sodium carbonate [Na<sub>2</sub>CO<sub>3</sub>]).

Article 15.2.25bis.

**Procedures for the inactivation of CSFV in bristles**

For the inactivation of CSFV in bristles for industrial use, they should be boiled for at least 30 minutes.

Article 15.2.25ter.

### Procedures for the inactivation of CSFV in litter and manure from pigs

For the inactivation of CSFV in litter and manure from pigs, one of the following procedures should be used:

- 1) moist heat treatment for at least one hour at a minimum temperature of 55°C; or
- 2) moist heat treatment for at least 30 minutes at a minimum temperature of 70°C.

Article 15.2. ~~2621~~.

### Introduction to surveillance: introduction

Articles 15.2. ~~2621~~ to 15.2. ~~3226~~ define the principles and provide a guide on the *surveillance* for CSF, complementary to Chapter 1.4., applicable to Member Countries seeking the OIE recognition of CSF status. This may be for the entire country or a *zone*. Guidance is also provided for Member Countries seeking recovery of CSF status for the entire country or for a *zone* following an *outbreak* and for the maintenance of CSF status.

The impact and epidemiology of CSF may vary in different regions of the world. The *surveillance* strategies employed for demonstrating freedom from CSF at an acceptable level of confidence should be adapted to the local situation. For example, the approach should be tailored in order to prove freedom from CSF for a country or *zone* where *wild* and *feral* pigs provide a potential reservoir of *infection*, or where CSF is present in adjacent neighbouring countries. The method should examine the epidemiology of CSF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is, therefore, latitude available to Member Countries to provide a well-reasoned argument to prove that absence of *infection* with CSFV is assured at an acceptable level of confidence.

## Annex 17 (contd)

*Surveillance* for CSF should be in the form of a continuing programme designed to establish that susceptible populations in a country, *zone* or *compartment* are free from *infection* with CSFV or to detect the introduction of CSFV into a population already defined as free. Consideration should be given to the specific characteristics of CSF epidemiology which include:

- the role of swill feeding, the impact of different production systems and the role of *wild* and *feral* pigs on disease spread;
- the role of semen in transmission of the virus;
- the lack of pathognomonic gross lesions and clinical signs;
- the frequency of clinically inapparent *infections*;
- the occurrence of persistent and chronic *infections*;
- the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV.

Article 15.2. ~~2722~~.

### General conditions and methods for surveillance: general conditions and methods

- 1) A *surveillance* system in accordance with Chapter 1.4. and under the responsibility of the *Veterinary Authority* should address the following aspects:
  - a) formal and ongoing system for detecting and investigating *outbreaks* of disease or CSFV *infection* should be in place;
  - b) a procedure should be in place for the rapid collection and transport of samples from suspected cases to a laboratory ~~for CSF diagnosis~~;
  - c) appropriate laboratory testing capability for CSF diagnosis;
  - ~~d)~~ a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
- 2) The CSF *surveillance* programme should:
  - a) include an *early warning detection* system throughout the production, marketing and processing chain for reporting suspected cases. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of CSF to the *Veterinary Authority*. The ~~notification reporting~~ system under the *Veterinary Authority* should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary paraprofessionals*) by ~~government~~ information programmes. Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated. Other important diseases such as African swine fever should also be considered in any differential diagnosis. As part of the contingency plan, personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in CSF diagnosis, epidemiological evaluation, and control;
  - b) implement, when relevant, regular and frequent clinical inspections and laboratory testing of high-risk groups (for example, where swill feeding is practised), or those ~~adjacent-neighbouring~~ to a CSF infected country or *zone* (for example, bordering areas where infected *wild* and *feral* pigs are present).

An effective *surveillance* system will periodically identify suspected cases that require follow-up and investigation to confirm or exclude *infection* with CSFV. The rate at which such suspected cases are likely to occur will differ between epidemiological situations and cannot, therefore, be reliably predicted. Applications for recognition of CSF status should, as a consequence, provide details in accordance with ~~Article 1.6.10.~~ Chapter 1.9. of the occurrence of suspected cases and how they were investigated and dealt with.

Member Countries should review their surveillance strategies whenever an increase in the likelihood of incursion of CSFV is perceived identified. Such changes include but are not limited to:

- a) an emergence or an increase in the prevalence of CSF in countries or zones from which live pigs or products are imported;
- b) an increase in the prevalence of CSF in wild or feral pigs in the country or zone;
- c) an increase in the prevalence of CSF in adjacent-neighbouring countries or zones;
- d) an increased entry from, or exposure to, infected wild or feral pig populations of adjacent-neighbouring countries or zones.

Article 15.2. ~~2823~~.

## Surveillance strategies

### 1. Introduction

The population covered by *surveillance* aimed at detecting disease and *infection* should include domestic pig population and wild and feral pig populations within the country or zone to be recognised as free from *infection* with CSFV.

The strategy employed to ~~establish~~ estimate the prevalence or demonstrate the absence of *infection with CSFV* may be based on clinical investigation or on randomised or targeted ~~clinical investigation or~~ sampling at an acceptable level of statistical confidence. If an increased likelihood of *infection* in particular localities or subpopulations can be identified, targeted sampling may be an appropriate strategy. This may include:

- a) swill fed farms;
- b) pigs reared outdoors;
- c) specific high-risk wild and feral pig subpopulations and their proximity.

Risk factors may include, among others, temporal and spatial distribution of past *outbreaks*, pig movements and demographics, ~~etc~~ and types of production systems.

Serology in unvaccinated populations is often the most effective and efficient surveillance methodology, for reasons of cost, ~~persistence~~ extended duration of antibody levels and the existence of clinically inapparent *infections*; ~~serology in unvaccinated populations is often the most effective and efficient surveillance methodology~~. In some circumstances, such as differential diagnosis of other diseases, clinical and virological *surveillance* may also have value.

The *surveillance* strategy chosen should be justified as adequate to detect the presence of *infection* with CSFV in accordance with Chapter 1.4. and the epidemiological situation. Cumulative survey results in combination with the results of routine *surveillance*, over time, will increase the level of confidence in the *surveillance* strategy.

When applying randomised sampling, either at the level of the entire population or within targeted subpopulations, the design of the sampling strategy should incorporate epidemiologically appropriate design prevalences for the selected populations. The sample size selected for testing should be large enough to detect *infection* if it were to occur at a predefined minimum rate. The choice of design prevalence and confidence level should be justified based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular, needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the approach selected, the sensitivity and specificity of the diagnostic tests should be considered in the survey design, the sample size determination and the interpretation of the results obtained.

## Annex 17 (contd)

The *surveillance* system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognised cross-reactivity with ruminant pestiviruses, among other factors mentioned in point 4. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of *infection* with CSFV. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as *animals* which may be epidemiologically linked.

### 2. Clinical surveillance

Clinical *surveillance* continues to be the cornerstone of CSF detection. However, due to the low virulence of some CSFV strains and the spread of diseases such as African swine fever, and those associated with porcine circovirus 2 *infection*, clinical *surveillance* should be supplemented, as appropriate, by serological and virological *surveillance*.

Clinical signs and pathological findings are useful for early detection; in particular, any cases where clinical signs or lesions suggestive of CSF are accompanied by high morbidity or mortality, these should be investigated without delay. In CSFV *infections* involving low virulence strains, high mortality may only be seen in young *animals* and adults may not present clinical signs.

*Wild* and *feral* pigs rarely present the opportunity for clinical observation, but should form part of any *surveillance* scheme and should, ideally, be monitored for virus as well as ~~antibody~~ antibodies.

### 3. Virological surveillance

Virological *surveillance* should be conducted:

- a) to monitor at risk populations;
- b) to investigate clinically suspected cases;
- c) to follow up positive serological results;
- d) to investigate increased mortality.

Molecular detection methods can be applied to large-scale screening for the presence of virus. If targeted at high-risk groups, they provide an opportunity for early detection that can considerably reduce the subsequent spread of disease. Epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in ~~disease free~~ previously free from CSF. Therefore, CSFV isolates should be sent to an OIE Reference Laboratory for further characterisation.

### 4. Serological surveillance

Serological *surveillance* aims at detecting antibodies against CSFV. Positive CSFV antibody test results can have five possible causes:

- a) natural *infection* with CSFV;
- b) *vaccination* against CSF;
- c) maternal antibodies;
- d) cross-reactions with other pestiviruses;
- e) non-specific reactors.

The *infection* of pigs with other pestiviruses may complicate a *surveillance* strategy based on serology. Antibodies to bovine viral diarrhoea viruses (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity. One route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with BVDV.

CSFV may lead to persistently infected, seronegative young animals, which continuously shed virus. CSFV *infection* may also lead to chronically infected pigs which may have undetectable or fluctuating antibody levels. Even though serological methods will not detect these animals, such animals are likely to be in a minority in a herd and would not confound a diagnosis based on serology as part of a *herd* investigation.

It may be possible to use for CSF surveillance sera collected for other survey purposes ~~for CSF surveillance~~. However, the principles of survey design and ~~the requirement for~~ statistical validity should not be compromised.

In countries or *zones* where *vaccination* has been recently discontinued, targeted serosurveillance of young unvaccinated animals can indicate the presence of *infection*. Maternal antibodies are usually found up to 8-10 weeks of age but may be occasionally last up to four and a half months and can interfere with the interpretation of serological results.

Marker vaccines and accompanying DIVA tests which fulfil the requirements of the *Terrestrial Manual* may allow discrimination between vaccinal antibody and that induced by natural *infection*. The serosurveillance results using DIVA techniques may be interpreted either at animal or *herd* level.

~~Member Countries should review their surveillance strategies whenever an increase in the risk of incursion of CSFV is perceived. Such changes include but are not limited to:~~

- ~~a) an emergence or an increase in the prevalence of CSF in countries or zones from which live pigs or products are imported;~~
- ~~b) an increase in the prevalence of CSF in wild or feral pigs in the country or zone;~~
- ~~c) an increase in the prevalence of CSF in adjacent countries or zones;~~
- ~~d) an increased entry from, or exposure to, infected wild or feral pig populations of adjacent countries or zones.~~

Article 15.2. 2924.

#### **Additional surveillance ~~procedures~~ for Member Countries applying for OIE recognition of ~~classical swine fever~~ CSF free status**

The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances in and around the country or *zone* and should be planned and implemented according to the conditions for status recognition described in Article 15.2.2. and 15.2.3, and methods described elsewhere in this chapter. The objective is to demonstrate the absence of *infection* with CSFV in domestic and *captive wild* pigs during the last 12 months and to assess the *infection* status in *wild* and *feral* pig populations as described in Article 15.2. 3426.

Article 15.2. 3025.

#### **Additional surveillance ~~procedures~~ for recovery of free status**

In addition to the general conditions described in this chapter, a Member Country seeking recovery of country or *zone* CSF free status, including a *containment zone*, should show evidence of an active *surveillance* programme to demonstrate absence of *infection* with CSFV.

Populations under this *surveillance* programme should include:

- 1) *establishments* in the proximity of the *outbreaks*;
- 2) *establishments* epidemiologically linked to the *outbreaks*;
- 3) animals moved from or used to repopulate affected *establishments*;
- 4) any *establishments* where contiguous culling has been carried out;
- 5) *wild* and *feral* pig populations in the area of the *outbreaks*.

## Annex 17 (contd)

The domestic and *captive wild* pig populations should undergo regular clinical, pathological, virological and serological examinations, planned and implemented according to the general conditions and methods described in these recommendations. Epidemiological evidence of the *infection* status in *wild* and *feral* pigs should be compiled. To regain CSF free status, the *surveillance* approach should provide at least the same level of confidence as within the original application for recognition of freedom.

Article 15.2. ~~3126~~.

### Surveillance for ~~classical swine fever virus~~ CSFV in wild and feral pigs

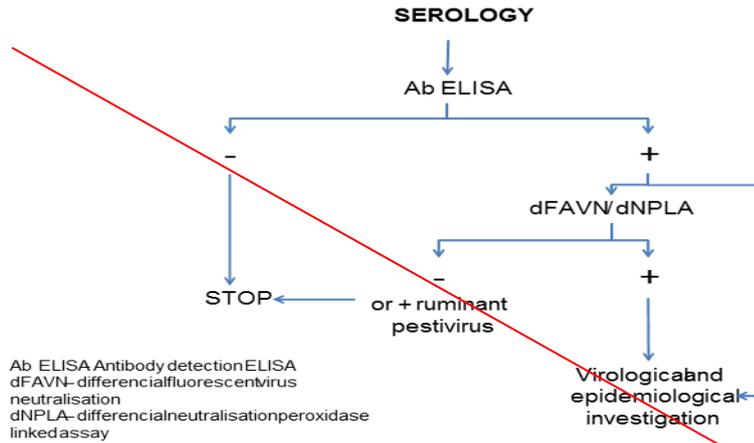
- 1) The objective of a *surveillance* programme is either to demonstrate that CSFV *infection* is not present in *wild* and *feral* pigs or, if known to be present, to estimate the distribution and prevalence of the *infection*. While the same principles apply, *surveillance* in *wild* and *feral* pigs presents additional challenges including:
  - a) determination of the distribution, size and movement patterns associated with the *wild* and *feral* pig population;
  - b) relevance and practicality of assessing the possible presence of CSFV *infection* within the population;
  - c) determination of the practicability of establishing a *zone* taking into account the degree of interaction with domestic and *captive wild* pigs within the proposed *zone*.

The geographic distribution and estimated size of *wild* and *feral* pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information to aid in the design of a monitoring system may include governmental and non-governmental *wildlife* organisations such as hunter associations.

- 2) For implementation of the monitoring *surveillance* programme, ~~it will be necessary to define the limits of the area over which *wild* and *feral* pigs range should be defined, in order to delineate the epidemiological units within the monitoring programme. It is often difficult to define epidemiological units for Subpopulations of *wild* and *feral* pigs may be separated from each other by natural or. The most practical approach is based on natural and artificial barriers.~~
- 3) The monitoring *surveillance* programme should involve serological and virological testing, including ~~animals~~ pigs hunted or found dead, road kills, ~~animals~~ pigs showing abnormal behaviour or exhibiting gross lesions during dressing.
- 4) There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:
  - a) areas with past history of CSF;
  - b) subregions with large populations of *wild* and *feral* pigs;
  - c) border regions with CSF affected countries or *zones*;
  - d) interface between *wild* and *feral* pig populations, and domestic and *captive wild* pig populations;
  - e) areas with farms with free-ranging and outdoor pigs;
  - f) areas with a high level of hunting activity, where animal dispersion and feeding as well as inappropriate disposal of waste can occur;
  - gf) other risk areas determined by the *Veterinary Authority* such as ports, airports, garbage dumps and picnic and camping areas.

Article 15.2.32.

**The use and interpretation of diagnostic tests in surveillance**



## GLOSSARY

### EU comment

The EU in general supports the proposed changes to the Glossary. We have inserted comments in the text below with the aim of helping improving the proposed definitions.

### CAPTIVE WILD [ANIMAL]

means an *animal* that has a phenotype not significantly affected by human selection but that is captive or otherwise lives under or requires direct human supervision or control, i.e. such as population management, regular contacts or handling, regular feeding, harvesting and protection from predators or slaughter, including this includes zoo animals and pets.

### FERAL [ANIMAL]

means an *animal* of a domesticated species that now lives without direct requiring human supervision or control.

### WILD [ANIMAL]

means an *animal* that has a phenotype unaffected by human selection and lives independently ly of direct without requiring human supervision or control.

### SLAUGHTER

means any killing procedure that causes the death of an animal by bleeding of animals primarily for human consumption.

### EU comment

The EU proposes the following revision:

**“means killing of animals primarily intended for human consumption.”**

### Justification

The EU believes that the word “intended” will make the definition more straight forward than “primarily” which leaves more space for interpretation.

### EUTHANASIA

means killing the act of inducing death using a method that causes a rapid and irreversible loss of consciousness with the most rapid, painless and distress free method possible minimum pain and distress to animal.

## EU comment

The EU proposes the following revision:

“means killing of animals with the most rapid, painless and distress free method possible.”

## Justification

For the sake of clarity.

## STUNNING

means any ~~mechanical, electrical, chemical or other~~ procedure that causes rapid immediate loss of consciousness with minimal pain and other types of suffering; when used before slaughter, the loss of consciousness lasts until death from the slaughter process; ~~in the absence of slaughter, the procedure would allow the animal to recover consciousness.~~

## EU comment

The EU proposes the following revision:

“means any procedure that causes rapid loss of consciousness ~~with minimal~~ without unnecessary pain, distress, fear and other types of suffering”

## Justification

It is key to ensure that there is no unnecessary pain caused by stunning methods. The necessary pain caused would equate to the minimal pain referred in this paragraph, but with the suggested wording it is made clear that such ‘minimal’ pain is only acceptable when this is unnecessary.

## DEATH

means the irreversible permanent loss of all vital functions brain activity demonstrable by the loss of brain stem reflexes. This may be confirmed through a combination of criteria such as dilated pupil and absence of corneal reflex, cardiac activity and breathing.

## EU comment

The EU proposes the following revision:

“means the permanent loss of all vital functions. This may be confirmed through a combination of criteria such as dilated pupil and absence of corneal reflex, cardiac activity and breathing observed over a sufficiently long period.”

## Justification

There is a risk that the criteria invoked may be a sign of unconsciousness and not of death. death is defined by prolonged absence (15 to 20 minutes for specialists!) and irreversible cardio-respiratory activity associated with a flat electroencephalogram.

## Reference

“Mécanismes neurobiologiques mis en œuvre dans le contexte de l’abattage, La conscience, l’inconscience et la mort dans le contexte de l’abattage Partie I. Mécanismes neurobiologiques impliqués lors de l’étourdissement et de la mise à mort”, Claudia Terlouw, Cécile Bourguet, Véronique Deiss, La revue scientifique “Viandes & Produits Carnés”, Référence de l’article : VPC-2015-31-2-2 Date de publication : 19 mars 2015. <https://www.viandesetproduitscarnes.com>

“L’évaluation de l’état d’inconscience en abattoir, La conscience, l’inconscience et la mort dans le contexte de l’abattage Partie II. Méthodes d’évaluation”, Claudia Terlouw, Cécile Bourguet, Véronique Deiss, La revue scientifique “Viandes & Produits Carnés”, Référence de l’article : VPC-2015-31-2-3 Date de publication : 23 mars 2015 [www.viandesetproduitscarnes.com](http://www.viandesetproduitscarnes.com)

#### ***DISTRESS***

means the state of an animal, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

#### **EU comment**

**EU proposes the following revision:**

“means the mental and physiological state of an animal, that has been unable to adapt to stressors and manifests abnormal physiological and/or behavioural responses. It can be acute or chronic and may result in pathological conditions.”

#### **Justification**

**Distress is an acute emotion or a longer-lasting mood that can alter the welfare state of the animal. Regarding the new definition of animal welfare proposed by the French Agency for Food, Environmental and Occupational Health & Safety, the welfare of an animal is the positive mental and physical state related to the satisfaction of its physiological and behavioral needs, as well as its expectations. This state varies according to the perception of the situation by the animal (ANSES, 2018). It has been widely shown that an acute or a long-lasting mental state participates in the decision-making of an individual.**

#### **Reference**

**ANSES, 2018 : <https://www.anses.fr/fr/system/files/SABA2016SA0288.pdf>**

Annex 18 (contd)

**PAIN**

means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

**SUFFERING**

means an unpleasant, undesired state of being that is the outcome of the impact on an animal of noxious negative stimuli and/or the absence of important positive stimuli. It is the opposite of good welfare.

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## CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY  
THE OIE**EU comment**

**The EU in general supports the proposed changes to this chapter.**

**Some specific comments are included in the text.**

## Article 1.3.1.

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

- Anthrax
- Crimean Congo hemorrhagic fever
- Equine encephalomyelitis (Eastern)
- Heartwater
- **Infection with animal trypanosomes of African origin (*T. vivax*, *T. congolense*, *T. simiae* and *T. brucei*)**
- Infection with Aujeszky's disease virus
- Infection with bluetongue virus
- Infection with *Brucella abortus*, *Brucella melitensis* and *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 bovis* and *Mycobacterium caprae* **[under study]**

**EU Comment**

**We welcome the decision not to delist *M. tuberculosis*.**

**As the Code Commission has not reached a decision and that no changes are proposed until new evidence are obtained, it is important that any infection with the full *Mycobacterium* complex, i.e. including *M. bovis*, *M. caprae* and *M. tuberculosis*, continues to be notified to the OIE. If in the Code the infection is marked 'under study', the obligation to notify could be misunderstood and considered that it is not required. For these reasons and to avoid any confusion, we suggest that this infection is described with its original current name, e.g. Infection with *Mycobacterium tuberculosis complex, bovis and Mycobacterium caprae* **[under study]****

- 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 viral diarrhoea

Annex 19 (contd)

- 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
- Theileriosis
- Trichomonosis
- **Trypanosomosis (tsetse transmitted).**

[...]

Article 1.3.9.

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

- Camelpox
- **Infection of dromedary camels with Middle East Respiratory Syndrome Coronavirus**

**EU comment**

**The EU strongly suggests that the above infection is not listed.**

**The Report of the Scientific Commission for Animal Diseases states that when a disease matches the listing criteria of Chapter 1.2 of the Terrestrial Code it should have a dedicated chapter, which should provide a clear case definition to support the notification obligation of Member Countries. Because of this, we believe it is not adequate to list this infection.**

- Leishmaniosis.

This draft chapter would replace Chapter 3.1 in the 2019 edition of the *Terrestrial Code*. Considering the significant changes in the text, only a clean version is provided.

## DRAFT CHAPTER 3.1.

# QUALITY OF VETERINARY SERVICES

### **EU comment**

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

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

#### Article 3.1.1.

##### **General considerations**

The quality of *Veterinary Services* depends on ethical, organisational, legislative and technical factors.

Compliance with standards of quality is critical for *Veterinary Services* to meet their animal health, animal welfare, and veterinary public health objectives, and is important for the establishment and maintenance of trust in international trade.

*Veterinary Services* should conform to the fundamental operating principles in Article 3.1.2., regardless of the political, economic or social situation of their country.

The key components of a country's *Veterinary Services* are presented in Articles 3.1.3 to 3.1.12. Four components are focused on governance aspects: Policy and Management, Personnel and Resources, the Veterinary Profession, and Stakeholders; and six components are focused on technical aspects: Animal Health, Animal Production Food Safety, Veterinary Medicinal Products, Laboratories, Animal Welfare and International Trade.

This chapter should be read in conjunction with other chapters in the *Terrestrial Code*, relevant chapters of the *Terrestrial Manual* with regards to quality of laboratories, diagnosis and vaccines, as well as relevant Codex Alimentarius texts.

#### Article 3.1.2.

##### **Fundamental operating principles**

*Veterinary Services* should comply with the following interrelating principles to ensure the quality of their activities:

1. Professional judgement

The personnel should have the relevant qualifications, expertise and experience to give them the competence to make sound professional judgements.

### **EU comment**

**For the heading of point 1 above, we suggest including the term 'knowledge' to read 'Knowledge and professional judgement'. 'Knowledge' should be a pre-requisite to be able to apply sound professional judgement.**

2. Independence and objectivity

Care should be taken to ensure that personnel are free from any undue commercial, financial, hierarchical, political or other pressures which might adversely affect their judgement or decisions. The *Veterinary Services* should, at all times, act in an objective manner.

3. Impartiality

*Veterinary Services* should be impartial. In particular, all the parties affected by their activities have a right to expect that their services are delivered reasonably and without discrimination.

4. Integrity

*Veterinary Services* should maintain a consistently high level of integrity. Any fraud, corruption or falsification should be identified and addressed.

Annex 20 (contd)

5. Transparency

*Veterinary Services* should be as transparent as possible in all their governance and technical activities, including but not limited to, disease reporting, policy and programme decision-making, human resources and financial issues.

6. Scientific basis

*Veterinary Services* should develop and implement their activities on a scientific basis, incorporating relevant inputs from fields such as risk analysis, epidemiology and economics.

**EU comment**

**There are different science fields that should be considered to develop the best possible legislation or policy options. For this reason, we suggest describing that the inputs should come ‘from natural and social science fields, such as...’**

**The scientific activities described should not be an exhaustive list, this is why we suggest deleting ‘and’ and replace it by ‘or’, i.e. ‘risk analysis, epidemiology ~~and~~ or economics.’**

Article 3.1.3.

**Policy and management**

*Veterinary Services* should have the leadership, organisational structure and management systems to develop, implement and update policies, legislation and programmes, incorporating risk analysis and sound epidemiological principles. *Veterinary Services*’ decision making should be free from undue financial, political and non-scientific influences.

The *Veterinary Authority* should coordinate with other *Competent Authorities* and should undertake active international engagement with OIE and other relevant regional and international organisations.

This component should comprise the following specific elements:

- 1) Comprehensive national *veterinary legislation* in accordance with Chapter 3.4, regularly updated with reference to changing international standards and science.

**EU comment**

**Usually legislation is already based on scientific evidence and changes in legislation are the result of new scientific evidence. We suggest modifying the last sentence to ‘...international standards and new scientific evidence science’.**

- 2) Implementation of *veterinary legislation* through a programme of communications and awareness, as well as formal, documented inspection and compliance activities.

**EU comment**

**‘Inspection’ is just one type of official control, which may include others such as audits. We suggest replacing the term ‘inspection’ by one with a broader meaning such as ‘control’**

- 3) Capability to perform *risk analysis* and cost-benefit analysis to define and adapt policies and programmes.

- 4) Policies or programmes that are well documented, resourced and sustained, appropriately reviewed and updated to improve their effectiveness and efficiency, and addressing emerging issues.

**EU comment**

**Thought this chapter policies and programmes are cited as separate elements. We believe that a government policy could have the form of a programme. For this reason we suggest starting the phrase as ‘Policies, including programmes...’**

**This comment should be considered in other parts of this chapter.**

- 5) Quality management systems with quality policies, procedures and documentation suited to the *Veterinary Services*’ activities, including procedures for information sharing, complaints and appeals and for internal audits.

**EU comment**

**We suggest that not only information is shared but also ‘knowledge’ as this will help strengthening the veterinary services. We suggest the inclusion of the term ‘knowledge’ as follows: ‘...including procedures for knowledge and information sharing...’**

- 6) Information management systems for collecting data to monitor and evaluate *Veterinary Services*’ activities and to perform *risk analysis*.

**EU comment**

**An effective policy cycle includes the evaluation and review of policies to assess if the desired objectives have been met. For this reason, we consider essential to include the use of data from information management systems as a source for policy evaluation. We suggest including the term ‘policy’ to read: ‘to monitor and evaluate *Veterinary Services*’ activities and policies, and to perform *risk analysis*’**

- 7) Organisational structures with defined roles and responsibilities for effective internal coordination from central to field levels (chain of command) for activities, which are periodically reviewed and updated as necessary.
- 8) Formal external coordination mechanisms with clearly described procedures or agreements for activities between the *Veterinary Authority*, *Competent Authorities* and stakeholders, incorporating a One Health approach.
- 9) Appropriate levels of official representation at international multilateral fora, with pre-consultation with stakeholders, active participation and sharing of information, and follow up on meeting outcomes.

**EU comment**

**Consultation with stakeholders should be carried out at all time during the policy development: before, during and after. For this reason, we suggest deleting the prefix ‘pre’ to read ‘...with ~~pre~~-consultation with stakeholders...’**

Article 3.1.4.

**Personnel and resources**

*Veterinary Services* should be appropriately staffed, including *veterinarians*, *veterinary paraprofessionals* or other personnel, with appropriate competencies through initial and continuing education to allow for their functions to be undertaken effectively and efficiently.

**EU comment**

**We consider that ‘education’ could be interpreted as a narrow term and it may be more helpful to replace it by a broader term to cover other activities, not just education, such as ‘professional development’ to read ‘...and continuing ~~education~~ professional development to allow...’.**

**This comment may be considered in other parts of this chapter where the term ‘education’ is used.**

Annex 20 (contd)

*Veterinary Services* should have functional and well-maintained physical resources, adequate operational resources for their ongoing and planned activities, and access to extraordinary resources to respond effectively to emergency situations or new emerging issues.

This component should comprise the following specific elements:

- 1) A core of full-time civil service employees with qualified *veterinarians* and *veterinary paraprofessionals*.
- 2) Formal, consistent and merit-based recruitment and promotion procedures.
- 3) Job descriptions, formal performance assessment and management procedures for *veterinarians*, *veterinary paraprofessionals* and other personnel that are defined and being implemented.
- 4) Personnel remuneration, sufficient to minimise the risk of conflicts of interest and to preserve independence.
- 5) *Veterinarians’* and *veterinary paraprofessionals’* education, knowledge, skills and practices, standardised and sufficient to perform relevant activities of the *Veterinary Services*.
- 6) *Veterinary paraprofessionals* are adequately supervised by *veterinarians*.

**EU comment**

**The activities carried out by veterinary paraprofessionals and which ones are subject to supervision by veterinarians vary across the world.**

**For this reason, we suggest adding ‘as appropriate’ at the end of the above bullet point 6)**

- 7) All personnel have access to continuing education programmes that are reviewed and updated as necessary.

**EU comment**

**In relation to the use of the term ‘education’, please see the comment above after the first paragraph of article 3.1.4.**

- 8) Established procedures for *Veterinary Services* to access personnel and other resources, including in emergencies.
- 9) Access to suitable physical resources at all levels (national, state/provincial and local), including, but not limited to, functional buildings, furniture, equipment, communications, information technology, transport and cold chain, which are maintained or renewed as necessary.

- 10) Access to sufficient operational resources for planned and continued activities, as well as for new or expanded operations, including but not limited to, contracts, fuel, per diem, vaccines, diagnostic reagents, personal protective equipment and other consumables.

Article 3.1.5.

#### **The veterinary profession**

*Veterinarians* and *veterinary paraprofessionals* are an essential component of *Veterinary Services*, whether as part of governmental authorities or as private service providers.

The *Veterinary Statutory Body* should regulate *veterinarians* and *veterinary paraprofessionals* to effectively and independently maintain educational and professional standards, including for both official tasks and veterinary clinical services. Mechanisms for coordination between the *Veterinary Authority*, the *Veterinary Statutory Body* and veterinary educational establishments should be in place.

#### **EU comment**

**Nowadays, the veterinary services are wider than just ‘clinical’ services.**

**We suggest the following wording in the above paragraph to allow covering all types of veterinary roles and tasks, e.g: The *Veterinary Statutory Body* should regulate *veterinarians* and *veterinary paraprofessionals* to effectively and independently maintain educational and professional standards ~~including for both official tasks and veterinary clinical services.~~ relevant to their role, including ~~for both official tasks, and veterinary clinical services~~ and other veterinary tasks as appropriate.**

The OIE has produced guidelines on the expected competencies for *veterinarians* and *veterinary paraprofessionals* as well as guidelines on the curricula necessary to deliver those competencies.

This component should comprise the following specific elements:

- 1) An independent *Veterinary Statutory Body*, legally responsible and adequately resourced for:
  - a) licensing and registration of *veterinarians* and *veterinary paraprofessionals* to perform defined activities of veterinary science or animal health;
  - b) setting minimum standards of education required to be registered or licensed as *veterinarians* or *veterinary paraprofessionals*.

#### **EU comment**

**It will be beneficial to provide an example of minimum standards of education adding the term ‘day-1 competencies’ as the minimum degree of competence that veterinary graduates should always have when concluding their veterinary studies and to be ready for their first day of professional activity.**

**We suggest adding ‘setting minimum standards of education (day-1 competencies) required to be registered...’.**

## Annex 20 (contd)

- c) setting minimum standards of professional conduct and competence of registered *veterinarians* and *veterinary paraprofessionals* and ensuring that these standards are met and maintained;
  - d) investigating complaints and applying disciplinary measures.
- 2) Independence of the *Veterinary Statutory Body* is ensured through transparent governance and funding arrangements including an elected, representative council or equivalent, and financial arrangements for the collection and management of registration fees.
  - 3) Sufficient veterinary clinical services are available of sufficient quality to meet the needs of animal owners, including their access to essential animal disease and injury diagnosis and treatment.

### Article 3.1.6.

#### **Stakeholders**

A range of individuals or organisations have an interest or concern in the activities of the *Veterinary Services*, for example livestock farmers, processors, traders, feed manufacturers, private *veterinarians* and *veterinary paraprofessionals*, as well as relevant non-governmental organisations (NGOs) and the general public.

*Veterinary Services* should communicate with these stakeholders in an effective, transparent and timely manner on *Veterinary Services* activities and developments in animal health, animal welfare and veterinary public health. They should also consult effectively with relevant stakeholders on *Veterinary Services* policies and programmes, involving mechanisms that actively seek their views for consideration and response.

#### **EU comment**

**As per the comment made in article 3.1.3. bullet point 4) we suggest include programmes as part of the policy options.**

*Competent Authorities* should, where applicable, have the authority and capability to develop or engage in public private partnerships to deliver animal health, animal welfare or veterinary public health outcomes. That is:

- to accredit, authorise or delegate to the private sector;
- the development or participation in collaborative joint programmes with producers or other stakeholders.

The OIE has produced guidelines for both public and private sectors to help advocate for, develop and implement public-private partnerships in the veterinary domain.

This component should comprise the following specific elements:

- 1) Good governance relevant to all stakeholder engagement is in place to ensure compliance with Article 3.1.2, incorporating transparency and effective monitoring and evaluation.
- 2) Ongoing, targeted and effective communication with stakeholders in accordance with Chapter 3.3.
- 3) Consultation mechanisms, including written invitation, meetings or workshops with non-government stakeholder representatives, with consultation inputs documented and duly considered.
- 4) Public private partnerships, in the form of official delegation or joint programmes, have the legal authority, formal agreements, and documented procedures, in accordance with Chapter 3.4.

### Article 3.1.7.

#### **Animal health**

*Veterinary Services* should organise and implement programmes to prevent, control or eradicate animal diseases, and should be able to identify animals to trace and control their movements.

*Veterinary Services* should organise and implement an effective animal health surveillance system and be prepared to respond effectively to sanitary emergencies.

This component should comprise the following specific elements:

- 1) Effective surveillance for the early detection, monitoring and reporting of animal diseases via an appropriate field animal health network, using laboratory confirmation and epidemiological disease investigation with prompt and transparent reporting, in accordance with relevant chapters, including Chapters 1.1., 1.2., 1.3., 1.4. and 1.5.

**EU comment**

**Modern surveillance systems are starting to make use of new information and data analysis technologies such as ‘big data’ and ‘artificial intelligence’.**

**We suggest including those to encourage member countries the use of these new information and data analysis technologies that could provide a new insight and advanced information to better prevent and control animal diseases.**

**‘...disease investigation with prompt and transparent reporting, and new data analysis technologies such as ‘big-data’ or ‘artificial intelligence’ in accordance with...’**

- 2) An updated list of *notifiable diseases* that includes relevant *listed diseases*.
- 3) Use of the formal procedures for self-declaration and official recognition by the OIE for both disease freedom and disease control programmes, in accordance with Chapter 1.6.
- 4) Emergency management, including preparedness and response planning, a legal framework, and access to the human, physical and financial resources to respond rapidly to sanitary emergencies in a well-coordinated manner, including for disposal and *disinfection* in accordance with Chapters 4.13. and 4.14.
- 5) *Official control programmes* for priority diseases with scientific and risk-based evaluation of their efficacy and efficiency, in accordance with the relevant chapters of the *Terrestrial Code*.
- 6) A programme for managing the risks to animal health from germplasm, including the collection, processing and distribution of semen, oocytes or embryos, in accordance with the relevant chapters in Section 4.
- 7) A programme for the official health control of bee diseases, in accordance with Chapter 4.15.
- 8) A programme for managing the risks to animal and public health from animal *feed*, including feeding animal materials to susceptible livestock, in accordance with Chapter 6.4.
- 9) A system for animal identification, traceability and movement control for specific animal populations as required for traceability or disease control, in accordance with Chapters 4.1. and 4.2.

Article 3.1.8.

**Animal production food safety**

*Veterinary Services* should contribute to assuring the safety of food of animal origin for domestic and export markets as part of a food safety system, with effective coordination of official controls between relevant *Competent Authorities*.

This component should comprise the following specific elements:

- 1) Regulation, inspection, authorisation and supervision of establishments and processes for production and processing of food of animal origin (slaughter, rendering, dairy, egg, honey and other animal product processing establishments) for export, national and local markets, including the inspection, sampling and testing of products, in accordance with Chapters 6.1. and 6.2.

### EU comment

**Official control activities are usually the result of a combination of inspection and auditing activities.**

**We suggest adding ‘and auditing’ after ‘inspection’ to provide a more accurate reflexion of official control activities and the opportunity to draw out the ‘verification’ aspects of the competent authority role.**

- 2) Implementation of procedures for ante-mortem and post-mortem inspection at slaughter facilities, incorporating *risk analysis* and principles of Hazard Analysis and Critical Control Point (HACCP), veterinary supervision, independent inspection, and the collection of information relevant to livestock diseases and zoonoses, in accordance with Chapters 6.2. and 6.3. and the relevant Codex Alimentarius texts.

### EU comment

**As per the comment above, we suggest incorporating in this bullet terms the concept of ‘auditing’, i.e. ‘...of Hazard Analysis and Critical Control Point (HACCP), veterinary auditing and supervision, independent inspection/ audit, and the ...’**

- 3) Regulation and implementation of controls on animal *feed* safety covering processing, handling, storage, distribution and use of both commercial and on-farm produced animal *feed* and *feed ingredients*, including risks such as microbial, physical, chemical and toxin contamination.
- 4) A residue monitoring programme for veterinary medicines (e.g. antimicrobials and hormones), chemicals, pesticides, radionuclides, heavy metals, etc. and the capacity to respond appropriately to adverse findings.
- 5) Identification and traceability of products of animal origin for the purposes of food safety, animal health or trade, in accordance with Chapter 6.2.

### Annex 20 (contd)

- 6) Procedures for corrective actions or sanctions in response to regulatory non-compliance to mitigate risks to the safety of food of animal origin for export or domestic markets in accordance with Article 6.2.3.

### EU comment

**It is important to stress that corrective actions should be ‘proportional’ and sanctions should be ‘proportional and dissuasive’ to avoid reoccurrence.**

**For this reason, we suggest the inclusion of those terms, i.e. ‘Proportional Procedures for corrective actions and/or proportional and dissuasive sanctions in response to...’**

- 7) Preparedness and response planning to manage food or *feed* safety incidents of animal origin.

Article 3.1.9.

### Veterinary medicinal products

*Veterinary Services* should regulate all *veterinary medicinal products* such as veterinary medicines, biologicals and medicated *feed*, in order to ensure their quality and safety, as well as their responsible and prudent use, including *monitoring* antimicrobial use and antimicrobial resistance, and minimising the associated risks.

This article should be read in conjunction with the *Terrestrial Manual*, which set standards for the production and control of vaccines and other biological products.

This component should comprise the following specific elements:

- 1) Effective regulatory and administrative control, in accordance with Article 3.4.11., including communications and compliance programmes for:
  - a) the market authorisation of *veterinary medicinal products*, including registration, import, manufacture, quality control, and reducing the risk from illegal imports;
  - b) responsible and prudent use of *veterinary medicinal products*, including the labelling, distribution, sale, dispensing, prescription and administration of these products.
- 2) *Risk management* and *risk communication* for antimicrobial use and antimicrobial resistance, based on risk assessment. This includes surveillance and control of the use of antimicrobials and the development and spread of antimicrobial resistant pathogens in animal production, animal origin food products, via a One Health approach, and in accordance with Chapter 3.4. and relevant chapters of Section 6.

Articles 3.1.10.

#### Laboratories

*Veterinary Services* should have access to quality *laboratory* diagnosis through a sustainable network of *laboratories*, capable of accurately identifying and reporting *infections* and *infestations* or other relevant hazards.

*Veterinary Services* require *laboratory* services for purposes such as early detection, measuring disease prevalence and progress with control, assessing *veterinary medicinal products* quality and protection, antimicrobial resistance surveillance, assessing the safety of food or *feed*, or supporting international trade (e.g. demonstration of freedom). The *laboratory* services include official government laboratories and other *laboratories* authorised by the *Competent Authorities* to conduct official testing, including private laboratories or those overseas.

#### EU comment

**In Chapter 1.6 the term ‘disease freedom’ has been deleted and replaced by ‘Animal health status’.**

**For consistency, you may wish to consider using ‘Animal health status’ as follows:**

**‘(e.g. demonstration of the animal health status freedom)’**

This article should be read in conjunction with the *Terrestrial Manual*, which sets laboratory diagnostic standards for all OIE *listed diseases* as well as several other diseases of global importance.

This component should comprise the following specific elements:

- 1) access to *laboratory* diagnosis that meets the needs of the *Veterinary Services*, which is efficient and sustainable with an appropriate throughput of samples, in accordance with the *Terrestrial Manual*;
- 2) access to approved *laboratories*, such as national, regional or international reference laboratories, to obtain or confirm a correct diagnosis for *notifiable diseases* and to investigate *emerging diseases* or hazards, in accordance with the *Terrestrial Manual*;

- 3) appropriate levels of laboratory biosafety and *biosecurity*;
- 4) formal *laboratory* Quality Management Systems and proficiency testing programmes, in accordance with the *Terrestrial Manual*.

Article 3.1.11.

#### **Animal welfare**

*Veterinary Services* should implement policies, legislation and programmes in accordance with Section 7.

#### **EU comment**

**As per the comment made in articles 3.1.3. bullet point 4) and article 3.1.6. we suggest include programmes as part of the policy options.**

This component should comprise the following specific elements:

- 1) *animal welfare* programmes, supported by suitable legislation, with appropriate stakeholder and public awareness and compliance inspection activities;
- 2) communication, consultation and coordination with stakeholders.

Article 3.1.12.

#### **International trade**

Through the implementation of OIE standards, *Veterinary Services* play a critical role in ensuring the safety of international trade of *commodities* and *veterinary medicinal products*, while avoiding unjustified barriers.

*Veterinary Services* should implement risk-based measures for import and export following relevant provisions in the *Terrestrial Code* and in accordance with Chapter 5.3. Quality of *Veterinary Services* is essential for these measures to be recognised and trusted.

This component should comprise the following specific elements:

- 1) *Sanitary measures* developed and implemented in accordance with Chapter 2.1. and other relevant chapters of the *Terrestrial Code*.
- 2) Effective implementation of *official veterinary controls* to prevent the entry of *diseases* and other *hazards* through effective border inspection and quarantine operations, in accordance with Chapter 5.6.
- 3) Effective application of relevant animal health measures at or before departure for exports, during transit through the country, and on arrival for imports, in accordance with Chapters 5.4., 5.5. and 5.7.
- 4) Effective development and implementation of international veterinary certification for *animals*, animal products, services and processes for export under their mandate, in accordance with importing country requirements and relevant chapters in Section 5.
- 5) Effective development, implementation and maintenance of equivalence and other types of sanitary agreements with trading partners, where applicable, in collaboration with national stakeholders, and in accordance with Chapter 5.3.
- 6) Regular and timely official notification to the OIE, WTO, trading partners and other relevant organisations of changes in animal disease status, regulations and sanitary measures and systems, in accordance with the procedures established by these organisations, including Chapters 1.1. and 1.3.
- 7) Where applicable, effective implementation and maintenance of disease-free *zones*, *compartments* or other high health status sub-populations for the purposes of trade, in collaboration with producers and other stakeholders, and in accordance with relevant chapters in Sections 4 and 5.
- 8) Active participation in the OIE and Codex Alimentarius standard setting processes.

This draft chapter would replace Chapter 3.2 in the 2019 edition of the *Terrestrial Code*. Considering the significant changes in the text, only a clean version is provided.

## DRAFT CHAPTER 3.2.

# EVALUATION OF VETERINARY SERVICES

### **EU comment**

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

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

#### Article 3.2.1.

##### **General considerations**

This chapter covers the evaluation of a country's *Veterinary Services*, including the various objectives and types of evaluation that may be considered.

Member Countries may develop their own mechanisms and methods for the evaluation of their *Veterinary Services*. The evaluation of the quality of *Veterinary Services* should be in accordance with Chapter 3.1.

The OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool) provides a thorough, benchmarked methodology for the consistent, comprehensive evaluation of *Veterinary Services*. The OIE PVS Tool is aligned with the OIE standards, in particular, with the quality standards for *Veterinary Services* defined in Chapter 3.1. Based on the OIE PVS Tool, the OIE has developed a capacity building platform, the PVS Pathway, for the sustainable improvement of a country's *Veterinary Services*' compliance with OIE standards.

#### Article 3.2.2.

##### **Objectives of the Evaluation of Veterinary Services**

The evaluation of *Veterinary Services* has the following objectives:

- 1) to provide an independent, objective perspective on the performance of *Veterinary Services*;
- 2) to verify performance, provide confidence, enhance reputation and avoid complacency, and as part of a process of continuous improvement;
- 3) to demonstrate compliance of the *Veterinary Services* with Chapter 3.1.;
- 4) to better advocate for, allocate and prioritise resources;
- 5) to generate trust between trading partners in the quality and integrity of *Veterinary Services*.

The evaluation of *Veterinary Services* can be performed by the country itself (self-evaluation), by another Country or Countries, or by OIE experts under the auspices of the OIE as part of the PVS Pathway.

#### Article 3.2.3.

##### **Self-evaluation of the Veterinary Services of a Member Country**

- 1) Member Countries should undertake a self-evaluation of their *Veterinary Services* periodically as part of their quality management system.

- 2) Self-evaluation may be undertaken by Competent Authorities for the whole or part of the Veterinary Services.

**EU comment**

**It is important that the principle of ‘independence’ is considered when a self-evaluation is carried out.**

**For this reason we suggest including the following text in bullet point 2)**

**‘2) Self-evaluation may be undertaken by the Competent Authorities for the whole or part of the Veterinary Services. The competent authorities should consider the principle of independence when carrying out self-evaluations and may appoint independent bodies to carry out such evaluations on their behalf.**

- 3) Self-evaluation at the sub-national level such as of individual provinces or states can usefully supplement national level evaluation.

**EU comment**

**Geographical administrative units at sub-national level receive different names, for this reason, we suggest using the generic term ‘regions’ and include provinces or states as examples. i.e. ‘...at the sub-national level such as of individual regions (e.g. provinces or states) can...’.**

- 4) The use of the OIE PVS Tool is encouraged.

Article 3.2.4.

**Evaluation of the Veterinary Services of a Member Country by another Member Country**

- 1) Every Member Country should recognise the right of another Member Country to request an evaluation of its *Veterinary Services* to facilitate decision-making on trade.
- 2) The evaluation should be in accordance with Chapter 3.1.
- 3) The evaluation process may be desktop or field based, and cover whole or part of the *Veterinary Services*, depending on its objective.

**EU comment**

**The evaluation process could also be both a desktop exercise and a field visit.**

**We suggest adding 'and/ or'**

- 4) A Member Country which intends to conduct an evaluation of another Member Country's *Veterinary Services* should give them notice in writing. This should define the purpose and scope of the evaluation and detail the information required.
- 5) Prior to the evaluation, the parties should agree on the objective, scope and approach of the evaluation, including any requirements of confidentiality.
- 6) The evaluation should be conducted in accordance with the Fundamental Operating Principles set-out for *Veterinary Services* in Article 3.2.2 in a timely and efficient manner, ensuring the level of evaluation activity is undertaken only to the extent necessary.
- 7) The evaluation should start with a review of available information including existing PVS Pathway or other reports, analysis of publicly available or previously provided information, or historical performance such as relating to safe trade or transparency.
- 8) The outcome of the evaluation conducted by another Member Country should be provided in writing to the evaluated country as soon as possible. The evaluation report should detail any findings which affect trade prospects. The Member Country which conducts the evaluation should clarify any points of the evaluation on request.

**EU comment**

**The evaluation report may contain errors or misunderstandings, this is why the evaluated country should have the opportunity to respond formally to the findings of the evaluation country.**

**For this reason we suggest adding at the end of the phrase '...on request, and provide an opportunity for the evaluated country to clarify or respond to the findings of the evaluating country before the production of the final evaluation report'**

- 9) The use of the OIE PVS Tool is encouraged.

Article 3.2.5.

**Evaluation of the Veterinary Services of a Member Country by OIE experts, under the auspices of the OIE**

- 1) The OIE has established procedures for the evaluation of the *Veterinary Services* of a Member Country using the OIE PVS Tool, following a voluntary request from the Member Country.
- 2) The report of such an evaluation belongs to the *Veterinary Authority* of the Member Country. The OIE

encourages Member Countries to make their reports publicly available.

- 3) Member Countries are encouraged to use these reports in a transparent way to achieve some or all of the objectives listed in Article 3.2.2.
  - 4) Support for further use of the evaluation report in national planning and targeted capacity building is available from the OIE as part of its PVS Pathway.
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DRAFT CHAPTER 3.X.

**INTRODUCTION TO RECOMMENDATIONS  
ON VETERINARY SERVICES**

**EU comment**

**The EU thanks the OIE and in general supports the proposed structure and content of this new Chapter 3.X.**

Article 3.X.1.

*Veterinary Services* are critical to global and national health security, food security and food safety, agricultural and rural development, poverty alleviation, safe international trade, wildlife and environmental protection; as such they are considered a global public good. To achieve these goals, *Veterinary Services* require good governance, including effective policy and management, personnel and resources, veterinary professionals and interaction with stakeholders.

Member Countries have the sovereign right to structure and manage the delivery of animal health, animal welfare and veterinary public health in the veterinary domain in their countries as they see fit. The veterinary domain covers a broad scope of possible activities. Section 3 focuses on aspects of the *Veterinary Services* that enable the OIE standards to be met even when under the responsibility of one or more *Competent Authorities*.

Member Countries should implement the OIE standards across their whole territory and should meet their obligations at the international level through representation by their respective OIE Delegate. The *Veterinary Authority*, including the OIE Delegate, should coordinate with other *Competent Authorities* to ensure international standards and responsibilities are met.

*Veterinary Services* have responsibility for implementing the activities necessary for the Member Country to comply with OIE standards. These activities can be delivered by a combination of individuals or organisations, public or private that are responsible to one or more *Competent Authorities*. *Veterinary Services* also include the personnel of the *Competent Authorities* themselves. The term *Veterinary Services* refers to the combination of a number of separate actors, with different organisational affiliations.

Section 3 provides standards to assist the *Veterinary Services* of Member Countries in meeting 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.

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DRAFT CHAPTER 7.5.

**ANIMAL WELFARE DURING SLAUGHTER**

**EU position**

**The EU thanks the OIE and supports the approach taken to revise this chapter. The EU includes a few preliminary comments for consideration in the further drafting.**

**The EU reserves its rights to provide detailed comments when the whole chapter is completed.**

Article 7.5.1.

**Introduction**

Providing good welfare to the animals at *slaughter* is ethically and economically beneficial. The implementation of animal welfare measures contributes to the improvement of workers' safety and product quality, and is essential for food safety [Blokhuis *et al.*, 2008; Lara and Rostagno, 2018].

**EU comment**

**The EU proposes the following revision:**

**“Providing good welfare to the animals at *slaughter* is ethically and economically beneficial. The implementation of animal welfare measures contributes to the improvement of economical returns, workers' ~~safety and~~ wellbeing and product quality, and is essential for food safety.”**

**Justification**

**By enhancing animal welfare at slaughter we would see greater economic returns, as the productivity and quality of the meat produced is improved.” total losses to the EU meat industry due to PSE ranged from €60.5 to €140.5 million in 2005; additionally, €14.2 million was lost due to bruising**

**Animal welfare improvements go beyond workers safety and extend to other wellbeing areas. For example, improved animal handling systems not only lead to better outcomes for animal welfare but make it easier for staff to move animals, enhancing their working environment and improving staff wellbeing.**

**References**

**Garcia Pinillos, R. , 2019**

**<https://veterinaryrecord.bmj.com/content/vetrec/183/6/198.full.pdf>**

## European Commission. Study on the stunning/killing practices in slaughterhouses and their economic, social and environmental.

consequences. 2007. <https://bit.ly/2O49WGX>. Accessed 8 August, 2018

Article 7.5.2.

### Scope

This chapter identifies potential *animal welfare hazards* during *slaughter* and provides recommendations for arrival and *unloading, lairage*, handling, *restraint, stunning* and bleeding of animals in *slaughterhouses/abattoirs*. It provides animal-based measures to assess the level of welfare and recommends remedial actions to be applied, when necessary.

This chapter applies to the *slaughter* in *slaughterhouses/abattoirs* of the following domestic animals: cattle, buffalo, bison, sheep, goats, horses, pigs, rabbits and *poultry*, hereafter referred as “animals”. Recommendations consider whether animals arrive at the *slaughterhouse/abattoir* in *containers* or are free-moving.

This chapter should be read with the guiding principles for animal welfare provided in Chapter 7.1. and relevant provisions of Chapters 6.2 and 6.3.

The principles underpinning these recommendations may also apply to the *slaughter* of other species and those slaughtered in other places.

Article 7.5.3.

### Definition for the purpose of this chapter

Bleeding: means the act of severing major blood vessels that supply the brain, to ensure death.

Article 7.5.4.

### Animal welfare hazards

*Hazards to animal welfare* during each of the pre-slaughter stages have an additive effect on the stress of the animals [Moberg and Mench, 2000].

At the *slaughterhouse*, animals are exposed to animal welfare hazards including fasting and water deprivation, mixing of unfamiliar *animals*, handling by humans, exposure to a novel environment (e.g. noise, lighting, flooring), forced physical exercise, limited space allowance, extreme weather conditions and inadequate stunning and bleeding. These *hazards* can have negative impacts on the welfare of the animals that can be assessed through animal-based and measures.

### EU comment

**The EU proposes the following revision:**

**“These hazards can have negative impacts on the welfare of the animals that can be assessed through animal-based and other measures. Hazards can have other welfare consequences such as pain.”**

### Justification

**Key technical stunning parameters measured are also important for assessment of hazards; especially concerning the hazard/risk of electro immobilisations in case of electrical stunning.**

### References:

**(EFSA, 2019) Nielsen, S.S., Alvarez, J., Bicout, D.J., Calistri, P., Depner, K., Drewe, J.A., Garin-Bastuji, B., Rojas, J.L.G., Schmidt, C.G., Chueca, M.Á.M., Roberts, H.C., Sihvonen, L.H., Spoolder, H., Stahl, K., Calvo, A.V., Viltrop, A., Winckler, C., Candiani, D., Fabris, C., Stede, Y.V. der, Michel, V., 2019. Slaughter of animals: poultry. EFSA J. 17, e05849. <https://doi.org/10.2903/j.efsa.2019.5849>**

Animal welfare hazards can be minimised by appropriate design of premises and choice of equipment, and through good management, training and competency of personnel.

#### Article 7.5.5.

##### **Criteria (or measures)**

The welfare of animals at *slaughter* should be assessed using outcome-based measures. Although consideration should be given to the resources provided as well as the design and management of the system, animal-based criteria are preferential.

##### Annex 23 (contd)

The routine use of these outcome-based measures and the appropriate thresholds should be adapted to the different situations in which animals are managed at a *slaughterhouse/abattoir*. It is recommended that target values or thresholds for animal welfare measurables be based on current scientific knowledge and appropriate national, sectorial or regional standards.

#### Article 7.5.6.

##### **Management**

The *slaughterhouse/abattoir* operator is responsible for the development and enforcement of a dedicated operating plan that should consider the following:

- design of premises and choice of equipment;
- training and competency of personnel;
- throughput (number of animals slaughtered per hour);
- maintenance and cleaning procedures;
- contingency plans.

##### **EU comment**

**The EU proposes to add an additional hyphen:**

**“- operating procedure and corrective action.”**

##### **Justification**

**It seems incomplete not to show in an operating plan the procedures and corrective actions.**

Article 7.5.7.

**Training and competency of personnel**

*Animal handlers* and other personnel have a crucial role to play in ensuring good *animal welfare* conditions from the time of arrival of the animals at the *slaughterhouse/abattoir* through to their *death*. Training for all personnel should emphasise the importance of *animal welfare* and their responsibility in contributing to the welfare of the animals that come through the *slaughterhouse/abattoir*.

*Animal handlers* should understand the behavioural patterns of animals and their underlying principles to carry out the required tasks whilst ensuring good *animal welfare*. They should be experienced and competent in handling and moving the animals and able to identify signs of pain and suffering. Personnel in charge of restraint and of *stunning* and bleeding operations should be familiar with the relevant equipment, their key working parameters and procedures. Personnel *stunning*, shackling and bleeding animals should be able to identify effective *stunning* of the animal and signs of recovery of consciousness, and should be able to take corrective actions, if necessary [EFSA, 2013a; EFSA 2013b].

**EU comment**

**The EU proposes the following revision:**

**“Personnel *stunning*, shackling and bleeding animals should be able to identify effective *stunning* of the animal and signs of recovery of consciousness, should be able to detect if an animal is still alive prior to dressing or scalding and should be able to take corrective actions, if necessary.”**

**Justification**

**Animals should not be dressed until death has been confirmed and so those who bleed animals need to be able to recognise the signs of death.**

Competencies may be gained through a combination of formal training and practical experience. These competencies should be assessed by the *Competent Authority* or by an independent body recognised by the *Competent Authority*.

Article 7.5.8.

**Design of premises and choice of equipment**

The design of premises and the choice of equipment used in a *slaughterhouse/abattoir* have an important impact on the welfare of animals. They should consider the animals' needs, in terms of their physical comfort including thermal conditions, protection from injury, protection from sudden or excessive noise, ability to perform natural and social behaviours as well as watering and feeding needs. Premises should be designed to eliminate distractions that may cause approaching animals to stop, baulk or turn back.

The design of the *slaughterhouse/abattoir* and choice of equipment should take into consideration the species, categories, quantities, and size or weight of the animals. *Restraint*, *stunning* and bleeding equipment is critical for the welfare of an animal at the time of *slaughter*. Appropriate back-up equipment should be available for immediate use in case of failure of the *stunning* equipment initially used.

Article 7.5.9.

**Throughput (number of animals slaughtered per hour)**

The throughput of the *slaughterhouse/abattoir* should never exceed the maximum specification of the design of the facilities or equipment and may be reduced depending on the welfare outcomes.

**EU comment**

**The EU proposes the following revision:**

**“The throughput of the *slaughterhouse/abattoir* should never exceed the maximum specification of the design of the facilities or equipment, ~~and may~~ The throughput needs to be continuously monitored and adjusted to any operational changes, such as staff numbers or line breakdowns. It may also need to be reduced depending on the welfare outcomes.”**

**Justification**

**It is key to ensure that the throughput is not only adjusted to the equipment specification, but also to operational factors. If there is no sufficient staff available to handle or monitor animals at a high speed the maximum throughput should be mandated by the staff numbers capabilities rather than the equipment specification. This point is slightly different to the one below as below refers to planning, whilst this relates to reacting to operational changes during the slaughter period.**

Personnel allocation should be adequate for the anticipated throughput and be sufficient to implement the *slaughterhouse/abattoir* operating plan as well as *ante mortem* and *post mortem* inspections.

Article 7.5.10.

**Maintenance and cleaning procedures**

All equipment should be clean and well maintained in order to ensure *animal welfare* and safety of personnel.

**EU comment**

**The EU proposes the following revision:**

**“All equipment should be clean and well maintained in accordance with manufacturer’s instructions in order to ensure animal welfare ~~and safety of personnel.~~”**

**Justification**

**The EU finds important to include concrete reference to manufacturer’s instructions and remove “safety of the personnel” as the main focus of this chapter is about animal welfare.**

Maintenance and cleaning of *unloading, lairage* and moving facilities contributes to ensuring that animals are handled smoothly, preventing pain and fear.

Maintenance and cleaning of restraining, stunning and bleeding equipment is essential to ensure reliable and efficient stunning and slaughter, thereby minimising pain, fear and suffering.

**EU comment**

**The EU propose the following revision:**

**“Maintenance and cleaning of handling, restraining, stunning and bleeding equipment is essential to ensure reliable and efficient stunning and slaughter, thereby minimising pain, fear and suffering.”**

**Justification**

**Handling equipment, which ranges from electric goads to other tools, needs to be well maintained and cleaned in the same way as other equipment.**

Article 7.5.11.

#### Contingency plans

Contingency plans should be in place at the *slaughterhouse/abattoir* to protect the welfare of the animals in the event of an emergency. The contingency plans should consider the most likely emergency situations given the species slaughtered and the location of the *slaughterhouse/abattoir*

Contingency plans should be documented and communicated to all responsible parties.

Article 7.5.12.

#### Arrival of free-moving animals

On arrival at the *slaughterhouse/abattoir*, animals will already have been exposed to *hazards* that may have negative impacts on their welfare. Any previous *hazards* will have a cumulative effect that may affect the welfare of the animals throughout the *slaughter* process. Therefore, animals should be transported to the *slaughterhouse/abattoir* in a manner that minimises adverse animal health and welfare outcomes, and in accordance with Chapters 7.2. and 7.3.

##### 1. Animal welfare concerns:

Delay in *unloading* of animals is the main *animal welfare* concern at arrival [NAMI, 2017].

Animals in *vehicles* have smaller space allowances than on farm, undergo water and feed deprivation, and may be exposed to thermal stress due to adverse weather conditions. In addition, stationary vehicles may have insufficient ventilation. Delays in *unloading* animals will prolong or exacerbate the impact of these *hazards*. Under these circumstances, injured or sick animals requiring urgent attention will not be identified and therefore the duration of their suffering will be increased.

##### 2. Animal-based and other measurables include:

It can be difficult to assess animal-based measures while animals are in the *vehicle*. Some measures that may be assessed include animals with injuries, or those that are sick or have died. Panting, shivering and huddling may indicate thermal stress. Drooling and licking may indicate prolonged thirst.

Animals dead on arrival or condemned on arrival should be recorded and monitored as an indicator of *animal welfare* prior to and during transport.

#### **EU comment**

**The EU proposes to add the following:**

**“Mortalities and injuries should be reported to the competent authority responsible for animal welfare during transport.”**

#### **Justification**

**This will enable welfare during transport to be improved as the competent authority can press and encourage the transporter concerned to improve their transport practices and also not to load unfit animals.**

Time from arrival to unloading and the environmental temperature and humidity can be used to establish relevant thresholds for corrective action.

3. Recommendations:

Animals should be unloaded promptly on arrival. This is facilitated by scheduling the arrival of the animals at the *slaughterhouse/abattoir* to ensure that there are sufficient personnel and adequate space in the *lairage* area.

Consignments of animals assessed to be at greater risk of *animal welfare hazards* should be unloaded first. When no space is immediately available, creating space should be a priority. Provisions should be made to provide shelter, shade or additional ventilation during waiting periods, or animals transported to an alternative nearby location where such provision is available.

4. Species-specific recommendations:

Pigs are especially sensitive to extreme temperatures and therefore special attention should be taken when dealing with delays in *unloading* this species.

**EU comment**

**The EU proposes the following revision:**

**“Pigs and young animals, weaned or not are especially sensitive to extreme temperatures and therefore special attention should be taken when dealing with delays in *unloading* this species.”**

**Justification**

**Very young animal, lacking fully developed temperature-regulating mechanisms, particularly the ability to increase heat production by increased metabolism, is much more sensitive to its thermal environment and requires higher temperatures.**

**Herpin. Bases métaboliques et physiologiques de l’acclimatation du porcelet au froid. INRA Productions Animales, Paris: INRA, 1989, 2 (4), pp.255-265. hal-00895873**

**<http://www.fao.org/3/s1250e/s1250e10.htm> : "very young animal, lacking fully developed temperature-regulating mechanisms, particularly the ability to increase heat production by increased metabolism, is much more sensitive to its thermal environment and requires higher temperatures."**

Article 7.5.13.

**Displacements of free-moving animals**

This article addresses the handling of animals during *unloading* and *lairage*, and in the killing area.

1. Animal welfare concerns:

During *unloading*, animals are exposed to similar *hazards* to those encountered when being loaded (see Chapters 7.2. and 7.3). Inappropriate equipment in the *vehicle* or the *slaughterhouse/abattoir*, such as a lack of lateral protection when unloading, excessively steep ramps or an absence of foot battens, may result in animals slipping, falling or being trampled, causing injuries. These *hazards* can also be associated with inappropriate handling and forced physical movement of animals that are unable to move independently as a result of weakness or injuries. Exposure to novel environments (e.g. noise, lighting, flooring) will cause fear and reluctance to move, or turning back.

## EU comment

The EU proposes the following revision:

“During *unloading*, animals are exposed to similar *hazards* to those encountered when being loaded (see Chapters 7.2. and 7.3). Inappropriate equipment in the *vehicle* or the *slaughterhouse/abattoir*, such as a lack of lateral protection when unloading, excessively steep ramps or an absence of foot battens, may result in animals slipping, falling or being trampled, causing injuries. The absence of ramps or lifts can result in animals being pushed or thrown off the vehicle.”

## Justification

The absence of a ramp results in extremely poor unloading practices and often leads to injuries.

## 2. Animal-based and other measurables include:

- a) animals running, slipping and falling;
- b) animals with broken limbs;
- c) animals turning-back, reluctant to move;
- d) animals that are unable to move by themselves;
- e) animals that strike against the facilities;
- f) frequency of use of excessive force by personnel;
- g) frequency of use of electrical prods;

## EU comment

The EU proposes to add the following:

“**h) frequency of vocalisation especially for pigs and cattle**”;

## Justification

Vocalisation is used as an indicator of pain at slaughterhouses.

## References

<https://www.nap.edu/read/1542/chapter/5#33>

<https://www.sciencedirect.com/science/article/pii/S0168159115002269>

[http://eprints.nottingham.ac.uk/43848/1/Hudson08\\_InPrac\\_PrePrint.pdf](http://eprints.nottingham.ac.uk/43848/1/Hudson08_InPrac_PrePrint.pdf)

<https://www.sciencedirect.com/science/article/pii/S1871141316302219>

<https://www.ingentaconnect.com/content/ufaw/aw/2009/00000018/00000004/art00021?crawler=true>

**Temple Grandin does describe it as a sensitive indicator of problems in cattle :**  
<https://www.grandin.com/livestock.handling.qa.html>

Animals are safely handled when these measures are below an acceptable threshold.

3. Recommendations:

Ramps should be positioned so that the animals can be handled safely. There should be no gap between the *vehicle* and the ramp, the gradient should not be too steep, and side barriers should be in place.

**EU comment**

**The EU proposes the following revision:**

**“Ramps or lifts should be provided and positioned so that the animals can be handled safely. There should be no gap between the *vehicle* and the ramp or lifts, the gradient should not be too steep, that there is a risk for the animals to injure themselves and side barriers should be in place. Design of the equipment including ramps and raceway should as far as possible promote the voluntary and natural displacements of the animals. This should also apply to the ambient condition such as light.”**

**Justification**

The Chapter’s text makes various comments about ramps but does not make the core point that they should be provided. The absence of ramps leads to animals being pushed or thrown off vehicles and often to injuries. The EU finds the wording that: “the gradient should not be too steep” as a bit vague and with the view to avoid providing exact information about the gradient, proposes to point out the relevant risk more clearly.

**Limitation of human interaction will benefit to the welfare of the animals and the safety of the workers.**

Preventive measures such as foot battens, rubber mats and deep groove flooring can help animals to avoid slipping.

Annex 23 (contd)

The unloading area and raceways should be well lit so that animals can see where they are going.

The design of unloading areas and raceways should aim to minimise the potential for distractions that may cause animals to stop, baulk or turn back when being unloaded (e.g. shadows, changes in flooring, moving objects). For details refer to Chapters 7.2. and 7.3.

Animals that are injured, sick or unable to rise require immediate action and, when necessary, should be euthanised without moving them and without delay. Refer to Articles 7.5.19. and 7.5.201.

**EU comment**

**The EU proposes to add the following:**

**“Such animals should never be dragged, nor should they be lifted or handled in a way that might cause further pain, suffering or exacerbate injuries.”**

**Justification**

The EU believes that it is important to reflect this to ensure continuous improved change in these practices.

Personnel should be calm and patient, assisting the animals to move using a soft voice and slow movements. They should not shout, kick, or use any other means that is likely to cause fear or pain to the animals. Under no circumstances should animal handlers resort to violent acts to move animals (see Article 7.5.20).

#### **EU comment**

**The EU proposes to add the following:**

**“Personnel should not stand between an animal and where they want it to move to as this may cause the animal to baulk. The presence of more personnel in the slaughterhouse than are needed to perform required tasks should be avoided as this leads to stress, fear and confusion for the animals.”**

#### **Justification**

**It often results in personnel shouting and beating animals in order to force them to move. Reflecting this issues ensure that these practices can be identified and corrected. The presence of more personnel is a common problem. It usually results in excess noise, shouting and movement. This frightens animals and makes them confused as to where they are being asked to move to and so can result in animals being beaten to force them to move.**

Mechanical aids and electric goads should be used in a manner to encourage and direct movement of the animals without causing distress and pain. Preferred mechanical aids include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles.

Mechanical aids and electric goads should not be used as a substitute for good facility design and handling. They should not be used repeatedly if an animal fails to respond or move. In such cases it should be determined whether some physical or other impediment is preventing the animal from moving.

Electric goads should only be used in extreme cases and not on a routine basis to move animals.

The use of electric goads should be limited to battery-powered goads applied to the hindquarters of adult pigs and large ruminants, and never to sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.

#### **EU comment**

**The EU proposes the following revision:**

**“The use of electric goads should be limited to battery-powered goads applied to the hindquarters of adult pigs and large ruminants which refuse to move, and only when they have room ahead of them in which to move. The shocks shall be adequately spaced and shall only be applied to the muscles of the hindquarters. Shocks shall not be used repeatedly if the animal fails to respond.”**

#### **Justification**

**The current paragraph implies that electric goads can be used indiscriminately in any adult pig or large ruminant’s hindquarter. This should never be the case as this may have severe welfare consequences and not result in improved handling. The additional text intends to ensure there are additional safeguards to prevent indiscriminate use.**

The manual lifting of animals should be avoided; if it is necessary, animals should not be grasped or lifted in a manner which causes pain or suffering and physical damage (e.g. bruising, fractures, dislocations).(See Article 7.5.20).

4. Species-specific recommendations:

None identified.

Article 7.5.14.

**Lairage of free-moving animals**

1. Animal welfare concerns:

Animals during lairage may be exposed to several animal welfare hazards including:

- a) food and water deprivation leading to prolonged hunger and thirst,
- b) absence of protection against extremes in climate leading to thermal stress,
- c) sudden or excessive noises, including from personnel, leading to fear,
- d) insufficient space to lie down and move freely leading to fatigue and aggressive behaviour,
- e) poor design and maintenance leading to distress and injuries,
- f) mixing of unfamiliar animals leading to aggressive behaviour,
- g) limited access to resources (e.g. drinkers, bedding) leading to aggressive behaviour.

Annex 23 (contd)

2. Animal-based and other measurables include:
- a) thermal stress (e.g. panting, sweating, shivering, huddling behaviour)
  - b) space allowance,
  - c) excessive soiling with faeces,
  - d) injuries (e.g. lameness, open wounds, fractures)
  - e) illness (e.g. limping, diarrhoea, coughing)
  - f) aggressive behaviours (e.g. mounting, fighting).

**EU comment**

**The EU proposes to add the following:**

**“(g) frequency of vocalisation especially for pigs and cattle”;**

**Justification**

**Vocalisation is used as an indicator of fighting or distress.**

**References**

<https://www.nap.edu/read/1542/chapter/5#33>

<https://www.sciencedirect.com/science/article/pii/S0168159115002269>

[http://eprints.nottingham.ac.uk/43848/1/Hudson08\\_InPrac\\_PrePrint.pdf](http://eprints.nottingham.ac.uk/43848/1/Hudson08_InPrac_PrePrint.pdf)

<https://www.sciencedirect.com/science/article/pii/S1871141316302219>

<https://www.ingentaconnect.com/content/ufaw/aw/2009/00000018/00000004/art00021?crawler=true>

**Temple Grandin does describe it as a sensitive indicator of problems in cattle :**

<https://www.grandin.com/livestock.handling.ga.html>

3. Recommendations:

Animals should have constant access to clean water. Water supply points should be designed according to the species and age of the animal, with environmental conditions that allow for effective consumption. The number and location of the water supply points should minimise competition.

Animals should be provided with feed in lairage if the duration between loading and expected time for slaughter exceeds 24 hours.

**EU comment**

**The EU proposes the following revision:**

**“Animals should be provided with feed in lairage if the duration between unloading and expected time for slaughter exceeds 24 12 hours.”**

### **Justification**

**There is a cumulative element of feed withdrawal on farm to be added to transport, therefore a maximum time of 12 hours following unloading is preferable to account for the extra time on farm without feed or water.**

**Under normal conditions horses for example spend 16 hours every day grazing (Berger, 1986), sheep 10 hours (Broom och Fraser 2007), and to go without food for 24 hours could cause them unnecessary stress and suffering. (Berger, J. 1986. Wild horses of the Great Basin. University of Chicago Press, Chicago. Broom D.M. och Fraser A.F. (2007) Domestic animal behaviour and welfare. p 87. Cambridge University Press, Cambridge)**

**Last but not least in the current OIE Chapter 7.5. Slaughter of animals it is stated 12 hours.**

The lairage should provide animals with protection against adverse weather conditions.

### **EU comment**

**The EU proposes the following revision:**

**“The lairage should provide animals with protection against adverse weather conditions including also shade.”**

### **Justification:**

**Shade is important to prevent heat stress; See e.g. articles in OIE Chapters: article 7.13.16 on Pig welfare, article 7.9.5 on Beef Cattle, article 7.12.7 on Working Equids**

Animals should be protected from excessive noise (e.g. ventilation fans, alarms, or other indoor or outdoor equipment).

### **EU comment**

**The EU proposes the following revision:**

**“Animals should be protected from excessive and sudden noise (e.g. ventilation fans, alarms, or other indoor or outdoor equipment).”**

### **Justification**

**Sudden noise may cause animals to panic and as a result, they may injure themselves or not move easily.**

### **Reference**

**Preparation of best practice on the protection of animals at the time of killing.**  
**<https://op.europa.eu/en/publication-detail/-/publication/ea4ef3e9-cda5-11e7-a5d5-01aa75ed71a1/language-en/format-PDF/source-search>**

Lairage areas should be free from sharp edges and other hazards that may cause injury to animals.

The lairage should provide enough space for all animals to lie down at the same time, to move freely and to move away in case of aggressive behaviours.

Lairage areas should have adequate lighting levels to allow inspection of the animals.

Animals from different groups (or different species) should not be mixed.

#### **4. Species-specific recommendations:**

None identified.

## EU comment

The EU proposes the following revision:

**“~~None identified.~~ Pigs should be kept in small groups when resting in lairage, when moving to the stunner and when stunned.”**

### Justification

**Pigs in smaller groups (up to 15 pigs) are easier to move to lairage pens, and to the stunner. Furthermore, there tend to be less aggression, when pigs are kept in smaller groups.**

### References

<https://www.sciencedirect.com/science/article/abs/pii/S0309174014005154>

<https://www.sciencedirect.com/science/article/abs/pii/S0309174016301048>

Article 7.5.15.

### Restraint for stunning or bleeding (free-moving animals)

#### 1. Animal welfare concerns:

The purpose of *restraint* is to facilitate the correct application of the stunning or bleeding equipment. Incorrect *restraint* may not only lead to ineffective stunning or bleeding, but also cause pain and distress.

Other hazards include:

- a) slipping or falling of animals entering the restraining area,
- b) struggling or escape attempts caused by insecure *restraint*,
- c) injuries and pain caused by excessive force of *restraint*,
- d) fear caused by prolonged *restraint*, which may exacerbate insecure or excessive *restraint*.

Annex 23 (contd)

In addition, slaughter without stunning increases the risk of pain and fear due to the need for robust *restraint* of conscious animals for neck cutting, especially if animals are turned on their sides or backs [von Holleben *et al.*, 2010; Pleiter, 2010].

#### 2. Animal-based and other measurables include:

- a) animal slipping or falling;
- b) struggling;
- c) escape attempts;
- d) vocalisation (cattle and pigs);
- e) reluctance to enter the restrainer;
- f) frequency of use of electric goads.

#### 3. Recommendations:

The restrainer should be narrow enough that the animals cannot move either backwards or forwards or turn around.

**EU comment**

**The EU proposes the following revision:**

**“Where individual restraint is used, the restrainer should be narrow enough that the animals cannot move either backwards or forwards or turn around.”**

**Justification**

**This is applicable to individual restraint but not to group restraint.**

The restrainer being used should be appropriate to the size of the animals and the restrainer should not be loaded beyond its design capacity.

**EU comment**

**The EU proposes to add the following sentences:**

**“In case of slaughter without stunning of cattle, the restrainer should restrain the head appropriately and should support the body of the animal appropriately.**

**The restraining should be maintained until the animal is unconscious.”**

**Justification**

**For cattle it is important that (in case of unstunned, religious slaughter) the head is restrained and the body is supported to avoid the animal collapsing in a way that inhibits/hinders bleeding and leads to later unconsciousness; it is important for adequate, fast bleeding. See studies below.**

**Practical experience also shows restraining problems with small ruminants; also for these ruminants it should be recommended to fully restrain the animal until it is unconscious.**

**References:**

**Verhoeven, M.T.W, Gerritzen, M.A., Hellebrekers, L.J., Kemp, B., Validation of indicators used to assess unconsciousness in veal calves at slaughter, Animal, p. 1-9, The Animal Consortium 2016**

**Mirabito, L. et al., Restraining systems for bovine animals slaughtered without stunning, SANCO/2012/10357, June 2015**

When restrainers are used that hold an animal with its feet off the floor, the animal must be held in a balanced, comfortable, upright position.

When a restrainer is used to rotate an animal from an upright position, the body and head must be securely held and supported to prevent struggling and slipping within the device.

Restrainers should not have sharp edges.

Non-slip flooring should be used to prevent animals from slipping or falling.

**EU comment**

**The EU proposes the following revision:**

**“Trip-floor restraint boxes designed to make animals lose their balance - i.e. a box with a floor that rises on one side upon entry to the box – should not be used.”**

**Justification**

**There is a high risk of injuries and stress for the animal. Restraint of animals during ritual slaughter should be addressed in a specific part of the standard. Trip-floor restraint boxes are targeted by NGOs because of their misuse during ritual slaughter.**

**These boxes result in animals slipping and sliding and trying, but failing, to regain their balance.**

Distractions (e.g. movements of equipment or people) should be minimised to prevent balking and improve ease of entry into the restrainer.

No animals should enter the restrainer until equipment and personnel are ready to slaughter that animal.

No animals should be released from the restrainer until the operator has confirmed loss of consciousness.

**EU comment**

**The EU proposes the following revision:**

**“Where the control of loss of consciousness could not be performed in the restrainer, the design of the stunning area should allow for a control after releasing and if relevant a safety restun of the animals. All these items should be included in the operating plan.”**

**Justification:**

**In some cases, both control of loss of consciousness and restun are not easy to perform in the restrainer.**

**The last sentence is in adequacy with the modification requested in article 7.5.6**

**“Management” page 3.**

4. Species-specific recommendations:

Gondolas for gas stunning of pigs should not be overloaded and pigs should be able to stand without being on top of each other.

Head *restraint* is recommended for cattle.

Article 7.5.16.

**Stunning of free-moving animals**

**EU comment**

**For the sake of clarity and easy reference, the EU suggests redrafting this section in order to separate the different stunning methods (mechanical, electrical and controlled atmosphere) and include separate sub-sections to cover:**

**- method description;**

- key parameters;

- hazards;

- indicators and;

- recommendations.

**For example, the EU finds essential having parameters for electrical stunning and would like to ask the OIE to provide them.**

1. Animal welfare concerns:

The main animal welfare concern associated with stunning is 'ineffective stunning' which results in pain, distress or fear during induction of unconsciousness and possible recovery before *death*.

The most common methods for stunning are mechanical, electrical and exposure to controlled atmosphere.

Annex 23 (contd)

Mechanical stunning is divided into penetrating and non-penetrating applications. Both applications aim to induce immediate loss of consciousness as the impact of the bolt on the skull results in concussion and disruption of normal brain function [Daly *et al.*, 1987; EFSA, 2004]. The main hazards preventing effective mechanical stunning are incorrect shooting position and incorrect direction of the impact. These may cause ineffective stunning and pain or short-lasting unconsciousness. Low bolt velocity, narrow bolt diameter or short length of bolt leading to shallow penetration, may also affect the effectiveness of stunning. In non-penetrating applications, high bolt velocity may cause fracture of the skull and ineffective stunning [Gibson *et al.*, 2014].

**EU comment**

**The EU proposes to add following sentence:**

**These may cause ineffective stunning and pain or short-lasting unconsciousness. Poor maintenance of the equipment, low bolt velocity, misuse of cartridge, narrow bolt diameter or short length of bolt leading to shallow penetration, may also affect the effectiveness of stunning. In non-penetrating applications, high bolt velocity may cause fracture of the skull and ineffective stunning [Gibson *et al.*, 2014]."**

**Justification**

**It is common sense and commonly reported by manufacturers that a poor maintenance of their apparatus particularly where the apparatus is not frequently used and subjected to moisture induces some dysfunction and a loss of performance. Manufacturers also recommend testing regularly the key parameter by using specific device.**

**The misuse of cartridge was the most common cause of failure a few years ago for three reasons: i) the use of only one type of cartridge because of a predominant category of animals and difficulty to stock other types of cartridge for only a few animals, ii) the use of only one type of cartridge to limit the effect of aging of components of the device, and iii) the use of one type of cartridge because of ignorance/lack of clarity of the manufacturers' recommendation (also no standardization of the color code between manufacturers). All the reasons result in poor stun efficiency, particularly of young bulls and this is the main reason of failure in slaughterhouses with the design of the stun area**

**and the positioning of the operator (effect on the positioning of the device and the angle of the shot).**

**The EFSA Journal (2004), 45, 1 - 29, Welfare aspects of the main systems of stunning and killing the main commercial species of animals**

Electrical stunning involves application of an electric current to the brain of sufficient magnitude to induce immediate unconsciousness [EFSA, 2004; Grandin, 1980]. The main hazards preventing effective electrical stunning are: incorrect electrode placement, poor contact, dirty or corroded electrode, low voltage/current or high frequency [EFSA, 2004].

Controlled atmosphere stunning methods involve the exposure to high concentrations of carbon dioxide (hypercapnia), low concentration of oxygen (hypoxia) or a combination of the two (hypercapnic hypoxia). Loss of consciousness is not immediate following exposure of animals to controlled atmosphere stunning. The main hazards causing increased distress during induction of unconsciousness are irritant or aversive gas mixtures, low gas temperature and humidity. The main hazards causing ineffective controlled atmosphere stunning are incorrect gas concentration and short gas exposure time [Anon, 2018; EFSA, 2004; Velarde *et al.*, 2007].

Rodriguez P, 2008. Assessment of unconsciousness during carbon dioxide stunning in pigs *Animal Welfare* 2008, 17: 341-349

2. Animal-based and other measurables include:

Effectiveness of stunning should be monitored at different stages: immediately after stunning, just before neck cutting, and during bleed-out [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

No single indicator should be relied upon alone.

*Mechanical stunning:*

An effective stun is characterised by the presence of all the following signs: immediate collapse; apnoea; tonic seizure; absence of corneal reflex; absence of eye movements.

The presence of any of the following signs may indicate an ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

**EU comment**

**The EU proposes the following revision:**

**“The presence of any of the following signs ~~may indicate an~~ a high risk of ineffective stun or recovery of consciousness; vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.”**

**Justification**

**For making the text more straight forward and ensure that the following signs indicate high risk of ineffective stun or recovery of consciousness.**

*Electrical stunning:*

An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex.

The presence of any of the following signs may indicate an ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

*Gas stunning:*

An effective stun is characterised by the presence of all the following signs: loss of posture; apnoea; absence of corneal reflex; absence of muscle tone.

The presence of any of the following signs may indicate an ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

3. Recommendations:

Animals should be stunned as soon as they are restrained.

In the case of ineffective stunning or recovery, animals should be re-stunned immediately using a backup system. Ineffective stunning or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Annex 23 (contd)

Stunning equipment should be cleaned, maintained and stored following manufacturer's recommendations.

**EU comment**

**The EU proposes to add the following:**

**“Regular test of the equipment according to the manufacturer’s procedure are recommended. Effectiveness of the stunning should be monitored regularly.”**

**Justification**

**This is an outcome based standard and nowadays the main manufacturers have developed relevant equipment to monitor the correct functioning of their stun device.**

*Slaughterhouses/abattoirs* should have standard operating procedures that define key operating parameters or follow the manufacturer's recommendations for stunning, such as:

a) *Mechanical:*

- position and direction of the shot [AVMA, 2016];
- grain of the cartridge or air pressure appropriate to the type of animal (captive bolt) [Gibson 2014];
- length and diameter of the bolt (captive bolt);
- calibre and type of gun and ammunition (free bullet).

b) *Electrical:*

- shape, size and placement of the electrodes [AVMA, 2016];
- pressure between electrode and head;

- electrical parameters (current, voltage and frequency);
- visual or auditory warning system to alert the operator to proper or improper function.

c) *Controlled atmosphere:*

- concentrations and exposure time;
- temperature and humidity.

**EU comment**

**The EU proposes to add the following:**

**“- rate of decompression (low atmospheric pressure system for stunning).”**

**References:**

**(EFSA, 2017) More, S., Bicout, D., Bøtner, A., Butterworth, A., Calistri, P., Depner, K., Edwards, S., Garin-Bastuji, B., Good, M., Schmidt, C.G., Miranda, M.A., Nielsen, S.S., Sihvonen, L., Spoolder, H., Willeberg, P., Raj, M., Thulke, H.-H., Velarde, A., Vyssotski, A., Winckler, C., Abrahantes, J.C., Garcia, A., Guajardo, I.M., Zancanaro, G., Michel, V., 2017. Low atmospheric pressure system for stunning broiler chickens. EFSA J. 15, e05056. <https://doi.org/10.2903/j.efsa.2017.5056>**

4. Species-specific recommendations:

Non-penetrating captive bolt should not be use in mature cattle and pigs [Finnie, 1993 and Finnie at al. ,2003].

The *Competent Authority* should determine effective electrical parameters, based on scientific evidence for different types of animals.

Article 7.5.17

**Bleeding of free-moving animals**

1. Animal welfare concerns:

The main animal welfare concern at the time of bleeding following stunning is the recovery of consciousness due to prolonged stun-to-stick interval or due to incomplete severance of the main blood vessels.

Bleeding without prior stunning increases the risk of animal suffering because the incision to sever blood vessels results in substantial tissue damage in areas well supplied with nociceptors. The activation of these nociceptors causes the animal to experience pain [Gregory, 2004; Gibson *et al.*, 2009]. Loss of consciousness due to bleeding is not immediate and there is a period during which the animal can feel fear, pain and distress [Gregory, 2004; Johnson *et al.*, 2015].

Absence of or ineffective stunning may result in animals being released from the *restraint*, shackled, and further processed while they are still conscious or have the potential to recover consciousness.

Annex 23 (contd)

2. Animal-based and other measurables include:

The main animal-based measurable is the blood flow (rate and duration).

For animal-based and other measurables of return of consciousness after stunning see Article 7.5.16

In cases of bleeding without stunning the animal-based and other measurables that indicate loss of consciousness include all the following: absence of muscle tone; absence of corneal reflex; absence of rhythmic breathing. In addition, cessation of bleeding can be used as an indicator of death.

**EU comment**

**The EU proposes the following revision:**

**“In cases of bleeding without stunning the animal-based and other measurables that indicate loss of consciousness include all the following”: “absence of muscle tone; absence of corneal reflex; permanent absence of rhythmic breathing, permanent collapse.”**

**Justification**

**Animals can drift in and out of consciousness during bleeding without stunning.**

**References**

**Research by Neville Gregory**

3. Recommendations:

- a) continuous and rapid blood flow should be assured after bleeding;
- b) cessation of blood flow should be assured before further processing;

**EU comment**

**The EU proposes the following revision:**

**“cessation of ~~blood-flow~~ life should be assured before further processing”**

**Justification**

**Death should be confirmed before further processing begins and using cessation of blood flow as the sole indicator is not recommended because where carotid ballooning occurs blood flow ceases but the animals may still be conscious.**

**The same applies, where the sticking is insufficient, and only leads to initial bleeding and not a sufficient bleed-out.**

- c) bleeding knives should be sharpened for each animal.

**EU comment**

**The EU proposes to add the following:**

**“d) Both carotid arteries or the blood vessels from which they arise should be severed.”**

**Justification:**

**This is necessary to minimise the time to irreversible loss of consciousness and death and so reduce suffering and the risk of animals regaining consciousness during bleeding. IT is also common practice in many countries already.**

**References:**

**EFSA, 2004. Opinion of the Scientific Panel on Animal Health and Welfare on a request from the Commission related to welfare aspects of the main systems of stunning and killing the main commercial species of animals, *The EFSA Journal* (2004), 45, 1-29**

*In addition, the following should be considered:*

*Slaughter with stunning:*

- a) the stun-to-stick interval should be short enough to ensure that the animal will die before recovering consciousness;
- b) unconsciousness should be confirmed before bleeding.

*Slaughter without stunning:*

- a) bleeding should be carried out by a single incision; any second intervention should be recorded and analysed to improve procedures.

4. Species-specific recommendations

None identified.

Article 7.5.18.

**Slaughter of pregnant free-moving animals**

1. Animal welfare concerns:

Foetuses in the uterus cannot achieve consciousness [EFSA, 2017; Diesch *et al.*, 2005]. However, if removed from the uterus the foetus may perceive pain or other negative impacts.

2. Animal-based and other measurables include:

None identified.

3. Recommendations:

Under normal circumstances, pregnant animals that would be in the final 10% of their gestation period at the planned time of *unloading* at the slaughterhouse/abattoir should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that females are handled separately.

The foetus should be left undisturbed in utero for at least 30 minutes after the *death* of the dam [EFSA, 2017; Anon, 2017]

In cases where the foetus is removed before 30 minutes has elapsed euthanasia should be carried out immediately.

Annex 23 (contd)

4. Species-specific recommendations:

None identified.

Article 7.5.19.

**Emergency killing of free-moving animals**

This article addresses animals that show signs of severe pain or other types of severe suffering before being unloaded or within the *slaughterhouse/abattoir*. These animals may correspond to animals unfit to travel as listed in Article 7.3.7. Principles described may also apply to animals that are not suitable for slaughter for commercial reasons, even if they do not present signs of pain or suffering.

1. Animal welfare concerns:

Some animals can arrive at *slaughterhouses/abattoirs* with injuries or severe illnesses that can cause undue pain and suffering. This is more likely in animals of low economic value.

2. Animal-based and other measurables include:

Animals requiring emergency killing are unable to walk independently or present severe injuries such as fractures, large open wounds, or prolapses. They may also present clinical signs of serious illness or being in a state of extreme weakness. New-born animals or animals that gave birth within the last 48 hours may also belong in this category.

3. Recommendations:

Animals should not be moved unless it can be done without causing further pain or suffering.

*Animal handlers* should euthanise the animal as soon as possible.

Emergency killing should be systematically recorded and analysed in order to improve procedures and prevent recurrences.

4. Species-specific recommendations:

None identified.

Article 7.5.20.

**Methods, procedures or practices unacceptable on animal welfare grounds for free-moving animals**

None of the following practices for handling animals are acceptable and should not be used:

- 1) crushing or breaking tails of animals;
- 2) applying pressure using an injurious object or applying an irritant substance to sensitive areas such as eyes, mouth, ears, ano-genital region or belly;

**EU comment**

**The EU proposes the following revision:**

**“....applying an irritant substance to sensitive areas such as eyes, mouth, ears, ano-genital region or belly”**

**Justification**

**Pressure with injurious objects or applying irritant substances should not happen to irrelevant of the body part. The current text seems to just prohibit it from sensitive areas.**

- 3) hitting animals with instruments such as large sticks, sticks with sharp ends, metal piping, stones, fencing wire or leather belts;
- 4) throwing or dropping animals;

**EU comment**

**The EU proposes the following revision:**

**“kicking, throwing or dropping animals;”**

**Justification**

**The EU believes that it is important to reflect this to ensure continuous improved change in these practices.**

- 5) grasping, lifting or dragging animals only by some body parts such as their tail, head, horns, ears, limbs, wool or hair;

Annex 23 (contd)

None of the following practices for restraining animals are acceptable and should not be used:

- 1) mechanical clamping of the legs or feet of the animals as the sole method of *restraint*;
- 2) breaking legs, cutting leg tendons or blinding animals;
- 3) severing the spinal cord, by using a puntilla or dagger;
- 4) applying electrical current that does not span the brain;
- 5) suspending or hoisting conscious animals by the feet or legs;
- 6) severing brain stem by piercing through the eye socket or skull bone;

**EU comment**

**The EU proposes to add the following:**

**“7) Forcing animals to the ground by one or more handlers jumping on and lying across the animal’s back.”**

**Justification**

**It results in fear, distress and often to injuries.**

Breaking the neck while the animal is still conscious during bleeding animals is also an unacceptable practice.

Article 7.5.XX.

**Articles on animals arriving in containers [to be developed]**

[...]

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## CHAPTER 8.Y.

INFECTION WITH ANIMAL TRYPANOSOMES  
OF AFRICAN ORIGIN**EU comment**

**The EU thanks the OIE and in general supports the proposed chapter and requests the OIE to consider the comments inserted in the text below.**

**Those comments focus primarily on concerns in relation to recommendations for compartments, other than the provisions in Article 8.Y.4.**

**Since no specific provisions are made as regards containment zones, it is recommended to supplement Article 8.Y.16 with a reference to Article 4.4.7.**

**However, the EU would have welcomed progress in the proposed chapters for Surra and dourine.**

Article 8.Y.1.

**General provisions**

- 1) Animal trypanosomes of African origin is a disease complex caused by several protozoan parasites of the genus *Trypanosoma*, transmitted mainly cyclically by the genus *Glossina* (tsetse flies), but also mechanically by several biting flies (e.g. tabanids, *Stomoxys* spp). The disease can be caused by many different trypanosomes and can affect various mammals such as horses, donkeys, camels, goats, sheep, pigs, dogs, cats and non-human primates. From the socio-economic point of view is particularly deleterious in cattle. Some trypanosomes of African origin (i.e. *T. brucei gambiense*, *T. brucei rhodesiense*) also affect humans and are responsible for a disease almost always fatal if untreated (sleeping sickness also known as human African trypanosomosis).

**EU comment**

**To improve clarity we suggest including the infection name in the third sentence of the paragraph above, to read:**

**‘From the socio-economic point of view, infection with African Trypanosomes is particularly deleterious in cattle’.**

- 2) *Infection* with several trypanosome species in the same animal could exist although they may not always be evidenced.
- 3) For the purposes of this chapter, ‘susceptible animals’ means domestic and *wild animals* from the following families: bovidae, suidae, equidae, camelidae, canidae, felidae and non-human primates.
- 4) For the purposes of the *Terrestrial Code*, *infection* with animal trypanosomes of African origin is defined as an *infection* of susceptible animals with one or more Salivarian trypanosomes of the subgenus *Duttonella* (only *T. vivax*), *Nannomonas* (only *T. congolense* and *T. simiae*) and *Trypanozoon* (*T. brucei* spp excluding *T. evansi* and *T. equiperdum*), hereafter referred to as ‘pathogenic agent’.
- 5) *Infection* of susceptible animals with *T. evansi* or *T. equiperdum* are covered by Chapter 8.X. and Chapter 12.3., respectively.

- 6) Other trypanosomes including *T. uniforme*, *T. godfreyi* and *T. suis*, which are rarely reported, of limited distribution and impact, do not play a significant role in the epidemiology of the disease; however, they should be considered in the *surveillance* system due to their interference (hidden *infection*) with the diagnosis of animal trypanosomes of African origin.

**EU comment**

**To improve clarity we suggest including in the last sentence of the above paragraph the name of the infection as listed in the Code:**

**‘...they should be considered in the surveillance system due to their interference (hidden infection) with the diagnosis of infection with animal trypanosomes of African origin’.**

- 7) The following defines the occurrence of *infection* with animal trypanosomes of African origin:
- a) the pathogenic agent has been observed in a sample from a susceptible animal; or
  - b) presence of genetic material specific to the pathogenic agent has been detected in a sample from a susceptible animal showing clinical signs consistent with *infection* with animal trypanosomes of African origin or which has an epidemiological link to a confirmed case; or

**EU comment**

**To improve the clarity of bullet point b) above we suggest the following editorial additions:**

**‘the presence of genetic material specific to the pathogenic agent has been detected in a sample from a susceptible animal showing clinical signs consistent with infection with animal trypanosomes of African origin or which has an epidemiological link to a confirmed case in any susceptible animal species; or’**

- c) antibodies have been detected in a sample from a susceptible animal showing clinical signs consistent with *infection* with animal trypanosomes of African origin or which has an epidemiological link to a confirmed case in any susceptible animal species.
- 8) For the purposes of the *Terrestrial Code*, the *incubation period* of *infection* with animal trypanosomes of African origin in susceptible animals shall be 90 days.
- 9) Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 8.Y.2.

**Safe commodities**

When authorising import or transit of the following *commodities* from susceptible animal, *Veterinary Authorities* should not require conditions related to animal trypanosomes of African origin regardless of the status of the *exporting country or zone*:

- 1) pasteurised *milk* and pasteurised *milk products*;
- 2) hair, wool and fibre;
- 3) gelatine;
- 4) horns, hooves and claws;
- 5) *meat products*;
- 6) hides and skins (except raw).

Article 8.Y.3.

**Country or zone free from infection with animal trypanosomes of African origin**

A *country or zone* may be considered free from *infection* with animal trypanosomes of African origin when:

- 1) the *infection* is notifiable in the entire country;
- 2) measures to prevent the introduction of the *infection* have been in place: in particular, the importations or movements of *commodities* into the country or *zone* have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*;
- 3) and either:
  - a) a country or *zone* may be considered free from *infection* with animal trypanosomes of African origin when the relevant provisions in point 2 of Article 1.4.6. have been complied with; or

**EU comment**

**The beginning of this section already states that the requirements contained in this section refer to when a country or zone can be considered free from the infection.**

**For this reason we suggest deleting the first part of bullet point a) above:**

**~~'a) a country or zone may be considered free from infection with animal trypanosomes of African origin when the relevant provisions in point 2 of Article 1.4.6. have been complied with; or'~~**

- b) for at least the past two years:
  - i) *surveillance* in accordance with Articles 8.Y.13. to 8.Y.16. has been in place in the entire country;
  - ii) there has been no *case of infection* with animal trypanosomes of African origin in the country, *zone* or *compartment*.

**EU comment**

**As per our initial introductory comment related to compartments, we believe the chapter should only cover compartments when those are recognised through bilateral agreements as it is the case in article 8.Y.4.**

**In other articles the reference of compartments is challenging when dealing with a vector borne disease. Similarly compartments are not covered in other vector borne diseases in the code such as BTV or LSD. For this reason we suggest deleting mentioning compartments in this article, in bullet point ii) above:**

**'ii) there has been no *case of infection* with animal trypanosomes of African origin in the country, or zone ~~or compartment~~.'**

A country or *zone* free from *infection* with animal trypanosomes of African origin neighbouring to an infected country or *zone* should include a *zone* in which *surveillance* is conducted in accordance with Articles 8.Y.13. to 8.Y.16.

Article 8.Y.4.

**Compartment free from infection with animal trypanosomes of African origin**

The establishment and bilateral recognition of a *compartment* free from *infection* with animal trypanosomes of African origin should follow the provisions laid down in this chapter and in Chapters 4.4. and 4.5.

Susceptible animals in the free *compartment* should be protected against the *vectors* by the application of an effective *biosecurity* management system.

**EU comment:**

**Following the argument expressed in the EU comment above we wish to propose the deletion of Article 8.Y.4. This will be in line with other relevant texts in the Code, for example those related with Bluetongue. Indeed, in the bluetongue chapter there is no mention of compartments and we believe it will be less confusing if the same approach is taken in this Chapter and this article is deleted. If OIE member countries wish to apply compartmentalisation based on bilateral agreements, they will be able to do so following the guidelines for compartmentalisation in Chapters 4.4. and 4.5.**

Article 8.Y.5.

**Recovery of free status**

Should a *case* of *infection* with animal trypanosomes of African origin occur in a previously free country or *zone*, its status may be recovered after the following:

- 1) infected *animals* have been isolated and then immediately treated, slaughtered, or killed and appropriately disposed of;
- 2) *animals* in contact with infected *animals* have been put immediately under *vector*-protection and tested;
- 3) and for six consecutive months, either:

**EU comment**

**Editorial comment to place ‘and’ at the end of bullet point 2) and delete it at the beginning of bullet point 3)**

**‘2) animals in contact with infected animals have been put immediately under vector-protection and tested; and**

**3) and for six consecutive months, either:**

- a) after the last case was slaughtered or killed, the *animals* in contact have undergone monthly repeated serological and agent detection tests with negative results in both tests; or
  - b) when treatment is applied to the infected *animals*, both treated and in contact *animals* have undergone monthly repeated serological and agent detection tests with negative results in both tests;
- 4) *surveillance* in accordance with Articles 8.Y.13. to 8.Y.16. has been carried out with negative results;
  - 5) appropriate *biosecurity* is in place, that may include *vector* control or *vector* protection in the affected area.

Otherwise, Article 8.Y.3. applies.

Article 8.Y.6.

**Recommendations for importation from countries, zones or compartments free from infection with animal trypanosomes of African origin**

**EU comment**

**As per our comments above we suggest not referring to ‘compartments’. The title will read:**

**‘Recommendations for importation from countries, or zones ~~or compartments~~ free from infection with animal trypanosomes of African origin’**

For susceptible animals

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

- 1) showed no clinical signs of *infection* with animal trypanosomes of African origin on the day of shipment;

- 2) were kept since birth in a free country, *zone* or *compartment* or were imported from a free country, *zone* or *compartment*;

**EU comment**

**As per our comments above we suggest not referring to ‘compartments’. Bullet point 2 above will read:**

**‘2) were kept since birth in a free country, or zone ~~or compartment~~ or were imported from a free country, or zone ~~or compartment~~;**

- 3) did not transit through an *infected zone* during transportation to the place of shipment or were protected from any source of animal trypanosomes of African origin during transportation to the place of shipment.

Article 8.Y.7.

**Recommendations for importation from countries, zones or compartments free from infection with animal trypanosomes of African origin**

**EU comment**

**As per our comments above we suggest not referring to ‘compartments’. The title will read:**

**‘Recommendations for importation from countries, or zones ~~or compartments~~ free from infection with animal trypanosomes of African origin’**

For semen

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

- 1) the donor males:
- a) were kept since birth in a free country, *zone* or *compartment* or were imported from a free country, *zone* or *compartment*;

**EU comment**

**As per our comments above we suggest not referring to ‘compartments’. Bullet point a) above will read:**

**‘a) were kept since birth in a free country, or zone ~~or compartment~~ or were imported from a free country, or zone ~~or compartment~~;**

Annex 24 (contd)

- b) showed no clinical signs of *infection* with animal trypanosomes of African origin on the day of collection;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.

Article 8.Y.8.

**Recommendations for importation from countries or zones infected with animal trypanosomes of African origin**

For semen

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

- 1) the donor males:
  - a) were kept in isolation in a *vector*-protected *artificial insemination centre* for at least 90 days prior to semen collection;
  - b) were subjected, with negative results, to an agent identification test and an ELISA test for antibody detection adapted to the epidemiological situation on samples collected at entrance of the *vector*-protected *artificial insemination centre* and at least 90 days after the first test;
  - c) showed no clinical signs of *infection* with animal trypanosomes of African origin during the isolation period and on the day of collection;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.

Article 8.Y.9.

**Recommendations for importation from countries, zones or compartments free from infection with animal trypanosomes of African origin**

**EU comment**

**As per our comments above we suggest not referring to ‘compartments’. The title will read:**

**‘Recommendations for importation from countries, or zones ~~or compartments~~ free from infection with animal trypanosomes of African origin’**

For *in vivo* derived embryos and for *in vitro* produced embryos

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

- 1) the donor females:
  - a) were kept since birth in a free country, *zone* or *compartment* or were imported from a free country, *zone* or *compartment*;

**EU comment**

**As per our comments above we suggest not referring to ‘compartments’. Bullet point a) above will read:**

**‘a) were kept since birth in a free country, or zone ~~or compartment~~ or were imported from a free country, or zone ~~or compartment~~;**

- b) showed no clinical signs of *infection* with animal trypanosomes of African origin on the day of collection;
- 2) the semen used for the production of embryos complied with the provisions of Article 8.Y.7. or Article 8.Y.8.;
- 3) the embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.

Article 8.Y.10.

**Recommendations for importation from countries or zones infected with animal trypanosomes of African origin**

For *in vivo* derived embryos and for *in vitro* produced embryos

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

- 1) the donor females:
  - a) were kept in isolation in a *vector-protected collection centre* for at least 90 days prior to the collection;
  - b) were subjected, with negative results, to an agent identification test and an ELISA test for antibody detection adapted to the epidemiological situation on samples collected at entrance to the *collection centre* and at least 90 days after the first test;
  - c) showed no clinical signs of *infection* with animal trypanosomes of African origin on the day of collection;
- 2) the semen used for the production of embryos complied with the provisions of Article 8.Y.7. or Article 8.Y.8.;
- 3) the embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.

Article 8.Y.11.

**Recommendations for importation from countries, zones or compartments free from infection with animal trypanosomes of African origin**

**EU comment**

**As per our comments above we suggest not referring to ‘compartments’. The title will read:**

**‘Recommendations for importation from countries, or zones ~~or compartments~~ free from infection with animal trypanosomes of African origin’**

For meat

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

- 1) were kept since birth in a free country, *zone* or *compartment* or were imported from a free country, *zone* or *compartment*,

**EU comment**

**As per our comments above we suggest not referring to ‘compartments’. Bullet point 1) above will read:**

**‘1) were kept since birth in a free country, or zone ~~or compartment~~ or were imported from a free country, or zone ~~or compartment~~;**

- 2) have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 8.Y.12.

**Recommendations for importation from countries or zones infected with animal trypanosomes of African origin**

For meat

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

- 1) comes from *animals* which have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results; and
- 2) either:
  - a) has been kept at a temperature lower than + 4°C for a minimum period of five days; or
  - b) has been subjected to any procedure of equivalent efficacy recognised by the *Veterinary Authority*.

Article 8.Y.13.

#### **Introduction to surveillance**

Articles 8.Y.13. to 8.Y.16. define the principles and provide guidance on *surveillance* for *infection* with animal trypanosomes of African origin, complementary to Chapter 1.4. and to Chapter 1.5.

The purposes of *surveillance* could be the demonstration of the absence of *infection*, the early detection of cases, or the measurement and monitoring of the *prevalence* and distribution of the *infection* in a country, *zone* or *compartment*.

#### Annex 24 (contd)

*Vectors* are an essential component of the epidemiology of animal trypanosomes of African origin. Therefore, the *surveillance* system should include a *vector surveillance* component to detect the presence and the estimate the abundance of tsetse flies. When appropriate, it should also allow the estimation of the *vector infection* rate with animal trypanosomes of African origin. *Vector surveillance* may also aim the estimation of mechanical *vectors* abundance.

The impact and epidemiology of animal trypanosomes of African origin widely differs between different regions of the world and therefore, it is not appropriate to provide specific recommendations for all situations. Member Countries should provide scientific data explaining the epidemiology of the disease in the concerned country or *zone* 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.

*Wildlife* should be considered in the *surveillance* system because they can serve as reservoirs of *infection* and as indicators of *risk* to humans and domestic *animals*. *Surveillance* in *wildlife* presents challenges that may differ significantly from those in domestic *animals*.

Article 8.Y.14.

#### **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, it should include:
  - a) a formal and ongoing system for detecting and investigating *outbreaks* of disease;
  - b) a procedure for the rapid diagnosis in the field or for the 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) The *surveillance* programme for animal trypanosomes of African origin should, at least:
  - a) in a free country, *zone* or *compartment*, have an *early warning system* which obliges farmers and workers, who have regular contact with susceptible animals as well as diagnosticians, to report promptly any suspicion of animal trypanosomes of African origin to the *Veterinary Authority*.

<b>EU comment</b>
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**As per our comments above we suggest not referring to ‘compartments’. Bullet point a) above will read:**

**a) in a free country, or zone ~~or compartment~~, have an early warning system which obliges...’**

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 animal trypanosomes of African origin. 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* should be investigated immediately, and samples should be taken and submitted to a *laboratory*;

b) include the conduct random or targeted serological or parasitological *surveillance* appropriate to the status of the country or *zone*.

Article 8.Y.15.

#### **Surveillance strategies**

The target population should include domestic and *wild* susceptible animals of epidemiological significance within the country or *zone*. Active and passive *surveillance* for animal trypanosomes of African origin should be ongoing as epidemiologically appropriate. *Surveillance* should be composed of random or targeted approaches using parasitological, serological, clinical and entomological methods appropriate for the status of the country or *zone*.

In a free country or *zone*, it is appropriate to focus *surveillance* in an area neighbouring to a border of an infected country or *zone*, considering relevant ecological or geographical features likely to interrupt the transmission of animal trypanosomes of African origin.

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with animal trypanosomes of African origin in accordance with Chapter 1.4. and Chapter 1.5., and with the prevailing epidemiological situation.

Annex 24 (contd)

If a Member Country wishes to declare freedom from *infection* with animal trypanosomes of African origin in a specific *zone*, the design of the *surveillance* strategy should be targeted to the susceptible population within the *zone*.

For random surveys, the sample size selected for testing should be large enough to detect evidence of *infection* if it was 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 the minimum expected *prevalence* and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4.

#### **EU comment**

**To improve clarity we suggest including in the first sentence of the above paragraph the name of the infection as listed in the Code:**

**‘For random surveys, the sample size selected for testing should be large enough to detect evidence of infection with animal trypanosomes of African origin if it was to occur at a predetermined minimum rate...’**

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 *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* are technically well defined. The design of *surveillance* programmes to prove the absence of *infection* of animal trypanosomes of African origin 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.

The results of random or targeted surveys are important in providing reliable evidence that no *infection* with animal trypanosomes of African origin is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results considering the movement history of the *animals* being sampled.

An active programme of *surveillance* of susceptible populations to detect evidence of *infection* with animal trypanosomes of African origin is essential to establish the *animal health status* of a country or *zone*.

#### 1. Clinical surveillance

Clinical *surveillance* aims to detect clinical signs of *infection* with animal trypanosomes of African origin in susceptible animals, particularly during a newly introduced *infection*. However, neither clinical nor post-mortem signs of *infection* with animal trypanosomes of African origin are pathognomonic. Therefore, diagnosis must rely on direct or indirect laboratory tests that confirm the presence of trypanosomes.

#### 2. Parasitological surveillance

Suspected *cases* of animal trypanosomes of African origin detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

Parasitological *surveillance* can be conducted to:

- a) confirm clinically suspected *cases*;
- b) identify parasite at the subgenus level;
- c) confirm active *infection* after positive serological results.

#### 3. Molecular techniques

Molecular techniques increase the sensitivity of the detection of active *infections*. They can also be applied to identify the parasite and to better characterise the genotype of circulating parasitic in a country or *zone*.

## Annex 24 (contd)

Molecular techniques can be used to:

- a) detect an active *infection*;
- b) characterise the parasite at the species, subspecies, group and population level.

### 4. Serological surveillance

- a) Serological testing of susceptible animals is one of the most effective methods for detecting the exposure to animal trypanosomes of African origin. The host species tested should reflect the epidemiology of the *disease*. Management variables that may influence likelihood of *infection*, such as the use of insecticides or animal treatment, should be considered.
- b) Due to cross reactions with *T. evansi*, *T. equiperdum*, *T. cruzi* and *Leishmania* spp, the presence of these pathogenic agents should be considered when interpreting the results of the serological *surveillance* system.
- c) Serological *surveillance* can be used to:
  - i) demonstrate individual or population freedom;
  - ii) evidence subclinical or latent *infection* by animal trypanosomes of African origin;
  - iii) determine by seroprevalence the magnitude of *infection* by animal trypanosomes of African origin in the host population.
- d) Positive test results can have four possible causes:
  - i) active *infection*;
  - ii) *infection* (after effective treatment or self-cure);

### **EU comment**

**To improve clarity we suggest the following editorial changes to bullet point ii) above:**

**'ii) previous infection (after effective treatment or self-cure immunological clearance);**

- iii) maternal antibodies;
- iv) cross reactions with *T. evansi*, *T. equiperdum*, *T. cruzi* and *Leishmania* spp.

### 5. Sentinel animals

Sentinel *surveillance* may provide evidence of freedom from *infection* or provide data on *prevalence* and *incidence* as well as the distribution of disease or *infection*. Sentinel *surveillance* may consist of:

- a) the identification and regular testing of one or more of sentinel animal units of known health or immune status in a specified geographical location to detect the occurrence of *infection* with animal trypanosomes of African origin;
- b) the investigation of clinical suspect cases targeting highly susceptible animals such as dogs, donkeys or horses.

6. Vector surveillance

For the purposes of this chapter, *vector surveillance* aims at determining different levels of *risk* by identifying the various *vector* species presence and abundance in an area or demonstrating the absence of *vectors*.

Demonstration of absence of tsetse flies may support the claim of freedom from *infection* with animal trypanosomes of African origin that are cyclically transmitted.

The most effective way of gathering *vector surveillance* data should consider the biology and behavioural characteristics of the local *vector* species and include traps, fly rounds, sticky targets or other collection tools. *Vector surveillance* should be based on scientific sampling techniques. The choice of the number and type of collecting tools to be used and the frequency of their use should consider the size and ecological characteristics of the area to be surveyed.

When sentinel *animals* are used, *vector surveillance* should be conducted at the same locations.

Article 8.Y.16.

#### **Additional surveillance procedures for recovery of free status**

In addition to the general conditions described in this chapter, a Member Country seeking recovery of country or *zone* free status, including a *containment zone*, should show evidence of an active *surveillance* programme to demonstrate absence of *infection* with animal trypanosomes of African origin.

#### **EU comment**

**As suggested at the beginning of this chapter, since no specific provisions are made as regards containment zones, it is recommended to supplement this Article 8.Y.16 with a reference to Article 4.4.7., to read:**

**‘In addition to the general conditions described in this chapter, a Member Country seeking recovery of country or *zone* free status, including a *containment zone* established in accordance with Article 4.4.7., should show evidence...’**

Populations under this *surveillance* programme should include:

- 1) *establishments* in the proximity of the *outbreak*;
  - 2) *establishments* epidemiologically linked to the *outbreak*;
  - 3) *animals* moved from or used to re-populate affected *establishments*.
-

## CHAPTER 8.15.

## INFECTION WITH RIFT VALLEY FEVER VIRUS

**EU comment**

**The EU in general supports the proposed changes to this chapter.**

Article 8.15.1.

**General provisions**

- 1) The aim of this chapter is to mitigate the animal and public health risks posed by Rift Valley fever (RVF) and to prevent its international spread.
- 2) For the purposes of this chapter:
  - a) 'epizootic area' means a part of a country or zone in which an epizootic of RVF occurs, and which does not correspond to the definition of zone;
  - b) 'epizootic of RVF' means a sudden and unexpected change in the distribution or increase in incidence of, or morbidity or mortality of RVF;
  - c) 'inter-epizootic period' means a period with low levels of vector activity and low rates of RVF virus (RVFV) transmission;
  - d) 'susceptible animals' means ruminants and dromedary camels.
- 3) Humans and many animal species are susceptible to *infection*. For the purposes of the *Terrestrial Code*, RVF is defined as an *infection* of ruminants susceptible animals with Rift Valley fever virus (RVFV).
- 4) The following defines the occurrence of *infection* with RVFV:
  - a) RVFV, excluding vaccine strains, has been isolated and identified as such from a sample from a ruminant susceptible animal; or
  - b) antigen or ribonucleic acid specific to RVFV, excluding vaccine strains, has been identified in a sample from a ruminant susceptible animal epidemiologically linked to a confirmed or suspected case of RVF, or giving cause for suspicion of association or contact with RVFV; or
  - c) antibodies to RVFV antigens which are not the consequence of *vaccination*, have been identified in a sample from a ruminant susceptible animal with either epidemiological links to a confirmed or suspected case of RVF, or giving cause for suspicion of association or contact with RVFV.
- 5) For the purposes of the *Terrestrial Code*, the *infective period* for RVF shall be 14 days.
- 6) In areas where RVFV is present, epizootics of RVF may occur following favourable climatic, environmental conditions and availability of susceptible host and competent *vector* populations. Epizootics are separated by inter-epizootic periods. The transition from an inter-epizootic period to an epizootic complies with point 1) d) of Article 1.1.3. in terms of notification.
- 6) For the purposes of this chapter:
  - a) 'area' means a part of a country that experiences epizootics and inter-epizootic periods, but which does not correspond to the definition of zone;

Annex 25 (contd)

- b) 'epizootic of RVF' means the occurrence of *outbreaks* at an incidence substantially exceeding that during an inter-epizootic period or the occurrence of indigenous human cases;
  - e) 'inter-epizootic period' means the period of variable duration, often long, with intermittent low level of vector activity and low rate of virus transmission, which is often not detected;
  - d) ruminants include dromedary camels.
- 7) The historical distribution of RVF has been parts of the African continent, Madagascar, some other Indian Ocean Islands and the south-western Arabian Peninsula. However, vectors, environmental and climatic factors, land-use dynamics, and animal movements may modify the temporal and spatial distribution of the infection.
- 78) When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.15.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the RVF status of the ruminant susceptible animal population of the *exporting country*.
- 89) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.15.2.

**Safe commodities**

When authorising import or transit of the following *commodities* and any products made from them, *Veterinary Authorities* should not require any RVF-related conditions, regardless of the RVF status of the ruminant susceptible animal population of the *exporting country*:

- 1) hides and skins;
- 2) wool and fibre.

Article 8.15.3.

**Country or zone free from RVF**

A country or a *zone* may be considered free from RVF when *infection* with RVFV is notifiable in the entire country and either:

- 1) it meets the requirements for historical freedom in point 1 a) of Article 1.4.6.; or
- 2) meets the following conditions:
  - a) an on-going pathogen-specific *surveillance* programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with RVFV in ruminants susceptible animals in the country or *zone* for a minimum of ten years; and
  - b) during that period no indigenous human cases have occurred in the country or *zone*.

A country or *zone* free from RVF will not lose its free status through the importation of ruminants susceptible animals that are seropositive, so long as they are either permanently identified as such or destined for immediate *slaughter*.

Article 8.15.4.

**Country or zone infected with RVFV during the inter-epizootic period**

A country or zone infected with RVFV, during the inter-epizootic period, is one that does not comply with Article 8.15.3, in which virus activity is present at a low level but the factors predisposing to an epizootic are absent.

Article 8.15.5.

**Country or zone infected with RVFV during an epizootic**

A country or zone infected with RVFV, during an epizootic, is one in which outbreaks of RVF are occurring at an incidence substantially exceeding that of the inter-epizootic period; or one in which indigenous human cases of RVF are occurring even in the absence of detection of animal cases.

Article 8.15.65.

**Strategies to protect from vector attacks during transport**

Strategies to protect animals from vector attacks during transport should take into account the local ecology and potential insecticide resistance of the vectors, and potential risk management measures include:

- 1) treating animals and vehicles/vessels with insect repellents and insecticides prior to and during transportation;
- 2) loading, transporting and unloading animals at times of low vector activity;
- 3) ensuring vehicles/vessels do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect-proof netting;
- 4) using historical and current information to identify low risk ports and transport routes.

Article 8.15.76.

**Recommendations for importation from countries or zones free from RVF**

**For ruminants susceptible animals**

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

- 1) were kept in a country or zone free from RVF since birth or for at least 14 days prior to shipment;

AND

- 2) either:
  - a) were vaccinated at least 14 days prior to leaving the free country or zone; or
  - b) did not transit through an epizootic area experiencing an epizootic during transportation to the place of shipment; or
  - c) were protected from vector attacks when transiting through an epizootic area experiencing an epizootic.

Article 8.15.87.

**Recommendations for importation from countries or zones infected with RVFV during the inter-epizootic period**

**For ruminants susceptible animals**

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

- 1) showed no clinical signs of RVF on the day of shipment;
- 2) met one of the following conditions:
  - a) were vaccinated against RVF at least 14 days prior to shipment ~~with a modified live virus vaccine~~; or
  - b) were held for at least 14 days prior to shipment in a *vector-protected quarantine station*, which is located in an area of demonstrated low *vector* activity. During this period the animals showed no clinical sign of RVF;

AND

- 3) either:
  - a) did not transit through an ~~area experiencing an epizootic area~~ during transportation to the *place of shipment*; or
  - b) were protected from *vector* attacks when transiting through an ~~area experiencing an epizootic area~~.

Article 8.15.98.

**Recommendations for importation from countries or zones infected with RVFV during an epizootic**

For ruminants susceptible animals

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the susceptible animals 4

- 1) showed no clinical signs of RVF on the day of shipment;
- 2) did not originate ~~from an in the epizootic area of the epizootic~~;
- 3) were vaccinated against RVF at least 14 days prior to shipment;
- 4) were held for at least 14 days prior to shipment in a *vector-protected quarantine station*, which is located in an area of demonstrated low *vector* activity outside ~~the of an epizootic area of the epizootic~~. During this period the animals showed no clinical signs of RVF;
- 5) either:
  - a) did not transit through an epizootic area ~~experiencing an epizootic~~ during transportation to the *place of shipment*; or
  - b) were protected from *vector* attacks when transiting through an epizootic area ~~experiencing an epizootic~~.

Article 8.15.109.

**Recommendations for importation from countries or zones ~~not free from infected with RVFV~~**

For semen and *in vivo* derived embryos of ruminants susceptible animals

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

- 1) showed no clinical signs of RVF within the period from 14 days prior to and 14 days following collection of the semen or embryos;

Annex 25 (contd)

AND

- 2) either:

- a) were vaccinated against RVF at least 14 days prior to collection; or
- b) were demonstrated to be seropositive on the day of collection; or
- c) testing of paired samples has demonstrated that seroconversion did not occur within 14 days of between semen or embryo collection and 14 days after.

Article 8.15. ~~11~~10.

**Recommendations for importation of fresh meat and meat products from ruminants susceptible animals from countries or zones not free from infected with RVFV**

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

1) the entire consignment of *meat* comes from:

- ~~1a)~~ ruminants which susceptible animals that showed no clinical signs of RVF within 24 hours before *slaughter*,
- ~~2b)~~ ruminants which susceptible animals that were slaughtered in an approved *slaughterhouse/abattoir* and were subjected to ante- and post-mortem inspections with favourable results;
- ~~3c)~~ carcasses which that were submitted to maturation at a temperature above 2°C for a minimum period of 24 hours following *slaughter*;

~~2)~~ the necessary precautions were taken to avoid contact of the products with any potential source of RVFV.

Article 8.15.10bis.

**Recommendations for importation of meat products from susceptible animals from countries or zones infected with RVFV**

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat products* comes from *meat* that complies with Article 8.15.10.

Article 8.15. ~~12~~11.

**Recommendations for importation from countries or zones not free from infected with RVFV**

For milk and milk products

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

- 1) was subjected to pasteurisation; or
- 2) was subjected to a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Article 8.15. 1312.

**Surveillance**

*Surveillance* should be carried out in accordance with Chapter 1.4.

- 1) During an epizootic, *surveillance* should be conducted to define the extent of the affected area.
- 2) During the inter-epizootic period, *surveillance* and monitoring of climatic factors predisposing an epizootic should be carried out in countries or *zones* infected with RVFV.
- 3) Countries or *zones* adjacent to a country or *zone* in which epizootics have been reported should determine their RVF status through an on-going *surveillance* programme.

To determine areas of low *vector* activity (see Articles 8.15. 87 and 8.15. 98.) *surveillance* for arthropod *vectors* should be carried out in accordance with Chapter 1.5.

Examination of *vectors* for the presence of RVFV is an insensitive *surveillance* method and is therefore not recommended.

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## CHAPTER 11.4.

## BOVINE SPONGIFORM ENCEPHALOPATHY

**EU position**

**The EU thanks the OIE for the very significant effort invested in the revision of chapter 11.4 on bovine spongiform encephalopathy. The EU welcomes the changes proposed in relation to the recovery of negligible BSE risk status.**

**However, we wish to submit the important comments inserted in the text below that need to be addressed before the revised chapter is presented for adoption.**

## Article 11.4.1.

**General provisions ~~and safe commodities~~**

The recommendations in this chapter are intended to ~~mitigate~~ manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agents in cattle (*Bos taurus* and *B. indicus*) only. BSE manifests in two main forms: classical BSE and atypical BSE. For the purpose of official BSE risk status recognition, BSE excludes 'atypical' ~~Atypical BSE~~ is as a condition that occurs at a very low rate believed and is assumed to occur spontaneously in any-all cattle populations. Oral exposure to contaminated feed is the main route of transmission of classical BSE. Given that cattle have been experimentally infected by the oral route with L-type BSE, atypical BSE is also potentially capable of being recycled in a cattle population if cattle are orally exposed to contaminated feed.

BSE primarily affects cattle. Other animal species may be naturally and experimentally susceptible to BSE, but they are not regarded as being epidemiologically significant, particularly when feeding ruminants with ruminant-derived protein meal is not practiced.

For the purposes of the *Terrestrial Code*:

- 1) BSE is an invariably fatal neurological prion disease of cattle caused by PrP<sup>BSE</sup>, including both classical (C-type BSE) and atypical strains (H- and L-type BSE). The term 'BSE' includes both classical and atypical forms, unless otherwise specified.
- 2) The occurrence of a BSE case is defined by the immunohistochemical (IHC) or immunochemical detection of PrP<sup>BSE</sup> in brain tissue of a bovid, with discrimination between atypical and classical BSE strains based on the Western immunoblot banding pattern, as described in the *Terrestrial Manual*.

For the purposes of this chapter:

- 3) 'Cattle' means a bovid of the species *Bos taurus* or *Bos indicus*.
- 4) 'Protein meal' means any final or intermediate solid protein-containing product, obtained when animal tissues are rendered, excluding blood and blood products, peptides of a molecular weight less than 10,000 daltons and amino-acids.

**EU comment**

**The EU has reservations on the proposed definition for "protein meal", which would be merging the former notions of "meat-and-bone meal" and "greaves".**

**Further assessment of the consequences of this proposed change is necessary, including in the perspective of its possible future extension to other chapters and/or reflection in the glossary, as mentioned in annex 35, 1, 1.1, a).**

- 2) ~~When authorising import or transit of other commodities listed in this chapter, Veterinary Authorities should require the conditions prescribed in this chapter relevant to the BSE risk status of the cattle population of the exporting country, zone or compartment.~~

- 3) ~~When authorising import of commodities according to the conditions prescribed in this chapter, the risk status of an importing country is not affected by the BSE risk status of the exporting country, zone or compartment.~~

When commodities are imported in accordance with this chapter, the BSE risk of the importing country or zone of destination is not affected by the BSE risk of the exporting country, the zone or compartment of origin.

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

Article 11.4.1bis.

Safe commodities

- 4) ~~When authorising the importation or transit of the following commodities and any products made from these commodities and containing no other tissues from cattle, Veterinary Authorities should not require any BSE related conditions related to BSE, regardless of the BSE risk posed by status of the cattle population of the exporting country, zone or compartment.~~

Annex 27 (contd)

- 1a) ~~milk and milk products;~~
- 2b) ~~semen and in vivo derived cattle embryos collected and handled in accordance with the relevant Chapters recommendations of the Terrestrial Code International Embryo Transfer Society;~~
- 3e) ~~hides and skins;~~
- 4d) ~~gelatine and collagen prepared exclusively from hides and skins;~~

**EU comment**

**The proposed amendment means that gelatine and collagen would be considered a safe commodity also when processed from any bones, including from bones that are considered as commodities with the greatest BSE infectivity (article 11.4.14). Considering that these commodities, “and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetic, pharmaceuticals including biologicals, or medical devices” (article 11.4.14, paragraph 1), the EU considers that the wording of this paragraph should not be amended, and should remain:**

**‘4) gelatine and collagen prepared exclusively from hides and skins;’**

**Consequently, article 11.4.14 should not be deleted, as proposed, but should be kept unchanged.**

- 5e) ~~tallow with maximum level of insoluble impurities of 0.15% in weight;~~
- 6) ~~and tallow derivatives made from this tallow;~~

**EU comment**

**As a consequence of the proposed split of the current paragraph e) into two separate paragraphs 5) and 6), all tallow derivatives, including tallow derivatives made from tallow with a level of insoluble impurities > 0.15%, would be considered a safe commodity, whatever the BSE status of the cattle population from which it is derived.**

**Considering that no further measure ensures that the risk associated with the insoluble impurities fraction of this tallow will be mitigated in the tallow derivatives made from tallow with a level of insoluble impurities > 0.15%, the EU considers that the wording of the current provision of chapter 11.4 should not be amended, and should remain:**

**‘5) tallow with maximum level of insoluble impurities of 0.15% in weight and tallow derivatives made from this tallow;’**

**Consequently, article 11.4.18 should not be deleted, as proposed, but should be kept unchanged.**

7f) dicalcium phosphate (with no trace of protein or fat);<sub>2</sub>

- g) ~~deboned skeletal muscle meat (excluding mechanically separated meat) from cattle which were not subjected to a stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante and post mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.4.14.;~~
- h) ~~blood and blood by-products, from cattle which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.~~

Other commodities of cattle can be traded safely if in accordance with the relevant articles of this chapter.

Article 11.4.2.

**The BSE risk status of the cattle population of a country, zone or compartment**

#### **EU comment**

**The EU can support the principle that all details regarding the risk assessment are gathered in Chapter 1.8. We also note that a very significant revision of this Chapter 1.8 has been drafted. But this revised chapter has been circulated to the OIE member countries under part C of the Code Commission report, instead of part B.**

**The EU would like to stress that the draft Chapters 11.4 and 1.8 need to be assessed and eventually approved simultaneously, in order to ensure full consistency of these two chapters.**

**We therefore look forward to having an opportunity to comment also on the draft Chapter 1.8 under part B of a future report of the Code Commission.**

The BSE risk status of the cattle population of a country, zone or compartment ~~is~~ should be determined on the basis of the following criteria:

- 1) ~~the outcome of a risk assessment, in accordance with,~~ based on the provisions of Chapter 1.8, of the ~~Terrestrial Code, that evaluates the likelihood of BSE being recycled within the cattle population by~~ identifying all potential factors associated with the for BSE occurrence of BSE and their historic perspective. Member Countries should review the risk assessment annually to determine whether the situation has changed.

A risk assessment for the purpose of BSE consists of:

- a) Entry assessment

An entry assessment evaluates the likelihood that the classical BSE agent has been introduced into the country, zone or compartment via imported commodities.

~~Entry assessment consists of assessing, through consideration of the following, the likelihood that the BSE agent has either been introduced into the country, zone or compartment via commodities potentially contaminated with it, or is already present in the country, zone or compartment:~~

- ~~i) the presence or absence of the BSE agent in the indigenous ruminant population of the country, zone or compartment and, if present, evidence regarding its prevalence;~~
- ~~ii) production of meat and bone meal or greaves from the indigenous ruminant population;~~
- ~~iii) imported meat and bone meal or greaves;~~
- ~~iv) imported cattle, sheep and goats;~~

Annex 27 (contd)

- ~~v) imported animal feed and feed ingredients;~~
- ~~vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 11.4.14. and may have been fed to cattle;~~
- ~~vii) imported products of ruminant origin intended for in vivo use in cattle.~~

~~The results of surveillance and other epidemiological investigations into the disposition of the commodities identified above should be taken into account in carrying out the assessment.~~

b) Exposure assessment

An exposure assessment evaluates the likelihood of cattle being exposed to BSE, either through imported commodities or as a result of the presence of BSE agents in the indigenous cattle population of the country, zone or compartment.

~~If the entry assessment identifies a risk factor, an exposure assessment should be conducted, consisting of assessing the likelihood of cattle being exposed to the BSE agent, through a consideration of the following:~~

- ~~i) recycling and amplification of the BSE agent through consumption by cattle of meat and bone meal or greaves of ruminant origin, or other feed or feed ingredients contaminated with these;~~
- ~~ii) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse/abattoir waste, the parameters of the rendering processes and the methods of animal feed manufacture;~~
- ~~iii) the feeding or not of ruminants with meat and bone meal and greaves derived from ruminants, including measures to prevent cross-contamination of animal feed;~~
- ~~iv) the level of surveillance for BSE conducted on the cattle population up to that time and the results of that surveillance;~~

c) Consequence assessment

A consequence assessment evaluates the likelihood of cattle becoming infected with BSE together with the likely extent of any subsequent recycling and amplification.

d) Risk estimation

Risk estimation combines the results and conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk that BSE agents have been recycled in the cattle population through the feeding of ruminant-derived protein meal, with indigenous cases arising as a consequence.

- 2) the ongoing implementation of a *surveillance* programme for classical BSE in the cattle population;
- 3) the history of occurrence and management of BSE cases.
- 2) ~~ongoing awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Articles 11.4.20. to 11.4.22.;~~
- 3) ~~the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;~~
- 4) ~~the examination carried out in accordance with the *Torrestrial Manual* in a laboratory of brain or other tissues collected within the framework of the aforementioned *surveillance* and monitoring system.~~

Annex 27 (contd)

~~When the *risk assessment* demonstrates negligible risk, the Member Country should conduct Type B *surveillance* in accordance with Articles 11.4.20. to 11.4.22.~~

~~When the *risk assessment* fails to demonstrate negligible risk, the Member Country should conduct Type A *surveillance* in accordance with Articles 11.4.20. to 11.4.22.~~

Article 11.4.3.

#### Negligible BSE risk

~~*Commodities* from The BSE risk of the cattle population of a country, zone or compartment pose a can be considered to be negligible risk of transmitting the BSE agent if the following conditions are met for at least eight years:~~

#### EU comment

**The wording of the introductory paragraph of this article 11.4.3 should be reinforced with the need to submit documented evidence not only as regards the provision of paragraph 1), but also as regards the provisions of paragraphs 2), 3), and 4). It should also be more precise on the period of 8 years to be considered, which should be the preceding 8 years.**

**The EU therefore suggests the wording of the introductory paragraph to be amended as follows:**

**‘The BSE risk of the cattle population of a country, zone or compartment can be considered to be negligible if the Member Country has demonstrated through documented evidence that the following conditions are met for at least the preceding eight years:**

**Consequently, the wording of paragraph 1) could be further amended as follows:**

**‘1) A risk assessment as described in Article 11.4.2. has been conducted, and ~~the Member Country has demonstrated through documented evidence that the likelihood of BSE agents being recycled in the cattle population has been negligible as the result of:~~**

- 1) ~~A *risk assessment*, as described in point 1) of Article 11.4.2., has been conducted, and the Member Country has demonstrated through documented evidence that the likelihood of BSE agents being recycled in the cattle population has been negligible as the result of: in order to identify the historical and existing risk factors, and the Member Country has demonstrated that appropriate specific measures have been taken for~~

the relevant period of time defined below to manage each identified risk;

EITHER:

a) livestock industry practices ensuring that protein meal derived from ruminants has not been fed to ruminants;

OR

b) effective and continuous mitigation of each identified risk ensuring that protein meal derived from ruminants has not been fed to ruminants.

#### **EU comment**

**The proposed pathway a) means that a country could be recognised with BSE negligible risk without enforcing the minimum Ruminant to Ruminant feed ban currently required across the board. This intention is further confirmed in the proposal for chapter 1.8.**

**The EU considers of utmost importance that the current Ruminant to Ruminant feed ban remains an intangible basis of the strategy to prevent a future recurrence of BSE in the world, whatever the livestock industry practises in the countries.**

**The fact that the livestock industry practises in a country do not include the usual feeding of ruminants with protein meal derived from ruminants cannot be considered a sufficient guarantee in itself, but must be backed by feed ban provisions.**

**The EU proposes to delete the following:**

**‘EITHER:**

**a) ~~livestock industry practices ensuring that protein meal derived from ruminants has not been fed to ruminants;~~**

**OR**

**b)’**

2) ~~The Member Country has demonstrated that Type B surveillance provisions as described in accordance with Articles 11.4.20. have been implemented; to 11.4.22. is in place and the relevant points target, in accordance with Table 1, has been met;~~

#### **EU comment**

**Editorial error: the correct reference above is ‘article 11.4.18’ instead of ‘11.4.20’.**

3) EITHER:

a) ~~there has been no case of BSE or, if there has been a case, every case of BSE has been demonstrated to have been imported or has been diagnosed as atypical BSE as defined in this chapter; and has been completely destroyed, and~~

~~i) the criteria in points 2) to 4) of Article 11.4.2. have been complied with for at least seven years; and~~

~~ii) it has been demonstrated through an appropriate level of control and audit, including that of cross contamination, that for at least eight years neither *meat-and-bone meal* nor *groaves* derived from ruminants has been fed to ruminants;~~

OR

- b) if there has been an indigenous case of classical BSE, ~~every indigenous case was born more than 11 years ago; and~~

EITHER:

- i) all cases were born at least eight years ago;

OR

Annex 27 (contd)

- ii) where a case was born within the preceding eight years, subsequent investigations have confirmed that the likelihood of BSE being recycled within the cattle population has continued to be negligible.

**EU comment**

**The EU welcomes and supports the proposals of the sub-paragraph 3) b).**

- i) ~~the criteria in points 2) to 4) of Article 11.4.2. have been complied with for at least seven years; and~~
- ii) ~~it has been demonstrated through an appropriate level of control and audit, including that of cross contamination, that for at least eight years neither *meat and bone meal* nor *greaves* derived from ruminants has been fed to ruminants;~~
- iii) ~~all BSE cases, as well as:~~
- ~~– all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or~~
  - ~~– if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE cases,~~
- ~~if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.~~

- 4) Any cases of BSE that have been detected have been completely destroyed or disposed of to ensure that they do not enter the animal feed chain.

~~The Member Country or *zone* will be included in the list of negligible risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and *feed* controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.~~

The country or the *zone* will be included in the list of countries or *zones* posing a negligible risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1) to 4) above. Documented evidence should be resubmitted annually for points 1) to 4) above.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

Article 11.4.3bis.

**Recovery of negligible BSE risk status**

When an indigenous case of classical BSE is reported in an animal born within the preceding eight years in a country or *zone* recognised as having a negligible BSE risk status, the negligible BSE risk status is suspended and the recommendations for controlled BSE risk status apply, pending the outcome of subsequent investigations

confirming that the likelihood of BSE being recycled within the cattle population continues to be negligible. The country or zone will regain negligible BSE risk status only after the submitted evidence has been accepted by the OIE.

## **EU comment**

**The EU welcomes and supports the proposed article 11.4.3bis.**

**However, the EU would welcome further details on the investigations to be conducted in the affected Member Countries and on the procedure that would be implemented in the OIE to assess the submitted evidence and reach a conclusion.**

**Also the EU would appreciate a confirmation that this provision will also be applicable to cases confirmed before the revised Chapter 11. 4 is formally approved and published.**

### Article 11.4.4.

#### **Controlled BSE risk**

~~Commodities from the cattle population of a country, zone or compartment pose a controlled risk of transmitting the BSE agent if the following conditions are met:~~

- ~~1) a risk assessment, as described in point 1) of Article 11.4.2., has been conducted in order to identify the historical and existing risk factors, and the Member Country has demonstrated that appropriate measures are being taken to manage all identified risks, but these measures have not been taken for the relevant period of time;~~

#### Annex 27 (contd)

- ~~2) the Member Country has demonstrated that Type A surveillance in accordance with Articles 11.4.20. to 11.4.22. has been carried out and the relevant points target, in accordance with Table 1, has been met; Type B surveillance may replace Type A surveillance once the relevant points target is met;~~

#### 3) EITHER:

- a) ~~there has been no case of BSE or, if there has been a case, every case of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2) to 4) of Article 11.4.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, that neither meat and bone meal nor greaves derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:~~

~~i) the criteria in points 2) to 4) of Article 11.4.2. have not been complied with for seven years;~~

~~ii) it cannot be demonstrated that controls over the feeding of *meat and bone meal* or *greaves* derived from ruminants to ruminants have been in place for eight years;~~

OR

- b) ~~there has been an indigenous case of BSE, the criteria in points 2) to 4) of Article 11.4.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, that neither *meat and bone meal* nor *greaves* derived from ruminants has been fed to ruminants;~~

~~and all BSE cases, as well as:~~

- ~~– all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or~~

- if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE cases,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

The BSE risk of the cattle population of a country, *zone* or *compartment* can be considered to be controlled provided the conditions of Article 11.4.3. are met, but at least one of the conditions has not been met for at least eight years.

## EU comment

**The EU understands and supports the intention expressed in the first paragraph of this article, but considers that the proposed wording lacks precision and could be misinterpreted, as it does not set any limit to the number of conditions which may not have been met, nor for how long.**

**The EU will be happy to consider a rewording by the Code Commission, possibly along the following suggestion, which clarifies that at least the condition number 1 (risk assessment and proof of no recycling) must have been met for the preceding 8 years including for the status of controlled BSE risk, as it is the most important one:**

**‘The BSE risk of the cattle population of a country, *zone* or *compartment* can be considered to be controlled provided all of the conditions of Article 11.4.3. are met, but at least one point 2, 3 or 4 has not been met for at least the preceding eight years.’**

~~The Member Country or *zone* will be included in the list of controlled risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and *food controls* be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.~~

The country or the *zone* will be included in the list of countries or *zones* posing a controlled risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1) to 4) of Article 11.4.3. Documented evidence should be resubmitted annually for points 1) to 4) of Article 11.4.3.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

Article 11.4.5.

## Undetermined BSE risk

The BSE risk of the cattle population of a country, *zone* or *compartment* is considered to be poses an undetermined BSE risk if it cannot be demonstrated that it meets the requirements for negligible or controlled risk of another category.

Annex 27 (contd)

~~Article 11.4.6.~~

## ~~Recommendations for the importation of bovine commodities from a country, *zone* or *compartment* posing a negligible BSE risk~~

~~For all commodities from cattle not listed in point 1) of Article 11.4.1.~~

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

country, ~~zone or compartment~~ complies with the conditions in Article 11.4.3.

Article 11.4.7-6.

Recommendations for ~~the~~ importation of cattle from a country, zone or compartment posing a negligible BSE risk ~~but where there has been an indigenous case~~

~~For cattle selected for export~~

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that cattle selected for export the animals came from a country, zone or compartment posing a negligible BSE risk.~~

- 1) ~~are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3 b) iii) of Article 11.4.3.;~~

**EU comment**

**The EU would like to underline that animal identification is the cornerstone of animal health management, whichever disease is being considered. We strongly recommend that a robust identification system applies at least to cattle selected for export, whatever the BSE risk status of the country.**

- 2) ~~were born after the date from which the ban on the feeding of ruminants with meat and bone meal and greaves derived from ruminants had been effectively enforced.~~

Article 11.4.8-7.

Recommendations for ~~the~~ importation of cattle from a country, zone or compartment posing a controlled BSE risk

~~For cattle~~

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that cattle selected for export:~~

- 1) ~~came from a the country, zone or compartment posing a controlled BSE risk; complies with the conditions referred to in Article 11.4.4.;~~

AND EITHER:

- 2) ~~cattle selected for export are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3 b) of Article 11.4.4.;~~

- 3) ~~cattle selected for export were born after the date from which the ban on the feeding of ruminants with meat and bone meal and greaves derived from ruminants was effectively enforced.~~

~~were born in the country, zone or compartment during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;~~

OR

3)

- a) are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime; and

- b) are demonstrated as having not been fed protein meal derived from ruminants.

**EU comment**

**The EU would like to underline that animal identification is the cornerstone of animal health management, whichever disease is being considered. A robust identification system should always apply to cattle selected for export in countries posing a controlled BSE risk.**

**The EU proposes to amend the wording of this article as follows:**

**‘Veterinary Authorities should require the presentation of an international veterinary certificate attesting that cattle selected for export:**

**1) came from a country, zone or compartment posing a controlled BSE risk;**

**2) are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime;**

**AND EITHER:**

**23) were born in the country, zone or compartment during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;**

**OR**

**34) —**

**~~a) are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime; and~~**

**~~b) are demonstrated as having not been fed protein meal derived from ruminants.’~~**

Annex 27 (contd)

Article 11.4.9-8.

**Recommendations for ~~the~~ importation of cattle from a country, zone or compartment posing an undetermined BSE risk**

For cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that cattle selected for export:

1) ~~the feeding of ruminants with *meat and bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;~~

2) ~~all BSE cases, as well as:~~

a) ~~all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or~~

b) ~~if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE cases,~~

~~if alive in the country, zone or compartment, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed;~~

- 3) ~~cattle selected for export:~~
- ~~a) are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime; in such a way as to demonstrate that they are not exposed cattle as demonstrated in point 2 above;~~
  - ~~b) were born at least two years after the date from which the ban on the feeding of ruminants with meat and bone meal and greaves derived from ruminants was effectively enforced.~~
- 2) are demonstrated as having not been fed protein meal derived from ruminants.

Article 11.4.10.9.

Recommendations for ~~the~~ importation of fresh meat and meat products from a country, zone or compartment posing a negligible BSE risk

#### EU comment

The EU considers that the proposed article does not address the potential zoonotic risk of atypical BSE, even though this risk was acknowledged by the ad-hoc group (annex 35, paragraph 1., I.1., b)), nor the risk of recycling the prion from atypical BSE cases. The commodities listed in article 11.4.14 (commodities with the greatest BSE infectivity) should therefore be excluded also in countries with a negligible risk, as currently enforced in the EU.

The EU therefore suggests the addition of the following paragraph:

**‘Veterinary Authorities should require the presentation of an international veterinary certificate attesting that ~~the cattle from which the fresh meat and meat products were derived:~~**

**1) the cattle from which the fresh meat and meat products were derived:**  
a) came from a the country, zone or compartment posing a negligible BSE risk;  
b) ~~2) have been subjected to an ante- and post-mortem inspections with~~  
 favourable results.

**2) the fresh meat and meat products were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:**  
a) the commodities listed in points 1) a) and 1) b) of Article 11.4.14.;  
b) mechanically separated meat from the skull and from the vertebral column from cattle over 30 months of age.’

~~For fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.4.1.)~~

~~Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the cattle from which the fresh meat and meat products were derived:~~

- ~~1) came from a the country, zone or compartment posing a negligible BSE risk; complies with the conditions in Article 11.4.3.;~~
- ~~2) the cattle from which the *fresh meat and meat products* were derived passed have been subjected to an ante- and post-mortem inspections with favourable results.;~~

- 3) ~~in countries with negligible BSE risk where there have been indigenous cases, the cattle from which the fresh meat and meat products were derived were born after the date from which the ban on the feeding of ruminants with meat and bone meal and grooves derived from ruminants had been effectively enforced.~~

Annex 27 (contd)

Article 11.4.14.10.

**Recommendations for the importation of fresh meat and meat products from a country, zone or compartment posing a controlled BSE risk**

For fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.4.1.)

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

- 1) ~~the country, zone or compartment complies with the conditions referred to in Article 11.4.4.;~~
- 2) ~~the cattle from which the fresh meat and meat products were derived passed ante- and post-mortem inspections;~~
- 3) ~~cattle from which the fresh meat and meat products destined for export were derived were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;~~
- 4) ~~the fresh meat and meat products were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:~~
  - a) ~~the tissues listed in points 1) and 2) of Article 11.4.14.;~~
  - b) ~~mechanically separated meat from the skull and vertebral column from cattle over 30 months of age.~~

1) the cattle from which the fresh meat and meat products were derived came from a country, zone or compartment posing a controlled BSE risk;

2) they have been subjected to ante-mortem inspection with favourable results;

AND EITHER:

3) they were born in the country, zone or compartment during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

OR

4) the fresh meat and meat products:

a) derived from cattle not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to slaughter, and

b) were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

i) the commodities listed in points 1) a) and 1) b) of Article 11.4.14.;

ii) mechanically separated meat from the skull and from the vertebral column from cattle over 30 months of age.

#### **EU comment**

**The EU is opposed to the option offered by paragraph 3), by which some cattle in countries with controlled BSE risk would not be subject to the mandatory withdrawal of**

**SRM. The country BSE risk classification has been established to differentiate between countries with negligible risk of BSE vs. countries where the risk of BSE cannot be ignored; mitigation measures are to be applied for products originating in a non-negligible BSE risk country to prevent the contamination of the animal population, but also to protect human health by preventing the possible consumer exposure to the prion. Therefore, and also taking consideration of the complexity of the food chain circuits and trade schemes, we consider proposing a system with various levels of application of the SRM provisions according to the sub-populations in a country with controlled BSE risk to be very hazardous.**

**The EU proposes the deletion of:**

**“~~AND EITHER:~~  
3) they were born in the country, zone or compartment during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;  
OR”**

Article 11.4.12-11.

**Recommendations for the importation of fresh meat and meat products from a country, zone or compartment posing an undetermined BSE risk**

~~For fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.4.1.)~~

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

Annex 27 (contd)

- 1) the cattle from which the *fresh meat* and *meat products* were derived originate:
  - a) are demonstrated as having have not been fed protein meal ~~meat and bone meal or greaves~~ derived from ruminants;
  - b) were subjected to an ~~passed~~ ante- and post-mortem inspections with favourable results;
  - c) were not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to slaughter, ~~were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;~~
- 2) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
  - a) the commodities ~~issues~~ listed in points 1) a) and 1) b) 3 of Article 11.4.14.3;
  - b) ~~nervous and lymphatic tissues exposed during the deboning process,~~
  - e) mechanically separated meat from the skull and from the vertebral column from cattle over 30 ~~42~~ months of age.

Article 11.4.13-12.

**Recommendations for importation of cattle-derived protein meal from a country, zone or compartment posing a negligible BSE risk on ruminant derived meat and bone meal or greaves**

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the cattle from which the protein meal was derived came from a country, zone or compartment posing a negligible BSE risk.

- 1) ~~Ruminant-derived meat and bone meal or greaves, or any commodities containing such products, which originate from a country, zone or compartment defined in Article 11.4.3., but where there has been an indigenous case of BSE, should not be traded if such products were derived from cattle born before the date from which the ban on the feeding of ruminants with meat and bone meal and greaves derived from ruminants had been effectively enforced.~~
- 2) ~~Ruminant-derived meat and bone meal or greaves, or any commodities containing such products, which originate from a country, zone or compartment defined in Articles 11.4.4. and 11.4.5. should not be traded between countries.~~

## **EU comment**

**The EU considers that the fact that the protein meal comes from a country posing a negligible BSE risk is not sufficient to mitigate the risk potentially associated with protein meal derived from ruminants, keeping in mind that this product has historically been by far the main vector of the recycling and spread of BSE.**

**Consistent with the EU request to keep the minimal ruminant-to-ruminant feed ban provision regardless of the BSE risk status (please refer to article 11.4.3, paragraph 1), the EU proposes to keep the requirement laid down in the current paragraph 1.**

**This article could therefore read as follows:**

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

**1) the cattle from which the protein meal was derived came from a country, zone or compartment posing a negligible BSE risk, and**

**2) Ruminant-derived protein meal, or any commodities containing such products, which originate from a country, zone or compartment defined in Article 11.4.3., but where there has been an indigenous case of BSE, should not be traded if such products were derived from cattle born before the date from which the ban on the feeding of ruminants with protein meal derived from ruminants had been effectively enforced.’**

### Article 11.4.13.

#### **Recommendations for importation of blood and blood products derived from cattle**

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

EITHER:

1) the blood and blood products came from a country, zone or compartment posing a negligible BSE risk;

OR

2) the blood and blood products came from a country, zone or compartment posing a controlled BSE risk and the cattle from which the blood and blood products were derived were born in the country, zone or compartment during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

OR

3) the blood and blood products were:

- a) collected from cattle not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to slaughter;
- b) collected in a manner that ensures they are not contaminated with nervous tissue.

Article 11.4.14.

**Recommendations in relation to the trade of ~~on~~ commodities with the greatest BSE infectivity ~~that should not be traded~~**

- 1) Unless covered by other articles in this chapter, the following commodities From cattle of any age originating from a country, zone or compartment posing a controlled or undetermined BSE risk, defined in Articles 11.4.4. and 11.4.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices:
  - a) tensils and distal ileum from cattle of any age;

#### **EU comment**

**The EU considers that the expression “distal ileum” lacks precision. In accordance with the measure implemented in the EU, which are based on an opinion from EFSA (Scientific Opinion on BSE risk in bovine intestines and mesentery - [EFSA Journal 2014;12\(2\):3554](#)), the EU suggests the following wording:**

**‘a) distal the last four metres of the small intestine ileum from cattle of any age;’**

- b) skull, brain, eyes, vertebral column and spinal cord from cattle that were at the time of slaughter over 30 months of age.
- 2) Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities listed in points 1) a) or 1) b) of this article, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk, (unless covered by other Articles in this chapter) should also not be traded.
- 3) Cattle-derived protein meal, or any commodities containing such products, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk, should not be traded.
- 2) From cattle that were at the time of slaughter over 30 months of age originating from a country, zone or compartment defined in Article 11.4.4., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.
- 3) From cattle that were at the time of slaughter over 12 months of age originating from a country, zone or compartment defined in Article 11.4.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.

These points do not apply to cattle in a country or zone with a controlled BSE risk when they are born during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

## EU comment

Consistently with the comment already expressed as regards article 1.4.10 paragraph 4, the EU opposes the proposed system by which a sub-population of cattle in a country with controlled BSE risk would be exempted from the SRM restrictions.

The EU therefore proposes that the last paragraph applies only to the provision under point 3, as it is the case in the current version of Chapter 11.4.

The following amendment is suggested:

‘3) Cattle-derived protein meal, or any commodities containing such products, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk, should not be traded. These points do not apply to cattle in a country or zone with a controlled BSE risk when they are born during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.’

Article 11.4.15.

~~Recommendations for the importation of gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices~~

## EU comment

Consistently with the position already expressed on article 11.4.1bis, point 4), the EU is opposed to the deletion of this article.

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

~~1) the commodities came from a country, zone or compartment posing a negligible BSE risk;~~

~~OR~~

~~Annex 27 (contd)~~

~~2) they originate from a country, zone or compartment posing a controlled or undetermined BSE risk and are derived from cattle which have passed ante- and post-mortem inspections; and that~~

~~a) vertebral columns from cattle over 30 months of age at the time of slaughter and skulls have been excluded;~~

~~b) the bones have been subjected to a process which includes all of the following steps:~~

~~i) degreasing,~~

~~ii) acid demineralisation,~~

~~iii) acid or alkaline treatment,~~

~~iv) filtration,~~

~~v) sterilisation at  $\geq 138^{\circ}\text{C}$  for a minimum of 4 seconds,~~

~~or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).~~

Article 11.4.1615.

**Recommendations for ~~the~~ importation of tallow (other than as defined in Article 11.4.1**bis**.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices**

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

- 1) the tallow came from a country, *zone* or *compartment* posing a negligible BSE risk; or
- 2) ~~the tallow~~ it originates from a country, *zone* or *compartment* posing a controlled BSE risk, is derived from cattle which have been subjected to an passed ante- and post-mortem inspections with favourable results, and has not been prepared using the commodities tissues listed in points 1) a) and 1) b) 2 of Article 11.4.14.

Article 11.4.1716.

**Recommendations for ~~the~~ importation of dicalcium phosphate (other than as defined in Article 11.4.1**bis**.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices**

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

- 1) the dicalcium phosphate came from a country, *zone* or *compartment* posing a negligible BSE risk; or
- 2) ~~it originates from a country, zone or compartment posing a controlled or undetermined BSE risk and~~ the dicalcium phosphate is a co-product of bone gelatine produced according to Article 11.4.15.

**EU comment**

**Consistently with the position already expressed on article 11.4.1bis, point 4), and on article 11.4.15, the EU considers that the reference to article 11.4.15, as regards the conditions of production of the bone gelatine from which the dicalcium phosphate is a co-product, should be kept instead of deleted. This point 2) should therefore read:**

**‘2) the dicalcium phosphate is a co-product of bone gelatine produced according to Article 11.4.15.’**

~~Article 11.4.18.~~

~~Recommendations for the importation of tallow derivatives (other than those made from tallow as defined in Article 11.4.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices~~

**EU comment**

**Consistently with the position already expressed on article 11.4.1bis, point 5) and 6), the EU is opposed to the deletion of this article.**

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

- 1) ~~the tallow derivatives originate from a country, zone or compartment posing a negligible BSE risk; or~~
- 2) ~~they are derived from tallow meeting the conditions referred to in Article 11.4.16.; or~~

- 3) ~~they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.~~

Annex 27 (contd)

Article 11.4.1917.

**Procedures for the reduction of BSE infectivity in protein meal ~~meat and bone meal~~**

The following procedure should be used to reduce the infectivity of any transmissible spongiform encephalopathy agents which may be present during the production of protein meal ~~meat and bone meal~~ containing ruminant proteins.

- 1) The raw material should be reduced to a maximum particle size of 50 mm before heating.
- 2) The raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

Article 11.4.2018.

**Surveillance ~~Surveillance: introduction~~**

**EU comment**

**The proposed surveillance system is to rely exclusively on clinical surveillance to detect BSE. This is not acceptable for the EU, where the past experience has shown that clinical surveillance only had not been sufficient to detect BSE in some of the EU Member States. The active surveillance of BSE in sub-groups well known to be at high risk (fallen stock and downer/emergency slaughter) proved to be essential to an efficient system of BSE. The testing of these cattle should not just be vaguely suggested, as laid down in the last proposed paragraph, but should be made a mandatory and central part of the surveillance system required by the standard.**

**This article should therefore be significantly reinforced, including with a clarification of the last paragraph of point 2) to make it much more explicit that at-risk cattle (fallen stock) must be tested as often as possible.**

**Additionally, as regards the passive clinical surveillance, the EU would appreciate confirmation that, when assessing the submissions of annual reconfirmation for the maintenance of the official BSE status, in accordance with last-but-one paragraphs of articles 11.4.3 and 11.4.4, the OIE will carefully scrutinize the clinical suspicions documented during the preceding 12 months.**

**The EU proposes the following wording:**

**‘1) Surveillance for BSE consists of the ~~regular~~ reporting of all animals with clinical signs suggestive of BSE to the Veterinary Authority for subsequent investigation and diagnosis. In addition, an appropriate number of the following categories of cattle should also be subject to laboratory testing:**

**a) Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance, and cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter or downer cattle);**

**b) Cattle over 30 months of age which are found dead or killed on farm, during transport or at a slaughterhouse (fallen stock).**

**The credibility of the surveillance programme is supported by:**

**a)c) compulsory notification of BSE throughout the whole territory by all those stakeholders involved in the rearing and production of livestock including farmers, herdsmen, veterinarians, transporters and slaughterhouse/abattoir workers;**

**b)d) an ongoing awareness programme to ensure that all stakeholders are familiar with the clinical signs suggestive of BSE as well as the reporting requirements;**

**e)e) appropriate laboratory investigations in accordance with the Terrestrial Manual and follow-up field investigation as necessary of all clinical suspects as well as an appropriate number of the categories of cattle referred to in paragraphs a) and b).**

**2) BSE is a progressive, fatal disease of the nervous system of cattle that usually has an insidious onset that is refractory to treatment. A range of clinical signs that vary in severity and between animals have been described for classical BSE:**

**a) progressive behavioural changes that are refractory to treatment such as increased excitability, depression, nervousness, excessive and asymmetrical ear and eye movements, apparent increased salivation, increased licking of the muzzle, teeth grinding, hypersensitivity to touch and/or sound (hyperaesthesia), tremors, excessive vocalization, panic-stricken response and excessive alertness;**

**b) postural and locomotory changes such as abnormal posture (dog sitting), abnormal gait (particularly pelvic limb ataxia), low carriage of the head (head shyness), difficulty avoiding obstacles, inability to stand and recumbency;**

**c) generalized non-specific signs such as reduced milk yield, loss of body condition, weight loss, bradycardia and other disturbances of cardiac rhythm.**

**Some of these signs are also likely to be relevant for atypical BSE, particularly those associated with difficulty in rising and recumbency. A nervous form resembling classical BSE may be observed with over-reactivity to external stimuli, unexpected startle responses and ataxia. In contrast, a dull form may be observed with dullness combined with a low head carriage and compulsive behaviour (licking, chewing, pacing in circles).**

**The clinical signs of BSE usually progress over a few weeks to several months, but in rare occasions cases can develop acutely and progress rapidly. The final stages are characterised by recumbency, coma and death.**

**Cattle displaying some of the above mentioned progressive neurological signs and that are refractory to treatment, are candidates for examination.**

**Since these signs are not pathognomonic for either classical or atypical BSE, all Member Countries with cattle populations may observe individual animals displaying clinical signs suggestive of BSE. The rate at which they are likely to occur cannot be reliably predicted as they will vary depending on the epidemiological situation in a particular country. In addition, in those countries where cattle are intensively reared and subjected to regular observation, it is likely that such animals will be more readily seen.**

**Behavioural changes, that may be very subtle in the early clinical phase, are best identified by those who handle animals on a daily basis and who can monitor them closely for a progression of the signs. In more extensive systems however, where cattle are not monitored as closely, situations may inevitably arise where an animal might be considered as a clinical suspect, yet if it was not observed for a period of time, it may only be initially seen as a downer (non-ambulatory) or found dead (fallen stock). Under such circumstances, ~~if there is an appropriate supporting clinical history,~~ these animals**

**that lie on the continuum of a progressive disease from clinical suspect to downer to fallen stock ~~may still be suitable candidates for~~ should be subjected to surveillance and laboratory investigation.**

- 1) Surveillance for BSE consists of the regular reporting of animals with clinical signs suggestive of BSE to the Veterinary Authority for subsequent investigation and diagnosis. The credibility of the surveillance programme is supported by:
  - a) compulsory notification of BSE throughout the whole territory by all those stakeholders involved in the rearing and production of livestock including farmers, herdsmen, veterinarians, transporters and slaughterhouse/abattoir workers;
  - b) an ongoing awareness programme to ensure that all stakeholders are familiar with the clinical signs suggestive of BSE as well as the reporting requirements;
  - c) appropriate laboratory investigations in accordance with the Terrestrial Manual and follow-up field investigation as necessary of all clinical suspects.
  
- 2) BSE is a progressive, fatal disease of the nervous system of cattle that usually has an insidious onset that is refractory to treatment. A range of clinical signs that vary in severity and between animals have been described for classical BSE:
  - a) progressive behavioural changes that are refractory to treatment such as increased excitability, depression, nervousness, excessive and asymmetrical ear and eye movements, apparent increased salivation, increased licking of the muzzle, teeth grinding, hypersensitivity to touch and/or sound (hyperaesthesia), tremors, excessive vocalization, panic-stricken response and excessive alertness;
  - b) postural and locomotory changes such as abnormal posture (dog sitting), abnormal gait (particularly pelvic limb ataxia), low carriage of the head (head shyness), difficulty avoiding obstacles, inability to stand and recumbency;
  - c) generalized non-specific signs such as reduced milk yield, loss of body condition, weight loss, bradycardia and other disturbances of cardiac rhythm.

Some of these signs are also likely to be relevant for atypical BSE, particularly those associated with difficulty in rising and recumbency. A nervous form resembling classical BSE may be observed with over-reactivity to external stimuli, unexpected startle responses and ataxia. In contrast, a dull form may be observed with dullness combined with a low head carriage and compulsive behaviour (licking, chewing, pacing in circles).

The clinical signs of BSE usually progress over a few weeks to several months, but in rare occasions cases can develop acutely and progress rapidly. The final stages are characterised by recumbency, coma and death.

Annex 27 (contd)

Cattle displaying some of the above mentioned progressive neurological signs without signs of infectious illness, and that are refractory to treatment, are candidates for examination.

Since these signs are not pathognomonic for either classical or atypical BSE, all Member Countries with cattle populations may observe individual animals displaying clinical signs suggestive of BSE. The rate at which they are likely to occur cannot be reliably predicted as they will vary depending on the epidemiological situation in a particular country. In addition, in those countries where cattle are intensively reared and subjected to regular observation, it is likely that such animals will be more readily seen. Behavioural changes, that may be very subtle in the early clinical phase, are best identified by those who handle animals on a daily basis and who can monitor them closely for a progression of the signs. In more extensive systems however, where cattle are not monitored as closely, situations may inevitably arise where an animal might be considered as a clinical suspect, yet if it was not observed for a period of time, it may only be initially

seen as a downer (non-ambulatory) or found dead (fallen stock). Under such circumstances, if there is an appropriate supporting clinical history, these animals that lie on the continuum of a progressive disease from clinical suspect to downer to fallen stock may still be suitable candidates for surveillance.

- 1) ~~Depending on the risk category of a country, zone or compartment with regard to bovine spongiform encephalopathy (BSE), surveillance for BSE may have one or more goals:~~
  - a) ~~detecting BSE, to a pre-determined design prevalence, in a country, zone or compartment;~~
  - b) ~~monitoring the evolution of BSE in a country, zone or compartment;~~
  - c) ~~monitoring the effectiveness of a food ban and/or other risk mitigation measures, in conjunction with auditing;~~
  - d) ~~supporting a claimed BSE status;~~
  - e) ~~gaining or regaining a higher BSE status.~~
  
- 2) ~~When the BSE agent is present in a country or zone, the cattle population will comprise the following sectors, in order of decreasing size:~~
  - a) ~~cattle not exposed to the infective agent;~~
  - b) ~~cattle exposed but not infected;~~
  - c) ~~infected cattle, which may lie within one of three stages in the progress of BSE:~~
    - i) ~~the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;~~
    - ii) ~~some will progress to a stage at which BSE is detectable by testing before clinical signs appear;~~
    - iii) ~~the smallest number will show clinical signs.~~
  
- 3) ~~The BSE status of a country, zone or compartment cannot be determined only on the basis of a surveillance programme but should be determined in accordance with all the factors listed in Article 11.4.2. The surveillance programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.~~
  
- 4) ~~With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for surveillance purposes:~~
  - a) ~~cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);~~
  - b) ~~cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter or downer cattle);~~

Annex 27 (contd)

  - c) ~~cattle over 30 months of age which are found dead or killed on farm, during transport or at an slaughterhouse/abattoir (fallen stock);~~
  - d) ~~cattle over 36 months of age at routine slaughter.~~
  
- 5) ~~A gradient is used to describe the relative value of surveillance applied to each subpopulation. Surveillance should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, zone or compartment. This approach is consistent with Articles 11.4.20. to 11.4.22.~~

- 6) ~~When establishing a *surveillance* strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.~~

~~Article 11.4.21.~~

#### ~~Surveillance: description of cattle subpopulations~~

- 1- ~~Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)~~

~~Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in *herd* hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle *animals* on a daily basis. Since BSE causes no pathognomonic clinical signs, all Member Countries with cattle populations will observe individual *animals* displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such *animals* should still be investigated as potential BSE affected *animals*. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.~~

~~This subpopulation is the one exhibiting the highest prevalence of 'classical' BSE. The accurate recognition, reporting and classification of such *animals* will depend on the ongoing owner/veterinarian awareness programme. This and the quality of the investigation and *laboratory* examination systems (Article 11.4.2.), implemented by the *Veterinary Services*, are essential for the credibility of the *surveillance* system.~~

- 2- ~~Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)~~

~~These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in Member Countries where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.~~

- 3- ~~Cattle over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock)~~

~~These cattle may have exhibited some of the clinical signs listed above prior to death, but were not recognised as being consistent with BSE. Experience in Member Countries where BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.~~

- 4- ~~Cattle over 36 months of age at routine slaughter~~

~~Experience in Member Countries where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine slaughter cattle 36 months of age or less is of relatively very little value (Table 2).~~

Annex 27 (contd)

~~Article 11.4.22.~~

#### ~~Surveillance activities~~

~~In order to implement efficiently a *surveillance* strategy for BSE, a Member Country should use documented records or reliable estimates of the age distribution of the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, *zone* or *compartment*.~~

~~The approach assigns 'point values' to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is~~

determined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, zone or compartment.

A surveillance strategy should be designed to ensure that samples are representative of the herd of the country, zone or compartment, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made should be fully documented, and the documentation retained for seven years.

The point targets and surveillance point values in this chapter were obtained by applying the following factors to a statistical model:

- 1) the design prevalence for Type A or Type B surveillance;
- 2) a confidence level of 95%;
- 3) the pathogenesis, and pathological and clinical expression of BSE:
  - a) sensitivity of diagnostic methods used;
  - b) relative frequency of expression by age;
  - c) relative frequency of expression within each subpopulation;
  - d) interval between pathological change and clinical expression;
- 4) demographics of the cattle population, including age distribution and population size;
- 5) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;
- 6) percentage of infected animals in the cattle population which are not detected.

Although the procedure accepts very basic information about a cattle population, and can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect animals provide many times more information than samples from healthy or dead-of-unknown-cause animals, careful attention to the input data can substantially decrease the procedure's cost and the number of samples needed. The essential input data are:

- 7) cattle population numbers stratified by age;
- 8) the number of cattle tested for BSE stratified by age and by subpopulation.

This chapter utilises Tables 1 and 2 to determine a desired surveillance points target and the point values of surveillance samples collected.

Within each of the subpopulations above in a country, zone or compartment, a Member Country may wish to target cattle identifiable as imported from countries or zones not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or zones not free from BSE.

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, *animals* from the other subpopulations should be tested.

1- Type A surveillance

The application of Type A *surveillance* will allow the detection of BSE around a design prevalence of at least one case per 100,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

2- Type B surveillance

The application of Type B *surveillance* will allow the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

Type B *surveillance* may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 11.4.3.) to confirm the conclusions of the *risk assessment*, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through *surveillance* targeted to maximise the likelihood of identifying failures of such measures.

Type B *surveillance* may also be carried out by countries, *zones* or *compartments* of controlled BSE risk status (Article 11.4.4.), following the achievement of the relevant points target using Type A *surveillance*, to maintain confidence in the knowledge gained through Type A *surveillance*.

3- Selecting the points target

The *surveillance* points target should be selected from Table 1, which shows target points for adult cattle populations of different sizes. The size of the adult cattle population of a country, *zone* or *compartment* may be estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size.

**Table 1. Points targets for different adult cattle population sizes in a country, zone or compartment.**

Points targets for country, zone or compartment		
Adult cattle population size (24 months and older)	Type A surveillance	Type B surveillance
>1,000,000	300,000	150,000
1,000,000	238,400	119,200
900,001-1,000,000	214,600	107,300
800,001-900,000	190,700	95,350
700,001-800,000	166,900	83,450
600,001-700,000	143,000	71,500
500,001-600,000	119,200	59,600
400,001-500,000	95,400	47,700
300,001-400,000	71,500	35,750
200,001-300,000	47,700	23,850
100,001-200,000	22,100	11,500

90,001-100,000	19,900	9,950
80,001-90,000	17,700	8,850
70,001-80,000	15,500	7,750
60,001-70,000	13,300	6,650
50,001-60,000	11,000	5,500
40,001-50,000	8,800	4,400
30,001-40,000	6,600	3,300
20,001-30,000	4,400	2,200
10,001-20,000	2,100	1,050
9,001-10,000	1,900	950
8,001-9,000	1,600	800
7,001-8,000	1,400	700
6,001-7,000	1,200	600
5,001-6,000	1,000	500
4,001-5,000	800	400
3,001-4,000	600	300
2,001-3,000	400	200
1,001-2,000	200	100

#### 4. Determining the point values of samples collected

Table 2 can be used to determine the point values of the *surveillance* samples collected. The approach assigns point values to each sample according to the likelihood of detecting *infection* based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of *surveillance* described in Chapter 1.4. and the epidemiology of BSE.

Because precise aging of the *animals* that are sampled may not be possible, Table 2 combines point values into five age categories. The point estimates for each category were determined as an average for the age range comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the *disease* and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the cattle *herd* of the country, *zone* or *compartment*. In addition, Member Countries should sample at least three of the four subpopulations.

**Table 2. Surveillance point values for samples collected from animals in the given subpopulation and age category.**

Surveillance subpopulation			
Routine slaughter <sup>1</sup>	Fallen stock <sup>2</sup>	Casualty slaughter <sup>3</sup>	Clinical suspect <sup>4</sup>
<b>Age <math>\geq</math> 1 year and <math>&lt;</math>2 years</b>			
0.04	0.2	0.4	N/A
<b>Age <math>\geq</math> 2 years and <math>&lt;</math>4 years (young adult)</b>			
0.1	0.2	0.4	260
<b>Age <math>&gt;</math> 4 years and <math>&lt;</math>7 years (middle adult)</b>			
0.2	0.9	1.6	750
<b>Age <math>\geq</math> 7 years and <math>&lt;</math>9 years (older adult)</b>			
0.1	0.4	0.7	220
<b>Age <math>\geq</math> 9 years</b>			
0.0	0.1	0.2	45

If a country, zone or compartment determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'casualty or emergency slaughter, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the surveillance point values accorded to the combined subpopulation would be that of 'fallen stock'.

The total points for samples collected may be accumulated over a period of a maximum of seven consecutive years to achieve the target number of points determined in Table 1.

Surveillance points remain valid for seven years (the 95th percentile of the incubation period).

Article 11.4.23.

#### **BSE risk assessment: introduction**

The first step in determining the BSE risk status of the cattle population of a country or zone is to conduct a risk assessment (reviewed annually), based on Section 2. of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective.

##### 1. Entry assessment

Entry assessment consists of assessing the likelihood that a BSE agent or has been introduced via the importation of the following commodities potentially contaminated with a BSE agent:

- a) meat and bone meal or greaves;
- b) live animals;
- c) animal feed and feed ingredients;
- d) products of animal origin for human consumption.

## Annex 27 (contd)

### 2- Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure BSE agent to cattle, through a consideration of the following:

- a) epidemiological situation concerning BSE agents in the country or zone;
- b) recycling and amplification of the BSE agent through consumption by cattle of *meat and bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;
- c) ~~the origin and use of ruminant carcasses (including fallen stock), by products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;~~
- d) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed; thorough epidemiological investigations of any indigenous case born after the date of the implementation of feed bans should be conducted.

The following recommendations are intended to assist *Veterinary Services* in conducting such a *risk assessment*. They provide guidance on the issues that need to be addressed when conducting a country-based assessment of BSE risk. They apply equally to self-assessment in preparation of dossiers for categorisation of countries. The recommendations are supported by greater detail in the questionnaire used for the submission of data for country assessment.

Article 11.4.24.

#### **~~The potential for the entry of the BSE agent through the importation of meat and bone meal or greaves~~**

This point is irrelevant if the exposure assessment outlined below in Article 11.4.27. indicates that *meat and bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past eight years. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat and bone meal* or *greaves* has not been fed to ruminants.

*Assumption:* That *meat and bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.

*Question to be answered:* Has *meat and bone meal, greaves*, or feedstuffs containing either been imported within the past eight years? If so, where from and in what quantities?

*Rationale:* Knowledge of the origin of *meat and bone meal, greaves* or feedstuffs containing either *meat and bone meal* or *greaves*, is necessary to assess the likelihood of entry of BSE agent. *Meat and bone meal* and *greaves* originating in countries of high BSE risk pose a higher likelihood of entry than that from low risk countries. *Meat and bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown likelihood of entry.

*Evidence required:*

- Documentation to support claims that *meat and bone meal, greaves* or feedstuffs containing either *meat and bone meal* or *greaves* have not been imported, OR
- Where *meat and bone meal, greaves* or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.
- Documentation on annual volume, by country of origin, of *meat, greaves* or feedstuffs containing them imported during the past eight years.
- Documentation describing the composition (on a species and class of stock basis) of the imported *meat and bone meal, greaves* or feedstuffs containing them.
- Documentation, from the country of production, supporting why the rendering processes used to produce *meat and bone meal, greaves* or feedstuffs containing them would have inactivated, or significantly reduced the titre of BSE agent, should it be present.

- Documentation describing the fate of imported *meat and bone meal* and *greaves*.

Article 11.4.25.

**The potential for the entry of the BSE agent through the importation of live animals potentially infected with BSE**

*Assumptions:*

- Countries which have imported ruminants from countries infected with 'BSEs are more likely to experience 'BSE.
- Cattle pose the only known risk although other species are under study.
- ~~Animals~~ Cattle imported for breeding may pose a greater risk than ~~animals~~ imported for *slaughter* because of the hypothetical risk of maternal transmission and because they are kept to a greater age than ~~animals~~ imported for *slaughter*.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 2.1.3.).

*Question to be answered:* Have live *animals* been imported within the past seven years?

*Rationale:* The likelihood of entry is dependent on:

- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
- feeding and management of the *animals* in the country of origin;
- use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat and bone meal* of imported *animals* represents a potential route of exposure of indigenous livestock even if *meat and bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

*Evidence required:*

- Documentation on the country of origin of imports. This should identify the country of breeding of *animals*, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the fate of imported *animals*, including their age at *slaughter*.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Annex 27 (contd)

Article 11.4.26.

**The potential for the entry of the BSE agent through the importation of products of animal origin potentially infected with BSE**

*Assumptions:*

- Semen, embryos, hides and skins or milk are not considered to play a role in the transmission of BSE.
- Countries which have imported products of animal origin from countries with 'BSEs are more likely to experience 'BSE.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 2.1.3.).

*Question to be answered:* What products of animal origin have been imported within the past seven years?

*Rationale:* The likelihood of entry is dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 11.4.14.);
- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical disease, or following active surveillance, or assessment of geographical BSE risk;
- feeding and management of the animals in the country of origin;
- use to which the commodity has been put as apart from representing risk of developing clinical disease, the slaughter, rendering and recycling in meat and bone meal of imported animals represents a potential route of exposure of indigenous livestock even if meat and bone meal and greaves, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at slaughter.

*Evidence required:*

- Documentation on the country of origin of imports. This should identify the country of breeding of animals the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the end use of imported animal products, and the disposal of waste.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.4.27.

**The potential for the exposure of cattle to the BSE agent through consumption of meat and bone meal or greaves of ruminant origin**

*Assumptions:*

- That the consumption by bovines of *meat and bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.
- That commercially-available products of animal origin used in animal feeds may contain *meat and bone meal* or *greaves* of ruminant origin.
- Milk and blood are not considered to play a role in the transmission of BSE.

*Question to be answered:* Has *meat and bone meal* or *greaves* of ruminant origin been fed to cattle within the past eight years (see Articles 11.4.3. and 11.4.4.)?

*Rationale:* If cattle have not been fed products of animal origin (other than milk or blood) potentially containing *meat and bone meal* or *greaves* of ruminant origin within the past eight years, *meat and bone meal* and *greaves* can be dismissed as a risk.

Article 11.4.28.

**The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production**

*Assumptions:*

- BSE has a long *incubation period* and insidious onset of signs, so cases may escape detection.
- Pre-clinical BSE infectivity cannot reliably be detected by any method and may enter rendering, in particular if specified risk materials are not removed.
- Tissues most likely to contain high titres of BSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.
- BSE may manifest in sudden death, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.
- BSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Article 11.4.19.
- BSE agent is present at much higher titres central nervous system, and reticulo-endothelial tissues (so-called 'Specified Risk Materials', or SRM).

*Question to be answered:* How has animal waste been processed over the past eight years?

*Rationale:* If potentially infected *animals* or contaminated materials are rendered, there is a risk that the resulting *meat and bone meal* could retain BSE infectivity.

Where *meat and bone meal* is utilised in the production of any animal feeds, the risk of cross-contamination exists.

*Evidence required:*

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.

- Documentation describing the definition and disposal of specified risk material, if any.
- Documentation describing the rendering process and parameters used to produce *meat and bone meal* and *greaves*.
- Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat and bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.
- Documentation describing monitoring and enforcement of the above.

Article 11.4.29.

#### **Conclusions of the risk assessment**

The overall risk of 'BSE in the cattle population of a country or zone is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the *risk assessment* to conclude that the cattle population of a country or zone is free from BSE risk, it should have demonstrated that appropriate measures have been taken to manage any risks identified.

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1. See point 4 of Article 11.4.21.
  2. See point 3 of Article 11.4.21.
  3. See point 2 of Article 11.4.21.
  4. See point 1 of Article 11.4.21.

CHAPTER 12.6.

**INFECTION WITH EQUINE INFLUENZA VIRUS**

**EU comments**

**The EU thanks the OIE and in general supports the proposed amendments to Chapter 12.6., and requests the OIE to consider the comments inserted in the text below.**

[...]

Article 12.6.6.

**Recommendations for the importation of domestic equids for unrestricted movement**

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

- 1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its *vaccination* status should be included in the veterinary certificate;

OR

- 2) came from a country, *zone* or *compartment* not known to be free from EI, were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and

**EU comment:**

**As a general remark, the absence of clinical signs “on the day of shipment” should be re-considered and possibly be replaced by “within 24 hours prior to shipment” since the actual shipment may be carried out on the day following that of the clinical examination required for certification.**

- 3) were ~~immunised~~ vaccinated in accordance with the recommendations of the manufacturer with a vaccine complying with the standards described in the *Terrestrial Manual* and considered effective against the epidemiologically relevant virus strains, ~~between 24 and 90 days before shipment either with a primary course or a booster; information on their vaccination status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12. in accordance with one of the following procedures:~~
  - a) between 14 and 90 days before shipment either with a primary course or a booster; or
  - b) between 14 and 180 days before shipment, if they are older than four years of age, previously having received during the period of 90 to 180 days prior to shipment at least four doses of the same vaccine at intervals not greater than 180 days.

**EU Comment**

In the text as currently written, a horse could, in theory, have been vaccinated at maximum 6-monthly intervals over, for example, 2 years and lapsed before the pre-export vaccination.

“Previously” could mean some time ago, rather than immediately prior to.

If the intention of this statement is that the horse should have consecutive vaccinations up to the date of pre-export vaccination, editing of this statement would better clarify the position.

Suggested edit:

**b)** between 14 and 180 days before shipment, if they are older than four years of age, ~~previously having received during the period of 900 to 180 days prior to shipment, up to the date of this pre-shipment vaccination,~~ at least four consecutive doses of vaccine at intervals not greater than 180 days.

Information on the vaccination status should be included in the international veterinary certificate or the passport in accordance with Chapter 5.12. as relevant.

For additional security, cCountries that are free of from EI or undertaking an eradication programme may also request that the domestic equids were ~~tested negative for EIV by~~ subjected to an agent identification test for EI described in the *Terrestrial Manual* with negative results, conducted on samples collected on two occasions, at 7 to 14 days four to six days after commencement of pre-export isolation and less than 5 within four days before of shipment.

**EU comment**

**Reference is included to samples collected on two occasions 4-6 days after commencement of pre-export isolation and within 4 days of shipment.**

**We suggest editing of the wording to provide greater clarity: ‘...on two occasions, with the first sample collected four to six days after commencement of pre-export isolation and the second sample collected within four days of shipment.’**

[...]

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