Organisation Mondiale de la Santé Animale

World Organisation for Animal Health

Organización Mundial de Sanidad Animal

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

**Paris, 4–13 February 2020**

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**EU comment**

**The EU would like to commend the OIE for its work, especially under the COVID-19 current circumstances, and thank in particular the Code Commission for having taken into consideration EU comments on the Terrestrial Code submitted previously.**

**A number of general comments on this report of the February 2020 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.**

**Please note that the EU comments regarding Annexes 3 to 15 (part A) as well as the EU comments on Annexes 16 to 26 (part B) are appended to this document.**

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

The COVID-19 pandemic has made it necessary to review the arrangements for Members' participation in international meetings, and in particular the 88th General Session of the World Assembly of Delegates of the OIE. In this context, the OIE Council held an extraordinary meeting on 6 March 2020, and decided in agreement with the Director General, that the OIE General Session for May 2020 would be restricted to Wednesday 27 May 2020 and be limited to the consideration of institutional matters (elections) and administrative matters (vote on the budget), so as to ensure the institutional functioning of the Organisation; and technical matters that require the approbation of the World Assembly on a regular annual basis, when that approbation is supported by mechanisms of technical and procedural oversight previously agreed by the World Assembly (Official Recognition of Status; Reference Centres; Register of Diagnostic Kits).

As a consequence, no new or amended chapters in the Aquatic Animal Health Code, the Terrestrial Animal Health Code, the Manual of Diagnostic Tests for Aquatic Animals or the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals will be proposed for adoption in 2020. Chapters that were to be proposed for adoption in 2020 will be proposed for adoption in May 2021.

To ensure a consistent approach across all three Specialist Commissions presenting international standards to the World Assembly, the OIE has decided to take the following approach:

1. All relevant texts that were to be proposed for adoption in May 2020 will be circulated in the respective Specialist Commission's February 2020 report noting that adoption has been postponed until May 2021, and that they will be open for one round of comments.
2. Only substantive comments that have not been submitted before will be considered.
3. The deadline for comments for relevant Code Commission Annexes is 3 July 2020.
4. Each Commission will consider such comments at its September 2020 or February 2021 meetings thereby spreading out this work and enabling them to progress other work items.
5. The texts (incorporating any revisions resulting from this process) will be included in the relevant Commission's February 2021 reports, to be proposed for adoption in May 2021.
6. This process does not alter the regular process applying to other chapters being circulated for comments.

The OIE Terrestrial Animal Health Standards Commission (the Code Commission) met at OIE Headquarters in Paris from 4 to 13 February 2020. The list of participants is attached as **Annex 1**.

The Code Commission thanked the following Members for providing comments: Argentina, Australia, Brazil, Canada, China (People's Republic of), Chinese Taipei, Costa Rica, Cuba, Japan, Korea (Republic of), Malaysia, Mexico, New Zealand, New Caledonia, Norway, Panama, Singapore, South Africa, Switzerland, Thailand, United States of America (USA), the OIE Americas Region, 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 International Coalition for Farm Animal Welfare (ICFAW), the International Egg Commission (IEC), the International Meat Secretariat (IMS) and other experts.

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 '~~strikethrough~~' and the chapters are annexed to this report. In Annexes 4 to 17, and 22, 23 and 26 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 have 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 15**) of this report, that were to be proposed for adoption in May 2020, will be proposed for adoption in May 2021 and are open for one additional round of comments. The Code Commission noted that the documents that were to be proposed for adoption were the result of a thorough process of analysis of all comments received from members and from experts, taking into account all positions that were duly argued. As these texts have already undergone extensive consultation, Members are requested to only submit comments to address substantive issues that have not been considered previously. **Part B** (**Annexes 16 to 26**) includes texts that are circulated for Member comments only. The reports of meetings of *ad hoc* Groups and other related documents are attached for information in **Part C** **(Annex 27)**.

All comments on relevant texts in **Part A and Part B** must reach OIE Headquarters **by 3 July 2020** for them to be considered by 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 '~~strikethrough~~' and additions using 'double underline'. Members should not use the automatic 'track-changes' function provided by word processing softwares 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, Deputy Director General (International Standards and Science), welcomed the Code Commission and thanked the members for taking time from their busy schedules to support the work of the OIE, extending this thanks to their employers and national governments. He provided a briefing on the OIE involvement in the COVID-19 international response led by WHO. Dr Stone noted the draft 7th Strategic Plan had recently been circulated to Delegates, and summarised the revisions to the OIE Headquarters' organigram made in late 2019 as a result of the organisational assessment processes linked to the strategy development. Dr Stone briefed the Commission on initiatives in relation to Good Regulatory Practices, including expectations relating to regulatory stewardship, the completion of the design phase of the OIE Observatory, and the initiation of work on an on-line commenting system for standards development and review. He noted the intention to produce a clear articulation of the OIE Science System, building on work over recent years to more clearly describe process and performance management expectations of Reference Centres, and committed to ongoing engagement with the Specialist Commissions during this work. Finally, he provided an update on the Specialist Performance Management System, focussing on the evaluation phase to be initiated in the second half of 2020 prior to the next elections for Specialist Commissions in 2021. The Code Commission thanked Dr Stone and highlighted the importance of the new commenting tools presented for the future work of the Commission. All members reiterated their full commitment, including for capacity development and informal dispute procedure.

## 2. Meeting with the Director General

Dr Monique Eloit, the OIE Director General, met with the Code Commission on 10 February 2020 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 7th Strategic Plan and on key issues of the upcoming 88th General Session to be held in May 2020. 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 sought for relevant Member comments received. The Code Commission wished to thank the Scientific Commission for this collaborative work. Consideration of the Scientific Commission's inputs is noted under the relevant agenda items.

During the February 2020 meeting, 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 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 relevant items on the work programmes and agendas of both Commissions such as the process and criteria for including diseases into the OIE-listed diseases and the development of disease-specific chapters for all of them, and to review jointly the list of chapters that could be presented for adoption in the next General Session.

### 4.2. Biological Standards Commission

The Code Commission and the Biological Standards Commission held a Joint meeting on 12 February 2020. The meeting provided an opportunity for members of both Commissions to meet and discuss items of common interest, especially their respective work on disease-specific chapters under revision, including infection with high pathogenicity avian influenza viruses, and other related topics such as the development of case definitions for OIE-listed diseases.

All members agreed that this meeting provided an excellent mechanism to strengthen collaboration between the two Commissions and they agreed to explore future joint meetings should both Commissions meet during the same week.

## 5. Code Commission's work programme

Comments were received from New Caledonia, Switzerland, the EU, the Comité Veterinario Permanente del Cono Sur (CVP) on behalf of Argentina, Bolivia, Brazil, Chile, Paraguay and Uruguay, and the OIE Americas Region.

The Code Commission acknowledged a comment to encourage more progress in the development of chapters on Surra and dourine, and explained that this issue was discussed with the Scientific Commission during this meeting period and invited Members to refer to the relevant section of this report (agenda item 5.1.9).

Regarding a query as to whether re-evaluation of risk associated with the importation of honey is planned, the Code Commission requested the OIE Secretariat to assess the need to work on the provisions regarding honey, including a possibility to create a Glossary definition for 'honey', and report back to the Commission at its next meeting.

The Code Commission acknowledged a comment regarding the implementation of containment zones, and explained that the issue would be addressed while dealing with other items currently in the work programme.

The Commission considered a concept note developed by the OIE Secretariat to propose a methodology to either develop or improve, where needed, the case definitions for listed terrestrial animal diseases, in view of difficulties for Members to notify through WAHIS. The Commission welcomed the initiative and acknowledged the importance of the issue and highlighted that this matter had already been in its work programme for some time. The Commission provided feedback on the proposed approach and requested the OIE Secretariat to propose a plan for action to be considered at its next September 2020 meeting.

The Code Commission updated its work programme and revised the order of items in each Section to reflect the level of prioritisation. The updated work programme is attached as **Annex 3** for Member comments.

**EU comment**

**The EU thanks the OIE for having taken into account or addressed many of its previous comments and in general supports the revised work programme of the Code Commission.**

**Specific comments are inserted in the text of Annex 3.**

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 Commission strongly encouraged Members to provide feedback on the proposed topics, as well as their level of prioritisation and possibly make propositions to the Commission.

### 5.1. Ongoing priority topics (except texts proposed for comments or adoption)

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

The OIE Secretariat updated the Code Commission on developments on this topic since its last discussion in September 2019.

Background

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 Commission considered the proposed amendments and provided its comments to the OIE Secretariat at its September 2019 meeting.

Update

The OIE Secretariat informed the Code Commission that feedback had been received from the Scientific Commission and Biological Standards Commission and that the Aquatic Animals Commission will provide comments at its February 2020 meeting.

The opinions of all the Specialist Commissions will be considered by an internal OIE working Group, and additional advice from the Code Commission and Aquatic Animals Commission would be sought if needed, to ensure alignment of definitions in the *Aquatic* and *Terrestrial Codes*.

The revised definitions, together with the relevant considerations of the other Specialist Commissions, will be presented to the Code Commission at its September 2020 meeting.

**5.1.2. Terminology: animal products, products of animal origin, by-products**

At its September 2019 meeting the Code Commission briefly discussed the use of the terms 'commodity', 'animal products', 'products of animal origin' and 'animal by-products' in the *Terrestrial Code* and the need to clarify the use of these terms and whether to develop definitions for some additional terms.

The Code Commission was informed that a Commission member together with the OIE Secretariat was trying to progress this work and would have more to report at the Commission's September 2020 meeting.

**5.1.3. Listing of diseases (chronic wasting disease) (Chapter 1.3)**

The Code Commission was informed that there was an error in the Scientific Commission's September 2019 report regarding the reporting of the assessments undertaken by experts for chronic wasting disease and requested that this be reassessed using the new guidance for the interpretation of the listing criteria and asked the OIE Secretariat to facilitate this request.

**5.1.4. Control of Shiga toxin-producing *E. coli* (STEC) in food-producing animals**

The OIE Secretariat updated the Code Commission on developments on this topic since its last discussion in February 2019.

Background

The Code Commission had agreed to include the 'control of Shiga toxin-producing *Escherichia coli* (STEC) in food-producing animals' in its work programme in light of new work being undertaken by the Codex Committee on Food Hygiene (CCFH) to develop draft "*Guidelines for the Control of Shiga Toxin-Producing Escherichia coli (STEC) in Beef Meat, Leafy Greens, Raw Milk and Cheese Produced from Raw Milk, and Sprouts*". The Commission had agreed to consider this item once the FAO/WHO expert meeting to conduct a systematic review of all possible interventions from primary production to the end of processing to control STEC in beef had been published.

Update

The OIE Secretariat informed the Code Commission that the FAO/WHO expert meeting was planned for later this year. The Commission requested to be informed when the report was published so that it could decide whether to progress work on this item.

**5.1.5. 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 OIE Secretariat updated the Code Commission on the latest developments on this topic since its last discussion in September 2019.

Background

At its September 2019 meeting, the Code Commission had requested that an *ad hoc* Group be convened to undertake a revision of 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, as well as provisions in relevant disease-specific chapters of the *Terrestrial Code* and the *Terrestrial Manual*, to resolve inconsistencies among the chapters and ensure that relevant texts reflect the latest scientific evidence and best practices regarding risk mitigation measures in the collection and processing of semen of animals. The *ad hoc* Group will also consider the inclusion of provisions to address equine semen in these chapters.

Update

The Code Commission considered the draft Terms of Reference for the *ad hoc* Group. The OIE Secretariat informed the Commission that the first meeting of this *ad hoc* Group is planned for 2020.

The OIE Secretariat wished to inform Members that the Terms of Reference and the meeting dates, once confirmed, will be uploaded onto the 'OIE calendar of *ad hoc* Groups' on the OIE website at: https://app.smartsheet.com/b/publish?EQBCT=9e202fcc2c804db5aac7bbe7d55aadb7 .

The Code Commission requested that the OIE Secretariat report back on the progress of this work at its next meeting.

**5.1.6. Collection and processing of oocytes and *in vitro* produced embryos from livestock and horses, to include bovine viral diarrhoea (Revision of Chapter 4.9)**

The OIE Secretariat updated the Code Commission on the latest developments on this topic since its last discussion in September 2019.

Background

The Code Commission has previously considered amending 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) based on a proposal submitted by the International Embryo Technology Society (IETS).

The Code Commission, at its September 2019 meeting, requested the OIE Secretariat to seek expert advice 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 for BVD free countries or zones.

Update

The OIE Secretariat informed the Code Commission that the consultation with IETS was ongoing.

The Code Commission requested the OIE Secretariat to continue this work and to also consult with relevant OIE Reference Laboratories and report back at its next meeting.

**5.1.7. Responsible and prudent use of antimicrobial agents in veterinary medicine (Chapter 6.10)**

At the February 2019 meeting of the Code Commission, comments were submitted requesting a review of Chapter 6.10, Responsible and prudent use of antimicrobial agents in veterinary medicine, given that this chapter had not been significantly reviewed for some time. The Commission had requested OIE Headquarters to seek advice from the OIE Working Group on Antimicrobial Resistance regarding this request.

The OIE Secretariat informed the Code Commission that the Working Group, which met in October 2019, considered the comments and agreed that given the similarity between the text in Chapter 6.10 and that under discussion at the Codex Alimentarius Task Force on Antimicrobial Resistance (TFAMR), it advised that any possible amendments to Chapter 6.10 should not be undertaken until completion of discussions at the TFAMR to avoid duplications and inconsistencies.

The Code Commission requested the OIE Secretariat to keep it informed regarding progress of the Codex work.

### 5.1.8. Report of the OIE *ad hoc* Group for the Revision of Chapter 7.7 Stray dog population control

Background

At its September 2018 meeting, the Code Commission agreed to revise Chapter 7.7, Stray dog population control, to ensure it was aligned with the OIE Global Strategy to end human death due to dog mediated rabies by 2030, and requested that an *ad hoc* Group be convened to commence this work.

Update

The OIE Secretariat informed the Code Commission that the first meeting of the OIE *ad hoc* Group for the Revision of Chapter 7.7 Stray dog population control was held at the OIE Headquarters on 5–7 November 2019. During the meeting, the *ad hoc* Group reviewed current recommendations that address monitoring and evaluation of stray dog control schemes and responsible dog ownership, and discussed additional recommendations that could support the Global Strategy.

The Code Commission reviewed the report of the *ad hoc* Group, considered its proposals and the following was agreed:

1. To restructure Chapter 7.7, as proposed and to update the text in line with current scientific information; to include in the revision of Chapter 7.7 the practical minimum recommendations for population control measures such as dog catching, housing or restraint.

2. To keep the focus on animal welfare and move the animal and public health recommendations to other relevant chapters; to add cross-references in other relevant chapters, notably animal health related ones.

3. To include information on rabies vaccination strategies in Chapter 8.14; consequently, the *ad hoc* Group was requested to provide a proposal regarding suitable text to be included in Chapter 8.14.

4. To provide further justification for the proposal to change the title and if changed, to expressly include the concept of welfare within it.

5. To further clarify the rationale for the *ad hoc* Group to propose to change the use of ‘Stray dog’ to ‘Free-roaming dog’ in the text and clarify its proposed new definition in the Glossary.

The Code Commission thanked the *ad hoc* Group for its work and requested that it continues its work, taking in consideration its guidance on the *ad hoc* Group’s proposals.

The report of the OIE *ad hoc* Group for the Revision of Chapter 7.7 Stray dog population control is attached as Annex 27 for Members' information.

### 5.1.9. Surra (draft Chapter 8.X) and Dourine (revised Chapter 12.3)

Background

In its September 2019 meeting, the Code Commission agreed to amend Article 1.3.1 to add 'Infection with animal trypanosomes of African origin (*T. vivax, T. congolense, T. simiae* and *T. brucei*)' to the diseases, infections and infestations listed by the OIE and circulated a draft new Chapter 8.Y, Infection with animal trypanosomes of African origin, for Member comments.

The Code Commission reiterated that the decision agreed by the Code Commission and the Scientific Commission was that three separate chapters on animal trypanosomes with different coverage of trypanosomes species and host animals would be developed. In addition to the development of a new draft Chapter 8.Y, Infection with animal trypanosomes of African origin, a draft new Chapter 8.X, Surra, and a revised Chapter 12.3, Dourine, had been proposed and extensively discussed since 2015, in particular their respective scopes. The Code Commission reminded Members that in February 2018 the Scientific Commission and the Code Commission had agreed to put Chapters 8.X and 12.3 on hold in light of the ongoing discussions related to Chapter 8.Y, Infection with animal trypanosomes of African origin.

Update

The Code Commission highlighted the complexity of defining the scope of these chapters and agreed with the Scientific Commission that notwithstanding the diagnostic issues, the scope of Chapter 8.X should address surra of multiple species including horses, and that the scope of Chapter 12.3 should remain as dourine of equids.

The Code Commission, together with Scientific Commission, agreed to consider comments received on the new draft Chapter 8.Y, Infection with animal trypanosomes of African origin, before progressing work on the other two chapters.

The Code Commission recognised this as a priority issue and will come back to the revision of the pending chapters as soon as comments received on the new Chapter 8.Y show a consensus on the proposed approach.

### 5.1.10. Rinderpest (Chapter 8.16)

The OIE Secretariat updated the Code Commission on the latest developments on this subject since its discussion in September 2019.

Background

In its September 2019 meeting, the Code Commission agreed on the approach to undertake a thorough review of Chapter 8.16, Rinderpest, and reviewed the Terms of Reference of the *ad hoc* Group.

Update

The OIE Secretariat informed the Code Commission that the meeting of the *ad hoc* Group on Rinderpest is scheduled for March 2020. The OIE Secretariat wished to inform Members that the Terms of Reference will be uploaded onto the 'OIE calendar of *ad hoc* Groups' on the OIE website at: https://app.smartsheet.com/b/publish?EQBCT=9e202fcc2c804db5aac7bbe7d55aadb7 .

The Code Commission requested the OIE Secretariat to report back on the progress of this work at its next meeting.

**5.1.11. Bovine spongiform encephalopathy (Chapter 11.4) and application for official recognition by the OIE of free status for bovine spongiform encephalopathy (Chapter 1.8)**

Comments were received from Australia, Brazil, Canada, China (People's Republic of), Chinese Taipei, Japan, Korea (Republic of), New Zealand, South Africa, Singapore, Switzerland, Thailand, USA, the EU and the IMS.

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). The OIE convened two *ad hoc* Groups, one on BSE risk assessment and one on BSE surveillance, which met twice and once, respectively, as well as one joint meeting between July 2018 and March 2019. The Code Commission, at its September 2019 meeting, reviewed the four *ad hoc* Group reports and the opinion of the Scientific Commission regarding the revised draft chapter, and circulated the revised draft chapter for comment.

Update

The Code Commission appreciated the large number of comments that had been submitted. The Commission considered all comments and identified those comments that needed further expert advice, and thanked the OIE Secretariat for having scheduled a joint *ad hoc* Group on BSE risk assessment and BSE surveillance to address these comments together with the draft revised Chapter 1.8. The Commission addressed the other comments and proposed that the amended text and some additional guidance be provided to the *ad hoc* Group in order to inform their future work. The two Commissions will review the report of the *ad hoc* Group once finalised.

**5.1.12. Theileriosis (Chapters 11.10 and 14.X)**

Due to time constraints the Code Commission was unable to address the following items, and proposed to discuss them at its September 2020 meeting:

– Chapter 11.10, Infection with *Theileria annulata*, *T. orientalis* and *T. parva*, and

– Draft chapter 14.X, Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi*.

**5.1.13. Contagious equine metritis (Chapter 12.2) and Equine piroplasmosis (Chapter 12.7)**

The OIE Secretariat updated the Code Commission on the latest developments on this topic since its last discussion in September 2019.

Background

At its February 2019 meeting, the Code Commission agreed to amend Chapter 12.2, Contagious equine metritis, and Chapter 12.7, Equine piroplasmosis, 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.

Update

The OIE Secretariat informed the Code Commission that electronic consultations with experts had been conducted between September and December 2019 and that the report of the electronic consultations including the draft chapters were provided to the Scientific Commission for review at its February 2020 meeting and that the draft chapters together with Scientific Commission's comments will be presented to the Code Commission for its review in September 2020.

### 5.2. New requests / proposals

#### 5.2.1. Infection with *Echinococcus granulosus* (Chapter 8.5) and Infection with *Taenia solium* (Porcine cysticercosis) (Chapter 15.4)

The OIE Secretariat informed the Code Commission that a request was received from the World Health Organisation (WHO) to update Chapter 8.5, Infection with *Echinococcus granulosus*, and Chapter 15.4, Infection with *Taenia solium* (Porcine cysticercosis), as well as the corresponding chapters in the *Terrestrial Manual*, in view of recent developments in the area of vaccines and vaccination.

The OIE Secretariat reported that the request regarding the *Terrestrial Manual* chapters was to be considered by the Biological Standards Commission at its February 2020 meeting.

The Code Commission acknowledged the request and agreed to wait for the opinion of the Biological Standards Commission before considering the inclusion of these topics in its work programme.

The Code Commission requested the OIE Secretariat to report back on progress of this work at its next meeting.

## 6. Texts proposed for adoption in May 2021 (PartA)

### 6.1. User's Guide

Comments were received from the EU and Switzerland.

Background

Amendments to the User's Guide were circulated to Members in the Code Commission's February and September 2019 meeting reports proposing amendments in point 3 of Section B for consistency with terminology used throughout the *Terrestrial Code*, and in point 5 of Section C to include a reference to Chapter 2.2.

Discussion

In point 3 of Section B, in response to a comment, the Code Commission agreed to remove the reference to 'tests for international trade' noting that tests for international trade have been removed from the *Terrestrial Code* and replaced by cross-references to the *Terrestrial Manual*.

The Code Commission did not agree with a comment to remove 'diagnosis' noting that the use of this term in the *Terrestrial Code* refers not only to laboratory tests but also to any other methods that could be used to identify the nature of the disease, such as clinical examination.

The Code Commission agreed to replace 'assessment' with 'recognition' to align with the terminology being proposed in the revised version of Chapter 1.6.

The revised points B3 and point C5 of the User's Guide are attached as **Annex 4** for Member comments. The adoption of the revised revised points of the User's Guide has been postponed until the 89th General Session in May 2021. As these have already undergone extensive consultation, Members are requested to only submit comments to address substantive issues that have not been considered previously.

**EU comment**

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

### 6.2. Glossary Part A ('epidemiological unit', 'captive wild [animal]', 'feral [animal]' and 'wild [animal]')

**Glossary definition for 'captive wild [animal]', 'feral [animal]' and 'wild [animal]'**

Comments were received from Argentina, Australia, Canada, New Caledonia, New Zealand, Norway, Switzerland, USA, the OIE Americas Region, the EU and ICFAW.

Background

At its September 2018 meeting, the Code Commission had 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. Arising from the proposed revision to the definition of 'captive wild [animal]', consequent amendments were also proposed to the Glossary definitions of 'feral [animal]' and 'wild [animal]', that were circulated in the Commission's September 2019 report.

**'Captive wild [animal]'**

The Code Commission recalled that examples were added to the definition of 'captive wild [animal]' at its September 2019 meeting in response to requests by Members to provide further elaboration on what was meant by 'human supervision or control'. At this meeting however, the Code Commission received comments, some of which were from the same Members, either querying the relevance of these examples or requesting to remove them.

In response to these comments and to keep the definition of 'captive wild [animal]' concise, the Code Commission proposed to delete the examples of 'human supervision or control'.

The Code Commission acknowledged that the examples may differ among Members and emphasised that the key difference between captive wild animals and feral and wild animals is that captive wild animals require human supervision and control. For this reason, the Commission did not agree with comments to delete 'requiring' before 'human supervision or control'.

**'Feral [animal]'**

The Code Commission did not agree with comments to delete 'without requiring' before 'human supervision or control' for the same reason given above.

The Code Commission did not agree with a comment to add 'and that can recover some biological patterns typical of its wild ancestors' after 'supervision and control' as it considered this to be too detailed and did not improve the text.

The Code Commission did not agree with a comment to add 'independently' after 'lives' and 'direct' before 'human supervision or control', explaining that the objective of these definitions in the *Terrestrial Code* is to highlight the difference in epidemiological significance between these populations and it was not necessary to provide this level of detail.

**'Wild [animal]'**

For the same reasons given above, the Code Commission did not agree with comments to delete 'without requiring' and to add 'direct' before 'human supervision or control'.

**Glossary definition for 'epidemiological unit'**

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

Background

The Code Commission reiterated that a Glossary definition should be concise and yet address essential information. The Commission noted that at its previous meeting some text in the definition for 'epidemiological unit' regarding how epidemiological units may be applied in practice had been moved to point 1(d) of Article 1.4.3 in Chapter 1.4, Animal Health Surveillance.

The Code Commission considered comments submitted, as well as advice provided by the Scientific Commission and amended the text to improve clarity.

**Glossary definition for 'poultry'**

As part of the revision of Chapter 10.4, Infection with avian influenza viruses, the Code Commission acknowledged that the term 'poultry' is used in many other chapters in the *Terrestrial Code* and therefore proposed to remove the definition of 'poultry' from Chapter 10.4 (See Item 6.9) and to amend the Glossary definition for poultry.

The revised Glossary definitions for 'epidemiological unit', 'captive wild [animal]', 'feral [animal]', 'wild [animal]' and 'poultry' are attached as **Annex 5** for Member comments. The adoption of the revised Glossary definitions has been postponed until the 89th General Session in May 2021. As thesehave already undergone extensive consultation, Members are requested to only submit comments to address substantive issues that have not been considered previously.

**EU comment**

**The EU thanks the OIE and in general supports the proposed changes to the Glossary.**

**One comment in relation to the definition of 'poultry' is inserted in the text of Annex 5.**

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

Comments were received from Argentina, Cuba, New Caledonia, Switzerland, the EU and AU-IBAR.

Background

Chapter 1.1 was revised by the Code Commission in September 2018 to address inconsistencies in notification by Members through the OIE World Animal Health Information System. Amendments were introduced in points 1, 2 and 3 of Article 1.1.3, and a new point (d) was added to Article 1.1.3. The Commission also reviewed and modified the chapter for consistency with other chapters in the *Code*, and to improve grammar and readability. This chapter has been circulated for comments three times.

Discussion

**Title**

To better reflect the approach taken for this revised chapter, the Code Commission agreed to amend the title to 'Notification of diseases and provision of epidemiological information'. This is also in alignment with Chapter 1.1 of the *Aquatic Animal Health Code*.

**Article 1.1.2**

The Code Commission acknowledged a comment requesting that, once the proposed replacement of 'immediate notification within 24 hours' by 'initial notification' in point 3 is adopted, it should also be reflected in WAHIS to avoid confusion, and requested the OIE Secretariat to forward this request to the OIE World Animal Health Information Department (WAHIAD).

The Code Commission did not agree with a comment requesting to add the term 'disinfection' before 'biosecurity' as it considered that 'disinfection' is included in the management component for 'biosecurity' as per the Glossary definition.

The Code Commission did not agree with a comment requesting to reinstate the terms 'infection' and 'infestation' noting that in this sentence the term 'disease' is used in a general manner. The Commission reminded Members that it had provided an explanation for the approach being applied in this chapter for these terms in its September 2019 report.

**Article 1.1.3**

In point 2, in response to a comment, the Code Commission acknowledged that the information available for the follow up reports might vary according with the evolution and epidemiology of each situation, nevertheless, they considered it necessary to maintain the specific reference to 'weekly reports' to ensure the application of a standard process.

For the same point, the Code Commission did not agree with a comment to add 'emerging diseases' after 'listed diseases' so that weekly reports be submitted following the initial notification of an emerging disease as it considered this a decision for OIE Headquarters. The notification for emerging diseases is described in Article 1.1.4. The Commission requested OIE Secretariat to seek the advice of the WAHIAD and report back to the Commission if a modification of Article 1.1.4 is deemed necessary.

The revised Chapter 1.1 is attached as **Annex 6** for Member comments. The adoption of the revised chapter has been postponed until the 89th General Session in May 2021. As the revised chapter has already undergone extensive consultation, Members are requested to only submit comments to address substantive issues that have not been considered previously.

**EU comment**

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

**One comment is inserted in the text of Annex 6.**

### 6.4. Animal health surveillance (Article 1.4.3)

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

Background

At its September 2019 meeting, as a consequence of the revision of the Glossary definition for 'epidemiological unit' the Code Commission amended the text of point 1(d) of Article 1.4.3 in Chapter 1.4, Animal Health Surveillance (see Item 6.2). The revised Article 1.4.3 was circulated for comments in the September 2019 meeting report.

Discussion

For the first paragraph of point 1(d), the Code Commission, together with the Scientific Commission, agreed with a comment to include text that links sampling units to epidemiological units, and amended the text accordingly.

For the second paragraph of point 1(d), the Code Commission did not agree with a comment to rephrase the sentence 'Usually, an *epidemiological unit* is a *herd* or a *flock*.', as it considered the text was clear as written.

The revised Article 1.4.3 is attached as **Annex 7** for Member comments. The adoption of the revised article has been postponed until the 89th General Session in May 2021. As the revised article has already undergone extensive consultation, Members are requested to only submit comments to address substantive issues that have not been considered previously.

**EU comment**

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

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

Comments were received from Australia, New Caledonia, Switzerland, USA, the EU and AU-IBAR.

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 items 6.9 and 6.10). Common provisions concerning procedures applicable to the diseases with official status recognition would be addressed in Chapter 1.6, Procedures for self-declaration and for official recognition by the OIE, instead of being repeated in each disease-specific chapter.

Discussion

In response to a comment requesting to include an elaboration of the administrative and technical screening processes in Chapter 1.6, the Code Commission agreed with the Scientific Commission that administrative procedures should not be included in the *Terrestrial Code*. These procedures are defined by the OIE Headquarters and are covered by Standard Operating Procedures which are available on the OIE website at www.oie.int/self-declaration.

**Title**

The Code Commission deleted 'an' before 'animal health status' in the title of the chapter for consistency with the grammatically correct heading of Article 1.6.1. This change has also been applied throughout the text.

**Article 1.6.1**

In response to a comment to replace 'and' with 'and/or' in the heading of Article 1.6.1, the Code Commission clarified that 'and' is more appropriate as both official recognition of animal health status and endorsement of official control programmes are being referred to in the article. The use of 'and/or' is not appropriate in the *Terrestrial Code*.

In point 2, the Code Commission agreed with a comment to use initialisms as the full names of the diseases with their initialisms in parentheses have been provided in point 1.

In point 2(d), in response to a comment on having an official status recognition process for dog-mediated rabies, the Code Commission was of the view that in the goal for the elimination of human deaths from dog-mediated rabies by 2030, the implementation of an official control programme is more crucial than instituting an official status recognition mechanism.

In paragraph 5, the Code Commission did not accept a comment to include 'along with' before 'the endorsement of official control programmes'. The Code Commission agreed with the Scientific Commission that the purpose of the sentence is to describe the link to relevant resolutions and is not specific to whether the disease has an official recognition of animal health status or an endorsed official control programme, or both.

In paragraph 6, the Code Commission did not accept a comment to replace 'or' with 'and/or' as this is not in line with the use of these terms in the *Terrestrial Code*. The Commission proposed to delete 'based on the provisions of Chapter 1.7 to 1.12' as this is already covered in paragraph 4.

**Article 1.6.2**

In the second sentence of paragraph 2, the Code Commission agreed with a comment to move 'within 24 months after suspension' to the beginning of the sentence for clarity.

**Article 1.6.3**

In the first sentence of paragraph 1, a comment was submitted stating that the Glossary definition of 'animal health status' refers to 'disease' and not 'infection' or 'infestation', which is inconsistent with the content in this article that refers to 'disease, infection or infestation'. The Code Commission will review this inconsistency as part of its ongoing work on how the terms 'disease', 'infection' and 'infestation' have been used in the *Terrestrial Code.*

The Code Commission partially agreed with a comment to rephrase the last sentence of paragraph 1 for clarity.

In the first indent of paragraph 2, the Code Commission did not agree with a comment to replace 'in' with 'for' before 'the entire country'. The Commission clarified that the context refers to the obligation to report notifiable disease in the entire country and thus 'in' is a more appropriate preposition. Furthermore, this preposition is used in several chapters in the *Terrestrial Code* and should be retained for consistency.

In the second indent, a comment was submitted to include 'disease' after 'infection or infestation' as 'disease' is also a determinant of 'animal health status'. The Commission reiterated its previous point that it will continue to review how the terms 'disease', 'infection' and 'infestation' have been used in the *Terrestrial Code* to ensure consistency.

In paragraph 4, in response to a comment requesting for more information on where and how the information on a loss of self-declared free status is made publicly available, the Code Commission noted the explanation provided by the OIE Secretariat that this information is available on the OIE website in the Standard Operating Procedures.

The revised Chapter 1.6, Procedures for official recognition of 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. The adoption of the revised chapter has been postponed until the 89th General Session in May 2021. As the revised chapter has already undergone extensive consultation, Members are requested to only submit comments to address substantive issues that have not been considered previously.

**EU comment**

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

### 6.6. Veterinary Legislation (Chapter 3.4)

Comments were received from Malaysia, New Caledonia, Switzerland, the EU and AU-IBAR.

Background

A thorough review of Chapter 3.4, Veterinary legislation, was undertaken by the *ad hoc* Group on Veterinary legislation in January 2018. The draft revised chapter has been circulated three times for comments.

Discussion

**Article 3.4.1**

The Code Commission did not agree with a comment to replace 'international standards and instruments' with 'legal standards and instruments available at the international level' as it considered the original wording to be appropriate language, clear as written, and that the proposed amendments may introduce unnecessary ambiguity.

**Article 3.4.2**

Regarding the definition of 'Veterinary domain', the Code Commission did not agree with a comment to reinstate the text 'consistent with a One Health approach', reiterating that this was outside the scope

of the chapter. 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 that the concept of 'One Health' was implicit in 'veterinary public health'. The Commission reminded Members that given that Chapter 6.1 is a horizontal chapter, this concept of the One Health approach applies to other chapters in the *Terrestrial Code*, when relevant.

**Article 3.4.3**

In the third paragraph of point 2, a comment was submitted to include 'supranational' based on the rationale that 'regional ' could be perceived as legislation of a region or territory which is part of a country, as opposed to legislation pertaining to more than one country. The Code Commission did not agree to this amendment but did consider that the word 'regional' could cause confusion in this context and referred to the Oxford dictionary definition of 'international law', which refers to a body of rules established by custom or treaty and recognised by nations as binding in their relations with one another. Based on this information, the Commission was of the view that 'international law' encompasses regional and supranational laws and thus there was no need to retain the word 'regional'.

In the first paragraph of point 4, the Code Commission did not agree with a comment to make an explicit reference to laboratories or other scientific institutions as it considered this to be covered under 'other relevant stakeholders'.

In point 5, the Code Commission agreed with a comment to include 'animals' for completeness. However, it did not agree with a comment to add 'health status of the country' after 'protect' as it considered this to be implicit, and that the proposed addition would be too restrictive. It also did not agree to delete the phrase 'against unintended adverse side effects of legal instruments' as it considered this to be an essential concept regarding the quality of legal drafting. The Commission explained that laws should be crafted carefully so they do not result in unintended abuse or harm to citizens, animals or the environment.

**Article 3.4.4**

In point 1, the Code Commission agreed with a comment to replace 'authorities' with 'powers' as this point refers to legal powers that are conferred to the responsible entity.

In point 6, the Code Commission agreed with a comment to include 'proportionate and dissuasive' before 'penalties and sanctions' to highlight that penalties and sanctions should be meaningful, to the point, neither too harsh nor too lax, and effective in achieving their objectives.

**Article 3.4.5**

In the third indent of point 1(d)(iii), the Code Commission did not agree to include 'where necessary, ' before 'destruction' as it considered it unnecessary, given that this section refers to powers of the Competent Authority, which has the discretion on when to exercise these powers. Notwithstanding, for clarity, the Commission separated 'seizure' and 'destruction' into two separate indented points recognising that these activities may not always be done in conjunction.

In the ninth indent, the Code Commission did not agree to add 'notification' given that 'notification' is a defined term in the Glossary of the *Terrestrial Code* and could be misunderstood. The Commission recalled that a review of the Glossary definition for 'notification' is in the work programme.

The Code Commission did not agree to delete point 1(d)(iv) and reiterated its previous explanation that the article does not prescribe the implementation of any specific compensation budget but recommends that veterinary legislation provide the Competent Authorities with the power to establish compensation mechanisms. It remains up to the country to define compensation mechanisms and sources of funding.

**Article 3.4.6**

In point 2, the Code Commission agreed with a comment to replace ‘if the veterinary legislation does not create a veterinary statutory body’ before ‘veterinary statutory body’ with ‘in the event that a Member Country is yet to have an existing’ with a slight modification for readability, noting that the proposed wording supports and encourages the creation of a veterinary statutory body, rather than leaving it open-ended.

**Article 3.4.7**

For point 1(c), in response to a comment requesting clarification of ‘recognised’ laboratory, the Code Commission proposed amendments to points 1(b) and 1(c) to draw a clearer distinction between the three types of laboratories listed. Point 1(b) refers to laboratories performing analysis of official samples, which should have specific requirements for approval by the Competent Authority. For clarity, the Commission proposed to replace ‘designated’ with ‘registered’. Point 1(c) refers to other laboratories which are not necessarily approved by the Competent Authority but are still subject to compliance requirements. In addition, the Commission agreed with a comment to delete the examples in point 1(c) agreeing that they were unnecessary and could be unintentionally restrictive.

**Article 3.4.8**

In point 4(b), the Code Commission agreed with a comment to include ‘packaging, labelling’ for completeness, and for consistency with Chapter 6.4, The control of hazards of animal health and public health importance in animal feed.

**Article 3.4.10**

In point 2, the Code Commission partially agreed with a comment to replace ‘free-roaming domestic ’ before ‘animals’ with ‘abandoned’ for congruency with the content described under this point but retained the term ‘domestic’.

**Article 3.4.11**

In paragraph 1, the Code Commission proposed to add references to the relevant chapters of the *Terrestrial Code* pertaining to antimicrobial resistance.

In point 1(b), the Code Commission agreed with a comment to replace ‘distribution’ with ‘wholesale and retail’ for consistency with how these issues are addressed in the article.

In point 4(c), the Code Commission accepted a comment to include ‘good distribution practices’ as it agreed that this should be covered.

In point 5(f), the Code Commission agreed with a comment that ‘a system of surveillance for falsification’ is not well-placed as this activity is not part of advertising. It thus agreed to move this point to 5(g) which describes a system of surveillance.

The Code Commission agreed with a comment to separate ‘reporting on adverse effects’ from point 5(g) to a new point 5(h). However, it did not agree with a comment to include ‘pharmacovigilance system’ as it considered this is implied under ‘a system for reporting on adverse effects’. Furthermore, the text of this chapter should not be too detailed.

**Article 3.4.12**

In point 1(c), the Code Commission agreed with a comment to replace 'including (slaughter)' with 'and (slaughter)' for consistency with Chapter 6.2, The role of the Veterinary Services in food safety systems, where slaughter is not identified to be part of primary production.

The revised Chapter 3.4, Veterinary legislation, is attached as **Annex 9** for Member comments. The adoption of the revised chapter has been postponed until the 89th General Session in May 2021. As the revised chapter has already undergone extensive consultation, Members are requested to only submit comments to address substantive issues that have not been considered previously.

**EU comment**

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

**One comment is inserted in the text of Annex 9.**

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

Comments were received from Australia, Cuba, Malaysia, Switzerland, the EU and AU-IBAR.

Background

The Code Commission added the development of a new chapter on outbreak management to its Work Programme at its February 2016 meeting. The first draft of this new chapter was circulated for Member comments in the Commission's February 2017 meeting report. Since that time, the Commission has made significant amendments to the text of this chapter having taken into consideration important feedback received from Members during six rounds of comments, as well advice provided by the Scientific Commission to address specific comments.

Discussion

The Code Commission partially agreed with a comment to replace 'cull' and 'culling' with 'kill' and 'killing', respectively, throughout this chapter as the 'killing' is defined in the Glossary and therefore the meaning is clear. Taking into account the context for the use of the terms 'cull' and 'culling' in relevant articles, the Commission proposed to replace 'culling' with 'selective *killing*' as a noun and to replace 'cull' with 'kill' as a verb. The Commission also requested the OIE Secretariat to ensure these terms are translated appropriately into French and Spanish especially because there is no good counterpart for 'cull' in the two languages.

**Article 4.Y.1**

The Code Commission noted a comment to add a point on communication with relevant stakeholders in the list of general components, and therefore proposed to add a point on awareness programmes using similar wording to that used in other disease-specific chapters.

**Article 4.Y.2**

In the fifth indent of point 2, in response to a concern that not all countries have the capacity to fund compensation, the Code Commission emphasised that this indent does not prescribe the implementation of any specific compensation mechanisms, but rather it recommends that Veterinary Services explore the sources of finance and develop a compensation policy. Moreover, the Commission stressed that all recommendations in the *Terrestrial Code* are meant to guide Members in the development of their measures, and that the compensation policy is an essential component in disease control efforts like other human and financial resources.

In the fifth indent of point 3, the Code Commission did not agree with a comment to add 'if relevant' as this inclusion could be applied to any points, and that all points would be specific to the disease of concern and the objectives of the control programmes. In the twelfth indent of point 3, the Commission did not agree with a comment to explicitly mention 'cleaning' as it considered it is clear enough as written.

**Article 4.Y.3**

In the first paragragh, the Code Commission did not agree with a comment to add 'on a risk analysis or an evaluation of the actual or likely impact of the disease and' before 'on the level of preparedness' as it considered all these points were covered in the text following this paragraph.

In point 3, the Code Commission considered a comment suggesting alternative wording for the explanation of simulation exercises, and made some minor amendments. The Commission did not agree with a comment to add 'regular' before 'organisation of simulation exercises' as the frequency of the exercises should be decided by the Veterinary Services.

**Article 4.Y.5**

In the first indent of point 2, the Code Commission did not agree with a comment proposing to add two more points regarding procedures for collection, treatment or safe disposal of contaminated commodities and fomites, noting that these points are already addressed. Nevertheless, the Commission proposed amendment to the text for clarity.

In the chapeau of point 3, the Code Commission did not agree with a comment to add 'in premises and/or restricted zones' before 'through' as it did not consider that the proposal improved the existing text, and explained that the indents under this point are not requirements but general considerations.

In the last paragraph, the Code Commission clarified that 'prevalence control'means prevention of an increase in prevalence and a reduction in prevalence when possible.

**Article 4.Y.6**

In the fourth paragragh of point 1, taking into account the advice from the OIE Wildlife Working Group, the Code Commission agreed to replace 'depopulation' with 'selective killing' in this context for wildlife.

**Article 4.Y.10**

In the fifth paragraph, the Code Commission did not agree with a comment to include 'cost benefit analysis' as it considered that aspect well covered in the paragraph that followed. The Commission explained that this sentence is simply describing the expected outcome of vaccination.

The revised new draft Chapter 4.Y, Official control programmes for listed and emerging diseases is attached as **Annex 10** for Member comments. The adoption of the revised new draft chapter has been postponed until the 89th General Session in May 2021. As the revised new draft chapter has already undergone extensive consultation, Members are requested to only submit comments to address substantive issues that have not been considered previously.

**EU comment**

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

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

Comments were received from Australia, Argentina, Canada, Chile, Costa Rica, Japan, Kazakhstan, Mexico, New Caledonia, New Zealand, Norway, Panama, Switzerland, South Africa, USA, EU, AU-IBAR, the OIE Americas Region, ICFAW, IEC, and experts.

**Background**

This new draft chapter on animal welfare and laying hen production systems is the last chapter to be developed on animal production systems based on the prioritised list developed by former OIE Animal Welfare Working Group. The initial draft chapter was developed by the *ad hoc* Group on Animal welfare and laying hen production systems and has been circulated for comments on three occasions in September 2017, 2018 and 2019.

The Code Commission reiterated that one of the objectives of the revised chapter was to enable the continuous development of country specific animal welfare recommendations and monitoring during implementation.

The Code Commission encouraged Members to refer to its past reports and relevant *ad hoc* Group reports as they include detailed information about previous revisions as well as the rationale for previous amendments. The Commission noted that given some comments submitted were similar to those submitted previously, and that the rationale for such comments was provided in previous reports, the Commission did not repeat these again in this report. The Commission urges Members not to repeat comments that have been made in previous reviews if they are justified by the same argument.

**General considerations**

A significant number of comments were received, some with opposing positions. The Code Commission considered all comments received, and consulted with the Chair of the *ad hoc* Group during its meeting to seek expert advice on some specific comments.

The Code Commission agreed to focus on reinforcing the outcome-based criteria (or measurables) rather than amending the specific recommendations. They agreed that this would ensure that all Members would be able to implement the chapter irrespective of the level of development of animal welfare measures for laying hens and layer pullets.

The Code Commission did not agree to include additional examples in the description of the criteria or in the recommendations noting that the examples provided are not intended to provide an exhaustive list.

The Code Commission agreed to add the term ‘animal’ before ‘welfare’ throughout the chapter, when appropriate but noted that this was not always needed e.g. when referring to layer pullets and layer hens.

The Code Commission agreed to add the term ‘layer’ before ‘pullets’ and ‘hens’ throughout the chapter for consistency.

The Code Commission revised the use of the term ‘may’ versus ‘can’ and replaced throughout the text as deemed appropriate to ensure consistency.

Since all behaviours were considered, included ‘motivated behaviours’ within the criteria, the Code Commission decided to not qualify behaviours as ‘highly’, ‘strongly’ and ‘complex’ throughout the text to simplify readability noting that these are qualitative terms that are difficult to interpret.

The Code Commission did not agree with the comment to delete the list of outcome-based measurables after each of the recommendations as it considered these to form the basis of the approach taken in the development of other production systems animal welfare chapters in the *Terrestrial Code*.

**Title of the chapter**

The Code Commission did not agree to add the term ‘commercial’ in the title to be consistent with other animal welfare chapters.

**Preamble (previously deleted)**

The Code Commission received a number of comments requesting to reinstate text that had been proposed in a previous version but subsequently deleted. The Commission reiterated that the rationale for not including a preamble was described in the Commission's report of September 2019. The Commission recalled that this text was generic in terms of the framework of the OIE standard-setting process and not specific to this chapter. The Commission recommended that if this kind of statement was included anywhere in the *Code*, the best fit would be in Chapter 7.1., Introduction to the recommendation for animal welfare.

**Article 7.Z.2**

The Code Commission did not agree to delete the term 'Commercial' from this article as this chapter only addresses animal welfare aspects of commercial laying hen production systems. So-called 'backyard flocks' are not addressed as there is no capacity to assess the criteria for all backyard flocks. The Commission noted that animal welfare principles are covered in Chapter 7.1, Introduction to the recommendations for animal welfare, for species not addressed in other animal welfare chapters of the *Terrestrial Code*.

The Code Commission did not agree to amend the definition of 'Completely outdoor systems' and explained that what defines the different production system concepts is the confinement and not measures such as the use or not of mechanical environmental control. Whether there is an outdoor area shelter or not, or other measures favouring good animal welfare is a different issue.

**Article 7.Z.3**

The Code Commission agreed to remove the examples in the first paragraph of this article (e.g. mortality rate), noting that these do not provide clarity (as intended) but rather confuse the reader. The Commission agreed to include the term 'motivated' in some of the behavioural criteria to highlight the importance of these behaviours.

In the third paragraph, the Code Commission agreed to add the term 'in English' after 'in alphabetical order', to clarify that the order is based on English spelling, which would clarify for the reader the order to be used in the corresponding chapters of the French and Spanish editions of the *Terrestrial Code*.

In point 1, the Code Commission did not agree with a comment to include the concept of how well beak trimming has been performed as it is not an indication of beak condition.

In point 2(a), the Code Commission did not agree to change the title to 'Sand bath or bedding material' as these do not describe a behaviour. It agreed to add the term 'motivated' to distinguish this behaviour from behaviours that are reactive. The Commission did not agree with the proposal to delete the term 'positive affect' as this is the term used in the scientific reference given [Widowski and Duncan, 2000], which is associated with a positive animal welfare outcome.

In point 2(b), the Code Commission agreed with the proposition to include the words 'in response to novel objects' to clarify the example assessing fearfulness of layer pullets and laying hens, but not 'level of flightiness'.

In point 2(d), the Code Commission agreed to replace 'ability' with 'opportunity' noting that it reflects better the way foraging behaviour decreases. It also agreed to replace 'food' with 'feed' which is the proper term for animals.

In point 2(e), the Code Commission did not agree to delete 'feather' from the title 'Injurious feather pecking' as it agreed feather pecking is the damaging behaviour which can lead to injuries and cannibalism. It agreed to include a text in relation to the possibility to develop secondary infections due to this behaviour.

In point 2(g), the Code Commission agreed to delete the term 'behavioural', when talking about social factors, and also agreed to include examples for social and environmental factors that could be indicative of problems in relation to nesting.

In point 2(h), the Code Commission agreed to include an example which could indicate problems with environmental factors that reduce perching behaviour.

In point 3, the Code Commission did not agree to add 'health and' given that the focus of this chapter is on animal welfare nor with the proposal to add 'management issues that might be associated with' .

In point 5, the Code Commission agreed to delete the complex term 'of aspect (of the production system)'.

In point 7, the Code Commission agreed to modify the example to 'e.g. poor flooring leading to foot injury' to provide further clarification and to move to the appropriate place in the text.

In point 8, the Code Commission did not agree to add the term 'morbidity' in the second sentence because we are referring to mortality and culling rates as well as morbidity rates.

In point 9, the Code Commission agreed to delete the term 'indicators' after 'performance' for clarity noting that it is the performance that is assessed. This is also for consistency with Chapter 7.10, Animal Welfare and broiler chicken production systems. This term was deleted throughout the chapter for consistency.

In point 9(d), the Code Commission agreed to clarify the indicator for the egg production by adding 'the number, size and weight of eggs per hen housed'.

In point 11, the Code Commission agreed to include the term 'impacting', to improve the use of the term animal welfare in the sentence.

**Article 7.Z.4**

The Code Commission agreed to move the last sentence of the first paragraph of this article to Article 7.Z.15, as Article 7.Z.15 refers specifically to the different thermal environments.

**Article 7.Z.5**

The Code Commission agreed to add the behaviours 'dust bathing, nesting and perching' to the list of outcome-based measurables.

**Article 7.Z.6**

In the first paragraph of the second sentence, the Code Commission did not agree with the comment to modify the text as the current text allowed flexibility. Similarly, it did not agree to replace the word 'bird' with 'layer pullet' to ensure consistency within the sentence.

In the second paragraph, the Code Commission did not agree with the proposed change to the order of the measures, noting that the list is in alphabetical order in English (based on the English version). The Commission did not agree to add 'where applicable' and 'where available' which are vague terms and not relevant in the context of this article.

**Article 7.Z.7**

The Code Commission did not agree with the comment to add text regarding the expression of locomotory and comfort behaviours in the first paragraph as this is already addressed in the second sentence of the same paragraph. The Commission also did not agree to change the term 'injuries' for 'injurious feather pecking and cannibalism' as this is implicit in the word 'injuries' and also is included in the list of outcome-based criteria.

**Article 7.Z.8**

The Code Commission agreed to delete the term 'always' from the first sentence of the article, as it agreed it did not improve the understanding of what an appropriate diet should be. The Commission

also agreed to include ‘and metabolic disorders’, in the list of criteria as it was agreed to use the full title of the criteria, as per Article 7.Z.3, when including them in the list after the recommendations.

**Article 7.Z.9**

The Code Commission did not agree to delete the terms ‘locomotion of’ because the primary purpose of flooring is to support the locomotion of the animal. Also, it was agreed to include an example to be more precise on which kind of behaviours could positively or negatively be affected.

**Article 7.Z.10**

The Code Commission did not agree with the comment to add ‘when dust bathing areas are provided, they should have friable and dry substrate’ as it considered this to be too detailed for the chapter.

**Article 7.Z.11**

The Code Commission did not agree with the proposal to delete the first sentence because this is a ‘desirable’ feature. The Commission did not agree with the proposal to add that ‘…substrate should be provided…’ as it considered this to be too prescriptive a statement.

**Article 7.Z.12**

The Code Commission did not agree with the proposal to replace ‘is desirable’ with expanded text as it considered the text as written was clear.

**Article 7.Z.14**

The Code Commission did not agree with the proposal to specify what was meant by ‘…kept in partially housed and completely outdoor systems…’ as it considered that the title of the article provides this information. The Commission clarified that this article is not relevant for systems with no outdoor area and did not agree to reinstate ‘outdoor area should provide shelter and shade for the birds’ due to being implicit.

**Article 7.Z.15**

The Code Commission agreed to keep the term ‘regularly’ instead of ‘frequently’, noting that it is difficult to define how frequent this should be done. The appropriate frequency should be determined by the animal handlers.

**Article 7.Z.17**

The Code Commission agreed to include the term ‘is practised’, in order to clarify that rapid changes in lighting is used only when moulting is practised, as described in Article 7.Z.20.

**Article 7.Z.19**

The Code Commission agreed to modify the second indent by adding ‘associated with’ to clarify that injurious feather pecking is associated with the behavioural phenotype of low propensity to feather pick, and not the genetics.

**Article 7.Z.20**

The Code Commission did not agree with the comment to add a sentence recommending the use of other management strategies to extend the first laying period, as it considered this to be too restrictive. The Code Commission highlighted that the text as currently written, explicitly mentions the potential risk of this procedure.

**Article 7.Z.21**

The Code Commission did not agree to move the sentence regarding dubbing and toe trimming to the first paragraph, noting that reordering the text would not provide any additional value and could potentially confuse users.

The Code Commission did not agree to add new text regarding the problems of beak trimming at a mature age, as it considered this addressed in the current text.

The Code Commission did not agree to expand the text regarding the potential of selective breeding for alternative beak profiles and shapes as it considered this too detailed and not currently used broadly.

**Article 7.Z.24**

The Code Commission did not agree to add a bullet point regarding disease or medical condition as it considered this to be already addressed in the third bullet point, 'rapid deterioration of a medical condition for which treatment has been unsuccessful'. Similarly, it did not agree with the proposal to include culling as a reason together with euthanasia as this aspect is covered in Article 7.Z.25.

The Code Commission agreed with the principle of several comments regarding the urgency to conduct euthanasia but did not agree to include new text noting that this aspect is included in Chapter 7.6, Killing for disease control purposes.

**Article 7.Z.25**

The Code Commission did not agree to delete the words 'for whatever reason', in the first paragraph, as this article not only applies to end-of lay flock, but also could be applicable to disaster situations. The Commission did not agree to add a reference to Chapter 7.6 noting that this is already included in the fourth paragraph.

**Article 7.Z.26.**

The Code Commission agreed with the proposal to add 'evacuation procedures' in the second sentence at the beginning of the article, as a useful example.

The Code Commission did not agree to add new criteria to the list of outcomes-based measurables as they were not relevant in emergency situations.

**Article 7.Z.27**

The Code Commission did not agree to add 'attitude' to the characteristics of the animal handled as this is included in the 'handling techniques' mentioned in the second paragraph.

In relation to the addition of the term 'humane' regarding the killing procedures, the Code Commission agreed to wait for the outcomes of discussions on this point after the next meeting of the *ad hoc* Group on the revision of Chapter 7.6, Killing of animals for disease control purposes.

**Article 7.Z.28**

The Code Commission agreed to include 'outdoor facilities' in the first and third paragraphs, to ensure that all the production systems included in the scope are covered by this article.

The Code Commission did not agree to include new criteria in the list of outcome-based measurables, as it considered that they are not in direct relation with the consequences of good or bad management of the inspection or the handling.

The revised new draft Chapter 7.Z, Animal welfare and laying hen production systems, is attached as **Annex 11** for Member comments. The adoption of the revised new draft chapter has been postponed until the 89th General Session in May 2021. As the revised new draft chapter has already undergone extensive consultation, Members are requested to only submit comments to address substantive issues that have not been considered previously.

**EU comment**

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

**The EU regrets that after three rounds of revisions none of the key comments have been satisfactorily addressed despite including solid scientific evidence to support our comments. The EU comments have been aimed to ensure good level of animal welfare in line with the guiding principles in Chapter 7.1., Article 7.1.2.**

**The fact that the provision of dust bathing areas, foraging areas, nesting areas and perches still remain only "desirable" in the current revision of this Chapter will not lead to any real improvement of the welfare conditions for laying hens. The importance for hens to have an access to such facilities is scientifically based and proven to work in practice.**

**In this context, the EU cannot support guidelines that do not clearly require laying hen producers to provide the aforementioned basic facilities.**

**6.9. Infection with avian influenza viruses (Chapter 10.4) [together with Diseases, infections and infestations listed by the OIE (Article 1.3.6)]**

**Infection with avian influenza viruses (Chapter 10.4)**

Comments were received from Argentina, Brazil, Canada, Costa Rica, Cuba, Japan, Korea (Republic of), Malaysia, New Zealand, South Africa, Switzerland, USA, the OIE Americas Region, the EU and AU-IBAR.

Background

A comprehensive review of Chapter 10.4, Infection with avian influenza viruses, was undertaken by the *ad hoc* Group on Avian influenza between 2017 and 2019. The draft revised chapter has been circulated for Member comments on two occasions.

**General considerations**

In response to comments received on the proposal to delist low pathogenicity avian influenza (LPAI) from Chapter 1.3, Diseases, infections and infestations listed by the OIE, the Code Commission considered all these comments together with the previous *ad hoc* Group reports and advice provided by the Chair of the *ad hoc* Group on Avian influenza on some specific comments.

The Code Commission extensively discussed the proposed delisting of LPAI and the ensuing consequences for Chapters 1.3 and 10.4. The Commission first noted that the assessment against the listing criteria conducted by the *ad hoc* Group had been correctly conducted and concluded that LPAI, including H5 and H7 subtypes, did not meet the criteria for listing and therefore should be deleted from the Chapter 1.3, while Chapter 10.4 should focus on infection with high pathogenicity avian influenza (HPAI) viruses.

On the other hand, the Commission also noted that at least one specific LPAI virus lineage (the H7N9 Chinese lineage LPAI) did meet the criteria for listing because of its zoonotic impact. After taking into account the scientific evidence available, the appropriate level of risk mitigation measures and coherency in the *Terrestrial Code*, the Code Commission agreed that infection with LPAI viruses having proven natural transmission to humans associated with severe consequences should be listed and notified to the OIE in accordance with Article 1.1.3.

Therefore, the Commission proposed to modify the list of notifiable diseases of OIE in Article 1.3.6, to add 'high pathogenicity' between 'infection with' and 'avian influenza virus', and to include a new

indent ‘Infection of domestic and *captive wild* birds with low pathogenicity avian influenza viruses having proven natural transmission to humans associated with severe consequences’.

**Title**

In line with the approach described above, the Code Commission agreed to maintain the title of Chapter 10.4 as ‘infection with high pathogenicity avian influenza viruses’ noting that whilst the scope of the chapter is HPAI, some recommendations are still addressing LPAI viruses in order to take into account the global issue of avian influenza viruses.

The Code Commission highlighted that many comments made throughout the chapter were addressed by this proposal and the rationale described above in ‘General considerations’ and therefore it would not provide individual responses to each comment in this report.

**Article 10.4.1**

In point 2(a), the Code Commission noted a comment asking for further clarification of the definition for HPAI and the methods used for the determination of the strain virulence in the *Terrestrial Manual*, and requested the OIE Secretariat to refer this comment to the Biological Standards Commission for its consideration. The Commission also noted that this revised chapter will be aligned with the revised Chapter 3.3.4, Avian influenza (infection with avian influenza viruses), in the *Terrestrial Manual*.

In point 2(c), the Code Commission did not agree with a comment requesting to include a specific number of birds kept in a single household as the number would vary greatly depending on the country, culture and economic situation, thus it is not possible to determine such number. The Code Commission did not agree either with a comment to delete the sentence referring to ‘single household’ as susceptibility and transmissibility are different, and the intent was to focus on the epidemiological relevance of the animals, which is negligible if they have no contacts with poultry. The Commission did not agree with a comment suggesting to exclude ‘fighting cocks’ from the definition for poultry as it considered fighting cocks relevant in the spread and control of avian influenza. The Code Commission agreed with amendments proposed by some Members for clarity and alignment with the epidemiology of the disease, and proposed amendments to the text accordingly.

In points 2(c) and 2(d), in response to a comment, the Code Commission acknowledged that the term ‘poultry’ is used in many other chapters in the *Terrestrial Code* and therefore proposed to remove the definition of ‘poultry’ from this chapter and to amend the Glossary definition for poultry.

In point 3, based on the approach described above in ‘General considerations’, the Code Commission amended the text accordingly.

In point 4, the Code Commission did not agree with a comment to include ‘including live poultry, or on the trade of birds other than poultry’ after ‘*poultry commodities*’ as the Glossary definition for commodities includes live animals and products of animal origin.

In point 5, the Code Commission did not agree with a comment suggesting to include other hemagglutinin subtypes on the basis that only H5 and H7 subtypes have demonstrated a natural ability to mutate to HPAI through a viable natural process. The Commission also noted that the monitoring considerations included in the chapter were for all subtypes of LPAI viruses.

The Code Commission did not agree with a comment that the monitoring of LPAI should be deleted. The Commission highlighted that the Glossary definition for monitoring is defined as ‘the intermittent performance and analysis of routine measurements and observations, aimed at detecting changes in the environment or health status of a population’ and is different from surveillance. In addition, the Commission noted that this was also consistent with the *ad hoc* Group’s view that the monitoring of LPAI may serve several purposes – such as the awareness programmes, which are also requirements for HPAI freedom, as described in Article 10.4.2, and the trade of live birds and hatching eggs as per the relevant articles in this chapter. Moreover, the commonly deployed screening tests and surveys would first detect AI viruses that will be further typed and this gives the possibility to use the data collected to monitor LPAI viruses.

In point 6, in response to a comment requesting to replace 'Vaccination is an effective complementary control tool …' with 'Vaccination may be an effective complementary control tool', the Code Commission amended the text accordingly for clarity. The Commission noted a comment saying that the use of vaccination against avian influenza depends on the country's own control measures and policy, and explained this is already captured as written.

**Article 10.4.1bis**

At the end of point 1, the Code Commission did not agree with a comment proposing to include 'or that has been retort-processed' but requested the OIE Secretariat to examine whether standard 'retort-processing' is sufficient to meet the condition described in this point in order to be considered as safe commodities.

The Code Commission did not agree with a comment to add 'raw cleaned edible birds nest' to the list of safe commodities as the HPAI virus could be contained in the nests because of feathers and possible faecal contamination. The Commission reminded Members that safe commodities should meet the criteria as described in Chapter 2.2, Criteria applied by the OIE for assessing the safety of commodities. Since 'cleaned' is an undefined process it cannot be determined whether the process would be effective at removing or inactivating the HPAI virus.

**Article 10.4.2**

The Code Commission did not agree with a comment to add 'in poultry' to the title of the article as HPAI is already defined as an infection of poultry in point 2(a) of Article 10.4.1.

The Code Commission acknowledged a comment requesting clarification regarding an awareness programme related to biosecurity and management of avian influenza viruses, and noted that the awareness programme, which depends on the production type or rearing system, should be targeted to all relevant stakeholders. The Commission also highlighted its importance as a requirement for a Member making a self-declaration of freedom from HPAI. In response to this comment the Commission added a separate point regarding the awareness programme for disease reporting for consistency with other disease-specific chapters.

**Article 10.4.2bis**

The Code Commission did not agree with a comment to delete 'high pathogenicity' from the article subheading, noting that the scope of this chapter is HPAI. The Commission considered that this response would address the same comment repeatedly made throughout the articles on trade of commodities of poultry.

**Article 10.4.2ter**

The Code Commission did not agree with comments requesting to explicitly indicate that more than one containment zone can be established, noting that the current text does not prohibit the establishment of more than one containment zone. In addition, the Commission noted that this article is about how a Member can establish a containment zone effectively. The Commission reiterated that there is a possibility to have more than one containment zone as long as each containment zone includes all epidemiologically linked outbreaks, as described in Chapter 4.4, Zoning and compartmentalisation.

**Article 10.4.2quater**

The Code Commission noted comments asking for further clarification regarding exactly when the counting of the waiting period starts and amended the text for clarity and for consistency with the wording used in other disease-specific chapters.

**Article 10.4.3**

In response to a comment seeking clarification on point 3 and saying that any requirement should only apply to H5 or H7 subtypes, the Code Commission reiterated that there is a risk of transmission of

Influenza A viruses of all subtypes through international trade of live birds, which the *ad hoc* Group had also recognised. The Commission agreed that Members need to take precautions in order to decrease the global circulation of the viruses that could facilitate their recombination. The Commission clarified that the proposed text was not meant to require pre-movement testing but that the establishment of origin should be included in the monitoring described in Article 10.4.22ter. The Commission considered that the proposed text is actually less stringent than the current provisions in Chapter 10.4 in terms of testing requirements but wider in the coverage of virus types. Therefore, the Code Commission did not propose any amendments to the text. The Commission noted that similar comments were made throughout the articles on trade of commodities and considered its response would address these other repeated comments.

The Code Commission did not agree with comments to add 'and meet the surveillance requirements in accordance to Article 10.4.22 point 2 of this chapter' at the end of last paragraph noting that it is already covered in point 2 of Article 10.4.22, i.e. that all vaccinated flocks should be tested to demonstrate freedom from HPAI. The Commission considered that this response would address the same comment repeatedly made throughout the articles on trade of commodities of poultry including hatching eggs. The Code Commission also noted a comment stating that the vaccination requirements may not always prevent the export of the virus and therefore there should still be a minimum period since vaccination to allow for seroconversion. The Commission considered that this concern is adequately addressed by point 2 of Article 10.4.22 and did not propose any amendment to the text.

**Article 10.4.4**

In point 2, in response to a comment asking for the scientific rationale to change the isolation period from 21 days (the incubation period for avian influenza in the existing chapter) to 28 days (two flock-level incubation periods proposed in the draft revised chapter), the Code Commission recalled that the *ad hoc* Group had provided a thorough analysis and rationale as to why the current chapter provided the 21-day incubation period, and that it had proposed the 28-day isolation period to ensure an appropriate safety margin. The Commission also noted that birds other than poultry may not show clinical signs, thus 28-day period would provide a safety margin in such cases.

In point 3, the Code Commission noted a comment querying whether 14 days is enough for antibodies to become detectable, and recalled that the *ad hoc* Group had proposed to retain 14 days as per the current chapter, which is now the same as one flock-level incubation period. The Commission also agreed with the *ad hoc* Group that the inclusion of 'serological or virological' was not necessary, as appropriate tests would need to be determined in accordance with the *Terrestrial Manual* depending on the purpose and other factors such as species, test available and type of management system.

The Code Commission did not agree with comments to add 'and meet the surveillance requirements in accordance with Article 10.4.22 point 2 of this chapter' at the end of last paragraph, as Article 10.4.4 is for live birds other than poultry and Article 10.4.22 is only about poultry. The Commission also noted these birds should be isolated and tested in accordance with points 2 and 3 of this article, which is more stringent than point 2 of Article 10.4.22, thus there would be no need to reference that point. The Commission considered that this response would address the same comment repeatedly made throughout the articles on trade of commodities of birds other than poultry including hatching eggs.

**Article 10.4.6**

In point 1, in response to a comment stating that clinical signs of the disease will not likely manifest in day old live birds thus it is more appropriate to sample the day-old live birds and test for the infection, the Commission noted that it is not practical to test day-old chicks and that testing of parent flocks provides sufficient knowledge of the status of the birds, and that inspection of day-old chicks would detect any mortalities that can be followed up by the testing. The Commission also emphasised that this point is a standard language as a generic condition for clinical observation of chicks to confirm they look healthy, and that all points from 1 to 4 should collectively make the risk to be negligible.

The Code Commission did not agree with a comment suggesting to require testing of eggshell surfaces using statistically appropriate samples, as the measurable metric for lack of contamination with AI viruses in a hatchery has not been validated as to the appropriate sampling type and the numbers needed to generate an appropriate level of confidence, according to the *ad hoc* Group.

**Article 10.4.13**

In point 2, the Code Commission did not agree with a comment to replace 'with favourable results' with 'have been found free of any signs suggestive of avian influenza', noting that 'favourable results' means all types of clinical signs and signs of particular diseases may not always be observed therefore it is more practical to be generic rather than focusing on the specific disease. The Commission also highlighted that 'with favourable results' is standard wording used throughout the *Terrestrial Code*.

**Article 10.4.15**

In point 1, the Code Commission acknowledged a concern expressed by Members that both requirements may not be necessary in this point and proposed amendments to the text.

**Article 10.4.16**

In point 2, the Code Commission did not agree with a comment requesting the reinstatement of 'washed and steam-dried at 100 °C for 30 minutes', as the deletion of this treatment from this article was a consequence of adding 'washed and steam-dried feathers and down from poultry and other birds' in the list of safe commodities in Article 10.4.1bis.

On the same point, the Code Commission noted a comment saying that 'fumigation with formalin' is not permitted in some Member Countries and if no other Members use it, this treatment should be deleted from the article. The Commission proposed not to delete this point as the formaldehyde fumigation is effective and efficient as an inactivation treatment. Nevertheless, the Commission requested the OIE Secretariat to investigate the appropriateness of retaining this treatment in the *Terrestrial Code* taking into account the impact on public health and the environment.

**Article 10.4.17bis**

In response to a concern of some Members that the inclusion of 'scientific specimens' in the article subheading and that the conditions required in this article may prevent the exchange of samples containing active virus between laboratories, the Code Commission proposed to amend 'scientific' to 'collection' in the subheading.

**Article 10.4.20**

In response to a comment claiming that there are contradictions between the subheading of this article and the inclusion of a monitoring system for LPAI in the text of this article, the Code Commission reaffirmed that this is not a contradiction nor an inconsistency, and encouraged Members to refer to the relevant reports of the *ad hoc* Group and the responses given in the relevant Commission reports which provide the justification to include recommendations for monitoring of LPAI in this chapter. Furthermore, the Commission highlighted that sampling and testing used for HPAI surveillance and diagnosis, both serological and virological, may also be used for the monitoring of LPAI.

The Code Commission did not agree with a comment to request moving the requirements regarding LPAI to a separate section of this chapter, noting that this article provides basic principles for surveillance for avian influenza including a monitoring of LPAI.

The Code Commission amended the text in line with the approach described above under 'General considerations'.

**Article 10.4.21**

The Code Commission did not agree with a comment saying that expectations from surveillance are not clear, especially in point 2(b) of this article and that provisions in Article 10.4.22 do not seem to be aligned in terms of the required type of surveillance or tests. The Commission highlighted that depending on species, production type and the risk relating to wild birds etc., Members may need to do more than clinical inspections and adjust the surveillance design, including sampling strategy, to address the risk appropriately.

In point 2(a), regarding a comment questioning if the intent of the last sentence was to take samples and submit them to a laboratory for appropriate tests only when the suspicion cannot be ruled out by other means, the Code Commission clarified that the suspicion of AI can never be resolved by epidemiological and clinical investigation alone and that further testing should be performed. It nevertheless proposed amendments to the text for clarity.

**Article 10.4.22**

In response to comments that the current text is still ambiguous, too long and too academic, the Code Commission proposed some amendments to the text in point 1 for improved clarity and readability, as well as consistency with the approach described above under 'General considerations' and in answer to a comment on Article 10.4.22ter.

In point 2, the Code Commission noted a comment stating that the purpose of sentinel birds is unclear, and it moved the sentence providing for the possible use of sentinel birds to the end of the second paragraph for clarity. The Commission did not agree with a comment saying that there is no need to perform virological and serological tests in all vaccinated flocks, but amended the text so that it does not indicate which testing should be performed to demonstrate the absence of infection.

The Code Commission did not agree with a comment saying that virological testing and the use of sentinel poultry should be done to ensure the absence of virus circulation in all vaccinated flocks, as the objective here is to detect infections with field virus in vaccinated populations. The Commission noted that this can be done by virological or serological surveillance in vaccinated birds, or with the use of sentinel birds, while noting that the use of sentinel birds has the added advantage of detecting HPAI based on clinical signs and mortality. The Commission also added that there are different types of vaccines that may require different types of tests to detect infections, and that the use of sentinel birds is not compulsory.

Furthermore, the Code Commission proposed to delete 'every six months or at shorter intervals' to clarify that minimum testing intervals should be determined based on risk.

The Code Commission did not agree with a comment proposing to reference the relevant paragraph of the corresponding chapter of the *Terrestrial Manual*, as chapters in the *Terrestrial Manual* are often revised and keeping the generic text without specific reference avoids the inclusion of incorrect references and the need for regular updates of such references in this chapter.

The Code Commission agreed with a comment to delete the specific reference to DIVA approaches in the corresponding chapter of the *Terrestrial Manual* noting that DIVA approaches may need to be further elaborated in the *Terrestrial Manual*. The Commission also noted that this point is about requirements for freedom with vaccination and the specificities around the DIVA approaches could be beyond the scope of this chapter.

**Article 10.4.22bis**

The Code Commission noted a comment querying what 'investigated' would mean in the first paragraph, and proposed an amendment to the text for clarity.

In the second paragraph, following a comment asking what activities would be included in active surveillance vs. passive surveillance, the Code Commission proposed an amendment to the text for clarity.

**Article 10.4.22ter**

In response to comments saying that the monitoring of LPAI should be exclusively limited to the LPAI viruses of H5 and H7 subtypes, the Code Commission reiterated the rationale previously stated and emphasised that any HPAI surveillance system would include sampling and testing that could support LPAI monitoring with minimal additional resources. The typing of detected viruses should be used for management purposes.

The Code Commission agreed with a comment stating that the inclusion of 'awareness and reporting' in the last sentence of the first paragraph is prescriptive and does not relate to HPAI, and proposed an amendment to the text accordingly.

The Code Commission acknowledged a comment proposing to include 'birds other than poultry' in the scope of LPAI monitoring but did not agree to do this noting that the inclusion of 'birds other than poultry' would cause significant and unnecessary financial and logistical challenges to many Members with unknown effectiveness. The Commission, however, explicitly included this type of birds in the scope of HPAI surveillance for freedom declaration and amended the text in point 1 of Article 10.4.22.

The Code Commission noted a comment proposing to add a sentence underlining the usefulness of LPAI monitoring or the early warning system for HPAI, and proposed an amendment of the text accordingly.

**Diseases, infections and infestations listed by the OIE (Article 1.3.6)**

Comments were received from Argentina.

The Code Commission did not agree with a comment that low pathogenic avian influenza of H5 and H7 subtypes should be maintained as an OIE-listed disease and referred the reader to the rationale provided in the section above for Chapter 10.4.

In line with the approach described in the section above for Chapter 10.4, the Code Commission proposed to add 'Infection of domestic and captive wild birds with low pathogenicity avian influenza viruses having proven natural transmission to humans associated with severe consequences' to Article 1.3.6.

Following the approach to naming diseases being applied in the *Terrestrial Code*, i.e. Infection of [animal] with [pathogenic agent], the Commission also proposed to amend the disease name for avian influenza in birds other than poultry including wild birds to read 'Infection of birds other than *poultry*, including wild birds, with influenza A viruses of high pathogenicity' for consistency with the new proposed listing.

The revised Chapter 10.4, Infection with high pathogenicity avian influenza viruses, attached as **Annex 12A** (clean version) and **Annex 12B** (track-changed version),

**EU comment**

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

**In particular, we wish to thank the OIE for taking into consideration our previous comments.**

**Comments are included in the text of Annex 12A.**

the revised Glossary definition for 'poultry' attached as part of **Annex 5** and the revised Article 1.3.6 attached as **Annex 13** are presented for Member comments. The adoption of these has been postponed until the 89th General Session in May 2021. As these texts have already undergone extensive consultation, Members are requested to only submit comments to address substantive issues that have not been considered previously.

**EU comment**

**The EU thanks the OIE and in general supports the proposed changes to the category of avian diseases and infections.**

**One comment is included in the text of Annex 13.**

**6.10. 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 New Caledonia, New Zealand, Switzerland, USA and the EU.

Background

At its September 2018 meeting, the Code Commission had agreed to harmonise the requirements for official recognition and maintenance of free status, and endorsement and maintenance of official control programmes in disease-specific chapters with official recognition (excluding Chapter 11.4, Bovine spongiform encephalopathy).

In February 2019, the Code Commission agreed to use Chapter 14.7, Infection with peste des petits ruminants virus (PPR), as the 'model chapter' to present relevant amendments. At this meeting, the Commission reviewed comments received on the proposed amendments to Chapter 14.7 and also applied changes pertaining to harmonisation, when relevant to Chapter 15.2, Infection with classical swine fever (see Item 6.10). The remaining chapters will be amended progressively.

Recommendations of the *ad hoc* Group on the Evaluation of peste des petits ruminants status of Members

The OIE Secretariat updated the Code Commission on several proposals made by the *ad hoc* Group on the Evaluation of peste des petits ruminants status of Members who met in December 2019.

The *ad hoc* Group had proposed to link the documentation of facilities holding PPR virus containing materials (PVCM) with the OIE procedure for official recognition and had drafted some additional text for Article 14.7.1 to define peste des petits ruminants virus-containing material. The Code Commission was of the view that the proposed text would be better placed in the *Terrestrial Manual* and requested the OIE Secretariat to consult with the Biological Standards Commission on this point.

The *ad hoc* Group also proposed to include text in Article 14.7.3 on the submission of information on PVCM holding facilities as part of the application for official recognition of free status by Members. The Code Commission acknowledged that the development of an inventory of such facilities would facilitate the sequestration and destruction of the PPR virus once the disease was eradicated. However, the Commission was of the view that the submission of such information concerns official status recognition and is not an epidemiological requirement for country or zone to be considered free of PPR. In addition, from a harmonisation perspective, there is no equivalent requirement in the disease-specific chapter of other diseases with official status recognition. The Code Commission recommended that the OIE Secretariat consider other ways of addressing this proposal outside of the *Terrestrial Code*.

The Code Commission recalled that at its meeting of September 2019, it had discussed a comment seeking clarification on whether the importation of vaccinated animals results in a loss of 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. The Commission noted the opinion of the *ad hoc* Group that there was no scientific evidence that small ruminants vaccinated against PPR would pose a risk to a naïve population. However, the Commission also considered the position of the *ad hoc* Group that in the absence of marker vaccines or a test to differentiate infected from vaccinated animals (DIVA) and the demanding level of surveillance that would be required to ensure the traceability of all vaccinated animals, the prohibition of imports of vaccinated sheep and goats by a country or zone having an official PPR free status should be maintained. In light of the above, the Commission concluded that notwithstanding the apparent inconsistency between point 6 of Article 14.7.3 and point 3(b) of Article 14.7.10 as a result of risk-related considerations, the management of the status of the country or zone and the difficulties in demonstrating freedom when there is no DIVA strategy justifies the prohibition on the importation of vaccinated animals by countries or zones recognised as officially free.

The *ad hoc* Group report on the Evaluation of peste des petits ruminants status of Members is appended to the February 2020 report of the Scientific Commission for Member information.

Discussion

The Code Commission did not agree with a comment to include text regarding a functional separation of the domestic population from the feral population in Chapter 14.7. The Commission recalled that the first paragraph of Article 14.7.1 states that 'only domestic sheep and goats play a significant epidemiological role' and since the occurrence of PPR in wild ruminants does not affect the status of the domestic population, there is no need to specify a functional separation between the domestic and wild ruminant populations.

**Article 14.7.3**

In the first sentence, the Code Commission did not agree with a comment to replace 'have been complied with' with 'compliant with' as this is not consistent with the language used across the *Terrestrial Code*. In addition, the use of the present perfect tense stresses that the country or zone has been assessed and shown to have continuously fulfilled the necessary requirements during the period.

In point 3(a), the Code Commission did not agree with a comment to specify in parenthesis 'point 2' after 'Article 1.4.6' as it considered this reference to be too specific. Furthermore, this reference is already covered in the first sentence of this article.

In point 4, the Code Commission did not agree with a comment to replace 'the infection' with 'PPRV' as the intention of this point is to prevent the introduction of infection, not prevent the introduction of the pathogenic agent, which it considered may take place, for example through the importation of biological specimens. The Commission further clarified that prevention of infection does not refer to just infected animals and would also apply to other commodities able to transmit the infection.

In point 6, the Code Commission deleted '[under study]' after considering the opinions of the *ad hoc* Group on the Evaluation of peste des petits ruminants status of Members (see above explanation).

In the first sentence of paragraph 3, the Code Commission agreed with a comment to add 'compliance with' before 'all points above' to improve clarity.

In the same paragraph, the Code Commission, together with the Scientific Commission, did not agree with comments requesting to replace '1) to 4)' with '1) to 6)' as documented evidence for points 5 and 6 would be difficult to provide and are unlikely to change on an annual basis.

**Article 14.7.7**

In the first sentence of paragraph 1, the Code Commission replaced 'restored' with 'recovered' for consistency with Chapter 15.2, Infection with classical swine fever.

In the last sentence, the Code Commission replaced 'The country or *zone* will regain PPR free status' with 'The PPR free status of the country or *zone* will be reinstated', as the term 'reinstated' better emphasises that this is an official status recognition process.

**Article 14.7.34**

Regarding a comment stating that there is inadequate transparency in how the OIE endorses official control programmes, the Code Commission noted the explanation by the OIE Secretariat that the Standard Operating Procedures are published on the OIE website at https://www.oie.int/en/animal-health-in-the-world/official-disease-status/official-recognition-policy-and-procedures/.

In response to a comment that there may be difficulties complying with the requirements listed in this article, the Code Commission noted the clarification provided by the OIE Secretariat that no changes had been proposed with regard to the provisions on annual reconfirmation of countries with an OIE endorsed official control programme for PPR. These countries must inform the OIE on an annual basis of the progress on the implementation of the official control programme based on the initially submitted programme that was endorsed.

In point 1(b), the Code Commission agreed with comment to delete 'livestock' as 'sheep and goats' is mentioned in the same sentence.

In point 3(b), the Code Commission, in agreement with the Scientific Commission, agreed with a comment to include the identification of vaccinated animals, but reworded the proposal. The Code Commission proposed to include a reference to Chapter 4.18, Vaccination, in point 3(a) and included a new point 3(b)(v) on 'strategy to identify vaccinated animals'.

In response to a comment stating that point 7 is redundant in view of point 8, the Code Commission agreed with the Scientific Commission that performance indicators are to assess the control measures to be implemented. Although this may be a component of point 8, the Code Commission proposed to retain the text for clarity.

Articles 14.7.3, 14.7.7, 14.7.24 and 14.7.34 are attached as **Annex 14** for Member comments. The adoption of these revised articles has been postponed until the 89th General Session in May 2021. As these have already undergone extensive consultation, Members are requested to only submit comments to address substantive issues that have not been considered previously.

**EU comment**

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

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

Comments were received from Argentina, Australia, Brazil, Canada, New Caledonia, USA, Switzerland, the OIE Americas Region and the EU.

Background

The revision of 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, and to ensure relevant alignment with the recent amendments to Chapter 15.1, Infection with African swine fever virus (ASF), adopted in 2019, as well as with other chapters on diseases for which the OIE grants official recognition of animal health status. The draft revised Chapter 15.2 was last circulated for comments in the Code Commission's September 2019 report.

In response to a comment regarding the removal of the previous Article 15.2.9, Importation of wild and feral pigs, and Article 15.2.15, Importation of fresh meat of wild and feral pigs, the Code Commission reiterated the rationale presented in its September 2019 report, i.e. that given the broad diversity of possible circumstances associated with wild and feral pigs, it was not possible to recommend precise and effective mitigation measures to be included in the *Terrestrial Code* for this disease that would apply to all possible situations. The Commission recalled that this does not preclude countries from conducting a risk analysis in accordance with the *Terrestrial Code*, to identify appropriate sanitary measures if needed.

Discussion

**Article 15.2.1**

In point 2, the Code Commission did not agree with a comment requesting to amend the text to improve clarity and explained that the current wording takes into account different possible epidemiological links, not only the relation with suspected or confirmed cases and that there is value in maintaining the detail in the proposed text, as in other similar articles.

In point 3, in response to a comment requesting to replace 'three months' by '90 days' to improve preciseness and clarity, the Code Commission did not agree to amend the text because the proposed text follows the approach used in the recently adopted Chapter 15.1, Infection with African swine fever virus. The same rationale is relevant for similar comments received for other articles.

The Code Commission did not agree with a comment requesting to reinstate the sentence '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', noting that new proposed

text in the last sentence of Article 15.2.1bis addresses this point in the same way it was done for Chapter 15.1.

**Article 15.2.2**

In point 3, the Code Commission, in agreement with the Scientific Commission, did not agree with a comment to delete the full point, as it considered that knowledge about the situation regarding the infection in wild and feral pigs was needed in order to determine the most appropriate mitigation measures, noting that a case in the wild and feral pig populations would not impact the CSF status if adequate measures were in place before detection of the case.

In point 7, in response to a comment, the Code Commission, in agreement with the Scientific Commission, amended the text to specify that the separation of the domestic and captive wild pig populations from the wild and feral pig populations, should be required only when justified by the risk of the spread of the disease from wild and feral to domestic pig populations.

In the fourth paragraph, the Code Commission did not agree with a comment to include 'In case a containment zone has been established' at the beginning of the paragraph, as it considered it unnecessary given that it is already defined by the title and the scope of the article.

**Article 15.2.3bis**

A new article defining a 'Country or zone infected with CSFV' was added for consistency with other chapters.

**Article 15.2.5**

The Code Commission did not agree with a comment requesting to delete 'the disinfection of the last establishment' throughout the article. The Commission considered that, although the definition of stamping out already includes the cleaning and disinfection of establishments, it is more precise to refer to the 'completion of the disinfection'. For consistency, similar amendments were made in other relevant chapters revised during this meeting.

The Code Commission amended the last paragraph of the article for consistency with other chapters.

**Article 15.2.5bis**

In point 1, the Code Commission added 'movement for' before 'for slaughter', for clarity and consistency with other chapters in the *Terrestrial Code*.

In points 4 and 5, in response to a comment, the Code Commission agreed to amend the text to specify that the transport and slaughter of pigs should be done under biosecure conditions. In response to another comment, the Commission amended the text of point 4 for clarity.

**Article 15.2.5ter (deleted)**

In response to comments and in agreement with the Scientific Commission, the Code Commission agreed to delete the previously proposed Article 15.2.5ter, 'Direct transfer of pigs within a country from a containment zone to a free zone for slaughter, as it considered that, as per the new definition for 'Country or zone infected with CSFV' added to Article 15.2.3bis and the definition of containment zone in Chapter 4.4., a containment zone is an infected zone, and therefore the provisions for movement of animals for slaughter from a containment zone would be covered by Article 15.2.5bis.

**Articles 15.2.7 and 15.2.9**

The Code Commission amended the title of these articles in view of the inclusion of the new definition for 'countries or zones infected with CSF' added to Article 15.2.3bis.

**Article 15.2.10**

In point 2, in response to a comment, the Code Commission agreed to amend the text from ‘fertilise the oocytes’ to ‘the semen used to inseminate the donors’, noting that this article refers indeed to *in vivo* derived embryos, not to *in vitro* produced embryos.

**Article 15.2.11**

The Code Commission amended the title of this article in view of the inclusion of the new definition for ‘countries or zones infected with CSF’ added to Article 15.2.3bis.

In point 1(a), in response to a comment requesting to harmonise the surveillance requirements listed in Articles 15.2.11 and 15.2.9, the Code Commission noted that this had been addressed by the amendments proposed in Article 15.2.9. The Code Commission amended the text for clarity.

In point 2, in response to a comment, the Code Commission agreed to amend the text from ‘fertilise the oocytes’ to ‘the semen used to inseminate the donors’, noting that this article refers to *in vivo* derived embryos, not to *in vitro* produced embryos.

**Article 15.2.12bis**

The Code Commission amended the title of this article in view of the inclusion of the new definition for ‘countries or zones infected with CSF’ added to Article 15.2.3bis.

In point 2, the Code Commission agreed with the comment to replace ‘Veterinary Services’ by ‘Veterinary Authority’ for consistency with other chapters.

In point 4(b), the Commission amended the text for clarity.

**Article 15.2.13**

In point 1(b), the Code Commission did not agree with a comment to replace the word ‘facility’ by ‘slaughterhouse/abattoir’, since the article relates to meat products and not meat. The Commission explained that this change (from ‘establishment’ to ‘facility’) was introduced in September 2019 for consistency with the Glossary definitions to avoid misinterpretation of the term ‘establishment’.

**Article 15.2.18**

In point 1, the Code Commission did not agree with a comment to amend the text to improve clarity as considered it was consistent with similar articles in the *Terrestrial Code*. In the same point, the Commission agreed to include a new item (b) referring to ‘any equivalent heat treatment which has been demonstrated to inactivate CSFV in meat’ for consistency with other chapters.

**Article 15.2.19ter**

In point 2, the Code Commission did not agree with a comment to modify the treatment time to 60 minutes, agreeing that this would not be consistent with point 1 of this article.

The Code Commission also noted that the term ‘swill’ needs to be defined, recalling that this was discussed in its September 2019 meeting and decided to include it in its work programme. The Code Commission agreed to request the OIE Secretariat to include this task within the ongoing work to prepare Guidelines on compartmentalisation for African Swine Fever, that would involve expert consultation. The Commission requested that the OIE Secretariat report back on the progress of this work at its next meeting.

**Article 15.2.23**

In point 1, the Code Commission agreed with a comment to amend the text to refer to ‘domestic and captive wild pig population’ for consistency within the chapter.

**Previous Article 15.2.32 (deleted)**

In response to a comment requesting to maintain Article 15.2.32 as it included useful information, the Code Commission reiterated that it had agreed previously to remove this kind of information, e.g. charts from the *Terrestrial Code*, as this format was not easy to update nor adapted to the *Terrestrial Code*. Nevertheless, the Commission acknowledged that this information could be useful for Members and requested the OIE Secretariat to explore ways to make this information available outside of the *Terrestrial Code*.

The revised Chapter 15.2, Infection with classical swine fever virus, is attached as **Annex 15** for Member comments. The adoption of the revised chapter has been postponed until the 89th General Session in May 2021. As the revised chapter has already undergone extensive consultation, Members are requested to only submit comments to address substantive issues that have not been considered previously.

**EU comment**

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

**We have included one comment within the body of the text in Article 12.2.19ter.**

## 7. Texts for comments (Part B)

### 7.1. Glossary Part B ('death', 'distress', 'euthanasia', 'slaughter', 'stunning' and 'suffering')

**Death**

The Code Commission agreed with the proposal to remove the second sentence of the definition as it considered it may be misinterpreted. Consequently, it proposed to delete the definition as a whole, noting that the meaning in the context of the *Terrestrial Code* is similar to that of a Dictionary definition.

**Distress**

The Code Commission did not agree with a comment to consider including text that an animal that cannot escape or avoid a negative stimulus will be also suffering, as it considered that the proposed addition was describing a situation and not describing what distress was, thus did not add clarity to the text.

**Euthanasia**

The Code Commission noted that the revised definition clarifies the difference between killing and euthanasia but should not include how as this aspect is addressed in the text of relevant animal welfare chapters, when relevant. The Commission agreed to add 'of an animal' to be more specific. The Commission did not agree with adding 'when it is in the interest of animal welfare' as it considered this to narrow down meaning. The Commission agreed to add 'method with the least pain and suffering possible' for consistency with the proposed changes made in the definition of 'Stunning'.

**Slaughter**

The Code Commission did not agree to add 'and animal consumption' at the end of the sentence, as the definition notes the primary consumer are humans but animal consumption or other uses associated with slaughter are not excluded.

The Code Commission did not agree to include the humane aspect in the definition, noting that the purpose of the definition is to define the action, i.e. to kill, rather than how this should be done. This aspect is addressed in the text of relevant animal welfare chapters. The Commission did not agree with the proposal to add 'by bleeding', as it deemed it unnecessary to specify in the definition the actual cause of death. The Commission agreed to change the term 'animals' to its singular form to be more specific and consistent with the agreed change to the definition of 'Euthanasia'.

**Stunning**

The Code Commission agreed to replace 'and other type of suffering' with 'pain and suffering' to be more specific but did not agree to include 'distress' and 'fear' noting that these are behavioural responses that occur before stunning rather than a physical reaction during stunning. In addition, these responses may be induced by actions other than stunning.

The Code Commission did not agree to add 'when used before killing' because the purpose of the definition is not to define at which point in a sequence of actions stunning should be done but rather to define what stunning is. How stunning is conducted is described in the text of relevant chapters.

The Code Commission agreed that the proposal to add the text 'without unnecessary pain' may confuse the reader. The Commission noted that as any type of pain should be minimised and agreed that this is already considered in the proposed text.

**Suffering**

The Code Commission agreed to include 'physical or mental state' to be more specific but did not agree to add 'that the animal cannot escape' as it considered this to be implicit. It agreed to replace 'important' with 'essential' to strengthen the definition.

The revised definitions on 'distress', 'euthanasia', 'pain', 'slaughter', 'stunning' and 'suffering' are attached as **Annex 16** for Member comments.

**EU comment**

**The EU supports in general the proposed changes to the Glossary and it has one new comment in Annex 16.**

**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 Switzerland, USA and the EU.

The Code Commission did not agree with comments to replace 'and' with 'and/or' in some disease names that includes more than one causative pathogenic agent, as 'and' here does not mean infection with all included pathogen species at the same time, but means that the disease name includes infection with each of those pathogen species. The Commission clarified that all species of pathogenic agent included in such listed disease names are notifiable.

**Infection with *Mycobacterium tuberculosis* complex**

The Code Commission agreed with the Scientific Commission's proposal described in its September 2019 report to reconsider the listing or delisting of *M. tuberculosis* at its September 2020 meeting. Based on this proposal, the Code Commission withdrew its proposal to amend the name of this disease, and invited Members to provide new scientific evidence to the OIE regarding the possibility and impact of transmission of *M. tuberculosis* from animals to humans or other animals.

**Infection with *Mycoplasma mycoides* subsp. *Mycoides* SC (Contagious bovine pleuropneumonia)**

The Code Commission noted a comment to replace 'SC' with 'small colony'. Taking into account that the corresponding chapter in the *Terrestrial Manual* is currently under revision, the Code Commission agreed to propose an amendment to the name once the corresponding chapter in the *Terrestrial Manual* has been adopted.

**Infection of dromedary camels with Middle East Respiratory Syndrome Coronavirus**

After considering a comment and advice of the Scientific Commission, the Code Commission proposed to change 'Infection of dromedary camels with Middle East Respiratory Syndrome Coronavirus' to 'Infection of dromedary camels with Middle East respiratory syndrome coronavirus',

using lower-case characters, which is also in line with the notation used by the World Health Organization.

The Code Commission, in agreement with the Scientific Commission, did not agree with a comment that 'Infection of dromedary camels with Middle East respiratory syndrome coronavirus' should not be listed until a disease-specific chapter with a clear case definition is developed, noting that such case definition should be drafted. The Code Commission recalled that not only the assessment for the listing had been conducted and this disease was considered to meet the criteria for listing, but also that a corresponding chapter in the *Terrestrial Manual* would be presented for adoption at the 89th General Session in May 2021, which will help Member Countries for their notification of cases. The Commission noted that the issue of lack of disease-specific chapters for the OIE-listed diseases is being well recognised by the Specialist Commissions and the work to resolve this issue is in progress.

The revised Articles 1.3.1, 1.3.2 and 1.3.9, Diseases, infections and infestations listed by the OIE, are attached as **Annex 17** for Member comments.

**EU comment**

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

**7.3. Quality of Veterinary Services (Chapter 3.1), Evaluation of Veterinary Services (Chapter 3.2) and new draft Chapter 3.X**

Background

The new draft Chapter 3.X and revised Chapters 3.1, Quality of Veterinary Services, and 3.2, Evaluation of Veterinary Services, were circulated for the first time in the Code Commission's September 2019 report. Chapters 3.1 and 3.2 had been revised to reflect the contemporary activities and responsibilities of the Veterinary Services and to better align with other chapters in the *Terrestrial Code*. An *ad hoc* Group on Veterinary Services was convened in July 2019 to revise these chapters. The *ad hoc* Group also proposed a new Chapter 3.X as an introductory chapter for Section 3 of the *Terrestrial Code.*

**Quality of Veterinary Services (Chapter 3.1)**

Comments were received from Chinese Taipei, New Caledonia, New Zealand, Singapore, Switzerland, the EU and AU-IBAR.

General comments

In response to a comment that it was not possible to comment on the proposed changes to Chapter 3.1 until the review of the Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' is completed, the Code Commission clarified that until the work on revising these definitions is finalised, the definitions in the Glossary are to be used. The Commission noted that the chapter will be updated, if necessary, once revised definitions have been adopted (see Item 5.1.1).

In response to a comment that certain elements in the current text of Chapters 3.1 and 3.2 have been omitted, the Code Commission noted that as no specific details had been provided it was difficult to identify the elements being referred to. The Commission reminded Members that the rationale for revising Chapters 3.1 and 3.2 was because these chapters have not been reviewed for a long time and that some of the content in the existing chapters was out of date, no longer reflected the broadened scope of the activity of Veterinary Services such as antimicrobial resistance and biothreats, or was not what might be appropriately regarded as standards.

**Article 3.1.2**

In point 1, the Code Commission did not agree with a comment to include 'knowledge' in the subheading as it considered knowledge to be inherent in sound professional judgement.

In point 6, the Code Commission partially agreed with a comment to include ‘social science’ to highlight the different scientific fields that should be considered. However, it did not agree with the second part of the comment to replace ‘and’ with ‘or’ after ‘epidemiology’ given that the use of the term ‘such as’ in the preceding part of the sentence implies that the list is not exhaustive.

In the same point, the Code Commission did not agree with a comment to include ‘research and development’ as they did not consider this to be a scientific ‘field’ and would be out of place in the list. Furthermore, research and development is inherent in the fields of risk analysis, epidemiology, economics and social science.

**Article 3.1.3**

In the last sentence of the first paragraph, in consideration of a comment to include ‘commercial’ and ‘hierarchical’ before ‘influences’ the Code Commission considered that it would be clearer to include this under ‘other non-scientific influences’ which would address all potential non-scientific influences.

In point 1, the Code Commission agreed with a comment to replace ‘science’ with ‘new scientific evidence’ for clarity.

In point 2, the Code Commission did not agree with a comment to replace ‘inspection’ with ‘control’ as it considered ‘inspection’ to be a clearer term. ‘Control’ implies compliance activities such as in official control programmes and could be confusing if used here.

In point 4, the Code Commission did not accept a comment to replace ‘or’ with ‘including’ as it did not agree that government policies could be in the form of programmes. The Commission noted that programmes are operational activities, although they may be based on policies.

In point 5, the Code Commission did not agree with a comment to include ‘knowledge’ as it considered that knowledge is a type of information.

In point 6, the Code Commission accepted a comment to include ‘policies’ with the rationale that data from information management systems can be a source for policy evaluation.

In point 7, the Code Commission did not agree with a comment to include ‘within the Veterinary Authority’ after ‘effective internal coordination’. The Commission did not agree that ‘field levels’ imply state or provincial level authorities. The Commission explained that ‘field level’ does not necessarily refer to the administrative levels within the country but encompasses operations in the field such as the management of borders or farms. Notwithstanding, the Commission also noted that this point covers the chain of command down to decentralised governments, where they exist.

In point 9, the Code Commission agreed with a comment to remove ‘pre’ before ‘consultation’ as consultation with stakeholders should be carried out at all times during the policy development.

**Article 3.1.4**

In the first paragraph, the Code Commission did not agree with a comment to replace ‘education’ with ‘professional development’ as it considered that the term ‘continuing education’ is used in other parts of the *Terrestrial Code*, OIE Guidelines on Veterinary Education and the OIE PVS Tool, so understood by Members. A similar comment for point 5 was not accepted for the same reason.

In point 6, the Code Commission did not agree with a comment to include ‘as appropriate’ to the end of the point as it considered this to be addressed by the word ‘adequately’. Furthermore, the Glossary definition for ‘veterinary paraprofessional’ states that these persons are ‘under the responsibility and direction of a veterinarian’.

In point 7, the Code Commission partially agreed with a comment to replace ‘education’ with ‘professional development’. The Commission proposed to replace ‘education’ with ‘professional development, including continuing education programmes’ as it recognised that continuing education is a means of achieving professional development.

**Article 3.1.5**

In paragraph 2, the Code Commission accepted a comment to add 'relevant to their role' after 'educational and professional standards', and to add 'other veterinary tasks as appropriate' to the end of the first sentence, as it agreed that the scope of Veterinary Services is broader than veterinary clinical services.

In point 1(b), the Code Commission did not agree with a comment to include 'day-1 competencies' in parenthesis as this point is intended to be generic.

In point 3, the Code Commission agreed with a comment to move 'quality' to the first part of the sentence for conciseness.

**Article 3.1.6**

In the last sentence of paragraph 2, the Code Commission did not agree with a comment to replace 'and' with 'including' to reflect that programmes are a subset of policies, for the same reason as given above in Article 3.1.3.

In point 3, the Code Commission did not agree with a comment to delete 'non-government (stakeholder representatives)' noting that this article refers to engagement with non-government stakeholder representatives. The Commission noted that engagement with government agencies is covered in points 7 and 8 of Article 3.1.3.

**Article 3.1.7**

In point 1, the Code Commission partially agreed with a comment to include 'data analysis technologies' as it agreed with the given rationale that modern surveillance systems are starting to make use of new information and data analysis technologies. However, the Commission did not agree to include the examples of 'big-data' or 'artificial intelligence' as the use of these technologies is not widespread across Member Countries.

In point 5, the Code Commission did not agree with a comment to include 'specific for the country' after 'priority diseases' as it considered this to be implicit as written. With regard to the comment requesting criteria to identify priority diseases, the Commission noted that this goes beyond the OIE mandate. National Veterinary Services may develop their own national or sub-national disease priorities as appropriate, considering the OIE listed diseases.

In point 8, the Code Commission agreed with a comment to replace 'livestock' with 'animals'.

**Article 3.1.8**

In point 1, the Code Commission agreed with a comment to include 'auditing' noting that this is an official activity carried out by Competent Authorities.

In point 3, the Code Commission did not agree with a comment to include 'auditing' because the point specifically refers to ante- and post-mortem inspection activities, not its oversight via auditing.

In point 4, the Code Commission did not agree with a comment to include 'based on chemical hazard analysis' after 'residue monitoring programme' as it considered that the sentence was intended to be general to highlight the range of residue risks.

In point 6, the Code Commission partially agreed with a comment to indicate that sanctions should be 'proportional and dissuasive' but did not agree to add the word 'proportional' before 'procedures'.

**Article 3.1.10**

In paragraph 2, the Code Commission agreed with a comment to replace 'protection' with 'effectiveness' as it considered this to be a more appropriate term.

In the same paragraph, the Code Commission agreed with a comment to replace ‘freedom’ with ‘animal health status’ for consistency with Chapter 1.6.

**Article 3.1.11**

In the first sentence, the Code Commission did not agree with a comment to replace ‘and’ with ‘including’ to reflect that programmes are a subset of policies, for the same reason as given above in Article 3.1.3.

The revised Chapter 3.1, Quality of Veterinary Services, is attached as **Annex 18** for Member comments.

**EU comment**

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

**Evaluation of Veterinary Services (Chapter 3.2)**

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

Discussion

**Article 3.2.2**

In point 2, the Code Commission did not agree with a comment to include ‘competence, history of’ after ‘verify’ and ‘of integrity’ after ‘enhance reputation’ as it did not consider that the proposal enhanced the existing text.

In point 3, the Code Commission did not agree with a comment to include ‘with the key components and operating principles’ after ‘demonstrate compliance’ as it considered this to be unnecessary and the demonstration of compliance should apply to the whole chapter.

In point 5, the Code Commission did not agree with a comment to add ‘as part of risk analysis in international trade’ to the end of the sentence. The Commission explained that this is a general statement not only addressing risk analysis. Furthermore, the link to risk analysis is covered in Chapter 2.1, Import risk analysis.

In the last sentence, the Code Commission partially agreed with a comment to include ‘on a non-discriminatory basis’ but proposed to incorporate this in Article 3.2.4.

**Article 3.2.3**

In point 2, the Code Commission did not agree with a comment to include the sentence ‘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’. The Commission considered the proposal to be too detailed for a general statement and noted that the principles for evaluation are covered in Article 3.2.1.

In point 3, the Code Commission agreed with a comment to add ‘regions’ to the list of examples of sub-national levels.

**Article 3.2.4**

In point 1, the Code Commission agreed with a comment to add ‘in a non-discriminatory manner’ to incorporate the concept of non-discrimination with respect to the evaluation of Veterinary Services.

In point 3, the Code Commission did not agree with a comment to replace ‘its objective’ with ‘the objectives of the evaluation’ as it considered this to be implicit.

In the same point, the Code Commission did not accept a comment to replace 'or' with 'and/or' as in this instance, 'or' includes the concept of 'and', as written conventionally in the *Terrestrial Code*.

In point 5, the Code Commission agreed with a comment to consider financing for the cost of evaluation and proposed to replace 'requirements of confidentiality' with 'financing and confidentiality requirements'.

In point 8, the Code Commission agreed with a comment to include 'and provide the opportunity for the evaluated country to clarify or respond to the findings before the production of the final evaluation report' to the end of sentence, with the rationale that the country under evaluation should have the opportunity to respond formally to the findings of the evaluating country.

The revised Chapter 3.2, Evaluation of Veterinary Services, is attached as **Annex 19** for Member comments.

**EU comment**

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

**One comment is inserted in the text of Annex 19.**

**Draft new Chapter 3.X Introduction to recommendations on Veterinary Services**

No comments were received for Chapter 3.X.

The new draft Chapter 3.X, Introduction to recommendations on Veterinary Services, is attached as **Annex 20** for Member comments.

**EU comment**

**The EU thanks the OIE and supports the proposed structure and content of this new Chapter 3.X.**

### 7.4. Zoning and compartmentalisation (Articles 4.4.6 and 4.4.7)

Background

The Code Commission recalled that during the last revision of Chapter 4.4, Zoning and compartmentalisation, adopted in 2018, some Members had requested clarification on the proposal to include new text in Article 4.4.6 on the concept of 'temporary protection zone'. At that time, in consultation with the Scientific Commission, it was agreed to not address these comments, but to discuss further how to manage, clarify and incorporate this concept into the *Terrestrial Code*. Both Commissions have discussed this concept over several dedicated meetings and have agreed on critical aspects of its implementation, the implications on animal health status, and the amendments required for its inclusion in the *Terrestrial Code*.

The proposed revision aims at improving the practical function of the 'protection zone' as a risk management strategy to minimise the impact that a disease introduction would have on the entire country or zone when an increased risk is considered to be temporary. The Code Commission, in agreement with the Scientific Commission, proposed to amend Article 4.4.6 to include clear provisions that could apply for all diseases (rather than creating or defining a new concept of 'temporary protection zone'). The Commissions also proposed that if further specific provisions are required concerning a specific infection or infestation, they will be addressed in the relevant disease-specific chapter.

Both Commissions also agreed to amend the use of the term 'protection zone' included in the current description of 'containment zone' in Article 4.4.7, in order to avoid confusion between this term and the new proposed description of a protection zone in Article 4.4.6.

A document presenting the background and explanation for this revision as discussed between the Code Commission and the Scientific Commission is presented as **Annex 24** in the February 2020 report of the Scientific Commission.

Proposed amendments

**Article 4.4.6**

The Code Commission amended the first paragraph of Article 4.4.6 to specify that a protection zone can be established as a temporary measure in response to an increased risk of disease, and that based on the results of a risk assessment more than one protection zone may be established.

After this paragraph, a new sentence was added to highlight the surveillance requirements in line with Chapter 1.4.

In the previous fourth paragraph, a reference to Articles 4.4.2 and 4.4.3 was introduced to avoid repeating principles already covered in Chapter 4. The text of this paragraph was also amended to ensure that the content of the previously numbered requirements (1 to 6) were addressed, and the numbered requirements (1 to 6) were deleted.

The last paragraph of the current text was replaced by new text stating that unless otherwise specified in the relevant disease-specific chapters of the *Terrestrial Code*, if the animal health status of a protection zone changes due to the occurrence of a case or the implementation of vaccination, the animal health status of the rest of the country or zone would not be affected.

The Code Commission also added a new paragraph regarding some specificities for the implementation of this concept for diseases for which the OIE grants official recognition of animal health status, including its temporality condition. Further details on the practical impact for the official status recognition procedures can be found in the Scientific Commission's February 2020 report.

Additionally, since the use of the term 'protection zone' in point 4(b) and point 7 of Article 4.4.7 would not be in line with the new definition of Protection Zone, the Code Commission revised the text of point 4(b) and point 7 of Article 4.4.7 for consistency.

The revised Articles 4.4.6 and 4.4.7 are attached as **Annex 21** for Member comments.

**EU comment**

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

**Comments are inserted in the text of Annex 21.**

**7.5. Animal welfare during slaughter (Revised Chapter 7.5)**

Comments were received from Australia, Argentina, China (People's Republic of), Japan, Mexico, New Caledonia, New Zealand, Norway, Switzerland, USA, the EU and the International Coalition for Animal Welfare (ICFAW).

Background

The OIE *ad hoc* Group on the Revision of Chapter 7.5, Slaughter of animals, and Chapter 7.6, Killing of animals for disease control purposes, has met three times (April 2018, November 2018, and June 2019) to progress work on a comprehensive review of Chapters 7.5 and 7.6. The objective of this review is to resolve inconsistencies in the methods used in the slaughter of animals and the killing of

animals for disease control purposes; to propose amendments to ensure that the text reflects current scientific knowledge; and to review the structure of both chapters. At its September 2019 meeting, the Code Commission reviewed the work of the *ad hoc* Group and agreed to seek Member comments on the new proposed structure of Chapter 7.5, Animal welfare during slaughter.

Discussion

**General comments**

The Code Commission noted that Member comments were supportive of the approach taken by the *ad hoc* Group.

In response to a comment concerned that some important information currently present in the chapter, e.g. the tables, may be lost in this revision, the Code Commission reminded Members that figures and tables not to be included in the revised chapters will be published on the OIE Website as has been done for the figures showing the recommended positions to perform different stunning methods that were removed from Chapters 7.5 and 7.6 when it was revised in 2016.

The Code Commission requested that the *ad hoc* Group be reconvened to continue its work to finalise development of the revised draft Chapter 7.5, Animal Welfare during slaughter, to include the recommendations on animals arriving in crates and containers, also taking into account some guidance provided by the Commission.

The Code Commission also requested the *ad hoc* Group to discuss the implications on the use of the term 'hazard' in the chapter and whether there is a need to amend the current definition of the Glossary to include animal welfare considerations.

The Code Commission noted a comment regarding the translation of the term 'killing' in Spanish and requested that the *ad hoc* Group consider whether there is a better translation for 'killing' in both Spanish and French taking into consideration the use of this term throughout the Spanish and French editions of the *Terrestrial Code*, and the use of this term in the definition for 'stamping-out'.

**EU comment**

**The EU thanks the OIE for its work on the revision of this new chapter and welcomes further efforts for its finalisation.**

**7.6. Infection with animal trypanosomes of African origin (Chapter 8.Y)**

Comments were received from Australia, China (People's Republic of), New Zealand, Switzerland, USA, and the EU.

Background

In February 2019, the Code Commission considered the assessments undertaken by the *ad hoc* Group on Animal trypanosomes of African origin that had been endorsed by the Scientific Commission. The *ad hoc* Group had conducted assessments for 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*. The Code Commission had proposed to amend Article 1.3.1 (of Chapter 1.3, Diseases, infections and infestations listed by the OIE) to include 'Infection with animal trypanosomes of African origin (*T. vivax*, *T. congolense*, *T. simiae* and *T. brucei*)' and to delete 'Trypanosomosis (tsetse-transmitted)' from Article 1.3.2.

Also at its February 2019 meeting, the Code Commission reviewed the new draft Chapter 8.Y, Infection with animal trypanosomes of African origin, that had been developed by the *ad hoc* Group, and circulated it for comments.

Discussion

**Article 8.Y.1**

In point 1, the Code Commission agreed with a comment to amend the text of the third sentence for clarity.

In the same point, the Code Commission did not agree with a comment to add 'wildlife including' before 'non-human primates', as it considered this reference would be unprecise and unclear. The Commission agreed with other proposed amendments to improve the clarity of the text.

In point 2, the Code Commission agreed with a comment to amend the text to include 'although not always evident using routine testing methods' to improve clarity.

In points 7 and 8, the Code Commission agreed to remove the reference to 'in susceptible animals', as it considered it was unnecessary given that the general definitions in this article address this point.

**Article 8.Y.2**

In the first paragraph, the Code Commission did not agree with a comment to add 'in accordance with Chapter 2.2'. The Commission recalled that this was standard text used throughout the *Terrestrial Code* for articles on safe commodities.

The Code Commission, in agreement with the Scientific Commission, considered that although transmission of infection with animal trypanosomes of African origin had occurred in carnivores as a result of feeding on infected dead animals, it agreed that based on available evidence, the risk of transmission via meat derived from animals slaughtered in a slaughterhouse and subjected to ante- and post-mortem inspections (this being a non-specific standardised risk mitigation process), is negligible. Consequently, the Commission proposed to include a new commodity, point 5, 'meat from animals that have been slaughtered in a slaughterhouse/abattoir and have been subjected to ante-and post-mortem inspections with favourable results' to the list of safe commodities and to delete Articles 8.Y.11 and 8.Y.12.

The Code Commission, in agreement with the Scientific Commission, agreed with Member comments that, based on the available evidence, the risk of transmission of infection with animal trypanosomes of African origin via semen from clinically healthy donors and embryos is negligible. Consequently, the Commission proposed to include new commodities, point 8 'semen collected and processed in accordance with Chapter 4.6' and point 9 'embryos' to the list of safe commodities and to delete Articles 8.Y.7 to 8.Y.10.

**Article 8.Y.3**

In point 2, the Code Commission agreed with a comment to amend the text for consistency with the definition of commodities.

In point 3(b)(ii) the Code Commission agreed with a comment to delete 'compartment', noting that this article only refers to 'Country or zone free'.

**Article 8.Y.4**

The Code Commission did not agree with a comment to delete the whole article. Although the Commission acknowledged the difficulties of implementing compartmentalisation for vector-borne diseases, the Commission agreed there was value in keeping this article to indicate that although difficult compartmentalisation was a possible disease control strategy. The Commission agreed that it was not possible to provide detailed recommendations that would fit all country situations and reminded Members that the provisions provided in Chapters 4.4 and 4.5 should be used, including for bilateral recognition of the compartment.

**Article 8.Y.6**

In the title, the Code Commission did not agree with a comment to delete 'compartment', noting that as the article refers to recommendations for the importation of susceptible species, all options of risk

mitigation measures or strategies should be included. This same rationale was applied to similar comments in other articles.

In the title, the Code Commission agreed with a comment to remove the subheading 'For susceptible species' and include 'of susceptible animals' within the title for consistency.

**Previous Article 8.Y.7 (deleted)**

As discussed under Article 8.Y.2, the Code Commission proposed to list 'semen collected and processed in accordance with Chapter 4.6' as a safe commodity and consequently proposed the deletion of Article 8.Y.7.

**Previous Article 8.Y.8 (deleted)**

As discussed under Article 8.Y.2, the Code Commission proposed to list 'semen collected and processed in accordance with Chapter 4.6' as a safe commodity and consequently proposed the deletion of Article 8.Y.8.

**Previous Article 8.Y.9 (deleted)**

As discussed under Article 8.Y.2, the Code Commission proposed to list 'embryos' as a safe commodity and consequently proposed the deletion of Article 8.Y.9.

**Previous Article 8.Y.10 (deleted)**

As discussed under Article 8.Y.2, the Code Commission proposed to list 'embryos' as a safe commodity and consequently proposed the deletion of Article 8.Y.10.

**Previous Article 8.Y.11 (deleted)**

As discussed under Article 8.Y.2, the Code Commission proposed to list 'meat that have been slaughtered in a slaughterhouse and have been subjected to ante-and post-mortem inspections with favourable results' as a safe commodity and consequently proposed the deletion of Article 8.Y.11.

**Previous Article 8.Y.12 (deleted)**

As discussed under Article 8.Y.2, the Code Commission proposed to list 'meat from animals that have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante-and post-mortem inspections with favourable results' as a safe commodity and consequently proposed the deletion of Article 8.Y.12.

**Article 8.Y.8 (Previous Article 8.Y.14)**

In point 2(a) the Code Commission agreed to delete the reference to 'compartment', as it was not relevant to this article.

In point 2(b) the Code Commission agreed with a comment and amended the text in line with Chapter 1.4, Animal health surveillance.

In this same point, the Code Commission did not agree with a comment to add a new point stating that 'the identification of any trypanosomes of the subgenuses Duttonella, Nannomonas and Trypanozoon in susceptible animals should be reported to the OIE as an infection with animal trypanosomes of African origin'. The Commission explained that, although it might be difficult to differentiate the species of trypanosomes causing an infection, Members must notify OIE listed diseases in accordance with Chapter 1.1 by using the diagnostic methods available.

**Article 8.Y.9 (Previous Article 8.Y.15)**

In point 2(c), the Code Commission did not agree with a comment to delete 'serological' and add 'on appropriate tests, such as serological or molecular methods' at the end of the sentence. Taking into

consideration the advice of the Biological Standards Commission, the Commission explained that molecular methods are used for confirmation following an initial screening identification by serology and that molecular techniques are further developed in point 3).

In point 4(d), the Code Commission, considering the advice of the Scientific Commission and the Biological Standards Commission, agreed with a comment and amended the wording of points 4(d), 4(d)(i) and 4(d)(ii) for clarity.

In point 6, the Code Commission agreed with a comment to amend the text for clarity and added a reference to Chapter 1.5, Surveillance for arthropod vectors of animal diseases.

**Article 8.Y.10 (Previous Article 8.Y.16)**

In the first paragraph, the Code Commission agreed to add 'established in accordance with Article 4.4.7' after 'containment zone', given that no specific provisions are included in this disease-specific chapter regarding containment zones.

The draft new Chapter 8.Y, Infection with animal trypanosomes of African origin, is attached as **Annex 22** for Member comments.

**EU comment**

**The EU thanks the OIE and in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 22.**

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

Comments were received from China (People's Republic of), Switzerland, USA and the EU.

Background

Proposed amendments to Chapter 8.15 were first circulated in the Code Commission's February 2019 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 chapter has been circulated twice for Member comments.

Discussion

**General comments**

In response to a comment to include the name of the commodity, for example 'susceptible animals' in the title of the trade related articles instead of as subheadings, the Code Commission agreed to apply this for consistency throughout this chapter, where relevant. The Commission noted that this practice has not been applied consistently throughout the disease-specific chapters of the *Terrestrial Code* and will standardise this progressively as the chapters are being revised.

The Code Commission did not agree with a comment to delete the word attacks in 'vector attacks' throughout the text as it considered that the key emphasis was to protect against 'vector attacks', given that the presence of vectors may be ubiquitous.

**Article 8.15.1**

In point 2(a), the Code Commission agreed with a comment to replace 'occurs' with 'is occurring' to indicate that the epizootic is ongoing.

In point 2(b), the Code Commission did not agree with a comment to include 'geographic' before 'distribution' as distribution in this context is not limited to geographical (spatial) distribution but could also refer to host distribution.

In points 4(b) and 4(c), the Code Commission proposed to add 'including in a human' after 'case of RVF' to oblige the notification of cases in animals when there are no virus isolations and only findings of RVF antigen or ribonucleic acid or seropositivity, without an epidemiological link to an animal case, but when cases in humans make it highly likely that there is active infection in animals.

In point 5, the Code Commission agreed with a comment from the Scientific Commission to include the incubation period of RVF to facilitate the establishment of appropriate risk mitigation measures by Members. Considering that sufficient information exists on the incubation period for RVF (refer to technical disease card available at https://www.oie.int/fileadmin/Home/eng/Animal_Health_in_the_World/docs/pdf/Disease_cards/RIFT_VALLEY_FEVER.pdf), the Code Commission proposed to add 'and the incubation period shall be seven days' to point 5.

In point 6, the Code Commission accepted a comment to include 'and other' before environmental conditions as climatic conditions are considered environmental conditions.

**Article 8.15.4**

In the first sentence, the Code Commission agreed with a comment to replace 'comply with' with 'meet the requirements', for consistency with the term used in Article 8.15.3.

**Article 8.15.5**

In the first sentence, the Code Commission did not agree to replace 'measures' with 'options' as the term 'include' already implies that all the measures listed are not mandatory.

In point 3, the Code Commission did not agree with a comment to add 'any equivalent measures that protect against any attacks by vectors' to the end of the point. The Commission clarified that the list contains possible risk management measures that Members may employ to protect against vector attacks and Members have the discretion to use any of these measures.

**Article 8.15.6**

In point 2(b), the Code Commission agreed with a comment to delete 'during transportation to the place of shipment' for clarity.

**Article 8.15.7**

In point 1, the Code Commission did not agree with a comment to include 'compatible with' after 'clinical sign' in Article 8.15.7 and throughout the text as it considered this to be unnecessary. Furthermore, this would not be consistent with the rest of the *Terrestrial Code.*

In point 2, the Code Commission did not agree with a comment to include 'at least' before 'one of the following conditions' as it is sufficient to have just one of the two conditions met.

In point 2(b), the Code Commission did not accept a comment to replace 'or' with 'and/or', for consistency, as in this instance 'or' includes the concept of 'and'.

In point 3(a), the Code Commission agreed to delete 'during transportation to the place of shipment' for clarity, as with the amendment to point 2(b) in Article 8.15.6.

**Article 8.15.8**

In the title of the article, the Code Commission did not agree with a comment to add 'period' after epizootic as 'epizootic' is used as a noun in this context and not as an adjective. The Commission highlighted that this is different from 'inter-epizootic period' where 'inter-epizootic' is used as an adjective.

In point 4, the Code Commission agreed with a comment to include 'AND' after the semicolon for consistency with the other articles in this chapter.

**Article 8.15.9**

In the title of this article, the Code Commission did not agree with a comment to replace 'infected' after 'countries or zones' with 'affected' as this would be inconsistent with the rest of the *Terrestrial Code*. This rationale applies to the rest of the text where the Member had provided the same comment.

In point 2(b), the Code Commission did not agree with a comment to add 'to the appropriate neutralising antibodies' after 'seropositive' as it considered this too detailed for the *Terrestrial Code.* Such information can be found in Chapter 3.1.18, Rift Valley fever (Infection with Rift Valley fever virus), of the *Terrestrial Manual*. Nonetheless, the Commission proposed amendments to this point for consistency with the wording across the *Terrestrial Code* and replaced 'demonstrated to be seropositive' with 'subjected to a serological test' and added 'with positive result' at the end of the point.

In point 2(c), the Code Commission did not agree with a comment to replace 'within 14 days of semen or embryo collection' with 'at a 14-day interval with negative results and completed within 7-10 days prior to the day of semen or embryo collection'. The Commission did not agree with the rationale provided by the Member that it is imperative to confirm a negative RVFV status of the donor animals prior to collection. While it agreed with the Scientific Commission that the collection of semen from an RVF infected animal could pose a risk to the human handler, the Code Commission explained that provisions for personnel performing such activities are covered in Chapter 4.6, General hygiene in semen collection and processing centres. The Commission clarified that the rationale for requiring paired seronegative samples is to ensure the detection of animals that might have become infected on the day of semen or embryo collection. For consistency with the wording used in the *Terrestrial Code*, the Commission proposed the following text 'were subjected to a serological test on two occasions with negative results on the day of collection and 14 days after collection'.

**Article 8.15.10**

In point 1, the Code Commission did not agree with a comment to add 'the following' after 'the entire consignment of meat comes from' as it considered this to be unnecessary.

In point 1(c), the Code Commission did not agree with a comment to replace 'submitted to maturation' with 'maturated' as this proposal was not consistent with the usage of this term in the rest of the *Terrestrial Code.*

In point 2, the Code Commission agreed with a comment that 'products' may be interpreted to exclude fresh meat, and thus replaced 'products' with 'meat' for clarity. Consequently, the Commission did not agree with a comment to add 'as applicable (see Article 8.15.10bis below)' after 'meat' as it considered this point to have been addressed.

**Article 8.15.10bis**

The Code Commission did not agree with a comment to replace 'meat' with 'susceptible animals' and explained that as per the Glossary definition for 'meat products', meat products are derived from meat and thus it would be more appropriate to refer to 'meat'.

The Code Commission did not agree with a comment to replace 'complies with' with 'are managed in compliance with provisions listed in' as it did not consider that the proposal improved the existing text.

**Article 8.15.11**

The Code Commission did not agree with a comment to replace 'subjected to pasteurisation' with 'pasteurised' as the proposal was not consistent with the use of this term in the rest of the *Terrestrial Code*. Furthermore, 'pasteurisation' is a Codex-defined term widely understood by Members.

**Article 8.15.12**

The Code Commission reiterated to the OIE Secretariat that further guidance on surveillance would be beneficial for Members, in particular surveillance during the inter-epizootic period in order to facilitate an early warning system indicating the start of an epizootic period.

The revised Chapter 8.15, Infection with Rift Valley fever virus, is attached as **Annex 23** for Member comments.

**EU comment**

**The EU in general supports the proposed changes to this chapter. One comment is inserted in the text of Annex 23.**

**7.8. Infestation with *Aethina tumida* (small hive beetle) (Article 9.4.5)**

Background

At its September 2019 meeting, the Code Commission received a comment to modify points 2 and 3 of Article 9.4.5 concerning the timing of inspection prior to export and area freedom from the occurrence of *Aethina tumida*, and requested the OIE Secretariat to consult experts on the proposal.

At this meeting, the Code Commission considered the comment together with the advice provided by two OIE Reference Laboratory experts and thanked them for their contributions.

Discussion

**Article 9.4.5**

In point 2, the Code Commission did not agree to replace 'immediately prior to dispatch' with 'in the 72 hours prior to the packing of the bees for export' as inspecting colonies immediately prior to dispatch ensures that no observable adult or larvae of *A. tumida* are present in the hive. Inspecting the hive 72 hours after packaging leaves sufficient time for one or several adults of *A. tumida* to enter the hive unobserved. However, the Commission proposed to replace 'immediately prior to dispatch' with 'on the day of packing' for clarity.

In point 3, the Code Commission did not agree to delete this point and invited the Member to submit a more comprehensive rationale to justify the deletion. The Commission agreed with the OIE Reference Laboratory experts that the absence of detection of *A. tumida* in an area was an important risk mitigation measure. However, considering the comment from one of the OIE Reference Laboratory experts that 100 km might be excessive, the Commission proposed to replace '100 km' with '50 km', which in conjunction with other measures, is currently used as an effective import risk mitigation measure by some Members.

Revised Article 9.4.5 is attached as **Annex 24** for Member comments.

**EU comment**

**The EU thanks the OIE and in general supports this revised Article 9.4.5. Comments are inserted in the text of Annex 24.**

**7.9. Avian mycoplasmosis (*Mycoplasma gallisepticum*) (Chapter 10.5)**

Background

In view of the proposed amendments to Chapter 3.3.5, Avian mycoplasmosis (*Mycoplasma gallisepticum*, *M. synoviae*), of the *Terrestrial Manual* to include a new table for available test methods and their purpose, the Code Commission, as per its work programme, commenced the work to review Chapter 10.5, Avian mycoplasmosis (*Mycoplasma gallisepticum*). The Commission thanked the OIE Reference Laboratory expert who provided comments.

Discussion

**Article 10.5.2**

In point 3, the Code Commission considered the comments of the expert, and proposed amendments to include provisions for an 'agent identification test' and 'serological test'. The Commission highlighted that the *Terrestrial Code* should not duplicate information in the *Terrestrial Manual* on diagnostic tests to be performed and reminded Members to refer to the *Terrestrial Manual* for standards on diagnostic tests.

**Article 10.5.3**

In point 3, in considering comments from the expert, the Code Commission proposed to replace 'a diagnostic test' with 'agent identification test'.

The Code Commission highlighted that this circulation signalled the beginning of the review of Chapter 10.5. The chapter would be further improved for consistency with the other disease-specific chapters in the *Terrestrial Code* as the Commission progressed with the review.

The revised Chapter 10.5, Avian mycoplasmosis *(Mycoplasma gallisepticum)*, is attached as **Annex 25** for Member comments.

**EU comment**

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

**Comments are included in the text of Annex 25.**

**7.10. Infection with equine influenza virus (Article 12.6.6)**

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

Background

At the Code Commission's February 2019 meeting, it had proposed amendments to Article 12.6.6 based on the results of a clinical trial coordinated by an OIE Reference Laboratory for equine influenza. The revised article has been circulated twice for Member comments.

Discussion

**Article 12.6.6**

In point 2, a comment requested replacing 'on the day of shipment' with 'within 24 hours prior to shipment' as shipment may be carried out on the calendar day following the day when the clinical examination is performed. The Code Commission did not agree to specify '24 hours' as it considered this to be implied.

In points 3(a) and 3(b), the Code Commission, in consultation with the Scientific Commission, did not agree with a comment to replace '14 and 90 days' with '21 and 90 days'. The Code Commission did not accept the rationale provided by the Member that this is the protocol followed by bilateral agreements and that horses should not receive vaccinations during the pre-export isolation period. The Commission explained that there is no contraindication against vaccinating animals during the pre-isolation period and highlighted that the vaccination protocol was based on a study that the horses seroconverted within 14 days after being vaccinated. The Commission added that it would be up to Members to negotiate their own bilateral agreements if in disagreement with the *Terrestrial Code*, based on an import risk analysis.

In point 3(b), a comment was submitted to delete this point as the scientific basis for this vaccination protocol has not yet been published. The Code Commission, in agreement with the Scientific Commission and the Biological Standards Commission, noted that the basis for this recommendation was in the final 2018 technical report from the OIE Reference Laboratory for equine influenza that evaluated equine influenza vaccination protocols prior to shipment. The information supporting the

proposed changes are covered in this report, although not yet publicly available. Given the validity of the findings, the Commission did not agree to delete point 3(b).

In the same point, the Code Commission agreed with a comment to replace 'previously' with 'up to the date of this pre-shipment vaccination' for clarity. The Commission did not agree to add 'consecutive' before 'four doses' as it considered that it was implicit and did not improve the existing text.

In the last sentence, a comment was submitted to add 'first sample collected' before 'four to six days after' and 'second sample collected within' before 'four days of shipment'. The Code Commission did not agree to specify 'first sample' and 'second sample' as it considered this to be implied. However, it replaced 'prior to' with 'within' to clarify that the second collection should take place during the four days before shipment.

The revised Article 12.6.6 is attached as **Annex 26** for Member comments.

**EU comment**

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

**8. Date of next meeting**

The next meeting will be held from 1–10 September 2020.

_____

…/Annexes

Annex 3

**EU comment**

**The EU thanks the OIE and in general supports the revised work programme of the Code Commission.**

**In particular, while acknowledging the important progress made so far, we would like to stress the importance of finalising the revision of the chapter on BSE that has been ongoing for many years. The future revised chapter should establish a proportionate and balanced framework for the control of BSE, addressing the comments we provided to the OIE in December 2019 (available here at p. 281-312 https://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_comments_tahsc-report_201909.pdf).**

**Furthermore, we welcome work on a new chapter on the application of zoning that should be treated as a priority. Indeed, much guidance is still urgently needed for many member countries in this "classical" animal disease control tool that is such a crucial basis for safe and fair international trade in animals and animal products on which other more recent and less used tools such as compartmentalisation can build.**

**Finally, we wish to reiterate our proposal for the OIE to progress on the revision of Chapter 6.10. on prudent and responsible use of antimicrobial agents, for which the EU had suggested a revised text in December 2018 (available here at p. 199-212 https://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_position_tahsc-report_201809.pdf). Indeed, now that the permanent OIE Working Group on AMR is well established, there is no reason why the OIE should not be pro-active and move forward in this important public health area where more detailed guidance is needed to further progress the international data collection on veterinary use of antimicrobial agents.**

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

| Subject | Issue by priority order | Status and Action (Onset of process / # of rounds for comments post-meeting) |
|---|---|---|
| **Horizontal chapters** | | |
| **General aspects** | 1) Work with AAHSC towards harmonisation, as appropriate, of the horizontal parts of the *Codes,* 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 and SCAD for accurate disease description and diagnostic in the *Manual* and case definitions in the *Code* and names of diseases and country and zone disease status | Ongoing<br>- Approach to the issue of 'case definitions' was agreed. |
| | 3) Revision and formatting of chapters (articles numbering, tables and figures) | Ongoing |

| Subject | Issue by priority order | Status and Action (Onset of process / # of rounds for comments post-meeting) |
|---|---|---|
| | 4) Revision of the Users' Guide | Ongoing<br>- Last amendments were proposed for adoption in May 2021. |
| | 5) Use of terms:<br>- biosecurity / sanitary measures<br>- disease / infection / infestation<br>- animal health status | Ongoing |
| **Glossary** | 1) 'epidemiological unit' | Proposed for adoption in May 2021 (Sep 2018/4th) |
| | 2) 'Competent Authority', 'Veterinary Authority'. 'Veterinary Services' | Ongoing |
| | 3) 'captive wild [animal]', 'feral [animal]' and 'wild [animal]' | Proposed for adoption in May 2021 (Sep 2018/3rd) |
| | 4) Review animal welfare terms 'death', 'distress', 'euthanasia', 'pain', 'slaughter', 'stunning' and 'suffering' | Revised and new definitions sent for comments (Sep 2019/2nd) |
| | 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 |
| **Horizontal issues not yet in the *Code*** | | |
| **Section 3. Veterinary Services** | 1) New introductory CH in Section 3 | Sent for comments (Sep 2019/2nd) |

Annex 3 (contd)

| Subject | Issue by priority order | Status and Action (Onset of process / # of rounds for comments post-meeting) |
|---|---|---|
| **Section 4. Disease control** | 1) New CH on official control programmes for listed and emerging diseases | Proposed for adoption in May 2021 (Feb 2017/ 7th) |
| | 2) New CH on biosecurity | Preliminary discussion<br>- Work in progress regarding guideline on ASF compartmentalisation;<br>- swill feeding to be further studied. |
| | 3) New CH on application of zoning | Preliminary discussion |
| **Section 6. Veterinary public health** | 1) Control of Shiga toxin-producing *E. coli* (STEC) in food-producing animals | Preliminary discussion pending FAO/WHO expert consultation |
| **Section 7. Animal welfare** | 1) New CH on animal welfare and laying hen production systems | Proposed for adoption in May 2021 (Sep 2017/4th) |
| **Horizontal chapters in need of revision** | | |
| **Section 1. Animal disease diagnosis, surveillance and notification** | 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 | Proposed for adoption in May 2021 (Feb 2018/5th) |
| | 2) CH 1.1 on notification of diseases, infections and infestations, and provision of epidemiological information | Proposed for adoption in May 2021 (Sep 2018/4th) |
| | 3) CH 1.3 on listed diseases:<br>• Avian influenza | Proposed for adoption in May 2021 |
| | 4) CH 1.3 on listed diseases:<br>• MERS-CoV<br>• Trypanosomes | Sent for comments (Sep 2019/2nd) |
| | 5) CH 1.3 on listed diseases:<br>• Chronic wasting disease<br>• Theileriosis (*T. lestoquardi*, *T. luwenshuni*, *T. uilenbergi* and *T. orientalis*)<br>• West Nile fever<br>• *M. paratuberculosis* | Ongoing or preliminary discussion |
| **Section 3. Veterinary Services** | 1) CH 3.4 on veterinary legislation | Proposed for adoption in May 2021 (Sep 2018/4th) |
| | 2) CHs 3.1 and 3.2 on Veterinary Services | Revised CHs sent for comments (Sep 2019/2nd) |
| **Section 4. Disease control** | 1) CH 4.4 on zoning and compartmentalisation | Revised CH sent for comments (Feb 2020/1st) |
| | 2) CH 4.6 on general hygiene in semen collection and processing centres | Ongoing |

Annex 3 (contd)

| Subject | Issue by priority order | Status and Action (Onset of process / # of rounds for comments post-meeting) |
|---|---|---|
| **Section 4. Disease control (contd)** | 3) CH 4.7 on collection and processing of semen | Ongoing |
| | 4) BVD in collection and processing of *in vitro* derived embryos (Inclusion in CH 4.9) | Ongoing |
| | 5) CH 4.14 on disinfection | Preliminary discussion |
| | 6) CH 4.8 on collection and processing of *in vivo* derived embryos | Preliminary discussion |
| | 7) CH 4.9 on collection and processing of oocytes and *in vitro* produced embryos from livestock and horses | Preliminary discussion |
| **Section 5. Trade measures** | 1) CHs 5.4 to 5.7 on measures applicable at departure and on arrival | Preliminary discussion |
| | 2) CH 5.12 on model certificates for competition horses | Preliminary discussion and pending revision of CHs on horse diseases |
| **Section 6. Veterinary public health** | 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 |
| **Section 7. Animal welfare** | 1) CH 7.5 on slaughter and CH 7.6 on killing of animals | CH 7.5 – AHG to address some Member comments and finalise the drafting (Onset: Sep 2019)<br>CH 7.6 – pending work of AHG |
| | 2) CH 7.7 on stray dog population control | Pending work of AHG |
| **Diseases not yet in the *Code*** | | |
| **Disease-specific chapters** | 1) New CH on animal trypanosomoses of African origin | Sent for comments (Sep 2019/2nd) |
| | 2) New CH on surra (and revision of CH on Dourine) | Pending progress in the work on new chapter on Trypanosomes of African origin |
| | 3) New CH on Crimean Congo hemorrhagic fever (MCs comments, listed disease without chapter) | Preliminary discussion |
| **Listed disease chapters/articles in need of revision** | | |
| **Sections 8 to 15** | 1) CH 10.4 on avian influenza | Proposed for adoption in May 2021 (Sep 2018/3rd) |

Annex 3 (contd)

| Subject | Issue by priority order | Status and Action (Onset of process / # of rounds for comments post-meeting) |
|---|---|---|
| **Sections 8 to 15 (contd)** | 2) CH 14.7 on peste des petits ruminants (Harmonisation of articles regarding official status recognition by the OIE) | Proposed for adoption in May 2021 (Feb 2019/3rd) |
| | 3) CH 15.2 on classical swine fever | Proposed for adoption in May 2021 (Feb 2017/4th) |
| | 4) CH 8.15 on Rift Valley fever virus | Sent for comments (Feb 2019/3rd) |
| | 5) CH 11.4 on bovine spongiform encephalopathy and CH 1.8 Questionnaire | AHG to address some Member comments (Onset: Feb 2015) |
| | 6) CH 11.10 on Theileriosis and new CH 14.X on infection with *Theileria* in small ruminants | Ongoing (Onset: Sep 2017/1st) |
| | 7) CH 12.6 on equine influenza | Sent for comments (Sep 2019/2nd) |
| | 8) CH 10.5 on avian mycoplasmosis | Sent for comments (Feb 2020/1st) |
| | 9) CH 9.4 on *Aethina tumida* (Small hive beetle) | Sent for comments (Feb 2020/1st) |
| | 10) CH 8.8 on foot and mouth disease | Pending outcome of discussion on protection zone (CH 4.4) (Onset: Sep 2015) |
| | 11) CH 12.3 on dourine | Pending progress in the work on new chapter on Trypanosomes of African origin |
| | 12) CH 8.16 on rinderpest | Pending work of AHG |
| | 13) CH 15.4 on porcine cysticercosis (request from WHO) | Pending expert advice |
| | 14) CH 8.5 on infection with *Echinococcus granulosus* (request from WHO) | Pending expert advice |
| | 15) Revision of safe commodities list to add lactose | Ongoing |
| | 16) CH 12.2 on contagious equine metritis | Pending work of HQs and expert advice |
| | 17) CH 12.7 on equine piroplasmosis | Pending work of HQs and expert advice |
| | 18) CH 8.11 on *Mycobacterium tuberculosis* complex | Ongoing |
| | 19) Revision of Article 15.3.9 on import of semen from countries not free from PRRS | Pending expert advice |

Annex 3 (contd)

| Subject | Issue by priority order | Status and Action (Onset of process / # of rounds for comments post-meeting) |
|---|---|---|
| **Sections 8 to 15 (contd)** | 20) CH 14.8 on scrapie | Pending expert advice |
| | 21) Pet food (for certification or safe commodities) | Pending expert advice |
| | 22) CHs on equine encephalomyelitis (Eastern, Western, Venezuelan) – inclusion of case definitions | Preliminary discussion |
| **Follow-up revision of chapters recently adopted** | | |
| **Recently adopted chapters** | 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 | *Ad hoc* Group |
| AMR | Antimicrobial resistance |
| AW | Animal Welfare |
| BSC | Biological Standards Commission |
| CH | Chapter |
| HQs | Headquarters |
| MERS-CoV | Middle East respiratory syndrome coronavirus |
| SCAD | Scientific Commission for Animal Diseases |
| WHO | World Health Organization |

Annex 4

# USER'S GUIDE

[...]

**EU comment**

**The EU thanks the OIE and supports the proposed changes to 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 recognition ~~assessment~~ of the animal 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.

[...]

Annex 5

# GLOSSARY

**EU comment**

**The EU thanks the OIE and in general supports the proposed changes to the Glossary.**

**One comment in relation to the definition of 'poultry' is inserted in the text below.**

***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.~~

***EPIDEMIOLOGICAL UNIT***

means a group of *animals* with ~~a defined epidemiological relationship that share approximately~~ the same likelihood of exposure to a pathogenic agent. In certain circumstances, the epidemiological unit may be a single animal.~~. 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.~~

***FERAL [ANIMAL]***

means an *animal* of a domesticated species that now lives without ~~direct~~ requiring human supervision or control.

***POULTRY***

means all ~~domesticated~~ birds~~, including backyard poultry,~~ reared or kept in captivity ~~used~~ for the production of ~~*meat* or eggs for consumption, for the production of other~~ any commercial animal products~~, for restocking supplies of game,~~ or for breeding ~~these categories of birds~~ for this purpose, ~~as well as~~ fighting cocks used for any purpose, and all birds used for restocking supplies of game or for breeding for this purpose, until they are released from captivity.

Birds that are kept in a single household, the products of which are used within the same household exclusively, are not considered *poultry*, provided that they have no direct or indirect contact with *poultry* or *poultry* facilities.

Birds that are kept in captivity for ~~any~~ other reasons ~~other than those reasons referred to in the preceding paragraph~~, including those that are kept for shows, ~~races~~ racing, exhibitions, zoological collections and competitions, ~~or~~ and for breeding or selling ~~these categories of birds~~ for these purposes, as well as pet birds, are not considered ~~to be~~ *poultry*~~.~~, provided that they have no direct or indirect contact with *poultry* or *poultry* facilities.

**EU comment**

**We are pleased to see that in the definition of 'poultry' birds kept in a single household for the same reasons as poultry (e.g. production of products, breeding, etc.) will not be**

**considered 'poultry' when they have no direct or indirect contact with poultry. However, we consider that adding the same phrase for birds kept for other reasons (the last paragraph above), means that any of those birds, even a pet bird, should be considered as 'poultry' if they have direct or indirect contact with poultry. According to the definition in Chapter 10.4., HPAI is the disease in poultry, therefore this will mean that in case that those birds have contact with poultry, an outbreak in those birds will need to be considered as HPAI and this will affect the status of the country. This is also a deviation from the current definition of 'poultry'.**

**For the above reasons, we would like to suggest that the last phrase of the last paragraph is deleted to read:**

**"Birds that are kept in captivity for other reasons, including those that are kept for shows, racing, exhibitions, zoological collections and competitions, and for breeding or selling for these purposes, as well as pet birds, are not considered *poultry*~~, provided that they have no direct or indirect contact with *poultry* or *poultry* facilities~~".**

***WILD [ANIMAL]***

means an *animal* that has a phenotype unaffected by human selection and lives independently ~~of direct~~ without requiring human supervision or control.

Annex 6

# CHAPTER 1.1.

# NOTIFICATION OF DISEASES~~, INFECTIONS AND INFESTATIONS,~~ AND PROVISION OF EPIDEMIOLOGICAL INFORMATION

**EU comment**

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

**We would like to suggest, to avoid any confusion, that changes such as 'immediate notification within 24 hours' that has been replaced by 'initial notification', and any other changes to the Code that affects WAHIS, that all are reflected in WAHIS, including the guidelines.**

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, the number and geographical distribution of affected animals and *epidemiological units*.

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) ~~I~~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:

   *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;

   ~~*d*~~*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*;

   ~~*e*~~*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~~;~~. E~~f~~or 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 has been ~~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.~~6~~5.

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.~~5~~4. and other relevant information.

Annex 7

CHAPTER 1.4.

# ANIMAL HEALTH SURVEILLANCE

**EU comment**

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

[ … ]

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.

*d)* Epidemiological unit

The relevant *epidemiological unit* for the *surveillance* system should be defined. To meet the objective of *surveillance*, the sampling *unit* selected for testing should reflect the defined *epidemiological unit* ~~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.

[…]

Annex 8

# 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 supports the proposed changes to this chapter.**

Article ~~1.6.21bis~~.1.6.1.

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

A Member Country~~ies~~ 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~~ CBPP;

   *b)* an *official control programme* for ~~foot and mouth disease~~ FMD;

   *c)* an *official control programme* for ~~peste des petits ruminants.~~PPR;

   *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.~~

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.~~3~~4. 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)~~[1] 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 recognition of a free *zone* ~~being~~ that is adjacent to another *zone* of the same status, it should be stated ~~if~~ whether the new *zone* is being merged or kept separate. If the proposed *zone* remains separate, details should be provided ~~of on~~ the control of the movement of ~~susceptible animals and their products~~ relevant *commodities* between the *zones* in accordance with Chapter 4.~~3~~4.

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. Within 24 months of suspension, ~~A~~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*.

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.

[1] ~~http://www.oie.int/en/animal-health-in-the-world/official-disease-status/official-recognition-policy-and-procedures/~~

Annex 8 (contd)

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 Country~~ries~~ 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~~ publication by the OIE ~~publish~~ of the self-declaration to ~~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)[2] 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, a~~A~~n *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 Country~~ies~~ 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.

Annex 9

# CHAPTER 3.4.

# VETERINARY LEGISLATION

**EU comment**

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

**One comment is 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~~.

Annex 9 (contd)

Article 3.4.3.

**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.

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.

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~~, and should provide legal certainty and protect citizens, animals and the environment against unintended adverse side effects of legal instruments. ~~It~~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.

Article 3.4.4.

**The drafting of veterinary legislation**

*Veterinary legislation* should:

1) be drafted in a manner that establishes clear ~~authorities~~ powers, rights, responsibilities and obligations (i.e. 'normative');

~~2)~~ ~~be unambiguous, with clear and consistent syntax and vocabulary;~~

~~3~~2) ~~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 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*;

~~7~~8) 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

~~8~~9) 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~~ coherent~~ly to~~ and effective~~ly~~ 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 ~~or~~ 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 of *commodities* and fomites; ~~and~~
- ~~–~~ destruction of ~~*animals*, products and food of animal origin~~ *commodities* and fomites;
- ~~*vi)* –~~ suspension of one or more activities of a~~n 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~~.~~;
- ~~establishment of compensation mechanisms;~~
- listing disease for mandatory reporting; and
- ordering of *disinfection, disinfestation* 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**

~~1.~~ ~~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*;~~

~~*c)* 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;~~

~~*c)* 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~~s~~*;

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~~ In the event that a Member Country is yet to 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~~ registered 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~~.

*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, packaging, labelling and quality control of animal feed in relation to the biological, chemical and physical *risks* of disease transmission;

*bc)* registration and, if necessary, approval of establishments facilities and the provision of health requirements for relevant operations; and

*cd)* distribution and use of animal feed in relation to the biological, chemical and physical *risks*; and

*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)* 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 logistic~~s~~ ~~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~~ abandoned 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 biologicals~~ medicinal products**

*Veterinary legislation* should provide a basis for assuring the quality of *veterinary* ~~medicines and biologicals~~ *medicinal products* and minimising the *risk* to human, animal and environmental health associated with their use, including the development of antimicrobial resistance, as described in Chapters 6.7. to 6.11.

1. General measures

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

*a)* definition of *veterinary* ~~medicines and biologicals~~ *medicinal products*, including any specific exclusions; and

*b)* regulation of the authorisation, importation, manufacture, ~~safety, efficacy,~~ ~~distribution~~ wholesale, retail, and usage of, ~~and~~ commerce in, and disposal of safe and effective *veterinary* ~~medicines and biologicals~~ *medicinal products*~~, including laboratory biosafety and biosecurity measures~~.

2. Raw materials for use in veterinary ~~medicines and biologicals~~ 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 biologicals~~ *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~~

~~*c*~~*b)* ~~requirements for~~ restrictions on substances in *veterinary* ~~medicines and biologicals~~ *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 biologicals~~ *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:

**EU comment**

**To have a more complete picture, in bullet point d) above, we suggest including other enforcement procedures, to read as follows:**

**"d) In defining the procedures for seeking and granting, suspending, withdrawing, 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.~~

~~5~~4. ~~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 and good distribution practices as appropriate;

*d)* reporting on adverse effects to the *Competent Authority*; and

*e)* mechanisms for traceability and recall.

~~6~~5. 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;

~~*d*~~*e)* the supervision by an authorised professional of organisations approved for the holding and use of *veterinary* ~~medicines and biologicals~~ *medicinal products*;

~~*e*~~*f)* the regulation of advertising claims and other marketing and promotional activities~~, including a system of *surveillance* for falsification~~; ~~and~~

~~*f*~~*g)* a system of *surveillance* of the quality of *veterinary medicinal products* marketed in the country, including a system of *surveillance* for falsification; and

*h)* a system for the reporting on adverse effects to the *Competent Authority*.

Article 3.4.12.

**Human food production chain**

*Veterinary legislation* should provide a basis for actions to safeguard the human food production chain through controls at all critical steps, consistent with national food safety standards 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*~~*b)* controls over all stages of the production, processing and distribution of food of animal origin;

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

~~*c*~~*d)* giving operators of food production ~~premises~~ facilities the primary responsibility for compliance with food safety requirements, including traceability established by the *Competent Authority*;

~~*d*~~*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;~~

~~*c*~~*a)* health standards including measures to control diseases, and monitoring and enforcement of maximum residue levels (MRL); ~~and~~

~~d~~*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.

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~~s~~ 2 Risk Analysis and Section 5 Trade measures, import/export procedures and veterinary certification.

Annex 10

CHAPTER 4.Y.

# OFFICIAL CONTROL PROGRAMMES ~~MANAGEMENT OF OUTBREAKS OF~~ FOR LISTED AND EMERGING ~~AND LISTED~~ DISEASES

**EU comment**

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

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 purpose~~s~~ 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. ~~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 analysis*~~e~~s 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.;

~~4~~5) regular and prompt animal disease reporting;

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 ~~eliminateing~~ minimising transmission;

~~5~~7) measures implemented to prevent introduction or spread of the relevant ~~disease~~ *infection* or *infestation*, including *biosecurity* and *sanitary measures* ~~including~~ such as movement control;

~~6~~8) a *vaccination* programme, ~~as~~ if ~~relevant~~ appropriate;

~~7~~9) ~~preparedness and contingency plans~~ measures to protect public health, ~~as~~ if appropriate;

~~8~~10) communication and collaboration ~~with other~~ among all relevant *Competent Authorities*~~.~~;

11) awareness programme for relevant stakeholders including the general public if appropriate.

~~In any case,~~ T~~t~~he 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~~ an *early* ~~*detection*~~ *warning system* ~~(including a warning procedure),~~ ~~and~~ 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 support~~ing~~ 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 a~~n~~ *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 investigation~~s~~ 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*;

– 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~~s~~ 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;

– 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 gain~~ing~~ or recovery of status, as relevant.

Article 4.Y.3.

**Emergency ~~P~~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, ~~Rrapid and effective response to a new occurrence or emergence of contagious infectious diseases~~ is dependent 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 ~~P~~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 testing of 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~~ an emergency response 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.

Annex 10 (contd)

Article 4.Y.4.

**Surveillance and early warning ~~detection~~ systems**

~~1)~~ 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, ~~*V*~~*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. ~~It~~ This depends on the ~~application~~ implementation of a combination of measures ~~that are~~ operating at the same time or consecutively~~.~~. These measures should aim~~ed~~ at:

1) ~~epidemiological investigation to~~ trace~~e~~ing ~~back and~~ forward and backward animals in contact and potentially infected or contaminated ~~products~~ *commodities* or fomites through epidemiological investigation~~:~~:

~~1~~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 disposal or treatment of other potentially contaminated ~~products~~ *commodities* and fomites, such as beddings and single use clothing and equipment;

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

~~2~~3) ~~stopping~~ preventing the spread of disease, *infection*~~,~~ or *infestation* through:

- movement restrictions on ~~*animals*~~ *commodities* and fomites, ~~*vehicles*, and equipment and people,~~ as appropriate;

- *biosecurity*;

- *vaccination*, treatment or ~~culling~~ selective *killing* 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~~ selective *killing* 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~~ selective *killing* 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~~ tThe 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~~ Selective killing 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~~ selective *killing* of *animals* is often a ~~the~~ preferred strategy for the control of ~~contagious~~ transmissible diseases.

*Veterinary Services* should adapt any strategy for ~~culling~~ selective *killing* 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~~ ~~o~~Other 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~~2. and 4.~~2~~3.

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 4.1~~2~~3.

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~~ Selective *killing* 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 susceptible *animals*. These ~~S~~slaughtered *animals* and their products should be processed separately from others.

~~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~~ for either *slaughter* or *killing* and disposeal ~~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~~ killed, 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~~ other ~~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 fomite~~s~~ (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.

Article 4.Y.8.

**Zoning**

The *Veterinary Authority* should use the tool of zoning in *official control programmes*, in accordance with Chapter 4.~~3~~4.

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 *zone~~s~~*, such as *zones* where *specific surveillance, vaccination* or other activities are conducted, can also be used.

Article 4.Y.~~8~~9.

**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~~.~~ ~~i~~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 4.1~~3~~4. 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.~~9~~10.

**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.~~17~~18.

*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 level~~s are~~ is low enough for the implementation of another strategy~~ies~~ such as a 'test and cull' strategy.

*Vaccination* ~~can~~ may also be used to minimise the impact of an *infection* by reducing clinical signs or economic losses.

Annex 10 (contd)

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~~.

Treatment can also be used as part of an *official control programme.* It ~~would~~ requires 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~~ selective *killing* 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.

Annex 10 (contd)

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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Annex 11

DRAFT CHAPTER 7.Z.

# ANIMAL WELFARE AND LAYING HEN PRODUCTION SYSTEMS

**EU comment**

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

**The EU regrets that after three rounds of revisions none of the key comments have been satisfactorily addressed despite including solid scientific evidence to support our comments. The EU comments have been aimed to ensure good level of animal welfare in line with the guiding principles in Chapter 7.1., Article 7.1.2.**

**The fact that the provision of dust bathing areas, foraging areas, nesting areas and perches still remain only *"desirable"* in the current revision of this Chapter will not lead to any real improvement of the welfare conditions for laying hens. The importance for hens to have an access to such facilities is scientifically based and proven to work in practice.**

**In this context, the EU cannot support guidelines that do not clearly require laying hen producers to provide the aforementioned basic facilities.**

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.

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 data and 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 in English, may be useful indicators of layer pullet or laying hen welfare:

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].

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~~ it is ~~are~~ motivated to perform, and ~~,~~ a good understanding of ~~their~~ its normal behaviour [Nicol, 2015], including ~~their~~ its 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~~ motivated behaviour providing body maintenance benefits. During dust bathing, layer pullets and laying hens ~~remove~~ ~~work~~ work 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~~ Good plumage condition 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~~ performance 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 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 in response to novel objects or when people, including *animal handlers,* walk through the pullet and hen areas of the poultry house [Jones, 1996; Waiblinger *et al* 2006].

*c)* Feeding and drinking behaviour

Changes in feeding or drinking behaviour ~~can~~ ~~may~~ may 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 is often reduced when pullets or hens are ill. *Feed* or water intake may also change as a result of heat stress [Lara L. J. & Rostagno ~~M. H.~~, 2013; Lin H. *et al.*, 2006] or cold stress [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~~ *feed*, 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~~ opportunity [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].

*e)* Injurious feather pecking and cannibalism

Injurious feather pecking can result in significant feather loss and may lead to cannibalism. Cannibalism is the tearing of the flesh of another layer pullet or laying hen, and ~~can~~ may result in severe injury, secondary *infection* 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].

*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 such as access to, or the suitability of nesting sites or disturbance by other layer pullets and laying hens [Cronin *et al.*, 2012; Cooper and Appleby, 1996; Gunnarsson *et al.*, 1999; Yue and Duncan, 2003; Widowski *et al.*, 2013].

*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, such as inadequate perch or poor space design, injuries or pullet rearing experience [Janczak and Riber, 2015; 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].

~~*i)*~~ Social behaviour

Layer p~~P~~ullets and laying 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].

~~*j*~~*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].

~~*k*~~*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.

~~*l*~~*m)* Vocalisation

Vocalisation ~~can~~ may indicate emotional states, both positive and negative. A good understanding of *flock* vocalisations and their causes is useful for good *flock* management ~~good *animal welfare*~~ [Zimmerman *et al.*, 2000; Bright, 2008; Koshiba *et al*., 2013].

3. Body condition

Poor body condition ~~is reflective~~ may indicate ~~of~~ *animal welfare* problems for individual layer pullets 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.

4. Eye conditions

Conjunctivitis ~~can~~ may indicate disease or the presence of irritants such as dust and ammonia. High ammonia levels ~~can~~ may also cause corneal burns and eventual blindness. Abnormal eye development ~~can may~~ may 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, infestations and 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~~ may be a consequence of the actions of other layer pullets and laying 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~~ poor flooring leading to foot injury), 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.

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 measure~~s~~ 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 and weight 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 [Blokhuis, 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 conditions impacting *animal 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~~ may arise in any system if one or more of these ~~elements~~ factors 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.

Annex 11 (contd)

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 layer pullets and laying hens are housed.

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. They should also be maintained to avoid injury or discomfort. Layer p~~P~~ullet and laying 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 the welfare of layer pullets and laying hens ~~welfare~~.

Outcome-based measurables include: body condition~~, culling and morbidity rates~~, dust bathing, fear behaviour, feeding and drinking behaviour, foot problems, foraging behaviour, incidence of diseases, *infections* and *infestations* and metabolic disorders, injury rates and severity, locomotory and comfort behaviours, ~~mortality rates~~, mortality, culling and morbidity rates, nesting, perching, performance ~~indicators~~, plumage condition, resting and sleeping, social behaviour and spatial distribution, thermoregulatory behaviour and vocalisations.

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* and metabolic disorders, injurious feather pecking and cannibalism, injury rate and severity, locomotory and comfort behaviours, mortality ~~rate~~, culling and morbidity rates, 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. Problems with space allowance may increase stress and the occurrence of injuries.

The following factors, in alphabetical order in English, should be considered when determining space allowance:

– age and ~~mass~~ weight 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*, *infestations* and metabolic disorders, injurious feather pecking and cannibalism, ~~*infections* and *infestations*,~~ injury rate and severity, locomotory and comfort behaviours, mortality rate, culling and morbidity rates, 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 layer pullets to access appropriate *feed* and water.

Outcome-based measurables include: body condition, foraging behaviour, incidence of diseases, *infections*, i*nfestations* and metabolic disorders, ~~injurious feather pecking, injury rate and severity, metabolic disorders,~~ mortality, culling and morbidity rates, 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~~ promote good health and allow the performance of ~~normal~~ behaviours, such as comfort and locomotory 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. The flooring should be easy to clean and disinfect.

When ~~litter~~ substrate is provided, it should allow the performance of behaviours, such as comfort and locomotory behaviours and be managed to remain dry and friable, and adequately treated or replaced when required to prevent disease and minimise any detrimental effects on *animal welfare*.

Annex 11 (contd)

Outcome-based measurables include: dust bathing, foot problems, foraging behaviour, incidence of diseases, *infections*, ~~and~~ *infestations* and metabolic disorders, injurious feather pecking, 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* and metabolic disorders, injurious feather pecking and cannibalism, 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. Foraging areas should be easy to inspect and maintain.

Outcome-based measurables include: foraging behaviour, incidence of diseases, *infections*, ~~and~~ *infestations* and metabolic disorders, injurious feather pecking and cannibalism, injury rate and severity and spatial distribution.

Article 7.Z.12.

**Nesting areas**

Access to 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. Nesting areas should be easy to inspect, clean and maintain.

Outcome-based measurables include: incidence of diseases, *infections*, ~~and~~ *infestations* and metabolic disorders, 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 layer pullets and laying 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].

Outcome-based measurables include: foot problems, injurious feather pecking and cannibalism, Incidence of diseases, *infections, infestations* and metabolic disorders, injury rate and severity, perching, plumage condition, resting and sleeping and spatial distribution.

Annex 11 (contd)

Article 7.Z.14.

**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 layer pullets and laying 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.

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]. Layer pPullets and laying 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* and metabolic disorders, injury rate and severity, locomotory and comfort behaviours, mortality, culling and morbidity and mortality rates, performance, plumage condition, social behaviour, spatial distribution, thermoregulatory behaviour and vocalisation.

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.

Although layer pullets and laying 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.

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 problems with the system can be detected and corrected before they cause an an *animal welfare* problem.

Outcome-based measurables include: mortality, culling and morbidity rate, mortality rates, 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. 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].

Annex 11 (contd)

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*, *infestations* and metabolic disorders, morbidity, culling 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, to allow layer pullets and laying hens to find *feed* and water, to stimulate activity, to stimulate onset of lay, to minimise the likelihood of injurious feather pecking and cannibalism, and to allow adequate inspection [Prescott *et al.*, 2003; Prescott and Wathes, 1999; Green *et al.*, 2000].

There should also be an adequate period of 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 if ~~during induced~~ moulting is practised, during which ~~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 and comfort 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, morbidity, culling and mortality rates, 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 layer pullet and laying 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],

– choosing genetics associated with a low propensity for injurious feather pecking [Craig and Muir, 1996; Kjaer and Hocking, 2004],

– increasing age at onset of lay [Pötzsch, 2001],

– increasing space allowance during rearing [Jung and Knierim, 2018],

– managing light ~~in~~ 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].

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 euthanised.

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: foraging behaviour, injurious feather pecking and cannibalism, injury rate and severity, mortality, ~~and~~ culling and morbidity rates, plumage condition, and vocalisation.

Article 7.Z.20.

**Moulting**

Induced moulting ~~can~~ may 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 lights 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 welfare of laying hens ~~welfare~~, including their welfare during the subsequent laying period. Total mortality and culling rates during the moulting period should not exceed normal variations in *flock* mortality and culling rates.

Outcome-based measurables include: body condition, feeding and drinking, foraging behaviour [Biggs *et al.*, 2004; Saiozkan *et al.*, 2016; Petek and Alpay, 2008], injurious feather pecking and cannibalism, injury rate and severity, ~~morbidity~~ ~~rate,~~ mortality, ~~and~~ culling and morbidity rates, 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~~ may 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.

Outcome-based measurables include: beak condition, body condition, feeding and drinking behaviour, foraging behaviour, injurious feather pecking and cannibalism, locomotory and comfort behaviours, mortality, culling ~~rate,~~ and morbidity rates, performance, plumage condition and vocalisations.

Article 7.Z.22.

**Animal health management, preventive medicine and veterinary treatment**

*Animal handlers* responsible for the care of layer pullets and laying 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.

Annex 11 (contd)

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 layer pullets and laying hens should be placed in a hospital area for observation and treatment, or euthanised in accordance with Chapter 7.6. as soon as possible.

Outcome-based measurables include: body condition, incidence of diseases, *infections*, ~~metabolic disorders and~~ ~~,~~*infestations* and metabolic disorders, injury rate and severity, mortality ~~morbidity~~, culling ~~rate, and mortality~~ and morbidity rates 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: mortality, culling and morbidity rates, incidence of diseases, *infections*, *infestations* and metabolic disorders~~, mortality rate,~~ and performance ~~indicators~~.

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:

– bone fractures or other injuries,

– diagnostic purposes,

– disaster management,

~~–~~ ~~diagnostic purposes,~~

– emaciation,

– 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 a layer pullet or a laying hen ~~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 layer pullet and laying 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. Laying ~~H~~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, culling and morbidity rates ~~at depopulation and on arrival at the destination~~, 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, evacuation procedures 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*, ~~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 e~~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: mortality, culling~~,~~ and morbidity ~~and mortality~~ rates.

Annex 11 (contd)

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 layer pullet and laying 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, *infections*, *infestations* and metabolic disorders, locomotory and comfort behaviours, performance, mortality, culling and morbidity rates, 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 or in outdoor facilities should be inspected at least daily. Inspection should have the following objectives:

– to collect and remove dead layer pullets and laying hens and dispose of them in accordance with Chapter 4.13.;

– to identify sick or injured layer pullets and laying hens and treat or euthanise 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 or outdoor facilities, 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, culling and morbidity rates, performance, spatial distribution and vocalisation.

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, culling and morbidity rates, performance, spatial distribution and vocalisation.

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Annex 12A

CHAPTER 10.4.

# INFECTION WITH HIGH PATHOGENICITY AVIAN INFLUENZA VIRUSES

**EU comment**

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

**In particular, we wish to thank the OIE for taking into consideration our previous comments.**

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

Article 10.4.1.

**General provisions**

1) This chapter deals with the *listed disease*, *infection* with high pathogenicity avian influenza viruses.

2) For the purposes of the *Terrestrial Code*:

*a)* High pathogenicity avian influenza means an *infection* of *poultry* by any influenza A virus that has been determined as high pathogenicity in accordance with the *Terrestrial Manual*.

*b)* An occurrence of *infection* with a high pathogenicity avian influenza virus is defined by the isolation and identification of the virus or the detection of specific viral ribonucleic acid, in one or more samples from *poultry*.

*c)* The *incubation period* at the *flock*-level for high pathogenicity avian influenza is 14 days.

3) 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, and *infection* of birds other than *poultry,* including *wild* birds, with influenza A viruses of high pathogenicity, are notifiable in accordance with Article 1.3.6.

**EU comment**

**For reasons of consistency, the EU suggests replacing "and" with "or" in the 3rd sentence of point 3 above ("[...], in domestic ~~and~~ or captive wild birds, [...]").**

4) A *notification* of *infection* of birds other than *poultry,* including *wild* birds, with influenza A viruses of high pathogenicity, or of *infection* of *poultry* or *captive wild* birds with low pathogenicity avian influenza viruses does not affect the high pathogenicity avian influenza status of the country or *zone*. A Member Country should not impose bans on the trade of *poultry commodities* in response to such *notifications*, or to other information on the presence of any influenza A virus in birds.

**EU comment**

**We believe there is a problem with the use of the term "poultry" in the second line of the paragraph above ("[...] or of infection of poultry or captive wild birds with low pathogenicity avian influenza viruses does not affect the high pathogenicity avian influenza status of the country or zone."). Indeed, using "poultry" here would mean that non-poultry (e.g. domestic pet birds, or "birds that are kept in a single household, the products of which..." in the meaning of the definition of poultry in Annex 5) would not be covered. Hence, the phrase "~~poultry~~ domestic or captive wild birds" should be used instead, which would also be consistent with the wording used in Articles 10.4.1.3., 10.4.20. and 1.3.6. (Annex 13). Please note that the EU comment in Annex 13 relating to the use of the term "domestic" – which seems not to be defined – remains pertinent and is also relevant in the context of Articles 10.4.1.3., 10.4.1.4. and 10.4.20. In any case, the use of the terms in these articles should be consistent, to avoid any confusion.**

**Furthermore, we usually do not insist on previous comments that have not been accepted by the Code Commission but we believe our previous comment on the above paragraph is pertinent to avoid unnecessary barriers to trade. However, it seems that our comment was not considered in full since the explanation given in the report of the Code Commission for not accepting the comment only refers to the definition of commodities. For this reason we are re-submitting a part of the suggestions for your consideration.**

**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*, 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."**

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) The use of *vaccination* against avian influenza may be recommended under specific conditions. Any vaccine 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* can be used as an effective complementary control tool when a *stamping-out policy* alone is not sufficient. Whether to vaccinate or not should be decided by the *Veterinary Authority* on the basis of the avian influenza situation as well as the ability of the *Veterinary Services* to implement the *vaccination* strategy, as described in Chapter 4.18.

7) Standards for diagnostic tests and vaccines, including pathogenicity testing, are described in the *Terrestrial Manual*.

Article 10.4.1bis.

**Safe commodities**

When authorising importation or transit of the following *commodities*, *Veterinary Authorities* should not require any conditions related to high pathogenicity avian influenza, 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 an $F_0$ value of 3 or above;

2) extruded dry pet food and 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.

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.

**Country or zone free from high pathogenicity avian influenza**

A country or *zone* may be considered free from high pathogenicity avian influenza when:

– *infection* with high pathogenicity avian influenza viruses is a *notifiable disease* in the entire country;

– an ongoing awareness programme is in place to encourage reporting of suspicions of high pathogenicity avian influenza;

– 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;

– an awareness programme is in place related to *biosecurity* and management of avian influenza viruses;

**EU comment**

**We believe and have already provided a comment expressing that it will be better that the above bullet point has more narrative to be clearer in its purpose, for example using the following text: "An awareness programme is in place, related to ~~*biosecurity* and management~~ the main risks and specifc measures necessary to mitigate them, including tailored biosecurity measures and prevention of introduction of avian influenza viruses".**

– *commodities* are imported in accordance with Articles 10.4.3. to 10.4.17bis.

*Surveillance* should be adapted to parts of the country or existing *zones* depending on historical or geographical factors, industry structure, population data and proximity to recent *outbreaks* or the use of *vaccination*.

Article 10.4.2bis.

**Compartment free from high pathogenicity avian influenza**

The establishment of a *compartment* free from high pathogenicity avian influenza should be in accordance with relevant requirements of this chapter and the principles described in Chapters 4.4. and 4.5.

Article 10.4.2ter.

**Establishment of a containment zone within a country or zone free from high pathogenicity avian influenza**

In the event of *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 purpose 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 4.4.7., 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*, the presence and potential role of birds other than *poultry*, including *wild* birds, and the proximity of *poultry establishment*s to 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 10.4.2quater., once the *containment zone* is clearly established. It should be demonstrated that *commodities* for *international trade* have originated from outside the *containment zone* or comply with the relevant articles of this chapter.

Article 10.4.2quater.

**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 may be regained after a minimum period of 28 days (i.e. two *flock*-level *incubation period*s) after a *stamping-out policy* has been completed (i.e. after the *disinfection* of the last affected *establishment*), provided that *surveillance* in accordance with Articles 10.4.20. to 10.4.22ter., in particular point 3 of Article 10.4.22., has been carried out during that period and has demonstrated the absence of *infection*.

If a *stamping-out policy* is not implemented, Article 10.4.2. applies.

Article 10.4.3.

**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) the *poultry* originated from a country, *zone* or *compartment* free from high pathogenicity avian influenza;

3) the *poultry* originated from a *flock* that was monitored for avian influenza viruses and was found to be negative;

4) the *poultry* are transported in new or appropriately 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 stated in the *international veterinary certificate*.

Article 10.4.4.

**Recommendations for the importation of live 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:

1) on the day of shipment, the birds showed no clinical signs of avian influenza;

2) the birds had been kept in isolation facilities approved by the *Veterinary Services* since they were hatched or for at least 28 days (i.e. two *flock*-level *incubation periods*) prior to shipment and showed no clinical signs of avian influenza during the isolation period;

3) a statistically appropriate sample of the birds was subjected, with negative results, to a diagnostic test for avian influenza within 14 days prior to shipment;

4) the birds are transported in new or appropriately sanitised *containers*.

If the birds have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be stated in the *international veterinary certificate*.

Article 10.4.5.

**Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza**

For day-old live poultry

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

1) the day-old live *poultry* had been kept in a country, *zone* or *compartment* free from high pathogenicity avian influenza since they were hatched;

   and

   *a)* the day-old live *poultry* were derived from parent *flocks* that were monitored for avian influenza viruses and were found to be negative at the time of collection of the eggs from which the day-old *poultry* hatched; or

   *b)* the day-old live *poultry* that hatched from eggs that had had their surfaces sanitised in accordance with point 4 d) of Article 6.5.5.;

AND

2) the day-old live *poultry* were transported in new or appropriately 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 stated in the *international veterinary certificate*.

Article 10.4.6.

**Recommendations for the importation of day-old live 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:

1) on the day of shipment, the birds showed no clinical signs of avian influenza;

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, with negative results, to a diagnostic test for avian influenza at the time of collection of the eggs;

4) the birds were transported in new or appropriately 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 stated in the *international veterinary certificate*.

Article 10.4.7.

**Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza**

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 high pathogenicity avian influenza;

2) *a)* the hatching eggs were derived from parent *flocks* that were monitored for avian influenza viruses and were found to be negative at the time of collection of the hatching eggs; or

*b*) the hatching eggs have had their surfaces sanitised in accordance with point 4 d) of Article 6.5.5.;

3) the hatching eggs are transported in new or appropriately 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 stated in the *international veterinary certificate*.

Article 10.4.8.

**Recommendations for the importation of hatching eggs 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:

1) a statistically appropriate sample of the parent *flock* birds was subjected, with negative results, to a diagnostic test for avian influenza 14 days prior to and at the time of collection of the hatching eggs;

2) the hatching eggs have had their surfaces sanitised in accordance with point 4 d) of Article 6.5.5.;

3) the hatching eggs are transported in new or appropriately 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 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, with negative results, to a diagnostic test for avian influenza within 14 days prior to semen collection.

Article 10.4.11.

**Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza**

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 high pathogenicity avian influenza;

2) the eggs for human consumption were transported in new or appropriately sanitised packaging materials and *containers*.

Article 10.4.12.

**Recommendations for the importation of egg products from 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:

1) the egg products are derived from eggs which meet the requirements of Article 10.4.11.; or

2) the egg products have been processed to ensure the inactivation of high pathogenicity avian influenza viruses, in accordance with Article 10.4.18.;

AND

3) the necessary precautions were taken to avoid contact of the egg products with any source of high pathogenicity avian influenza viruses.

Article 10.4.13.

**Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza**

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 originated from a country, *zone* or *compartment* free from high pathogenicity avian influenza;

2) which were slaughtered in an approved *slaughterhouse/abattoir* in a country, *zone* or *compartment* free from high pathogenicity avian influenza and were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., with favourable results.

Article 10.4.14.

**Recommendations for the importation of meat products from 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:

1) the *meat products* from *poultry* are derived from *fresh meat* which meets the requirements of Article 10.4.13.; or

2) the *meat products* from *poultry* have been processed to ensure the inactivation of high pathogenicity avian influenza viruses in accordance with Article 10.4.19.;

AND

3) the necessary precautions were taken to avoid contact of the *meat products* from *poultry* with any source of high pathogenicity avian influenza viruses.

Article 10.4.15.

**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 obtained from *poultry* which originated in a country, *zone* or *compartment* free from high pathogenicity avian influenza and that the necessary precautions were taken to avoid contamination during processing with any source of high pathogenicity avian influenza viruses;

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 reached at least 74°C; or

*c)* any equivalent treatment that has been demonstrated to inactivate avian influenza viruses;

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of high pathogenicity avian influenza viruses.

Article 10.4.16.

**Recommendations for the importation of feathers and down from poultry not listed in Article 10.4.1bis.**

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

1) these *commodities* originated from *poultry* as described in Article 10.4.13. and were processed in 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)* fumigation with formalin (10% formaldehyde) for 8 hours;

*b)* irradiation with a dose of 20 kGy;

*c)* any equivalent treatment which has been demonstrated to inactivate avian influenza viruses;

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of high pathogenicity avian influenza viruses.

Article 10.4.17.

**Recommendations for the importation of feathers and down of birds other than poultry not listed in Article 10.4.1bis.**

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 using one of the following:

*a)* fumigation with formalin (10% formaldehyde) for 8 hours;

*b)* irradiation with a dose of 20 kGy;

*c)* 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 high pathogenicity avian influenza viruses.

Article 10.4.17bis.

**Recommendations for the importation of collection specimens, skins and trophies of 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:

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 10.4.18.

**Procedures for the inactivation of high pathogenicity avian influenza viruses in egg products from poultry**

The following time/temperature combinations are suitable for the inactivation of high pathogenicity avian influenza viruses present in 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 |

These time/temperature combinations are indicative of a range that achieves a 7-$\log_{10}$ reduction of avian influenza virus infectivity. These are examples for a variety of egg products but, when supported by scientific evidence, variations of these time/temperature combinations may be used, and they may be used for other egg products, if they achieve equivalent inactivation of the virus.

Article 10.4.19.

**Procedures for the inactivation of high pathogenicity avian influenza viruses in meat products from poultry**

The following time/temperature combinations are suitable for the inactivation of high pathogenicity avian influenza viruses in *meat products*.

| | **Core temperature (°C)** | **Time** |
|---|---|---|
| Meat products from poultry | 60.0 | 507 seconds |
| | 65.0 | 42 seconds |
| | 70.0 | 3.5 seconds |
| | 73.9 | 0.51 second |

These time/temperature combinations are indicative of a range that achieves a 7-$\log_{10}$ reduction of avian influenza virus infectivity. When supported by scientific evidence, variations of these time/temperature combinations may be used if they achieve equivalent inactivation of the virus.

Article 10.4.19bis.

**Procedures for the inactivation of high pathogenicity avian influenza viruses in collection specimens and in skins and trophies**

For the inactivation of high pathogenicity avian influenza viruses in collection specimens and in skins and trophies, one of the following procedures should be used:

1) boiling in water for an appropriate time to ensure that any 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-$Na_2CO_3$) 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, treatment for at least 28 days with salt (NaCl) containing 2% washing soda (sodium carbonate-$Na_2CO_3$); 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 10.4.20.

**Principles of surveillance for avian influenza**

The following are complementary to Chapter 1.4. and should be applied by Member Countries seeking to determine their high pathogenicity avian influenza status.

These principles are also necessary to support *vaccination* programmes, to monitor low pathogenicity avian influenza viruses, especially H5 and H7, in *poultry* and to detect high pathogenicity avian influenza in *wild* birds.

The impact and epidemiology of avian influenza differ widely among different regions of the world and therefore it is impossible to provide detailed recommendations for all situations. Variables such as the frequency of contacts between *poultry* and *wild* birds, different *biosecurity* levels and production systems, and the commingling of different susceptible species including domestic waterfowl, may require different *surveillance* strategies to address each situation. Furthermore, domestic waterfowl 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 explain the epidemiology of avian influenza in the region of concern and also to demonstrate how all the risk factors have been taken into account. Member Countries have flexibility to provide a science-based approach to demonstrate absence of *infection* with high pathogenicity 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:

1) Some H5 and H7 low pathogenicity avian influenza viruses have the potential to mutate into high pathogenicity avian influenza viruses and currently it is not possible to predict whether and when this mutation will occur.

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 is notifiable in accordance with Article 1.1.3.

**EU comment**

**For reasons of consistency, the EU suggests replacing "and" with "or" in point 3 above ("[...], in domestic ~~and~~ or captive wild birds, [...]").**

Article 10.4.21.

**Surveillance for early warning of high pathogenicity avian influenza**

1) An ongoing *surveillance* programme for avian influenza should be in 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.

2) The high pathogenicity avian influenza *surveillance* programme should include the following.

*a)* An *early warning system* for reporting suspected *cases*, in accordance with Article 1.4.5. throughout the production, marketing and processing chain. Farmers and workers who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of avian influenza to the *Veterinary Authority*. All suspected *cases* of high pathogenicity avian influenza should be investigated immediately and samples should be taken and submitted to a *laboratory* for appropriate tests.

*b)* Implementation, as relevant, of regular and frequent clinical inspection, or serological and virological testing, of high-risk groups of *animals*, such as those adjacent to a country or *zone* infected with high pathogenicity avian influenza, 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)* Immediate investigation of the presence of antibodies against influenza A viruses that have been detected in *poultry* and are not a consequence of *vaccination*. 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*.

Article 10.4.22.

**Surveillance for demonstrating freedom from infection with high pathogenicity avian influenza**

1. A Member Country declaring freedom of the entire country, a *zone* or a *compartment* from high pathogenicity avian influenza in *poultry* should provide evidence 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 design of the *surveillance* programme will depend on the epidemiological circumstances and it should be planned and implemented in accordance with this chapter and Article 1.4.6. 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).

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.

The sampling strategy may be risk-based if scientific evidence is available, and provided, for the quantification of risk factors. Specific risks could include those linked to the types of production, possible direct or indirect contact with *wild* birds, multi-age *flocks*, local trade patterns including live bird markets, use of possibly contaminated surface water, the presence of more than one species at the *establishment* and poor *biosecurity* in place.

Data from different *surveillance* activities can be included to increase the sensitivity of the *surveillance* system. If this is to be done, data from structured (e.g. surveys and active *surveillance*) and non-structured (e.g. passive *surveillance*) sources should be combined and the sensitivity of each activity should be quantified in order to be able to quantify the sensitivity of the overall *surveillance* system.

The *surveillance* programme should include *surveillance* for high pathogenicity avian influenza viruses in birds other than *poultry,* including *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 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 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. Based on the epidemiology of avian influenza in the country, *zone* or *compartment*, a decision may be reached to vaccinate only certain species or other *poultry subpopulations*.

In all vaccinated *flocks* tests should be performed to ensure the absence of virus circulation. The tests should be repeated at a frequency that is proportionate to the *risk* in the country, *zone* or *compartment*. The use of sentinel *poultry* may provide further confidence in the absence of virus circulation.

Member Countries seeking the demonstration of freedom from high pathogenicity avian influenza in vaccinated population should refer to the chapter on avian influenza (*infection* with avian influenza viruses) 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 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. The use of sentinel birds may facilitate the interpretation of *surveillance* results.

*Populations* under this *surveillance* programme should include:

*a)* *establishments* in the proximity of the *outbreaks*;

*b)* *establishments* epidemiologically linked to the *outbreaks*;

*c)* *poultry* used to re-populate affected *establishments*;

*d)* any *establishments* where preventive depopulation has been carried out.

Article 10.4.22bis.

**Surveillance of wild bird populations**

Passive *surveillance*, i.e. sampling of birds found dead, is an appropriate method of *surveillance* in *wild* birds because *infection* with high pathogenicity avian influenza 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, including through the collection and submission of samples to a *laboratory* for appropriate tests.

Active *surveillance,* i.e. sampling of live *wild* birds, 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.

*Surveillance* in *wild* birds should be targeted towards times of year, species and locations in which *infection* is more likely.

*Surveillance* in *wild* birds should be enhanced by raising awareness, 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 10.4.22ter.

**Monitoring of low pathogenicity avian influenza in poultry populations**

*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 should be in place.

*Monitoring* the presence and types of low pathogenicity avian influenza viruses can be achieved through a combination of clinical investigation when *infection* is suspected because of changes in production parameters, such as reductions in egg production or *feed* and water intake, and active serological and virological *surveillance*, which can be supported by the information obtained by the *surveillance* system for high pathogenicity avian influenza.

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 whether there is clustering of infected *flocks* regardless of whether the seropositive birds are still present at the *establishment* or whether active virus *infection* has been detected. Hence, *monitoring* of low pathogenicity avian influenza will also enhance early detection of high pathogenicity avian influenza.

Annex 13

# CHAPTER 1.3.

# DISEASES, INFECTIONS AND INFESTATIONS LISTED BY THE OIE

**EU comment**

**The EU thanks the OIE and in general supports the proposed changes to the category of avian diseases and infections.**

**One comment is included in the text below.**

[…]

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 of birds other than *poultry*, including *wild* birds, with influenza A viruses of high pathogenicity ~~in birds other than *poultry* including wild birds~~
– Infection of domestic and *captive wild* birds with low pathogenicity avian influenza viruses having proven natural transmission to humans associated with severe consequences

**EU comment**

**We would like to understand what category of birds are included under "domestic birds". There is not such definition in the Glossary of the Code and in fact the term 'domestic' has been removed from the current definition of poultry in Annex 5. Glossary.**

**We believe that they refer to poultry, other birds than poultry (racing, shows, single household, exhibitions, zoological collections and competitions) and pet birds, but we would like confirmation that this is the case.**

– Infection with Newcastle disease virus
– Infectious bursal disease (Gumboro disease)
– Pullorum disease
– Turkey rhinotracheitis.

[…]

_____

Annex 14

CHAPTER 14.7.

# INFECTION WITH PESTE DES PETITS RUMINANTS VIRUS

**EU comment**

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

[...]

Article 14.7.3.

**~~PPR free c~~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;

~~5~~6) 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.~~

~~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 compliance with all points above and relevant ~~points~~ provisions 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 ~~3~~4) 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.

[...]

Article 14.7.7.

**Recovery of free status**

~~When~~ Should an ~~a PPR~~ *outbreak* of PPR ~~or PPRV *infection*~~ occur~~s~~ in a previously ~~PPR~~ free country or *zone*, its status may be ~~restored~~ recovered ~~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 of the country or *zone* will be reinstated only after the submitted evidence has been accepted by the OIE.

Annex 14 (contd)

[…]

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 ($Na_2CO_3$);

   *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.~~

A Member Country~~ies~~ may, on a voluntary basis, apply for endorsement of ~~their~~ its *official control programme* for PPR in accordance with Chapter 1.6., when ~~they~~ it has ~~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~~ary~~ 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*;

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~~ performs ~~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, it should be in accordance with Chapter 4.18. and~~,~~ documented~~ary~~ 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)* the strategy to identify vaccinated animals;

*vi)* technical specification of the vaccines used and description of the vaccine licensing procedures in place;

*vii)* ~~if relevant, proposed timeline for the transition to the~~ use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;

*viii)* the proposed strategy and work plan including the timeline for ~~the~~ transition to the cessation of ~~the use of~~ *vaccination*;

4) ~~*b)*~~ 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*;

~~5~~7) performance indicators for assessing the effectiveness of the control measures to be implemented;

~~6~~8) 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 14 (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.~~

Annex 15

CHAPTER 15.2.

# INFECTION WITH CLASSICAL SWINE FEVER VIRUS

**EU comment**

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

**We have included one comment within the body of the text in Article 12.2.19ter.**

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 range~~ing~~, 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 pig~~s~~ 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 pig~~s~~ ~~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.~~

~~*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 an $F_0$ 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.~~3~~2.

**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;~~

1~~3~~) 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~~4~~) 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) if relevant, the domestic and *captive wild* pig populations ~~are~~ have been separated by appropriate *biosecurity*, effectively implemented and supervised, from the *wild* and *feral* pig populations, based on the assessed likelihood of spread of the disease 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 1.6.910. 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 compliance with all points above and relevant ~~points~~ provisions 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.~~4~~3.

**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 15.2.3bis.

**Country or zone infected with CSFV**

A country or *zone* shall be considered as infected with CSFV when the requirements for acceptance as a CSF free country or *zone* are not fulfilled.

Annex 15 (contd)

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 minimis~~e~~ing the impact on the ~~entire~~ rest of the country or *zone*.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE.

~~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.~~6~~5., once the *containment zone* is ~~clearly~~ established. ~~It should be demonstrated that *commodities* for *international trade* have originated outside the *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.~~36~~5. have been fulfilled.

The recovery of the CSF free status of the *containment zone* should follow the provisions of Article 15.2.~~6~~5. and be achieved within 12 months of its approval.

Article 15.2.~~6~~5.

**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 Article~~s~~ 15.2.~~263~~025~~. 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* has been implemented, 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 CSF free status of the country or *zone* will ~~regain CSF free status~~ be reinstated 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.~~6~~5bis.

**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 movement for *slaughter*;

2) the pigs were kept in the *establishment* of origin under *approved biosecurity* 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~~ subjected to *disinfection* 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 under *approved biosecurity* and is not approved for the export of *fresh meat* ~~during~~ from the time the pigs arrive~~d~~ from the *infected zone* until ~~it is handling~~ the *meat* of those pigs has ~~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.~~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 15.2.65ter.~~

~~**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 to 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 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;~~

~~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 has 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 15.2.2318. The *fresh meat* from those pigs should be identified and kept separate from other pig products until treated.~~

Annex 15 (contd)

~~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.~~7~~6.

**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:

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.~~8~~7.

**Recommendations for importation from countries or zones ~~considered infected with classical swine fever virus~~ infected with ~~not free from~~ CSFV**

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 *Terrestrial 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 of the semen 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 4.6. and 4.7.

Article 15.2.119.

**Recommendations for importation from countries or zones considered infected with classical swine fever virus not free from infected with CSFV**

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 of the semen 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 monthsduring that period;

   *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 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

      *iiii)* 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

      *iii)* 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 boar is negative for virus genome;

2) the semen was collected, processed and stored in conformity accordance with the provisions of Chapters 4.6. and 4.7.

Annex 15 (contd)

Article 15.2.~~12~~10.

**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 of the embryos in a country, *zone* or *compartment* free from CSF;

   *b)* showed no clinical sign of CSF on the day of collection ~~of the embryos~~;

2) the semen used to ~~fertilise the oocytes~~ inseminate the donors complied with the conditions in Articles 15.2.~~10~~8. or Article 15.2.~~11~~9., as relevant;

3) the embryos were collected, processed and stored in accordance with Chapters 4.8. and 4.10., as relevant.

Article 15.2.~~13~~11.

**Recommendations for importation from countries or zones ~~considered infected with classical swine fever virus~~ ~~not free from~~ infected with CSFV**

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 of the embryos in an *establishment* in which *surveillance*, in accordance with Articles 15.2.~~26~~21. to 15.2.~~32~~26., demonstrated that no *case* of CSF occurred ~~in the past three months~~ during that period;

   *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~~i~~)* ~~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~~ inseminate the donors 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 4.8. and 4.10., as relevant.

Article 15.2.~~14~~12.

**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~~ were kept in a country, *zone* or *compartment* free from CSF, or which ~~have been~~ were imported in accordance with Article 15.2.~~7~~6. or Article 15.2.~~8~~7.;

2) ~~have been~~ were slaughtered in an approved *slaughterhouse/abattoir*, where they ~~have been~~ were 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.~~14~~12bis.

**Recommendations for importation from countries or zones ~~not free from~~ infected with CSFV, 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~~ is derived~~s~~ ~~complying~~ complied ~~complying~~ with Article 15.2.~~8~~7.;

2) the pigs were transported under the supervision of the *Veterinary ~~Services~~ Authority*, in a *vehicle* which was ~~cleaned and disinfected~~ subjected to *disinfection* 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~~ that did not fulfil the conditions of Article 15.2. ~~8~~7.~~required for export~~;

4) the pigs were slaughtered in a~~n 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~~ were 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.;~~

~~1~~2) ~~that~~ which have been ~~were~~ subjected ~~with favourable results~~ to a post-mortem inspection in accordance with ~~C~~hapter 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;~~.~~

Annex 15 (contd)

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 from 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.;

*b)* in a processing establishment facility that, at the time of processing:

*i)* is was approved for export by the *Veterinary Authority* for export purposes;

*ii)* processing processes processed only *meat* of from 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.

Annex 15 (contd)

Article 15.2.~~19~~14.

**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.~~24~~19bis. 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.~~20~~15.

**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.~~24~~19ter. 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.~~21~~16.

**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.~~25~~20. 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.~~21~~16bis.

**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

Annex 15 (contd)

2) were processed in a manner ~~to ensure the destruction of~~ that has been demonstrated to 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.~~22~~17.

**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.~~23~~18.

**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 treatment~~s:

~~*a)* heat treatment in a hermetically sealed container with a F0 value of 3.00 or more;~~

*a)* ~~*b)*~~ a heat treatment for at least 30 minutes at a minimum temperature of 70°C, which should be reached throughout the *meat*.

*b)* any equivalent heat treatment which has been demonstrated to inactivate CSFV in *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 ~~Aw~~ $a_w$ 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.~~24~~19.

**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 procedure~~s~~ should be used: ~~salting~~ treating treatment for at least 30 days ~~either~~ with: phosphate supplemented ~~dry~~ salt, ~~or saturated brine (Aw $a_w$< 0.80)~~ containing 86.5% NaCl, 10.7% $Na_2HPO_4$ and 2.8% $Na_3PO_4$ (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.~~24~~19bis.

**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.~~24~~19ter.

**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~~.~~;

**EU comment**

**In our previous round of comments we suggested 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 made 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.~~25~~20.

**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 [$Na_2CO_3$]) 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 to the solution;

5) in the case of raw hides, salting for at least 28 days with sea salt containing 2 ~~percent~~ % washing soda (sodium carbonate [$Na_2CO_3$]).

~~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:~~

Annex 15 (contd)

~~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.~~26~~21.

**Introduction to surveillance~~: introduction~~**

Articles 15.2.~~26~~21. to 15.2.~~32~~26. define the principles and provide ~~a guide~~ guidance 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.

*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~~ in 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 variability in genotype~~ic~~, antigens~~ic~~, and virulence ~~variability~~ exhibited by different strains of CSFV.

Article 15.2.~~27~~22.

**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*~~c~~) 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~~ Given that 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* infected with CSFV (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~~ among 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 ~~of from~~, or exposure to, infected *wild* or *feral* pig populations ~~of~~ from~~adjacent~~ neighbouring countries or *zones*.

Article 15.2.~~28~~23.

**Surveillance strategies**

1. Introduction

The population covered by *surveillance* aimed at detecting disease and *infection* should include the domestic and *captive wild* pig populations and *wild* and *feral* pig populations within the country or *zone* to be recognised as free from ~~*infection* with~~ CSF~~V~~.

The strategy employed to ~~establish~~ estimate the prevalence or demonstrate the absence of *infection* with CSFV ~~*infection*~~ 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 system~~s~~.

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~~g~~ targeted sub-populations, 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.

The design of the *surveillance* system ~~design~~ should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of *infection* with CSFV because of the recognised cross-reactivity with ruminant pestiviruses, among other factors mentioned in point 4. There should ~~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 of *infection* with CSFV. However, ~~due~~ owing 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~~ situations ~~where~~ in which clinical signs or lesions suggestive of *infection* with CSFV ~~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 CSF~~V~~ can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in ~~disease free~~ areas previously free from CSF. Therefore, CSFV isolates should be sent to an OIE Reference Laboratory for further characterisation.

4. Serological surveillance

Serological *surveillance* ~~aims~~ is aimed 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.

Infection with CSFV may lead to persistently infected, seronegative young animals, which continuously shed virus. CSFV *infection* may also lead to chronically infected pigs ~~which~~ that 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* of CSF 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 at up to 8-10 weeks of age but may be occasionally last up to ~~four and a half~~ 4.5 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 at *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.~~29~~24.

**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.~~31~~26.

Article 15.2.~~30~~25.

**Additional surveillance ~~procedures~~ for recovery of free status**

In addition to the general conditions described in this chapter, a Member Country seeking recovery of free status of a 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*.

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~~ this chapter. 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.~~31~~26.

**Surveillance for ~~classical swine fever virus~~ CSFV in wild and feral pigs**

1) The objective of a *surveillance* programme is either to demonstrate that *infection* with CSFV ~~*infection*~~ is not present in *wild* and *feral* pigs or, if it is 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 *infection* with 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 geographical 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~~ hunting 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 in which ~~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~~ bordering ~~CSF-affected~~ countries or *zones* *infected* with CSFV;

*d)* interface between *wild* and *feral* pig populations, and domestic and *captive wild* pig populations;

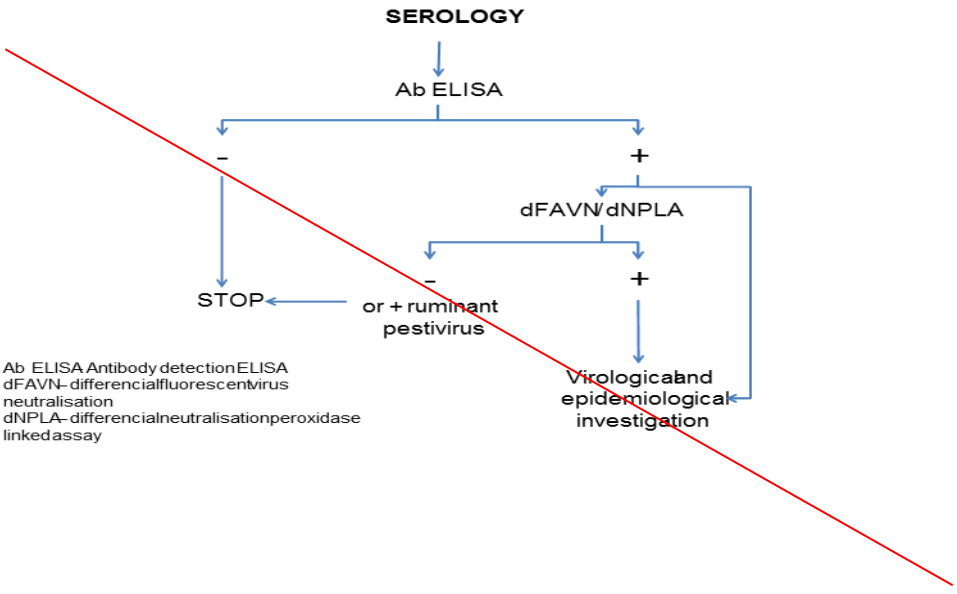
*e)* areas with farms with free-ranging and outdoor pigs;

*f)* areas with a high level of hunting activity, where animal dispersion and feeding as well as inappropriate disposal of waste can occur;

~~*g*~~*f)* 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**~~



Annex 16

# GLOSSARY

**EU comment**

**The EU supports in general the proposed changes to the Glossary and it has one new comment as regards the definition of stunning.**

~~***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.~~

***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.

***EUTHANASIA***

means *killing* of an *animal* ~~the act of inducing *death* using a method that causes a rapid and irreversible loss of consciousness~~ with the most rapid~~,~~ method and with the least *pain*~~less~~ and ~~*distress free*~~ *suffering* ~~method~~ possible ~~minimum pain and distress to *animal*~~.

***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.~~

***SLAUGHTER***

means ~~any~~ *killing* ~~procedure that causes the *death* of an *animal* by bleeding~~ of an *animal*~~s~~ primarily for human consumption.

***STUNNING***

means any ~~mechanical, electrical, chemical or other~~ procedure that causes rapid ~~immediate~~ loss of consciousness with minimal pain ~~and other types of~~ and *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 pain and suffering;"**

**Justification**

**The EU believes that the word "rapid" should be deleted from the definition of stunning for two reasons:**

- **it is not relevant for all stunning methods and in particular for controled athmosphere methods;**

- **the speed in the lost of consciousness is not of importance if the stunning method is not efficient enough and causes pain and suffering.**

**Therefore, the word "rapid" does not bring any added value to this definition.**

***SUFFERING***

means an unpleasant, undesired physical or mental state of being that is the outcome of the impact on an animal of ~~noxious~~ negative stimuli ~~and/~~or the absence of ~~important~~ essential positive stimuli. ~~It is the opposite of good welfare.~~

_____

Annex 17

CHAPTER 1.3.

# DISEASES, INFECTIONS AND INFESTATIONS LISTED BY THE OIE

**EU comment**

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

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
– 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
– 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 ~~R~~respiratory ~~S~~syndrome ~~C~~coronavirus
– Leishmaniosis.

Annex 18

DRAFT CHAPTER 3.1.

# QUALITY OF VETERINARY SERVICES

**EU comment**

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

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.

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.

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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 and social science.

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 other 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~~ new scientific evidence.

2) Implementation of *veterinary legislation* through a programme of communications and awareness, as well as formal, documented inspection and compliance activities.

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.

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.

6) Information management systems for collecting data to monitor and evaluate *Veterinary Services*' policies and activities 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.

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.

*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*.

7) All personnel have access to professional development, including continuing education programmes that are reviewed and updated as necessary.

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 relevant to their role, including ~~for both~~ official tasks, ~~and~~ veterinary clinical services and other veterinary tasks as appropriate. Mechanisms for coordination between the *Veterinary Authority*, the *Veterinary Statutory Body* and veterinary educational establishments should be in place.

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*;~~.~~

Annex 18 (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 quality 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.

*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~~ to develop~~ment~~ or participat~~eion~~ 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 and data analysis technologies, in accordance with relevant chapters, including Chapters 1.1., 1.2., 1.3., 1.4. and 1.5.

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~~ *animals*, in accordance with Chapter 6.4.

9) A system for *animal identification*, *animal 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 and auditing 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.

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~~ animal diseases and zoonoses, in accordance with Chapters 6.2. and 6.3. and the relevant Codex Alimentarius texts.

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.

6) Procedures for corrective actions ~~or~~ and for proportional and dissuasive 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.

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 and~~,~~ 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 the ~~*veterinary medicinal products*~~ quality and ~~protection~~ effectiveness of *veterinary medicinal products*, antimicrobial resistance *surveillance*, assessing the safety of food or *feed*, or supporting *international trade* (e.g. demonstration of ~~freedom~~ *animal health status*). 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.

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.

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 *subpopulations* 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.

Annex 19

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.**

**One comment is 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**

**In our previous comments, we mentioned the importance of the principle of 'independence' when a self-evaluation is carried out. We wish to insist and**

**For this reason we suggested 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 regions, provinces or states can usefully supplement national level evaluation.

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, in a non-discriminatory manner, 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.

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 financing and confidentiality 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, and provide the opportunity for the evaluated country to clarify or respond to the findings 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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Annex 20

DRAFT CHAPTER 3.X.

# INTRODUCTION TO RECOMMENDATIONS ON VETERINARY SERVICES

**EU comment**

**The EU thanks the OIE and 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 *animal welfare* and veterinary public health, as well as to establish and maintain confidence in their *international veterinary certificates*.

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Annex 21

CHAPTER 4.4.

# ZONING AND COMPARTMENTALISATION

**EU comment**

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

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

[…]

Article 4.4.6.

**Protection zone**

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

A *protection zone* can be established as a temporary measure in response to an increased *risk* of disease. The *protection zone* can be established within or outside a *free zone* or within a free country. Based on the results of a *risk assessment*, more than one *protection zone* may be established.

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

Increased *surveillance*, in accordance with Chapter 1.4. and the relevant disease-specific chapter, should be implemented in the *protection zone* and the rest of the country or *zone*, including *surveillance* of *wildlife* and *vectors* as relevant.

In addition to the general considerations in Article 4.4.2. and the principles in Article 4.4.3., t~~T~~hese measures should include intensified movement control. ~~and *surveillance* and specific~~ *animal identification* and *animal traceability* to ensure that *animals* in the *protection zone* are clearly distinguishable from other populations. *Vaccination* of susceptible *animals* in accordance with Chapter 4.18. may also be applied.

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

~~2) testing or *vaccination* of *animals* moved;~~

~~3) specific procedures for sample handling, dispatching and testing;~~

~~4) enhanced *biosecurity* including *disinfection* and disinsection procedures for *vehicles/vessels* and vehicles used for transportation of animal products, *feed* or fodder, and possible compulsory routes for their movements within, to or from the *zone*;~~

~~5) specific *surveillance* of susceptible *wildlife* and relevant *vectors*;~~

~~6) awareness campaigns aimed at the public or targeted at breeders, traders, hunters or *veterinarians*.~~

~~Anytime the status of the *protection zone* changes, the status of the country or *zone* in which it was established should be redetermined in accordance with the relevant *listed disease*-specific chapters.~~

Unless otherwise specified in the relevant disease-specific chapters of the *Terrestrial Code*, if the *animal health status* of an established *protection zone* changes due to the occurrence of a *case* or implementation of *vaccination*, the *animal health status* of the rest of the country or *zone* is not affected.

Regarding diseases for which the OIE grants official recognition of *animal health status*, a *protection zone* is considered as effectively established when the conditions described in this article and in the relevant disease-specific chapters have been applied and documented evidence is submitted to the OIE. A *protection zone* established on a temporary basis should be limited to less than 24 months from the date of its approval by the OIE. If a Member wishes to make the *protection zone* permanent, the process for official recognition by the OIE should be followed.

**EU comment**

**The EU queries whether, in the first sentence of the paragraph above, it is sufficient for the documented evidence to be submitted to the OIE. Would it not be necessary to have some sort of evaluation of that evidence by the OIE (at the level of HQ, Scientific Commission or ad hoc group). Perhaps the words "and was accepted by" could be added at the end of that sentence (between "and documented evidence is submitted to" and "the OIE"). Furthermore, the EU would suggest clarifying that this paragraph concerns not only the diseases for which the OIE grants official recognition of animal health status, but is also limited to decisions by the OIE on the re-instatement of the status itself. Otherwise, it might be misunderstood as requiring approval by OIE under all circumstances. Therefore, the EU suggests the following amendments:**

**"Regarding diseases for which the OIE grants official recognition of animal health status, a protection zone is considered by the OIE in the context of re-instatement of official status as effectively established when the conditions described in this article and in the relevant disease-specific chapters have been applied and documented evidence is submitted to and was accepted by the OIE. A protection zone established on a temporary basis should be limited to less than 24 months from the date of its approval by the OIE in the context of official status recognition. If a Member wishes to make the protection zone permanent, the process for official recognition by the OIE should be followed.".**

Article 4.4.7.

**Containment zone**

1) In the event of *outbreaks* in a country or *zone* previously free from a disease, a *containment zone*, which includes all epidemiologically linked *outbreaks* may be established to minimise the impact on the rest of the country or *zone*.

2) A *containment zone* is an *infected zone* that should be managed in such a way that *commodities* for *international trade* can be shown to have originated either from inside or outside the *containment zone*.

3) Establishment of a *containment zone* should be based on a rapid response, prepared in a contingency plan, and that includes:

   – appropriate control of movement of *animals* and other *commodities* upon declaration of suspicion of the specified disease;

   – epidemiological investigation (trace-back, trace-forward) after confirmation of *infection* or *infestation*, demonstrating that the *outbreaks* are epidemiologically related and all contained within the defined boundaries of the *containment zone*;

   – a *stamping-out policy* or another effective emergency control strategy aimed at eradicating the disease;

   – *animal identification* of the susceptible population within the *containment zone* enabling its recognition as belonging to the *containment zone*;

   – increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* demonstrating no occurrence of *infection* or *infestation*;

   – *biosecurity* and *sanitary measures*, including ongoing *surveillance* and control of the movement of *animals*, other *commodities* and fomites within and from the *containment zone*, consistent with the *listed disease*-specific chapter, when there is one, to prevent spread of the *infection* or *infestation* from the *containment zone* to the rest of the country or *zone*.

4) A *containment zone* is considered as effectively established when the following is demonstrated:

   EITHER

   *a)* there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the disposal of the last detected *case*;

   OR

*b)* ~~the *containment zone*~~ it comprises ~~an *infected*~~ a *zone* where *cases* may continue to occur and ~~a *protection*~~ another *zone* where no *outbreaks* have occurred for at least two *incubation periods* after the control measures above are in place and which ~~that~~ separates the *zone* where *cases* may continue to occur ~~the *infected zone*~~ from the rest of the country or *zone*.

5) The free status of the areas outside the *containment zone* is suspended pending the effective establishment of the *containment zone*. Once the *containment zone* has been established, the areas outside the *containment zone* regain free status.

6) The free status of the *containment zone* should be regained in accordance with the relevant *listed disease*-specific chapters or, if there are none, with Article 1.4.6.

7) In the event of an occurrence of a *case* of the *infection* or *infestation* for which the *containment zone* was established, either in the *containment zone* defined in point *a)* or in the ~~*protection zone*~~ where no *outbreaks* had occurred as defined in point *b)*, the rest of the country or *zone* is considered infected.

**EU comment**

**We would like to suggest not to use the term 'defined' in point 7 above to avoid any confusion with the terms for which there is a definition in the Glossary. In addition, the references to points 4 a) and b) should be clear. We would suggest the following amended wording:**

**"In the event of an occurrence of a *case* of the *infection* or *infestation* for which the *containment zone* was established, either in the *containment zone* ~~defined~~ as described in point 4 *a)* or in the ~~*protection zone*~~ where no outbreaks had occurred as ~~defined~~ described in the second part of point 4 *b)*, the rest of the country or *zone* is considered infected."**

Annex 22

CHAPTER 8.Y.

# INFECTION WITH ANIMAL TRYPANOSOMES OF AFRICAN ORIGIN

**EU comment**

**The EU thanks the OIE and in general supports the proposed changes to this chapter. Comments are inserted in the text below.**

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~~ The disease ~~is~~ has a ~~particularly~~ significant socio-economic impact ~~deleterious~~ ~~in~~ on cattle production. Some trypanosomes of African origin (*i.e. T. brucei gambiense, T. brucei rhodesiense*) also affect humans and are responsible for a disease known as sleeping sickness or human African trypanosomosis, which is almost always fatal if untreated ~~(sleeping sickness also known as human African trypanosomosis)~~.

2) *Infection* with several trypanosome species in the same animal could exist although ~~they~~ this may not always be detected ~~be evidenced~~ using routine testing methods.

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 sspp* excluding *T. evansi* and *T. equiperdum*), hereafter referred to as 'pathogenic agent'.

5) *Infection* of susceptible animals with *T. evansi* or *T. equiperdum* is 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~~,~~ and 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 *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

   *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 the import or transit of the following *commodities* from susceptible animals, *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* from animals that have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results;

~~5~~6) *meat products*;

~~6~~7) hides and skins (except raw);

8) semen collected and processed in accordance with Chapter 4.6.;

9) embryos.

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 susceptible animals and other *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)* 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~~,~~ or *zone* ~~or *compartment*~~.

**EU comment**

**The EU suggests including in point 3 above the possibility for a country or zone to be recognised as free from infection with animal trypanosomes of African origin when the absence of the competent vector has been demonstrated by a surveillance programme, as is the case in several other vector-borne disease specific chapters of the Code (e.g. AHS, BT, EHD).**

**Furthermore, for reasons of consistency, we would suggest aligning the wording in the**

**paragraph below with established wording used in other chapters in the Code (e.g. AHS, BT, LSD, RVF), that is, to replace "neighbouring to" with "adjacent to". This comment is relevant also for the second paragraph of Article 8.Y.9.**

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.

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;

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;

AND

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 of susceptible animals from countries, 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*;

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**~~

~~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*;~~

~~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**~~

~~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*;~~

~~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 *vector*-protected *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**

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*;

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~~7.

**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*.

*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~~ assist with the estimation of the abundance 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~~8.

**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 or ~~,~~ *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*.

   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 reliably predicted ~~reliably~~. All suspected *cases* should be investigated immediately, and samples should be taken and submitted to a *laboratory*;

   *b)* include the conduct of random or targeted serological or parasitological surveys ~~*surveillance*~~ appropriate to the status of the country or *zone*.

Article 8.Y.~~15~~9.

**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.

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. 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 parasit*esie* in a country or *zone*.

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~~ different possible causes:

*i)* ~~active~~ *infection*;

*ii)* antibodies from previous *infection* (after effective treatment or self-cure);

*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

This point should be read in conjunction with Chapter 1.5.

For the purposes of this chapter, *vector surveillance* aims at determining different levels of *risk* by identifying the ~~various *vector* species~~ presence and abundance of various *vector* species in an area or by 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 colleting 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~~10.

**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* established in accordance with Article 4.4.7., should show evidence of an active *surveillance* programme to demonstrate absence of *infection* with animal trypanosomes of African origin.

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*.

Annex 23

# CHAPTER 8.15.

# INFECTION WITH RIFT VALLEY FEVER VIRUS

**EU comment**

**The EU in general supports the proposed changes to this chapter. One comment is inserted in the text below.**

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 is occurrings, 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.

32) 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~~)~~.

43) 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, including in a human, 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, including in a human, or giving cause for suspicion of association or contact with RVFV.

**EU comment**

**While in principle agreeing with the insertion of "including in a human" in points b) and c) above, this appears to create an inconsistency with the case definition in point 3 ("*For the purposes of the Terrestrial Code, RVF is defined as an infection of susceptible animals with RVFV*") as well as with the definition of "susceptible animals" in point 2 b) ("*means***

***ruminants and dromedary camels*”). Thus, “a case of RVF” cannot be construed as one occurring in a human (“*including in a human*”). To avoid confusion, we would suggest amending the insertion as follows:**

**“~~including in~~ or to a human infected with RVFV”.**

5~~4~~) For the purposes of the *Terrestrial Code*, the *infective period* for RVF shall be 14 days and the *incubation period* shall be 7 days.

~~6) For the purposes of the *Terrestrial Code*, the *incubation period* for RVF shall be 7 days.~~

7~~65~~) In areas where RVFV is present, epizootics of RVF may occur following favourable climatic~~,~~ and other 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*;~~

~~*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;~~

~~*c)* '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*.~~

7~~8~~) 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*.

8~~9~~) 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~~ meet the requirements of 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.~~6~~5.

**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 r~~*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.~~7~~6.

**Recommendations for importation of susceptible animals 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.~~8~~7.

**Recommendations for importation ~~of susceptible animals~~ 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.~~9~~8.

**Recommendations for importation ~~of susceptible animals~~ 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 ~~1~~

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;

AND

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.~~10~~9.

**Recommendations for importation of semen and *in vivo* derived embryos of susceptible animals 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;

AND

2) either:

*a)* were vaccinated against RVF at least 14 days prior to collection; or

*b)* were subjected to a serological test ~~demonstrated to be seropositive~~ on the day of collection, with positive result; or

*c)* were subjected to a serological test on two occasions with negative results on the day of collection and 14 days after collection ~~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:

~~1~~*a)* ~~ruminants which~~ susceptible animals that showed no clinical signs of RVF within 24 hours before *slaughter*;

~~2~~*b)* ~~ruminants which~~ susceptible animals that were slaughtered in an approved *slaughterhouse/abattoir* and were subjected to ante- and post-mortem inspections with favourable results;

~~3~~*c)* 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~~ *meat* 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.

Annex 23 (contd)

Article 8.15.~~12~~11.

**Recommendations for importation of milk and milk products of susceptible animals 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.~~13~~12.

**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 to 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.~~8~~7. and 8.15.~~9~~8.) *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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Annex 24

CHAPTER 9.4.

# INFESTATION WITH *AETHINA TUMIDA* (SMALL HIVE BEETLE)

**EU comment**

**The EU thanks the OIE and in general supports this revised Article 9.4.5. Comments are inserted in the text below.**

[…]

Article 9.4.5.

**Recommendations for the importation of individual consignments containing a single live queen bee, accompanied by a small number of associated attendants (a maximum of 20 attendants per queen)**

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

1) the bees come from *apiaries* situated in a country or *zone* free from *A. tumida*;

OR

2) the bees come from hives or colonies which were inspected ~~immediately prior to dispatch~~ on the day of packing and show no evidence of the presence of *A. tumida* based on a visual inspection and the use of one of the methods described in the relevant chapter of the *Terrestrial Manual*; and

**EU comment**

**The EU considers that the inspection can be done on the day of packing but ensuring that the packing, including covering with a fine mesh, is completed immediately after the inspection has been conducted, and that all precautions are taken to prevent the infestation or contamination of the cages.**

**Based on our comment we suggest the following alternative wording:**

**"2) the bees come from hives or colonies which were inspected ~~immediately prior to dispatch~~ on the day of packing, ~~and~~ show no evidence of the presence of *A. tumida* based on a visual inspection and the use of one of the methods described in the relevant chapter of the *Terrestrial Manual* and the packing of the queens into queen cages is completed immediately after inspection; and"**

3) the bees come from an area of at least ~~100~~ 50 km radius where no *apiary* has been subject to any restrictions associated with the occurrence of *A. tumida* for the previous six months; and

**EU comment**

**The EU prefers to keep the 100 km radius. The European Reference Laboratory estimates that a distance of 50 km is not enough to insure that *A. tumida* does not**

**circulate in the area surrounding the honeybee colonies producing the queens. We consider that any reduction of the number of kilometres should be based on solid scientific evidence on how far small hive beetle can fly or be transported by the wind.**

4) the bees and accompanying packaging presented for export have been thoroughly and individually inspected and do not contain *A. tumida*; and

5) the packaging material, containers, accompanying products and food are new; and

6) all precautions have been taken to prevent *infestation* or contamination with *A. tumida*, in particular, measures that prevent *infestation* of queen cages such as no long term storage of queens prior to shipment and covering the consignment of bees with fine mesh through which a live beetle cannot enter.

**EU comment**

**In line with our previous comment in bullet point 2) we would like to suggest the following additions to bullet point 6):**

**"6) all precautions have been taken to prevent *infestation* or contamination with *A. tumida*, in particular, measures that prevent *infestation* of queen cages such as no long term storage of queens prior to shipment and covering the cages or the whole consignment of bees immediately after the inspection with fine mesh through which a live beetle cannot enter."**

2) all precautions have been taken to prevent contamination with *A. tumida*.

**EU comment**

**We believe this last bullet point 2 is redundant and it meant to be deleted**

**("~~2) all precautions have been taken to prevent contamination with *A. tumida*.~~").**

[...]

Annex 25

CHAPTER 10.5.

# AVIAN MYCOPLASMOSIS (*MYCOPLASMA GALLISEPTICUM*)

**EU comment**

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

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

Article 10.5.1.

**General provisions**

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

Article 10.5.2.

**Establishment free from avian mycoplasmosis**

To qualify as free from avian mycoplasmosis, an *establishment* should satisfy the following requirements:

1) it is under *official veterinary control*;

2) it contains no bird which has been vaccinated against avian mycoplasmosis;

3) 5% of the birds, with a maximum of 100 birds of different age groups present in the *establishment*, are subjected to ~~the serum agglutination test with negative results at the age of 10, 18 and 26 weeks, and thereafter at 4-week intervals (the results of at least the last two tests carried out on adult birds should be negative);~~:

   *a)* an agent identification test at the age of 10, 18 and 26 weeks with negative results, and thereafter at 4-week intervals with negative results on at least the last two tests; or

   *b)* a serological test at the age of 10, 18 and 26 weeks with negative results, and thereafter at 4-week intervals with negative results on at least the last two tests;

**EU comment**

**It is not possible to reliably eliminate MG from an infected flock. When the testing is performed at flock level (as the age intervals indicate above) all results should be negative in order to maintain the status as a flock free from mycoplasmosis. All flocks on an establishment should be free/test negative.**

**For this reason, we suggest the following wording for bullet points a) and b) above:**

**"a) an agent identification test with negative results at the age of 10, 18 and 26 weeks ~~with negative results~~, and thereafter at 4-week intervals ~~with negative results on at least the last two tests~~; or**

***b)* a serological test at the age of 10, 18 and 26 weeks with negative results, and thereafter at 4-week intervals ~~with negative results on at least the last two tests~~;"**

4) all birds introduced into the *flocks* come from an *establishment* free from avian mycoplasmosis.

Article 10.5.3.

**Recommendations for the importation of chickens and turkeys**

*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the birds:

1) showed no clinical sign of avian mycoplasmosis on the day of shipment; and

2) come from an *establishment* free from avian mycoplasmosis; ~~and/~~or

3) were kept in a *quarantine station* for the 28 days prior to shipment and were subjected to ~~a diagnostic~~ an agent identification test for avian mycoplasmosis with negative results, on two occasions, at the beginning and at the end of the 28-day period.

**EU comment**

**We suggest the use of a serological test instead of an agent identification test. This will allow the possibility of detecting antibodies that may indicate previous exposure and an infection that might pass undetected. The possibilities/risks that birds in this category have been vaccinated and/or treated with antibiotics must also be taken into account.**

**We suggest rewording bullet point 3) above as follows:**

**"3) were kept in a *quarantine station* for the 28 days prior to shipment and were subjected to ~~an agent identification~~ a serological test for avian mycoplasmosis with negative results, on two occasions, at the beginning and at the end of the 28-day period."**

Article 10.5.4.

**Recommendations for the importation of day-old birds**

*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *day-old birds*:

Annex 25 (contd)

1) come from *establishments* free from avian mycoplasmosis and from hatcheries which comply with the standards referred to in Chapter 6.5.;

2) were shipped in clean and unused packages.

Article 10.5.5.

**Recommendations for the importation of hatching eggs of chickens and turkeys**

*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:

1) have been disinfected in accordance with the standards referred to in Chapter 6.5.;

2) come from *establishments* free from avian mycoplasmosis and from hatcheries which comply with the standards referred to in Chapter 6.5.;

3) were shipped in clean and unused packages.

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Annex 26

CHAPTER 12.6.

# INFECTION WITH EQUINE INFLUENZA VIRUS

**EU comment**

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

[...]

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

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 21 and 90 days before shipment either with a primary course or a booster; information on their *vaccination* status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12.~~ 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 up to the date of this pre-shipment *vaccination*, at least four doses of ~~the same~~ 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, c~~Countries 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~~ ~~prior to~~ within four days ~~before~~ of shipment.

[...]