EUROPEAN UNION

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Subject: 88th General Session of the OIE - May 2021

Dear Director General,

Please find attached, for your informal information, annexes indicating the intended positions of the European Union (EU) to be raised on the reports of the Terrestrial and Aquatic Animal Health Standards Commissions (Annexes 1 and 2, respectively) and drafts proposed for adoption at the 88th General Session of the World Assembly of National Delegates of the OIE to be held virtually in May 2021.

Furthermore, we take this opportunity to inform you that the EU supports the adoption of the 38 draft revised chapters of the OIE *Terrestrial Manual* to be proposed for adoption this year. While supporting its adoption as proposed, the EU will comment on Chapter 3.4.12. on Lumpy Skin Disease. The intended EU position on the OIE *Terrestrial Manual* chapters is at Annex 3.

These EU positions will also be uploaded electronically on the General Session website beginning of May.

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

Yours sincerely,

Dr Susana Guedes Pombo CVO and OIE Delegate Portugal	Dr Bernard Van Goethem Director for Crisis Preparedness in Food, Animals and Plants European Commission, DG Health and Food Safety
[Signed electronically]	*[Signed electronically]*

Dr Monique Eloit
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Annexes: 3

Copy: All Directors / Chief Veterinary Officers of the EU 27 and Iceland, Liechtenstein, Norway, Switzerland, and Albania, North Macedonia, Montenegro, Serbia and Turkey; General Secretariat of the Council of the EU.

WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

ANNEX 1

Original: English

February 2021

REPORT OF THE MEETING OF THE OIE
TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION
Paris, 2–11 February 2021

PART A - Texts to be proposed for adoption in May 2021

EU position

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

A number of general comments on this part A of the report of the February 2021 meeting of the Code Commission as well as the intended positions of the EU on the draft Terrestrial Code chapters proposed for adoption at the 88th OIE General Session are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report (appended as Annexes 3 to 21 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 OIE Terrestrial Animal Health Standards Commission (the Code Commission) held its meeting electronically from 2 to 11 February 2021. The list of participants is attached as **Annex 1**.

Considering the ongoing COVID-19 pandemic the 88th Annual General Session of the World Assembly of Delegates will be held virtually from Monday 24 to Friday 28 May 2021. During the 88th General Session new and revised chapters of the OIE International standards (the *Aquatic Animal Health Code*, the *Terrestrial Animal Health Code*, the *Manual of Diagnostic Tests for Aquatic Animals* and the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*) will be proposed for adoption.

To facilitate this process, the **February 2021 meeting report of the Code Commission will be distributed in two parts**: **Part A** (herewith) provides information about the new and revised texts for the *Terrestrial Code* that will be proposed for adoption at the 88th General Session; and **Part B** (to be published in April 2021) will provide information about other topics discussed at the Commission's February 2021 meeting including texts circulated for comments and information.

In preparation of the virtual 88th General Session, the OIE will organise a series of information webinars to ensure that Members are well aware of the background and key aspects of the standards being presented for adoption. Attendance to these webinars will be by invitation only. Please note that Delegates will soon receive detailed information about the virtual 88th General Session, and in particular the process for commenting and adoption of standards shortly.

The Code Commission thanked the following Members for providing comments: Argentina, Australia, Armenia, Belize, Brazil, Canada, Chile, China (People's Republic of), Chinese Taipei, Colombia, Cuba, Dominican Republic, Ecuador, Japan, New Caledonia, New Zealand, Norway, Peru, Saudi Arabia, Singapore, Switzerland, Thailand, the United Kingdom (UK), the United States of America (USA), Zimbabwe, Members of the OIE

Americas region, the Member States of European Union (EU), the African Union Inter-African Bureau for Animal Resources (AU-IBAR) on behalf of African Members of the OIE. The Code Commission also thanked the following organisations for providing comments: the International Coalition for Farm Animal Welfare (ICFAW), the International Egg Commission (IEC), the World Renderers Organization (WRO), as well as various experts of the OIE scientific network.

The Code Commission reviewed the Member comments that were submitted on time and supported by a rationale, and amended relevant texts, as appropriate. **The Commission did not consider comments where a rationale had not been provided or that were unclear and difficult to interpret.** Due to the large volume of work, the Commission was not able to draft a detailed explanation for the reasons for accepting or not each of the comments received, and focused its explanations on the major comments. Where amendments were of an editorial nature, no explanatory text has been provided. The 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 '<u>double underline</u>' and '~~strikethrough~~', and are annexed to this report. In **Annexes 3, 4, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 20 and 21** 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 considering longstanding issues. The 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 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.

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1. Welcome from the Deputy Director General

OIE Deputy Director General, International Standards and Science, Dr Matthew Stone welcomed members of the Code Commission, noting that this was the last meeting in the three-year term, a term during which excellent productive output has been maintained despite significant challenges. He acknowledged that the OIE had drawn heavily on the Specialist Commissions as it responded to the COVID-19 pandemic, and the response has always been in the spirit of goodwill, innovation and scientific excellence. Dr Stone thanked all members for their contributions during the term, including the forthcoming meeting, and extended this appreciation to the members' employing institutions and national governments. Dr Stone briefed the members on the ongoing design process for a full-virtual OIE General Session. He summarised the ongoing work on the OIE standards development and review system, including Standard Operating Procedures development and planning for digital tools. Finally, he provided an overview of the OIE's continuing support to the COVID-19 pandemic response, including *ad hoc* groups, the development and implementation of the OIE Wildlife Health Management Framework and the compilation of services under the OIE Supporting Veterinary Services Resilience paper.

The members of the Code Commission thanked the Deputy Director General for the excellent support provided by the OIE Secretariat throughout these three years and especially acknowledged the improved coordination of the OIE Headquarters' teams involved as well as the strong collaboration between the OIE Specialist Commissions.

2. Meeting with the Director General

Dr Monique Eloit, the OIE Director General, met the Code Commission on 8 February 2021 and commended the Commission's work during this three-year term and thanked its members for their support and commitment to achieving OIE objectives. She recognised the Commission's efforts and adaptability to develop new ways of working to sustain the OIE standards setting process despite the challenges imposed by the COVID-19 pandemic. Dr Eloit provided an update on progress in the implementation of the 7th OIE Strategic Plan and highlighted that this plan represents a milestone in the history of OIE, not only due to the technical challenges it implies by promoting new priorities such as aquatic animal health and wildlife health but also because it entails major structural changes towards digital transformation and data management. The Director General recognised that these transformations demand significant resources and will also impact the way the Commission and its Secretariat undertake some of their work. Dr Eloit acknowledged the work already being done by the Commission and the OIE Secretariat to strengthen the discussions and communication with Members regarding their work programme and highlighted that prioritisation of its work programme would be critical during this coming period given the likely constraints on resourcing. Dr Eloit expressed her belief that the new tools and processes developed by the organisation will also support the Commission, and therefore OIE Members, to develop more efficient ways of working, especially in standard setting.

The Code Commission thanked Dr Eloit for making time to meet with its members and commended the excellent work of the Secretariat for meeting preparations and its work during the meeting especially given the challenges of a virtual meeting.

3. Adoption of the agenda

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

4. Texts proposed for adoption in May 2021

The Code Commission considered comments received on the following new and revised texts previously circulated for Member comments and its responses are presented below.

4.1. User's Guide

Comments were received from Switzerland, the USA and the EU on the annex circulated in the Code Commission's February 2020 meeting report.

Background

Amendments to the User's Guide were last circulated in the Code Commission's February 2020 meeting report 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. This text has been circulated three times for comments. At its September 2020 meeting, the Commission reviewed comments received and agreed to defer its discussion until its February 2021 meeting.

Discussion

In point 3 of Section B, the Code Commission did not agree with a comment to add a reference to surveillance for animal health and arthropod vectors of animal disease in the second sentence. The Commission agreed that the first sentence of this point 3 already addresses this point of surveillance and that there was no need for a detailed and exhaustive list. Moreover, the Commission also noted that the second sentence of this point 3 only aimed at highlighting some specific procedures.

In point 5 of Section C, the Code Commission did not agree with a comment to amend the text of the second paragraph to reflect all titles of Chapters 5.1 to 5.3, as it considered again that the text was intended to provide a guide for users rather than detailed information. However, the Commission added the word 'general' before 'obligations and ethical responsibilities of importing and exporting countries' to better stress this approach. With the same rationale, the Commission did not agree with a comment to add references to other chapters in the third paragraph.

Revised point 3 of Section B and point 5 of Section C of the User's Guide are presented as **Annex 3**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

The EU supports the adoption of these revised points of the User's Guide.

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

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

Comments were received from Belize, Colombia, Switzerland and the USA on the annex circulated in the Code Commission's February 2020 meeting report.

Background

At its September 2018 meeting, the Code Commission had proposed a revision to the Glossary definitions for 'captive wild [animal]' in response to a comment submitted for Chapter 15.1,

Infection with African swine fever, which was under revision at that time. Arising from the proposed revision of 'captive wild [animal]', consequent amendments were also proposed to the definitions of 'feral [animal]' and 'wild [animal]' and were circulated for the first time in the Commission's September 2019 report. The amended definition for 'captive wild [animal]' has been circulated three times for comments, and the amended definition for 'feral [animal]' and wild [animal]'), twice.

At its September 2020 meeting, the Code Commission reviewed comments received and agreed to defer its discussion until its February 2021 meeting.

Discussion

'Captive wild [animal]'

The Code Commission noted that no further comments were received regarding the proposed amendments.

'Feral [animal]'

The Code Commission agreed with a comment to delete 'now' from the amended text given that the meaning of the definition is not dependent on a time reference, but on the reference to 'an animal of a domesticated species' in contrast to an 'animal that has a phenotype not significantly affected by human selection' as used for the definition of wild animals.

'Wild [animal]'

The Code Commission did not agree with a comment to replace 'phenotype unaffected by human selection' with 'phenotype not significantly affected by human selection' for consistency with the definition of captive wild [animal]. The Commission did not consider that this change improved the definition and explained that the text had been proposed by the OIE Wildlife Working Group's experts.

b) 'Epidemiological unit'

Background

At its September 2018 meeting, in response to comments and in agreement with the Scientific Commission, the Code Commission agreed to amend the Glossary definition for 'epidemiological unit' to include the possibility that an epidemiological unit can consist of only one animal. The amended definition for 'epidemiological unit' has been circulated four times for comments, the last time in the Code Commission's February 2020 meeting report.

At its September 2020 meeting, the Code Commission reviewed comments received and agreed to defer its discussion until its February 2021 meeting.

Discussion

No comments were received on the amended Glossary definition for 'epidemiological unit'.

c) 'Poultry'

Comments were received from China (People's Republic of), Singapore, the UK, the USA and the EU on the annex circulated in the Code Commission's February 2020 meeting report. An additional comment was received from New Zealand for the Commission's February 2021 meeting.

Background

In its February 2020 report, 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 4.14) and to amend the Glossary definition for poultry.

The amended text had been previously circulated for comments as part of the revised Chapter 10.4. A proposed modification to the Glossary definition for poultry was circulated for comments in the Commission's February 2020 report.

The Code Commission considered comments received at its September 2020 meeting as part of the discussion of Chapter 10.4, Infection with avian influenza viruses. The Commission's responses to these comments can be found under Item 6.7 of the September 2020 meeting report. At this meeting, the Commission addressed one additional comment that was received.

Discussion

The Code Commission did not agree with a comment to add 'domestic' before 'birds' to align with Chapter 10.4. The Commission noted that this point had been discussed in its September 2020 report, where it replaced 'poultry' with 'domestic' in point 4 of Chapter 10.4. The Commission noted that it had previously agreed with the *ad hoc* Group on Avian influenza, and the Scientific Commission, that birds of wild origin but reared in captivity for commercial purposes should be considered poultry based on the epidemiological risk of spreading avian influenza. Furthermore, the Commission explained that as the term 'poultry' is used in many other chapters and is not limited to Chapter 10.4, the definition needs to address all uses in the *Terrestrial Code*.

The Code Commission did not agree with a comment to add 'current' before 'direct or indirect contact'. Although it agreed with the comment that ex-commercial poultry that gets rehomed as backyard poultry for home consumption should be excluded from the definition, the Commission noted that the text is worded in the present tense, i.e. 'have no direct or indirect contact', and thus considered that it was unnecessary to be more specific by adding 'current'.

Revised Glossary definitions for 'epidemiological unit', 'captive wild [animal]', 'feral [animal]', 'wild [animal]' and 'poultry' are presented as **Annex 4**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

The EU supports the adoption of these revised Glossary definitions.

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

Comments were received from Australia, Switzerland and the EU on the annex circulated in the Code Commission's February 2020 meeting report.

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 to ensure consistency with other relevant chapters in the *Terrestrial Code*, and to improve grammar and readability. This chapter has been circulated for comments four times, the last time in February 2020. At its September 2020 meeting, the Commission reviewed comments received and agreed to defer its discussion until its February 2021 meeting.

Discussion

General comments

The Code Commission acknowledged a comment noting the need to ensure that OIE WAHIS procedures are updated to ensure alignment with any relevant changes, once adopted, in this chapter. The Commission confirmed that OIE Headquarters has mechanisms to ensure that all relevant

modifications of the Codes are incorporated into OIE WAHIS processes at the beginning of the year following adoption.

Article 1.1.4

In point 1, the Code Commission did not agree with a comment to amend the text to reinforce the importance of notification of emerging diseases as soon as sufficient information is available, as it considered that the current text was clear. The Commission reminded Members that transparent, clear, and timely notification is a compulsory duty of OIE Members.

The Code Commission considered the feedback from the OIE World Animal Health Information and Analysis Department (WAHIAD) on a comment discussed in its February 2020 meeting related to the frequency of reporting follow-up reports for emerging diseases. The Commission noted that this comment should be considered in the context of Article 1.1.4 (rather than 1.1.3), and recognised that the information on emerging diseases would not necessarily evolve every week, hence a follow-up report is not necessarily needed to be sent every week. Therefore, the Commission agreed not to modify the current wording that provides adequate flexibility by encouraging reporting at any frequency needed.

Revised Chapter 1.1, Notification of diseases, infections and infestations, and provision of epidemiological information, is presented as **Annex 5**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

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

A comment is inserted in the text of Annex 5.

4.4. Diseases, infections and infestations listed by the OIE (Articles 1.3.1, 1.3.2, 1.3.6 and 1.3.9)

a) Articles 1.3.1, 1.3.2, and 1.3.9

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

Background

At its September 2019 meeting, in the context of the discussion of new Chapter 8.Y, Infection with animal trypanosomes of African origin, the Code Commission agreed to amend Article 1.3.1 to include 'Infection with animal trypanosomes of African origin (*T. vivax*, *T. congolense*, *T. simiae* and *T. brucei*)', and to delete the current 'Trypanosomosis (tsetse-transmitted)' from Article 1.3.2. This decision was based on the assessment done by a dedicated *ad hoc* Group, which had been endorsed by the Scientific Commission in February 2019. At the same meeting, in agreement with the Scientific Commission's conclusion on the assessments of pathogenic agents against the listing criteria, the Code Commission agreed to amend Article 1.3.9 to add 'Infection of dromedary camels with Middle east respiratory syndrome coronavirus'. The amended articles have been circulated three times for comments.

Discussion

Article 1.3.1

The Code Commission did not agree with a comment to replace 'infection' with 'infestation' at the fifth indent as the use of the term 'infection' for an internal blood parasite was consistent with the Glossary definition of infection and in line with the experts' discussion.

The Commission noted a comment received on proposed new Chapter 8.Y, Infection with animal trypanosomes of African origin, proposing to replace 'animal trypanosomes of African origin' by 'specific animal salivarian trypanosomes' in the name of the listed disease. However, the Commission did not agree to introduce any modifications to the disease name at this time and invited Members to refer to Item 4.12 of this report for its rationale.

No comments were received on revised Articles 1.3.2 and 1.3.9.

b) Article 1.3.6

Background

The revised Article 1.3.6 was first circulated for comments in the Code Commission's September 2019 report, in line with proposed changes made to Chapter 10.4. The revised article was to be proposed for adoption at the May 2020 General Session. However, due to the postponement of the 88th General Session, the revised text was circulated for an additional round of comments in the February 2020 report of the Commission. The Commission considered and discussed comments received at its September 2020 meeting. No further comments were received on revised Article 1.3.6 at the February 2021 meeting.

Revised Articles 1.3.1, 1.3.2, 1.3.6 and 1.3.9 are presented as **Annex 6**, and are proposed for adoption at the 88th General Session in May 2021.

EU position

The EU supports the adoption of these revised articles.

4.5. Animal health surveillance (Article 1.4.3)

Comments were received from Switzerland and the EU on the annex circulated in the Code Commission's February 2020 meeting report.

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. The revised Article 1.4.3 was circulated twice for comments, the last time in its February 2020 meeting report. At its September 2020 meeting, the Commission reviewed comments received and agreed to defer its discussion until its February 2021 meeting.

Discussion

The Code Commission noted general comments supporting the proposed changes and that no specific comments were received.

Revised Article 1.4.3 is presented as **Annex 7**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

The EU supports the adoption of this revised article.

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

Comments were received from Switzerland and the EU on the annex circulated in the Code Commission's February 2020 meeting report.

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. Common provisions concerning procedures applicable to the diseases for which the OIE grants official recognition of status would be addressed in Chapter 1.6, Procedures for self-declaration and for official recognition by the OIE, instead of being repeated in relevant disease-specific chapters. The revised Chapter 1.6 was circulated five times for comments, the last time in its February 2020 meeting report. At its September 2020 meeting, the Commission reviewed comments received and agreed to defer its discussion until its February 2021 meeting.

Discussion

Article 1.6.2

In the second paragraph, in response to a request from the Scientific Commission, the Code Commission agreed to amend the text referring to the time limit for Members to apply for the recovery of a previously recognised animal health status to accommodate the need for flexibility in the OIE procedures for some diseases. The Commission did not agree to include a reference to the OIE Standard operating procedures (SOP) for status recognition in this article because SOP is based on existing standards and not the other way around.

Revised Chapter 1.6, Procedures for self-declaration and for official recognition by the OIE, is presented as **Annex 8**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

The EU supports the adoption of this revised chapter.

4.7. Quality of Veterinary Services (Chapter 3.1), Evaluation of Veterinary Services (Chapter 3.2), and new chapter on Veterinary Services (Chapter 3.X)

Background

Chapters 3.1, Quality of Veterinary Services, and 3.2, Evaluation of Veterinary Services, 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, Veterinary Services, as an introductory chapter for Section 3 of the *Terrestrial Code*. The new Chapter 3.X and revised Chapters 3.1 and 3.2 have been circulated three times for comments, the last time in the Code Commission's September 2020 report.

General comments

In response to a comment that Chapters 3.X and 3.1 should not be adopted until the Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' are finalised, the Code Commission reiterated its previous response that until the work on revising these definitions is completed, the current definitions in the Glossary are to be used. The Commission noted that these chapters will be reviewed and updated, if necessary, once work on revising these definitions has been completed (refer to Part B of this report).

The Code Commission agreed with comments requesting to develop a definition of 'One Health' in order for Members to have a shared understanding of all that One Health encompasses. The Commission acknowledged that One Health is not only the domain of the OIE and therefore requested OIE Headquarters to consider the possibility of developing a definition of 'One Health' in collaboration with the Tripartite and other relevant partners.

a) New chapter on Veterinary Services (Chapter 3.X)

Comments were received from Australia, Singapore, Switzerland, the USA, Zimbabwe, the EU and the Members of the OIE Americas Region.

Discussion

Article 3.X.1

In the first sentence, the Code Commission did not agree with a comment to add 'and ecosystem' after 'wildlife', as it considered that the scope of ecosystem is more far-reaching than animals. Furthermore, 'environmental protection' is covered in the latter part of the sentence.

In the second paragraph, regarding a comment to add 'as applicable' after 'veterinary domain' and to delete 'as they see fit' because this term would imply that Members could disregard OIE

standards, the Code Commission clarified that with the exception of notification of a listed disease, infection or infestation, OIE standards are not mandatory. Nonetheless the Commission proposed to replace 'as they see fit' with 'as they consider appropriate' for consistency with the language used in the *Terrestrial Code*.

In paragraph 5, the Code Commission did not agree with a comment to add 'national, regional and' before 'international veterinary certificates' as it considered this to be too detailed, and it is a defined term. The Commission explained that the OIE standards on certification are intended for international veterinary certificates, although they can be used for national and subnational purposes.

b) Quality of Veterinary Services (Chapter 3.1)

Comments were received from Australia, Colombia, New Caledonia, Singapore, Switzerland, the UK, the USA, Zimbabwe, the EU, the Members of the OIE Americas Region and the AU-IBAR.

Discussion

Article 3.1.2

In point 7, the Code Commission agreed with a comment that 'One Health approach' is not defined, and thus proposed to add 'collaboratively, including via' before 'One Health approach' to improve clarity.

Article 3.1.3

In the first sentence of the first paragraph, the Code Commission agreed with a comment to add 'economics and social science' before 'principles', for consistency with point 6 of Article 3.1.2, but did not agree to add 'sound' before 'risk analysis' as it considered this to be implicit. For the same reason, the Commission proposed to delete 'sound' before 'epidemiological'.

In the second paragraph, a comment requested to replace 'governmental authorities' with the original text 'Competent Authorities' as it considered that authorities at the provincial level do not fall under 'governmental'. The Code Commission did not agree and clarified that 'governmental' was not synonymous with 'national' and could also cover provincial authorities.

In the same paragraph, the Code Commission did not agree with a comment to add 'activities' after coordination as it considered the statement to be clear as written. Furthermore, coordination is not limited to activities, but would also include strategies and approaches.

In point 3, the Code Commission agreed with a comment that the outcome of risk analysis should be used to justify resource requirements to policy makers, and made changes accordingly.

In point 6, the Code Commission did not agree with a comment to add 'performance' after 'policies', noting that this is different from the scope of Article 3.1.3 which is on policy and management.

In point 8, the Code Commission agreed with comments to add 'other relevant governmental authorities'. The Commission did not agree to add 'non-governmental authorities' as it considered this was addressed by the term 'stakeholders'.

In point 9, the Code Commission did not agree with a comment to add 'relevant' before 'stakeholders' as it considered this to be implied. Further information on stakeholders is also provided in Article 3.1.6.

Article 3.1.4

In point 1, the Code Commission agreed with a comment to add ‘and sufficient’ after ‘qualified’.

In point 4, the Code Commission agreed with a comment to add ‘and regular’ after ‘sufficient’.

Article 3.1.5

In point 3, the Code Commission did not agree with a comment to add a new point on public sector professionals, including the chief veterinary officer. The Commission clarified that public sector veterinary professionals are addressed by the reference to ‘governmental authorities’ in the opening paragraph, and by the reference to ‘official tasks’ in the second paragraph.

In the same point, the Code Commission agreed with a comment to add ‘and extension’ before ‘services’, and to add ‘awareness of and’ before ‘access to’.

Article 3.1.6

In the first sentence, the Code Commission did not agree to add ‘ecologists’ as it considered this to be potentially confusing and to be already covered under ‘researchers’.

Article 3.1.7

In the first sentence, the Code Commission agreed with a comment to add ‘detect’ after ‘prevent’. However, it did not agree to add ‘disease sources’ after ‘trace’ as the act of tracing is for animal movements. For clarity, the Commission proposed to replace ‘and should be’ with ‘including through being’.

In the second paragraph, the Code Commission did not agree with a comment to add ‘and timely’ after ‘effectively’ as it considered timeliness to be part of effectiveness.

Article 3.1.8

The Code Commission noted a comment supporting the additions made to the first two paragraphs.

In the first sentence of the first paragraph, the Code Commission did not agree with a comment to add ‘primary production stages of the farm to table food continuum’, as it considered this to be too prescriptive. Furthermore, it commented that the roles and responsibilities of the Veterinary Services and human health authorities in the continuum vary between Members.

In point 2, the Code Commission did not agree with a comment to include ante-mortem and post-mortem inspections for ‘on-farm slaughter when authorised’, noting that few countries implement post-mortem inspections for on-farm slaughter, which is mainly for personal consumption.

Article 3.1.9

In point 1(b), the Code Commission agreed with a comment to add ‘and appropriate safe disposal’ after ‘administration’.

c) <u>Evaluation of Veterinary Services (Chapter 3.2)</u>

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

<u>Discussion</u>

The Code Commission noted comments that supported the proposed changes to this chapter.

Article 3.2.3

In point 2, regarding a comment seeking clarification on the principle of independence, the Code Commission clarified that the objective was to maximise the objectivity and reliability of the self-evaluation, and this could be done through different approaches, including with the use of independent evaluators.

Article 3.2.4

In point 6, the Code Commission noted a comment that the correct article reference should be Article 3.1.2 and not Article 3.2.2, and made the change accordingly.

Revised Chapters 3.1 and 3.2 and new Chapter 3.X are presented as **Annexes 9, 10 and 11**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

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

4.8. Veterinary legislation (Chapter 3.4)

Comments were received from Australia, Chinese Taipei, Switzerland, the UK and the EU on the annex circulated in the Code Commission's February 2020 meeting report.

Background

A thorough review of Chapter 3.4, Veterinary legislation, was undertaken by the *ad hoc* Group on Veterinary legislation in January 2018. The revised chapter has been circulated four times for comments. At its September 2020 meeting, the Code Commission reviewed comments received and agreed to defer its discussion until its February 2021 meeting.

Discussion

Article 3.4.2

The Code Commission did not agree with a comment to retain the reference to 'One Health' under the definition of 'Veterinary Domain'. While the Commission agreed that veterinary public health should contribute to One Health, it noted that this is an article on definitions, and thus the definition should focus on activities under the 'Veterinary Domain', and not how the activities should be conducted.

Article 3.4.5

In the ninth indent of point 1(d), the Code Commission did not agree with a comment to replace 'listing disease for' with 'request of', and to add 'of listed disease' after 'mandatory reporting'. It clarified that this point is about designating a list of diseases that are reportable within the country.

Article 3.4.11

In point 3(d), the Code Commission agreed with a comment to add 'suspending, withdrawing' after 'granting'.

Revised Chapter 3.4, Veterinary legislation, is presented as **Annex 12**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

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

4.9. New chapter on official control programmes for listed and emerging diseases (Chapter 4.Y)

Comments were received from Australia, China (People's Republic of), Chinese Taipei, Colombia, Switzerland, the USA and the EU on the annex circulated in the Code Commission's February 2020 meeting report.

Background

The Code Commission added the development of a new chapter on outbreak management to its work programme at its February 2016 meeting. The new chapter was circulated for comments the first time in the Commission's February 2017 meeting report. Since that time, the Code Commission has made significant amendments to the text having taken into consideration important feedback received from Members as well as advice provided by the Scientific Commission to address specific comments. The revised chapter has been circulated seven times for comments. At its September 2020 meeting, the Code Commission reviewed comments received and agreed to defer its discussion until its February 2021 meeting.

Discussion

General comments

The Code Commission did not agree with a comment to limit this new chapter's application to diseases for which the OIE grants official recognition of status. The Commission noted that official control programmes are not limited to these diseases, but in the context of the *Terrestrial Code*, cover any programme approved, managed, or supervised by the Veterinary Authority to control a pathogenic agent or disease by specific measures applied throughout the country, or within a zone or compartment of that country. The Commission reminded that this chapter was drafted following the request of Members, and while noting its complementarity with other horizontal chapters in the *Terrestrial Code*, it is aimed at filling some specific gaps that exist in the current *Terrestrial Code*.

Article 4.Y.1

In the third paragraph, the Code Commission agreed with a comment to add 'to be prepared, developed and' before 'implemented', to improve clarity and consistency with the purpose of the chapter as stated in the previous paragraph.

In the sixth paragraph as well as the list of points that follows this paragraph, the Code Commission did not agree with a comment to replace 'infection or infestation' with 'disease'. The Commission referred Members to the convention explained in its September 2019 meeting report regarding the use of these terms, and considered that in this context, the use of the terms' infection or infestation' was more appropriate. Following this rationale, the Commission agreed to amend the text to ensure alignment with the use of 'infection or infestation' elsewhere in this article.

In the seventh paragraph, the Code Commission agreed with a comment that the phrase 'exit strategy options' was not clear and agreed to replace it with 'options for revising or ending them'.

In the last paragraph, the Code Commission agreed with a comment to add 'from both epizootic or enzootic situations' to better reflect that the term 'outbreaks' referred to the occurrence of one or more cases in an epidemiological unit, in either of those epidemiological contexts. The Commission also agreed to replace 'trained' with 'proficient' as that is the real objective, not the training itself.

Article 4.Y.2

In point 1, the Code Commission did not agree with a comment to delete 'disease' after 'listed', as it considered that, although it would be grammatically correct, the convention was to use the full terms as defined in the Glossary.

In point 2, the Code Commission did not agree with a comment to replace 'sources of finance' with 'financial resources' in several indents, as it considered that the original text was clear and the intention of this point was to focus on the sources, not on the resources.

In the second indent of point 3, the Code Commission did not agree with a comment to remove ‘case’ after suspected, as it considered that the repetition was necessary to precisely indicate that there are different procedures for both ‘suspected cases’ and ‘confirmed cases’.

In the tenth indent of point 3, the Code Commission did not agree with a comment to replace ‘products of animal origin’ with ‘products of either animal or non-animal origin’, as the non-animal origin products are covered as fomites in the following points.

Article 4.Y.3

In the first paragraph of point 1, the Code Commission agreed with a comment to improve clarity and replaced ‘to what extent’ with ‘the level of preparedness needed’.

In the third paragraph of point 1, the Code Commission did not agree with a comment to replace ‘pathogenic agents’ with ‘pathogens’ and noted that ‘pathogenic agent’ is the term used in the *Terrestrial Code*, after many exchanges with Members when dealing with the revision of the Glossary of terms.

In point 2, the Code Commission agreed with a comment to amend the wording of some indents to improve clarity.

In points 2(a), (b), (c) and (d), the Code Commission amended the wording to use consistent terminology.

In point 3, the Code Commission did not agree with a comment to expand the text to include other workshops and seminars and considered that although correct, it was too detailed and did not add any significant value to the chapter.

Article 4.Y.5

In the last paragraph, the Code Commission did not agree with a comment to add ‘management and’ before ‘coordination’, as it considered that the focus for this text was on coordination and not management.

Article 4.Y.6

In point 1, the Code Commission did not agree with a comment to add ‘and, for emerging diseases, in accordance with available scientific information’ at the end of the sixth paragraph, as considered this was implicit.

Article 4.Y.7

In the second paragraph, the Code Commission agreed with a comment to amend the text, to better reflect that movement restrictions should be based on risk analysis, as movements of negligible risk are critical for business continuity during an outbreak.

Article 4.Y.9

In the second paragraph, the Code Commission did not agree with a comment to provide further details regarding disinfection processes, noting that such details should be addressed in Chapter 4.14, General recommendations on disinfection and disinfection. The Commission noted that the revision of Chapter 4.14 is included in the Commission’s work programme (refer to Part B of this report).

Article 4.Y.10

In the fourth paragraph, the Code Commission agreed with a comment to add ‘increase the herd immunity for and’ before ‘decrease the shedding’ to better reflect the benefits derived from vaccination.

In the fifth paragraph, the Code Commission did not agree with a comment to add more details regarding identification of vaccinated animals, to avoid being too prescriptive, and noted that such details are already provided in Chapter 4.18, Vaccination.

Article 4.Y.11

In the first paragraph, the Code Commission agreed with a comment to add new text to highlight the importance of communication with Competent Authorities of trading partners to control transboundary animal diseases. The Commission also added a reference to neighbouring countries for the same reason.

New Chapter 4.Y, Official control programmes for listed and emerging diseases, is presented as **Annex 13**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

The EU supports the adoption of this new chapter.

4.10. Zoning and compartmentalisation (Articles 4.4.6 and 4.4.7)

Comments were received from Argentina, Brazil, Canada, Japan, New Zealand, Switzerland, the USA, the EU and the AU-IBAR.

Background

During the last revision of Chapter 4.4, Zoning and compartmentalisation, that was adopted in 2018, some Members had proposed to include new text in Article 4.4.6 on the concept of 'temporary protection zone' to minimise the impact that a disease introduction would have on the entire country or zone. At that time, the Code Commission, in consultation with the Scientific Commission, agreed to not address these requests but rather to discuss further how to manage, clarify and incorporate this concept into the *Terrestrial Code*. Since that time, 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 Articles 4.4.6 and 4.4.7. As a result of the exchanges and discussions between the Code Commission and the Scientific Commission it was considered that a better approach would be to modify the current 'protection zone' by including provisions for its establishment as a temporary measure, rather than incorporating a new concept 'temporary protection zone'.

The proposed revised texts for Articles 4.4.6 and 4.4.7 were circulated twice for comments, the last time in the Code Commission's September 2020 report.

Discussion

Article 4.4.6

In response to a comment, the Code Commission agreed to include, in the second paragraph, a limit of 24 months for a protection zone that would be established as a temporary measure, regardless of the official recognition of animal health status by the OIE. The Commission recognised that once a protection zone is established temporarily within a free country or zone in response to an increased risk of disease, it should be lifted as soon as the risk is mitigated. If a disease incursion occurs, it would either become a containment zone or a normal infected zone. If the protection zone cannot be lifted because the risk is continuing, then the protection zone cannot be considered temporary anymore, and a more permanent arrangement should be foreseen. Accordingly, the Commission also agreed to delete the second indent in the ninth paragraph of Article 4.4.6 as it considered this to be redundant given the change proposed in the second paragraph.

In the sixth paragraph, the Code Commission did not agree with an editorial comment to revise the wording for clarity, as it considered that it implied modifying the sense of the original text.

Article 4.4.7

The Code Commission did not agree with a comment to revise the wording of point 4(b). The Commission emphasised that the text in this point is clear as written, as it refers to the role of the 'outer zone' in separating the 'inner zone' from the rest of the country or zone. The Commission also noted that the word 'zone' being used in italics refers to the defined term in the Glossary, and implies compliance with all specific provisions provided elsewhere in the *Terrestrial Code* (e.g. Chapter 4.4, Chapter 1.4).

The Code Commission did not agree with a comment to include a new point (c) referring to the need to establish similar measures within neighbouring countries when a containment zone is bordering on the territory of another country. The Commission agreed that the epidemiological situation in the neighbouring country should be taken into consideration and cross border coordination would undoubtedly improve the efficiency of the measures in the national territory. Nonetheless, as countries cannot implement measures outside of their national territories, this cannot be considered mandatory. Nevertheless, all provisions related to border control and surveillance should be effectively implemented. The Commission also noted that for these cases, the proposed change for Article 4.4.6 provides a suitable approach for dealing with this situation.

The Code Commission did not agree with a comment to amend the text specifying that a containment zone is considered effectively established when the conditions described in the article and the relevant disease-specific chapters have been applied and documented evidence is submitted and accepted by the OIE. The Commission explained that this was already addressed in the chapeau of point 4 and point 6 of this article.

The Code Commission did not agree with a comment to revise point 7 to improve clarity. The Commission emphasised that if a case occurs in a containment zone (as described in point 4(a) or in the 'outer zone' of a containment zone, as described in point 4(b)), the country or zone that was free will lose its status. The Commission noted that the borders of an established containment zone cannot be further modified.

The Code Commission considered a request from the Scientific Commission to introduce new amendments in Article 4.4.7 regarding the temporality of containment zones. The Code Commission noted that this topic was out of the scope of the current revision and decided not to address it at this stage, given that the amended text was to be proposed for adoption in May 2021. The Code Commission agreed to further discuss this with the Scientific Commission.

Revised Articles 4.4.6 and 4.4.7 are presented as **Annex 14**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

The EU supports the adoption of this revised chapter.

4.11. New chapter on animal welfare and laying hen production systems (Chapter 7.Z)

Comments were received from: Australia, Canada, Chile, China (People's Rep. of), Dominican Republic, Colombia, New Caledonia, Norway, Peru, Switzerland, the USA, the UK, Zimbabwe, the EU, the AU-IBAR, the IEC and the ICFAW.

Background

The new Chapter 7.Z, Animal welfare and laying hen production systems, was the last chapter to be developed on animal production systems based on the prioritised list developed by the former OIE Animal Welfare Working Group. The draft chapter was developed by the *ad hoc* Group on Animal welfare and laying hen production systems in 2016 and was considered by the Code Commission at its February 2017 meeting. The proposed new chapter was circulated four times for comments, the last time in the Code Commission's September 2020 report.

Discussion

General comments

The Code Commission noted that despite having considered comments and having made relevant amendments that reflect scientific evidence, Members continue to hold opposing views for a number of articles including recommendations on Dust bathing, Article 7.Z.10; Foraging Areas, Article 7.Z.11; Nesting areas, Article 7.Z.12; and Perches, Article 7.Z.13. The Commission reiterated that as the scope of this chapter is for all types of production, it did not agree with several comments that were considered too limiting in scope. For the same reason, it also did not agree with comments to replace 'is desirable' with 'should' throughout the chapter.

The Code Commission noted that there has been a tremendous amount of work done to develop this important chapter; it is based on sound science, and it is well balanced between different and opposing views in terms of implementation. It will provide, to OIE Members, a new welfare standard for laying hen production systems that takes into consideration the diversity of production systems around the world. The Commission noted that no new comments of substance had been received during this round of comment. The Commission agreed that delaying the adoption of this new chapter would prevent Members from having access to an animal welfare standard for laying hen production systems and therefore may delay the implementation of improvements in such production systems.

The Secretariat also presented to the Code Commission a proposal to respond to a pending Member comment from the September 2020 meeting about the use of the terms 'outcome-based measurables' versus 'outcome-based measures'. The Commission decided not to discuss the proposal in this meeting, but rather include it in its work programme, as the potential changes and impact go beyond this chapter.

The Code Commission reminded Members to use the official Commission translation of the reports to have a correct understanding of the text when submitting their comments. The use of the official translation will ensure better alignment of the three linguistic versions. The Commission requested that this be addressed and presented in the corresponding Annexes in its Spanish and French reports.

The Code Commission considered all comments received with justification and amended the text accordingly.

Article 7.Z.1

The Code Commission did not agree with a comment proposing to add 'intended for human consumption or for meat meal' to the definition of 'End-of-lay hens' because the purpose (or what is done with these hens) is not relevant for this definition.

Article 7.Z.2

In the first paragraph, the Code Commission did not agree to replace the term 'birds' with 'chicks' because 'day-old bird' is a defined term in the glossary.

The Code Commission agreed with the comment to add the term 'layer' in front of 'pullet' and reviewed the use of this term throughout the chapter and amended the text accordingly, thereby addressing similar comments made in other articles.

The Code Commission did not agree with the comment to remove the term 'laying' between 'laying pullets' and 'laying hens' because they considered these as two different types of production animals and so they should be identified accordingly.

In the third paragraph, the Code Commission did not agree with a comment that proposed new text caveating that the recommendations may not be applicable for different systems. The Commission noted that the text already considered different systems with the use of the term 'or'. Similarly, it did not agree with a comment to specify 'in cages or cage-free' in completely housed systems because the text is flexible enough to allow for either options, and the text should apply to any types of systems.

Article 7.Z.3

In the penultimate sentence of the first paragraph, the Code Commission agreed with the comment to add ‘production systems’ but it decided to do so between the terms’ different’ and ‘situations’.

In the second paragraph, the Code Commission did not agree to replace ‘depopulation’ with ‘depletion’ because the latter has a different meaning. Moreover, the term ‘depopulation’ is used in other chapters of the *Terrestrial Code* to express the same objective as intended in this chapter.

In the second paragraph, the Code Commission did not agree to add the term ‘health’ in front of ‘monitoring’ because by definition, ‘monitoring’ aims at detecting change in health status.

In the third paragraph, the Code Commission did not agree with the proposal to remove or change ‘in alphabetical order in English’ because it was important to inform the reader how the terms are ordered i.e. alphabetically rather than by importance, priority or categories. The Commission understands that the order is not alphabetical in the Spanish and French versions, but it is equally important for readers to know why the terms are presented in this order.

In point 2, first paragraph, the Code Commission did not agree to add text to caveat that some behaviours may not apply to different housing systems. The Commission noted that the performance of certain behaviours is dependent on the production system and therefore not all outcome-based measurables presented are suitable for every system.

In point 2, first paragraph, the Code Commission did not agree to split the third sentence because it considered the two parts (separated with ‘and’) to be linked where the second part is a consequence of the first part.

In point 2(a), the Code Commission did not agree with the proposal to remove ‘is a motivated behaviour’, because it needs to be stated that these behaviours are innate and animals are compelled to perform them even in the absence of any specific stimuli. Also, this wording emphasises the fact that when some of these behaviours are performed, good animal welfare is achieved. The Commission noted that this term is used consistently throughout this chapter. This response applies to the same comment made in points 2(d), 2(g) and 2(h).

In point 7, the Code Commission agreed with a comment to add the term ‘equipment,’ before ‘environment conditions’ because injuries can be a consequence of ‘equipment’.

Article 7.Z.4

In the first paragraph, the Code Commission did not agree with the proposal to remove the seemingly repeated terms ‘management practices’ because ‘environmental management practices’ are distinct from ‘animal management practices’ and do not mean the same as ‘environmental and animal management practices’.

In the last sentence of the first paragraph, the Code Commission agreed with the proposal to remove the term ‘serious’ due to the subjective meaning of the term. It also replaced the second term ‘problems’ with ‘issues’ to improve readability.

In the third paragraph, the Code Commission did not agree to add ‘may apply’ at the end of the first sentence because the sentence is clear as written.

Article 7.Z.5

In the last paragraph, the Code Commission did not agree with the proposal from various Members to add ‘include’, ‘may include’ or ‘suggested’ to the outcome-based measurables throughout the chapter. The Commission noted the importance of ensuring alignment with the use of these terms in other chapters. The Commission reiterated the importance of reading the chapter as a whole, for example, Article 7.Z.3 explains that the list of measurables presented is not exhaustive, and its use should be adapted to different production systems and situations.

Article 7.Z.6

In the first paragraph, the Code Commission agreed with the proposal to replace ‘birds’ with ‘layer pullets’ in the last sentence but removed the terms ‘layer pullets’ from the beginning of that sentence to avoid unnecessary repetition.

Article 7.Z.7

In the first paragraph, the Code Commission did not agree with the proposal to merge the first sentence with the second by adding ‘if possible’ and deleting ‘is desirable’. Also, it did not agree with the comment suggesting to replace ‘is desirable’ with ‘should be provided’. The Commission noted that those two opposite comments have been addressed by the *ad hoc* Group and previous discussion in the Commission. The *ad hoc* Group as well as the Commission considered that *the recommendation in this chapter should be applicable to all production systems considered in the scope of the chapter* (see *ad hoc* Group report attached to September 2019 Code Commission report) and thus the current text *allowed for the continuous development of country specific animal welfare recommendations and monitoring for implementation* (see September 2019 Code Commission report). On the same grounds, the Commission did not take similar comments made in Articles 7.Z.9, 7.Z.10, 7.Z.11, 7.Z.12, and 7.Z.13.

The Code Commission did not agree with the proposal to add ‘flock or group size’ to the list of factors to consider when determining space allowance because space allowance is not dependent on the group size, but rather on an individual animal basis. The group size is dependent on the space allowance, but not the other way around.

Article 7.Z.8

In the first paragraph, the Code Commission considered a comment and added ‘production system’ as it agreed it was a factor to consider to ensure appropriate nutrition.

Article 7.Z.9

In the last paragraph, the Code Commission did not agree with the proposal to delete ‘dust bathing’ and ‘foraging behaviour’ and noted that the list of outcome-based measurables is presented for guidance and should be used in accordance with the type of production system. Similarly, the Commission did not agree with the proposal to add ‘appropriate for the type of housing and management’ because it considered that it is implicit, i.e. that these factors should be considered when choosing the outcome-based measurable.

Article 7.Z.12

In the first paragraph, the Code Commission did not agree to replace ‘areas’ with ‘boxes’, as the term ‘areas’ is more generic and includes ‘nest boxes’.

In the first paragraph, the Code Commission did not agree with the proposal to add ‘under relevant management system’ in the first sentence because it considered that the term ‘desirable’ implies it is recommended when appropriate. The Commission did not agree with a similar comment made in Article 7.Z.13.

Article 7.Z.13

In the first paragraph, the Code Commission did not agree with the deletion of ‘all’ in the second sentence because it considered that perches should be provided to all birds that can use them and not just by a limited number of birds.

Article 7.Z.14

In the third paragraph, the Code Commission did not agree with the proposal to remove ‘standing’ in front of ‘water’ because the issue comes from the accumulation of water or water that is standing rather than water itself.

Article 7.Z.15

In the fourth paragraph, the Code Commission did not agree to change ‘be’ for ‘are’ or ‘can be’ because the use of ‘be’ is grammatically correct.

Article 7.Z.16

In the first paragraph, the Code Commission considered the comment to add ‘housing’, to the ‘type or systems’, and agreed to add the term ‘design and equipment’ after ‘housing’ to be more specific as to the possible causes that can affect the air quality.

In the second paragraph, the Code Commission did not agree with the proposal to change the ammonia concentration ‘25 ppm’ to ‘10 ppm’ and reiterated that 10 ppm, as stated in the reference provided, is the concentration that is detectable by humans and 25 ppm corresponds to the level where tissue damage is detected in birds.

In the third paragraph, the Code Commission did not agree with the proposal to remove the sentence on ‘dust levels should be kept to a minimum’ because this is based on a recommendation in the reference provided, which shows evidence of a clear synergy between ammonia and dust impairing pulmonary function.

Article 7.Z.19

In the first paragraph, the Code Commission did not agree with the addition of ‘prophylactic’ and ‘therapeutic’ partial beak removal as it considered that the list of management methods provided is not exhaustive and should not be too prescriptive.

The Code Commission did not agree to add ‘implementing beak treatment at day-of-age in the hatchery’ to the bulleted list, because ‘partial beak removal’ is already considered as a final course of action if management methods are unsuccessful. The Commission did not agree to remove the management method ‘providing nesting areas during lay’ because this addition was based on the scientific evidence that nesting areas do alleviate feather pecking, per reference provided to the Commission.

In the second paragraph, the Code Commission did not agree to add ‘layer pullet and laying hens’ at the beginning of the sentence as it considered that the article clearly refers layer pullets and layer hens.

In the third paragraph, the Code Commission did not agree to replace ‘euthanised’ with ‘salvaged’ because the concept of ‘salvaged’ was covered under ‘treated’. ‘Treated’ does not imply that the bird must return to the flock.

In the fourth paragraph, the Code Commission did not agree to replace ‘partial beak removal’ with ‘beak trimming’ because it considered that both terms refer to the same management method and ‘partial beak removal’ is easier to translate into French and Spanish. The Commission did not agree with a similar comment made in Article 7.Z.21.

Article 7.Z.21

In the first paragraph, the Code Commission removed the term ‘therapeutic’ in front of ‘partial beak removal’ to be consistent with Article 7.Z.19.

In the second paragraph, the Code Commission did not agree to add ‘shape’ to ‘beak’ in the outcome-based measurables because it considered that ‘beak condition’ includes ‘beak shape’.

Article 7.Z.22

In the third paragraph, the Code Commission did not agree to add ‘and infestation’ after ‘prevention of diseases’ because ‘diseases’ in this context include infestations.

In the fifth paragraph, the Code Commission did not agree to add a caveat explaining when a bird should be transferred to the hospital area because it considered this to be self-explanatory.

Article 7.Z.24

In the second paragraph, the Code Commission did not agree with the proposal to add 'impossibility or physical inability to access food or water' as a reason for euthanasia because it considered that the proposed reason would be a consequence of other reasons already listed and not a reason in itself.

Article 7.Z.25

In the fourth paragraph, the Code Commission agreed with the proposal to delete the second sentence noting that it was out of context.

Article 7.Z.26

In the first paragraph, the Code Commission did not agree to remove 'evacuation procedures' because it considered that the terms 'where relevant' written before made it clear that an 'evacuation procedure' was not compulsory.

Article 7.Z.29

The Code Commission did not agree to add 'and wild birds' to the title 'Protection from predators' of this article because it considered that this article is not meant to say 'protect from wild birds' but simply 'prevent access to wild birds' as a general biosecurity measure mentioned in the first paragraph.

In the second paragraph, the Code Commission did not agree to add 'predation rate' to the list of 'outcome-based measurables' as it considered it was not a criterium as defined in Article 7.Z.3, but rather it could be considered as cause of mortality, which is already included in the list.

New Chapter 7.Z, Animal welfare and laying hen production systems, is presented as **Annex 15**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

The EU cannot support the adoption of this new chapter. The rationale is provided in the text of Annex 15.

4.12. New chapter on infection with animal trypanosomes of African origin (Chapter 8.Y)

Comments were received from Australia, Switzerland, Thailand, Zimbabwe, the EU and the AU-IBAR.Background

At 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 new Chapter 8.Y, Infection with animal trypanosomes of African origin, for comments. The Code Commission together with the Scientific Commission had agreed that three separate chapters on animal trypanosomes would be developed to address the different coverage of trypanosomes species and host animals, and that a new Chapter 8.Y would be the first to be developed.

The draft chapter was developed by an *ad hoc* Group and the proposed new chapter was circulated for comments on three occasions, the last time in the Code Commission's September 2020 report.

Discussion

General comments

The Code Commission noted a comment seeking clarification on the use of terms 'competent vectors' and 'competent tick vectors' in the *Terrestrial Code* and requesting the inclusion of genera or species of competent vectors in all relevant chapters. In response the Commission considered that the term 'competent' referred to a vector's capability to transmit the disease and found no added

value on further defining these terms for the purpose of the *Terrestrial Code*. The Commission also explained that it was not always possible to provide a detailed list of competent vectors for every disease and that such a list could even vary according to the region. The Commission highlighted that the detailed provisions for surveillance for arthropod vectors is provided in Chapter 1.5.

Title

The Code Commission considered a comment to change the term 'animal trypanosomes of African origin' to 'specific animal salivarian trypanosomes' in the title and across the whole chapter. In line with the opinion of the Scientific Commission, the Code Commission agreed with the rationale for that change, that Article 8.Y.1.4 defines the range of trypanosomes targeted in the chapter and that creating disease names that have geographical indicators of little or no scientific value should be avoided. Nevertheless the Code Commission noted that the current title was proposed after thorough expert consultation and had already undergone three rounds of comments. However, the Commission agreed to review this again in the future, noting that it would also require harmonisation with the *Terrestrial Manual* as well as with the use of the disease name by the World Health Organisation (WHO).

Article 8.Y.1

At its September 2020 meeting, the Code Commission did not agree with a comment to add 'cyclically transmitted by tsetse flies' to the definition of animal Trypanosomes of African origin in points 1 and 4, based on previous discussions of the *ad hoc* Group on Animal trypanosomes of African origin. The Code Commission noted that the Scientific Commission's September 2020 report provided a rationale to support this decision.

In point 1, the Code Commission agreed with a comment to replace 'cattle' with 'animal', noting that the chapter refers to many species and not only to cattle.

In point 2, the Code Commission agreed with a comment to replace 'could exist' with 'may occur' to avoid ambiguity but did not agree to delete the reference to 'routine testing methods' as it considered it was relevant for this to be highlighted in the context of these general provisions. The Commission highlighted that specific recommendations for diagnostic techniques are provided in the *Terrestrial Manual*.

Article 8.Y.3

The Code Commission did not agree with a comment to delete point 3(c). Nevertheless, the Commission agreed with the rationale that the absence of competent vectors should not be the only basis on which a country can declare freedom from a disease and noted that this was in line with Article 1.5.1. The Commission noted that compliance with points 1 and 2 of this article is also required, and agreed to amend point 3 to specify that the absence of cases for at least the past two years would always apply, and that it should be complemented either with specific surveillance, in accordance with the relevant articles of this chapter, or with the absence of competent vectors.

Article 8.Y.7

In the fifth paragraph, the Code Commission did not agree with a comment to delete the recommendation for wildlife to be considered in the surveillance system. The Commission recognised the challenges of implementing surveillance programmes in wildlife but agreed that the text was clear as presented and that it does not imply a mandatory requirement to establish dedicated wildlife surveillance programmes, but rather it recommends to consider wildlife, for example to address surveillance targeting 'at risk' domestic populations that could be in contact with wildlife.

Article 8.Y.8

In point 2(a), the Code Commission agreed with a comment to amend the text to also include stakeholders who are neither owners nor keepers but have regular contact with susceptible animals, noting that this is particularly relevant for wildlife.

Translation changes were included in the Spanish version of the chapter to better align with the versions in French and English.

New Chapter 8.Y, Infection with animal trypanosomes of African origin, is presented as **Annex 16**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

The EU supports the adoption of this new chapter.

4.13. Infestation with Aethina tumida (Small hive beetle) (Article 9.4.5)

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

Background

At its February 2020 meeting, the Code Commission agreed to amend Article 9.4.5 in response to a comment concerning the timing of inspection prior to export and the area freedom from the occurrence of infestation with *Aethina tumida*. The revised article has been circulated for comments on two occasions, the last time in the Code Commission's September 2020 report. The Commission consulted OIE Reference Laboratory experts for advice to support its discussions during this revision.

Discussion

Article 9.4.5

The Code Commission did not agree with a comment to revert to a 100 km radius. The Commission noted that the rationale for changing this to 50 km had been noted in its September 2020 report. The Commission reiterated that this decision was not only based on empirical evidence from a single country and that this is not an isolated measure, but rather one of a number of measures presented in this chapter that together ensures the commodity can be traded safely.

The Code Commission also noted references presented by Members and considered that they supported the chosen radius. One publication stated that maximum recorded foraging range of bees (euglossine bees) is 24 km (Janzen, 1971), 50 km being twice that distance; another noted that a smaller radius might allow for more intensive surveillance and, hence, increase the likelihood of detecting infested apiaries within the surveillance zone, and could also make controls on movements within the zone more feasible (EFSA Journal 2015;13(12):4328, 77 pp) The Commission considered this specifically relevant for a surveillance zone aiming at detecting a potential incursion of the pathogenic agent from infected areas, making the certification more reliable.

Revised Article 9.4.5 is presented as **Annex 17**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

The EU in general supports the adoption of this revised article.

A comment is inserted in the text of Annex 17.

4.14. Infection with avian influenza viruses (Chapter 10.4)

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

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. A revised chapter was to be proposed for adoption at the May 2020 General Session. However, due to the postponement of the 88th General Session and to the fact that other related texts had been concomitantly sent for comments (Glossary definition of poultry and OIE list of diseases), the revised text was circulated for an additional round of comments in the February 2020 report of the Code Commission. At its September 2020 meeting, the Commission considered comments received on the revised chapter together with those on the revised Glossary definition for 'poultry' and the revised Article 1.3.6, and circulated Chapter 10.4 for another round of comments. The revised Chapter 10.4, Infection with avian influenza viruses, has been circulated for comments on four occasions.

Discussion

General comments

The Code Commission wished to highlight that comments received on Chapter 10.4 were not of a substantial nature and some explicitly supported the proposed amendments. The Commission thanked Members for their engagement in the revision of this chapter and acknowledged the valuable contributions received throughout the review process that assisted the Commission to develop a version that addressed Members concerns.

In response to a comment requesting that H5 and H7 low pathogenicity avian influenza (LPAI) viruses should be notified to the OIE because they mutate easily and usually cause infection, the Code Commission reminded Members that this issue had been addressed by the *ad hoc* Group on Avian influenza at its last meeting and had been extensively discussed during previous meetings of the Commission. The Commission encouraged Members to thoroughly review previous relevant Commission reports. The Commission also considered the advice provided by the Chair of the *ad hoc* Group on Avian influenza for this meeting, and reiterated that LPAI viruses are a heterogeneous group that are lineage specific, and literature does not support that all H5 and H7 LPAI viruses quickly and easily mutate to high pathogenicity avian influenza (HPAI) viruses. The vast majority of H5 and H7 LPAI strains do not mutate to HPAI viruses. Some H5 and H7 lineages have a propensity to mutate to HPAI and thus a monitoring programme as proposed in the revised chapter would identify such viruses allowing Members to take actions to mitigate risks. The Commission reminded Members that the current Chapter 10.4, which does not appropriately manage the different risks posed by LPAI and HPAI, while not having resulted in an improvement of the global epidemiological situation, has resulted in severe negative trade impacts for both LPAI and HPAI notification, and this has led to disproportions in notification and trade restrictions based predominantly on H5 and H7 LPAI reported from Members with intense surveillance programmes, and therefore biased against those with the most sophisticated active surveillance programmes capable of detecting LPAI infections.

The Code Commission disagreed with a comment that notification of specific LPAI subtypes with zoonotic potential as emerging disease was inappropriate. The Commission noted another comment supporting the approach in the revised chapter and agreed that once a Member identifies and notifies to the OIE the occurrence of a specific LPAI subtype with zoonotic potential as an emerging disease in accordance with Article 1.1.4, further occurrence of that specific LPAI subtype in other Member Countries would also need to be notified as an emerging disease. Based on the data gathered through these initial notifications, the subtype could then be assessed as to whether it would fit the listed disease, infection and infestation as per indent 10 of Article 1.3.6, and subsequent notification as per Article 1.1.3. The Commission agreed that this would require good coordination and emphasised that the OIE Headquarters should develop the mechanisms within the OIE World Animal Health Information System (OIE WAHIS) to facilitate this. While the Commission agreed with the Member that important animal health information should be provided to the OIE through OIE WAHIS in accordance with Article 1.1.6, it did not agree that WAHIS is the main platform for the exchange of scientific data on avian influenza viruses other than official notifications. The Commission noted that other platforms exist, such as the OIE/FAO Network of Expertise on Animal Influenza (OFFLU), for OIE Reference Laboratories and avian influenza experts to share scientific information, and in this way allow the identification and tracking of potentially zoonotic LPAI subtypes.

Article 10.4.1

In point 4, the Code Commission did not agree with a comment to replace ‘domestic’ with ‘all domestic birds including poultry’, noting that it was clear as written, and domestic birds would encompass more than just those included in the definition of poultry.

Article 10.4.20

In point 1, the Code Commission did not agree with a comment to invert the point and to begin the sentence with ‘it is not possible to predict which H5 and H7 low pathogenicity avian influenza viruses will mutate into high pathogenicity avian influenza viruses and when these mutations will

occur' as it considered that this would have the same meaning as currently written without providing any additional value.

In point 2, the Code Commission proposed to replace 'in order to fulfil notification obligations of' with 'is notifiable as' for consistency with the wording in point 3. In the same point, the Commission did not agree with a comment to replace 'Article 1.1.4' with 'Article 1.1.3. 1d'. The Commission clarified that low pathogenicity avian influenza viruses in poultry *per se* is a known pathogen but not a listed disease, hence it would fit point (a) of the Glossary definition of 'emerging disease'.

In point 3, the Code Commission did not agree with a comment to replace 'Article 1.1.3' with 'Article 1.1.4' and clarified that as per the proposed revised Article 1.3.6 (see Item 4.4), 'infection of domestic or captive wild birds with low pathogenicity avian influenza viruses that have been proven to be transmitted naturally to humans with severe consequences' would become a listed disease, and thus, once these changes are adopted, would have to be notified in accordance with Article 1.1.3.

Revised Chapter 10.4, Infection with avian influenza viruses, is presented as **Annex 18**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

The EU commends the OIE for this revision of the important chapter on avian influenza. The EU fully supports the new focus on HPAI in commercial poultry, while not neglecting relevant LPAI strains. We welcome the balanced and risk-based approach of this chapter and its trade facilitating direction. We are confident that this revised chapter will contribute to safe, smooth international trade, and look forward to it being implemented by all OIE member countries. The EU therefore supports the adoption of this revised chapter.

4.15. Avian mycoplasmosis (Mycoplasma gallisepticum) (Chapter 10.5)

Comments were received from Switzerland and the EU.

Background

At its February 2020 meeting, the Code Commission reviewed Chapter 10.5, Avian mycoplasmosis *(Mycoplasma gallisepticum)*, to align it with proposed amendments to Chapter 3.3.5, Avian mycoplasmosis *(Mycoplasma gallisepticum, M. synoviae)*, of the *Terrestrial Manual*. The Commission consulted OIE Reference Laboratory experts for advice to support its discussion during this revision. The revised Chapter 10.5, Infection with avian mycoplasmosis, has been circulated twice for comments.

Discussion

Article 10.5.3

In point 3, the Code Commission agreed with a comment to amend the text to clarify that both a serological test and an agent identification test should be performed at the end of the quarantine period. The Commission acknowledged that this was in line with the expert advice discussed in its February 2021 meeting. Therefore, the Commission proposed to delete the word "respectively" for clarity.

Revised Chapter 10.5, Avian mycoplasmosis *(Mycoplasma gallisepticum)*, is presented as **Annex 19**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

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

4.16. 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 China (People's Republic of), Switzerland and the EU on the annex circulated in the Code Commission's February 2020 meeting report.

Background

At its September 2018 meeting, the Code Commission had agreed to harmonise the provisions for official recognition and maintenance of free status, and endorsement and maintenance of official control programmes in disease-specific chapters with official recognition of status (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 to Members. The revised articles have been circulated three times for comments, the last time in the Commission's February 2020 report. At its September 2020 meeting, the Code Commission reviewed comments received and agreed to defer its discussion until its February 2021 meeting given that selected comments relevant to the official recognition of animal health status had been sent to the Scientific Commission for its opinion.

Discussion

General comments

Although Article 14.7.1 was not circulated for comments, a Member requested that 'cattle, camels and buffaloes' be added to the definition of infection with PPRV in the second paragraph. The Code Commission did not agree with this comment and in agreement with the Scientific Commission, reiterated that at current time, there is not enough evidence on the epidemiological role of these species and wildlife in the transmission of PPRV. As additional data emerges on the role of wildlife and other species in the epidemiology of the disease, the surveillance guidance of this chapter would be revised accordingly.

Article 14.7.3

In point 6, the Code Commission did not agree with a comment to replace 'since the cessation of vaccination' with 'for rearing' as this point was not to address the potential spread of the disease from vaccinated animals, but rather was a condition for the recognition of the free status of a country or zone. It noted the advice of the Scientific Commission 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.

Article 14.7.24

In point 3(a), the Code Commission proposed changes to improve the readability of this point.

Revised Articles 14.7.3, 14.7.7, 14.7.24 and 14.7.34 are presented as **Annex 20**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

The EU supports the adoption of this revised chapter.

4.17. Infection with classical swine fever virus (Chapter 15.2)

Comments were received from Canada, China (People's Republic of), Chinese Taipei, Ecuador, Switzerland, Thailand, the UK, the USA, the Members of the OIE Americas Region and the EU on the annex circulated in the Code Commission's February 2020 meeting report.

Background

The revision of Chapter 15.2, Infection with classical swine fever virus, was undertaken in response to comments submitted by Members, experts, and the *ad hoc* Group on Classical swine fever, and to ensure relevant alignment with recent amendments to Chapter 15.1, Infection with African swine fever virus (ASF), adopted in 2019, as well as with disease-specific chapters with official recognition of status. The revised chapter has been circulated four times for comments, the last time in the Code Commission's February 2020 report. At its September 2020 meeting, the Code Commission reviewed comments received and agreed to defer its discussion until its February 2021 meeting given that selected comments relevant to the official recognition of animal health status had been sent to the Scientific Commission for its opinion.

Discussion

Article 15.2.1

In the fifth paragraph, the Code Commission agreed with a comment to add 'may' before 'be persistently infected' for clarity.

The Code Commission did not agree to comments proposing the reinstatement of the sixth paragraph concerning the imposition of 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. However, the Commission addressed the proposal by introducing a modified text harmonised with the equivalent provision in Chapter 10.4, Infection with avian influenza viruses, which was inserted as a new paragraph after the case definition.

In addition, the Code Commission wished to emphasise that harmonisation across different disease-specific chapters does not imply using the exact same text, and that the provisions would also depend on the conditions or specificities for each disease. In this disease-specific chapter, the Commission highlighted that the free status of CSF only concerns the domestic and captive wild pig subpopulation, making it possible, as in Chapter 10.4, for Members to have a free status while cases are notified in wild animals. The Commission reminded Members that this is unlike Chapter 15.1 where a free status could be for all suids, not just domestic and captive wild pigs.

Article 15.2.2

The Code Commission proposed to delete 'CSF' before 'free country or zone' as it considered this to be implied here and was consistent with other recently updated chapters. This change was also applied to the rest of the chapter, where appropriate.

Article 15.2.3bis

In response to a comment seeking clarification on the inclusion of Article 15.2.3bis in this chapter and not in other relevant chapters, the Code Commission clarified that the article on 'country or zone infected' is harmonised with other disease-specific chapters on diseases for which the OIE grants official recognition of status, whereby countries or zones that are not recognised as officially free by the OIE are considered infected.

The Code Commission proposed to replace 'shall be' with 'is' for consistency with the language used in the *Terrestrial Code.*

Article 15.2.4

In the first paragraph, the Code Commission did not agree with a comment to modify the text for consistency with Chapter 10.4, and clarified that for diseases for which the OIE grants official status recognition (such as classical swine fever), there are specific provisions pertaining to status recognition that should be covered, including provisions on containment zones.

In the fourth paragraph, the Code Commission proposed to replace 'these areas' with 'the areas outside the containment zone' for clarity. The Commission also proposed to replace 'is established'

with ‘has been approved by the OIE’. In the same paragraph, it did not agree with a comment requesting to reinstate the last sentence as it considered this unnecessary since reference has been made to Article 4.4.7, and there was no need to duplicate the point.

A comment was received to delete the fifth paragraph with the rationale that the sentence is inconsistent with point 7 of Article 4.4.7 and to harmonise with Chapter 10.4. While the Code Commission agreed on the necessity to align this paragraph with the revised Article 4.4.7, it did not agree to delete it, but added ‘as described in point 7 of Article 4.4.7’ after ‘containment zone’ for clarity. This is also consistent with the other chapters on diseases for which the OIE grants official status recognition.

In the sixth paragraph, the Code Commission did not agree with a comment to delete ‘and be achieved within 12 months of its approval’. It noted the explanation provided by the Scientific Commission in its September 2020 report, that a containment zone is an instrument to quickly control limited outbreaks that are epidemiologically linked in order to reinstate the free status of the rest of the territory outside the containment zone. Should a more long-term strategy be needed, the permanent establishment of zones should be considered.

Article 15.2.5

In the first sentence, the Code Commission did not agree with a comment to replace ‘recovered’ with ‘reinstated’, as this article refers mainly to the conditions that countries have to comply with for the recovery of status, irrespective of the official reinstatement of the status by the OIE, as stated at the last paragraph of the article. Furthermore, the use of the term ‘recover’ is consistent with the title of this article.

In point 3, the Code Commission did not agree with a comment to move the word ‘validated’ before ‘means’, as it considered that this would have the same meaning as currently written without providing any additional value.

Article 15.2.5bis

In the title of the article, the Code Commission did not agree with a comment to italicise ‘free zone’ as terms are not italicised in titles as per conventions in the *Terrestrial Code.*

The Code Commission did not agree with a comment requesting a review of the provisions in this article and that a reduction of the radius from 10-km to three km, or a reduction in the waiting period of three months would be of an equivalent risk if the requirements for biosecurity and treatment of meat and meat by-products are maintained. Although the Code Commission concurred with the comment that the airborne transmission of CSF is less important than FMD, it agreed with the Scientific Commission, that based on the highly infectious nature of CSF, as well as its potential for not showing apparent clinical signs and the likelihood of delayed or under-reporting in backyard farms, as well as the prolonged presence of the live virus in products and fomites, the 10-km radius together with the three month period without occurrence of CSF would provide an adequate level of safety and confidence in moving pigs from an infected zone.

In response to a comment seeking clarification of the italicised term ‘approved biosecurity’, the Code Commission explained that ‘approved’ and ‘biosecurity’ are two terms that are separately defined in the Glossary.

In response to a comment stating that the slaughterhouse/abattoir should not be approved for export until the sixth indent is also complied with, i.e., disinfection is completed, the Code Commission, in agreement with the Scientific Commission, proposed to merge the fifth and sixth indents to reflect this point.

Article 15.2.6

While the Code Commission partially agreed with a comment to include the type of commodity in the title of the article, it decided not to make this change now, and requested the OIE Secretariat to explore this as part of its work on developing a framework for*Terrestrial Code* standards (refer to

Part B of this report), as this would also impact other disease-specific chapters. This rationale also applies to similar comments from the same Member made elsewhere in the text.

In point 2, the Code Commission noted a comment requesting to replace 'past' with 'previous'. However, since this change would be inconsistent with the rest of the *Terrestrial Code*, the Commission requested the OIE Secretariat to explore this as part of the work to develop a framework for *Terrestrial Code* standards.

Articles 15.2.9 and 15.2.11

In point 1(c)(iii), the Code Commission, in agreement with the Scientific Commission, did not agree with a comment to replace 'collection' with 'vaccination'. The Code Commission agreed with the Scientific Commission that the requirement does not imply the 're-vaccination' of each donor pig before testing. The Code Commission referred to the explanation in the Scientific Commission's report of September 2020 that such an amendment would imply that vaccination is a sufficient risk management measure regardless of the timing of vaccination in relation to collection, whereas the intent of the requirement is to demonstrate that, if a donor animal is seropositive in the period following collection this is due to vaccination and not to infection. The Code Commission, in agreement with the Scientific Commission, also did not agree with a comment to specify that the antibodies present in the donor animals should be a result of vaccination as they considered this to be implicit in the text as currently written.

Article 15.2.12bis

In point 4(b), in response to a comment enquiring if 'shipment for export' means the same as the time when the meat is dispatched from the abattoir, the Code Commission, in agreement with the Scientific Commission, explained that there should be no case of CSF between the last disinfection carried out before the last slaughter and the dispatch of meat from that slaughterhouse/abattoir for export. For clarity, the Code Commission proposed to revert to the original text, but replaced 'shipment' with 'consignment'.

Article 15.2.17

In point 2, after consultation with the OIE Collaborating Centres on Food Safety on how temperature-pressure conditions should be presented, the Code Commission proposed to add 'under saturated steam conditions' after 'maintained', and to replace '3 bar' with '2 bar'. The Commission highlighted that there were no changes made to the minimum requirements, but a stipulation of the processes already involved in the heating process. It noted the advice of the Collaborating Centres that the temperature parameter was paramount, and that under saturated steam conditions, a pressure of 3 bar would bring the temperature to 133°C, and that a pressure of 2 bar would be sufficient to achieve a temperature of 121°C.

In point 3, the Code Commission did not agree with a comment to replace 'demonstrated to inactivate' with 'validated for inactivation'. The Commission noted that 'validated' would imply specifications on 'who' should be the entity to validate the procedure. Furthermore, the Commission did not agree with the comment that 'demonstration' implied that it might have only occurred in one attempt and considered the statement to be clear as written, and consistent with the other relevant disease-specific chapters in the *Terrestrial Code*.

Article 15.2.18

In point 1(b), the Code Commission did not agree with a comment to replace 'demonstrated to inactivate' with 'validated for inactivation' for the reason given above (in Article 15.2.17).

In point 2, the Code Commission did not agree with a comment to reinstate the last sentence and clarified that the critical parameters are a_w value and pH, and not time. As long as points 2(a) and 2(b) are achieved, it was not necessary to specify a time requirement.

In point 3, the Code Commission did not agree with a comment to reinstate points 3(a) and 3(b) and to delete the sentence 'meat should be cured with salt and dried for a minimum of six months'. It reiterated its previous explanation that more specificity as to the different styles of ham was not needed, and this provision was in line with the equivalent provision in Chapter 15.1, Infection with African swine fever virus.

Article 15.2.19ter

In points 1 and 2, the Code Commission did not agree with a comment to add ‘internal core’ before ‘temperature’, but instead added ‘which should be reached throughout the product’ for consistency with Article 15.2.18.

In point 2, the Code Commission did not agree with comments to replace ‘30 minutes’ with ‘60 minutes’, reiterating its previous explanation that this would not be consistent with point 1 of the same article. Furthermore, the comparison of swill to manure by the Member is inappropriate, as swill, unlike manure, is not homogeneous, and therefore would demand specific requirements.

In point 3, the Code Commission did not agree with a comment to replace ‘demonstrated to inactivate’ with ‘validated for inactivation’ for the same reason given above (in Article 15.2.17).

Article 15.2.21

In the first paragraph, the Code Commission agreed with a comment to add ‘free’ before ‘status’. It proposed to delete ‘CSF’ as it considered this to be implied. This rationale also applies to similar comments from the same Member made elsewhere in the text.

In the second sentence of the second paragraph, the Code Commission agreed with a comment to replace ‘and’ with ‘or’ after ‘wild’.

Articles 15.2.24 and 15.2.25

The Code Commission did not agree with a comment to add ‘CSF’ before ‘free’ in the title of Article 15.2.25 for consistency with Article 15.2.5. For the same reason, it proposed to delete ‘CSF’ from the title of Article 15.2.24.

Article 15.2.26

In point 4(e), the Code Commission agreed with a comment that farms that feed swill are at high risk with regard to CSF, and thus in agreement with the Scientific Commission, proposed to add a new point on ‘establishments that feed swill’.

The Code Commission, in agreement with the Scientific Commission, did not agree with a comment to replace point 4(f) with a more general statement on opportunistic wildlife surveillance. It considered the current description of high-risk hunting areas in 4(f) to be more specific. Furthermore, the opportunistic collection of samples is already covered in Article 1.4.4.

Revised Chapter 15.2, Infection with classical swine fever virus, is presented as **Annex 21**, and will be proposed for adoption at the 88th General Session in May 2021.

EU position

The EU supports the adoption of this revised chapter.

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…/Annexes

Annex 3

USER'S GUIDE

EU position

The EU supports the adoption of these revised points of the User's Guide.

[...]

B. *Terrestrial Code* content

[...]

3) The standards in the chapters of Section 1 are designed for the implementation of measures for the diagnosis, surveillance and notification of ~~pathogenic agents~~ diseases, infections and infestations. The standards include procedures for notification to the OIE~~, tests for international trade,~~ and procedures for the 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 general 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 4

GLOSSARY

EU position

The EU supports the adoption of these revised Glossary definitions.

CAPTIVE WILD [ANIMAL]

means an *animal* that has a phenotype not significantly affected by human selection but that is captive or otherwise lives under or requires ~~direct~~ human supervision or control. ~~, i.e. such as population management, regular contacts or handling, regular feeding, harvesting and protection from predators or *slaughter*.; including this includes zoo *animals* and pets.~~

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.

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 5

CHAPTER 1.1.

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

EU position

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

We note with appreciation that further to the adoption of this revised chapter, relevant changes will be made in OIE-WAHIS to align with revised wording. In addition to referring to "initial notification" instead of "immediate notification", we would suggest OIE-WAHIS avoid overly alarmist language and design in email messages. For example, use of the term "ALERT - ALERTE - ALERTA", repeated three times in capital letters in the three OIE official languages, in both the subject line and the body of the email seems inappropriate.

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~~i~~n 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~~;~~. F~~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 6

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY THE OIE

EU position

The EU supports the adoption of these revised articles.

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 1.3.6.

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
– Infection with Newcastle disease virus
– Infectious bursal disease (Gumboro disease)
– Pullorum disease
– Turkey rhinotracheitis.

[…]

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 7

CHAPTER 1.4.

ANIMAL HEALTH SURVEILLANCE

EU position

The EU supports the adoption of this revised 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 position

The EU supports the adoption of this revised 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 Resolution~~s~~ ~~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)~~ 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, except otherwise stated in the disease-specific chapter, ~~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 the specified period ~~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.

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~~ inform~~ation 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) 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-declaration~~s 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

DRAFT CHAPTER 3.1.

QUALITY OF VETERINARY SERVICES

EU position

The EU thanks the OIE and supports the adoption of this revised 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.

Annex 9 (contd)

5.) Transparency

Veterinary Services should be as transparent as possible in all their governance and technical activities, including but not limited to, disease reporting, policy and programme decision-making, human resources and financial issues.

6.) Scientific basis

Veterinary Services should develop and implement their activities on a scientific basis, incorporating relevant inputs from fields such as *risk analysis*, epidemiology, and economics and social science.

7.) Intersectoral collaboration

Veterinary Services should operate in collaboratively, including via a One Health approach, sharing professional knowledge and experience with all relevant sectors and actors while optimising the use of resources.

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, economics and social science principles. *Veterinary Services'* decision Decision-making by *Veterinary Services* should be free from undue financial, political and other non-scientific influences.

The *Veterinary Authority* should coordinate with other *Competent Authorities* governmental authorities, and should undertake active international engagement with the OIE and other relevant regional and international organisations.

This component should comprise the following specific elements:

1) Ccomprehensive national *veterinary legislation* in accordance with Chapter 3.4, regularly updated with reference to changing international standards and science new scientific evidence.;

2) Iimplementation of *veterinary legislation* through a programme of communications and awareness, as well as formal, documented inspection and compliance activities.;

3) Ccapability to perform *risk analysis* and cost—benefit analysis to define, review, and adapt and resource policies and programmes.;

4) Ppolicies or programmes that are well documented, resourced and sustained, appropriately reviewed and updated to improve their effectiveness and efficiency, and that addressing emerging issues.;

5) Qquality 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) Iinformation management systems for collecting data to monitor and evaluate *Veterinary Services*' policies and activities and to perform *risk analysis*.;

7) Oorganisational structures with defined roles and responsibilities for effective internal coordination of activities from central to field levels (chain of command) for activities, which are periodically reviewed and updated as necessary.;

8) Fformal external coordination mechanisms with clearly described procedures or agreements for activities (including preparedness and response mechanisms) between the *Veterinary Authority*, *Competent Authorities*, other relevant governmental authorities and stakeholders, incorporating a One Health approach.;

9) ~~A~~appropriate levels of official representation at international multilateral fora, ~~with~~ involving ~~pre-~~consultation with stakeholders, active participation and sharing of information, and follow up on meeting outcomes.

Annex 9 (contd)

Article 3.1.4.

Personnel and resources

Veterinary Services should be appropriately staffed, including *veterinarians*, *veterinary paraprofessionals* ~~or~~ and other personnel, with appropriate competencies obtained 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~~a core of full-time civil service employees ~~with~~ including qualified and sufficient *veterinarians* and *veterinary paraprofessionals*~~,~~;

2) ~~F~~formal, consistent and merit-based recruitment and promotion procedures~~,~~;

3) ~~J~~job descriptions, formal performance assessment and management procedures for *veterinarians*, *veterinary paraprofessionals* and other personnel that are defined and being implemented~~,~~;

4) ~~P~~personnel remuneration, sufficient and regular to minimise the risk of conflicts of interest and to preserve independence~~,~~;

5) ~~V~~*veterinarians*' and *veterinary paraprofessionals'* education, knowledge, skills and practices~~,~~ that are standardised and sufficient to perform relevant activities of the *Veterinary Services*~~,~~;

6) ~~V~~*veterinary paraprofessionals* are adequately supervised by *veterinarians*~~,~~;

7) ~~A~~all personnel have access to professional development, including continuing education programmes that are reviewed and updated as necessary~~,~~;

8) ~~E~~established procedures for *Veterinary Services* to access personnel and other resources, including in emergencies~~,~~;

9) ~~A~~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) ~~A~~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 roles, 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.

Annex 9 (contd)

This component should comprise the following specific elements:

1) There is an~~An~~ independent *Veterinary Statutory Body*~~,~~ that is legally responsible and adequately resourced for:

   a) licensing and registration of *veterinarians* and *veterinary paraprofessionals* to perform defined activities ~~of~~ related to veterinary science or animal health;

   b) setting minimum standards of education required to be registered or licensed as *veterinarians* or *veterinary paraprofessionals*;

   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 and extension services are available ~~of sufficient quality~~ to meet the needs of animal owners, including ~~their~~ providing awareness of and access to essential diagnosis and treatment for animal disease and injury ~~diagnosis and treatment~~.

Article 3.1.6.

Stakeholders

A range of individuals ~~or~~ and organisations have an interest in or concern ~~in~~ with the activities of the *Veterinary Services*, for example livestock farmers, processors, traders, feed manufacturers, *wildlife* managers, researchers, 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~~ stakeholders' 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) ~~G~~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) ~~O~~ongoing, targeted and effective communication with stakeholders in accordance with Chapter 3.3.;

3) ~~C~~consultation mechanisms, including written invitation~~s~~, meetings or workshops with non-government stakeholder representatives, with consultation inputs documented and duly considered~~.~~;

4) ~~P~~public private partnerships, in the form of official delegation or joint programmes, which have ~~the~~ legal authority, formal agreements~~,~~ and documented procedures~~,~~ in accordance with Chapter 3.4.

Annex 9 (contd)

Article 3.1.7.

Animal health

Veterinary Services should organise and implement programmes to prevent, detect, control or eradicate animal diseases, ~~and should be~~including through being 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) ~~E~~effective surveillance for the early detection, monitoring and reporting of known and *emerging* animal diseases, including in *wildlife*, 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) ~~A~~an updated list of *notifiable diseases* that includes relevant *listed diseases*~~.~~;

3) ~~U~~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) ~~E~~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) ~~O~~*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~~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~~a programme for the official health control of bee diseases, in accordance with Chapter 4.15.;

8) ~~A~~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~~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) ~~R~~regulation, inspection, authorisation, ~~and~~ supervision and auditing of establishments and processes for production and processing of food of animal origin (*slaughtering*~~,~~; 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) ~~I~~implementation of procedures for ante-mortem and post-mortem inspection at slaughter facilities, including *slaughter* associated with live *animal markets*, 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~~ including zoonoses, in accordance with Chapters 6.2. and 6.3. and the relevant Codex Alimentarius texts~~.~~;

Annex 9 (contd)

3) ~~R~~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~~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) ~~i~~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) ~~P~~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) ~~P~~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 sets standards for the production and control of vaccines and other biological products.

This component should comprise the following specific elements:

1) ~~E~~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 and appropriate safe disposal of these products~~.~~;

2) ~~R~~*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 of animal origin~~, via~~. This should be coordinated using a One Health approach, and in accordance with Chapter 3.4. and relevant chapters of Section 6.

Article~~s~~ 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*, implementing antimicrobial resistance *surveillance*, assessing the safety of food or *feed*, or supporting *international trade* (e.g. demonstration of~~ freedom~~ *animal health status*), as well as for associated research. 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~~ abroad.

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* ~~Q~~quality ~~M~~management ~~S~~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) ~~S~~*sanitary measures* developed and implemented in accordance with Chapter 2.1. and other relevant chapters of the *Terrestrial Code*~~.~~;

2) ~~E~~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) ~~E~~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) ~~E~~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) ~~E~~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) ~~R~~regular and timely official notification to the OIE, ~~WTO~~World Trade Organization, 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.;

Annex 9 (contd)

7) ~~W~~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) ~~A~~active participation in the OIE and Codex Alimentarius standard setting processes.

Annex 10

DRAFT CHAPTER 3.2.

EVALUATION OF VETERINARY SERVICES

EU position

The EU supports the adoption of this revised chapter.

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 the compliance 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 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.

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~~ that 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 ~~F~~fundamental ~~O~~operating ~~P~~principles set ~~-~~out for *Veterinary Services* in Article 3.~~2~~1.2 in a timely and efficient manner, ensuring that 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 that 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.

Annex 11

DRAFT CHAPTER 3.X.

INTRODUCTION TO RECOMMENDATIONS ON VETERINARY SERVICES

EU position

The EU supports the adoption of this new chapter.

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 national and *international trade*, *wildlife* health 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 in a One Health approach.

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~~consider appropriate. 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 that 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~~ in establishing and maintaining confidence in their *international veterinary certificates*.

Annex 12

CHAPTER 3.4.

VETERINARY LEGISLATION

EU position

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

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 12 (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 12 (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*.~~

Annex 12 (contd)

~~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~~;

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*.

Annex 12 (contd)

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~~;

~~b~~c) registration and, if necessary, approval of ~~establishments~~ facilities and the provision of health requirements for relevant operations; ~~and~~

~~c~~d) 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.

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*.

Annex 12 (contd)

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~~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; and

~~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.

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, 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;~~

Annex 12 (contd)

~~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.

Annex 12 (contd)

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~~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 13

CHAPTER 4.Y.

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

EU position

The EU supports the adoption of this new 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 to be prepared, developed and 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~~ ~~their~~ 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~~ options for revising or ending them.

Official control programmes and the application of their components should be regularly evaluated. Learning from past *outbreaks*, from both epizootic or enzootic situations, ~~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~~ proficient 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 a 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~~ and 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.

Annex 13 (contd)

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.

The *Veterinary Authority* should define emergencies and integrate emergency preparedness including planning~~, and practice~~ equipping, training and ~~exercising~~ exercises within the *official control programmes* ~~against~~ for these diseases as ~~one~~ part 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 the level of preparedness needed~~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~~ subnational authorities~~,~~ and ~~all~~ relevant stakeholders should do~~,~~; ~~comprise any comprehensive preparedness and response system~~

   – how they should be organised, equipped, trained ~~equipped~~ and exercised to be ready to do it;

   – how their actions should be activated, managed and coordinated.

   This implies the development of:

   a) an emergency 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) an emergency response plan (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*~~ previous ~~emergency~~ emergencies, for example following an after-action review.

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.

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;~~

Annex 13 (contd)

- ~~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;~~

- ~~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~~ concurrently or consecutively~~,~~. These measures should aim~~ed~~ at:

1) ~~epidemiological investigation to~~ tracing ~~back and~~ forward and backward in-contact 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.

Annex 13 (contd)

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*.

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). Based on risk analysis, t~~T~~hey 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 group~~s~~ 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 *zones*, 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.

Annex 13 (contd)

Although *vaccination* may hide ongoing *infection* or ~~agent~~ transmission of pathogenic agents, it can be used to increase the *herd* immunity for and 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.

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. Communication with *Competent Authorities* of neighbouring countries and trading partners is important for the control of transboundary animal diseases.

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.

Annex 13 (contd)

Article 4.Y.13.

Further outbreak investigation, monitoring, evaluation and review

In order to gather information required for any management information system, *Veterinary Services* should conduct an in-depth epidemiological investigation of each *outbreak* to build up ~~a~~ detailed first-hand, field-based knowledge of how the disease is transmitted, ~~and~~ to inform further disease control plans. This requires staff who have been trained in ~~the way to conduct it~~ appropriate methods and in the use of the standardised data collection forms.

Furthermore, feedback from persons involved in the organisation and implementation of *official control programmes* should be gathered.

The ~~Information~~ information gathered and experience gained should be used to monitor, evaluate and review ~~disease~~ the *official control programmes* ~~plans~~ in order to improve them.

Annex 14

CHAPTER 4.4.

ZONING AND COMPARTMENTALISATION

EU position

The EU supports the adoption of this revised chapter.

[…]

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~~ may be established as a temporary measure in response to an increased *risk* of disease. In such case, it may be maintained up to 24 months.

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~~ on the basis of 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.

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.

~~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*, i~~If the *animal health status* of an established *protection zone* changes ~~due~~ owing 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, provided the measures in

place prevent the spread of disease and allow ~~for~~ the subsequent establishment of a *containment zone* in accordance with the criteria in Article 4.4.7.

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~~ because 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~~ has been submitted to and ~~was~~ accepted by the OIE;

- ~~An *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 in accordance with Chapter 1.6. and the relevant disease-specific chapters.

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 either 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 are 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~~ to be effectively established when the following is demonstrated, unless otherwise specified in the disease-specific chapter:

   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*~~ an inner *zone* where *cases* may continue to occur and ~~a *protection*~~ an outer *zone* where no *outbreaks* have occurred for at least two *incubation periods* after the control measures above ~~are~~ have been put in place and which ~~that~~ separates the inner *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~~ described in point 4 a) or in the ~~*protection*~~ outer *zone* where no *outbreaks* had occurred as ~~defined~~ described in point 4 b), the rest of the country or *zone* ~~is considered infected~~ loses its free status.

Annex 15

DRAFT CHAPTER 7.Z.

ANIMAL WELFARE AND LAYING HEN PRODUCTION SYSTEMS

EU position

The EU cannot support the adoption of this new chapter.

In its previous comments, the EU indicated it would not be able to support the adoption of this chapter unless the EU's comments were taken into account.

Those EU comments were summarised as follows:

'The fact that the provision of (1) sufficient space for the expression of locomotory and comfort behaviours, (2) substrate for comfort and foraging behaviours, (3) nesting areas and (4) 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 but rather cement the status quo in many countries. The importance for hens to have an access to such facilities is scientifically based and proven to work in practice. Use of the term "desirable" is therefore unacceptable for the EU.

Instead, in relation to the points above, the EU requests use of the term "should", which is common practice throughout the OIE Code, indicating that OIE international standards represent recommendations, not obligations. The only exception are the disease notification obligations in Chapter 1.1., where the term "shall" is used to indicate Member Countries' obligations under OIE Organic Statutes. Thus, use of the term "should" in Chapter 7.Z. would not represent an obligation for Member Countries to immediately comply with these new standards, but rather encourage countries to gradually converge with these international recommendations, leading to an overall progressive improvement of the welfare conditions of laying hens in the mid to long term.'

As the revised chapter does not take those comments into account, the EU confirms it cannot support the adoption of this chapter.

Article 7.Z.1.

Definitions

For the purposes of this chapter the following definitions apply:

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 layer pullet-rearing farm through to the removal of end-of-lay hens from the laying production facilities. Layer pullet and ~~L~~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 layer 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.~~ for example, 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 production systems and 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 it is motivated to perform, and a good understanding of layer pullet and laying hens normal behaviour [Nicol, 2015], including 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 motivated behaviour providing body maintenance benefits. During dust bathing, layer pullets and laying hens 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. 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 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 may be less productive [Barnett *et al.*, 1992] and more prone to injurious feather pecking behaviour [de Haas *et al.*, 2014]. Methods have been developed for evaluating fearfulness [Forkman *et al.*, 2007], for example by observing layer pullet and laying hen behaviour in response to novel objects or when people, including *animal handlers,* walk through the layer pullet and laying hen areas of the poultry house [Jones, 1996; Waiblinger *et al*., 2006].

c) Feeding and drinking behaviour

Changes in feeding or drinking behaviour 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 layer pullets or laying hens are ill. *Feed* or water intake may also change as a result of heat stress [Lara ~~L. J.~~ & Rostagno, 2013; Lin H. *et al.*, 2006] or cold stress [Alves *et al.*, 2012].

d) Foraging behaviour

Foraging is a motivated behaviour [de Jong *et al.*, 2007, Nicol *et al.,* 2011]. Foraging is the act of searching for *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 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 *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 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 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 layer pullets and laying 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 layer 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].

j) Social behaviour

Layer pullets 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].

k) Spatial distribution

Uneven spatial distribution of layer pullets and laying hens may indicate fear reactions, thermal discomfort or, uneven availability or use of resources such as light, *feed* or water, shelter, nesting areas or comfortable resting locations [Rodríguez-Aurrekoetxea and Estevez, 2016; Bright and Johnson, 2011].

l) Thermoregulatory behaviour

Prolonged or excessive panting and wing spreading are observed during heat stress [Mack, 2013; Lara and Rostagno, 2013]. Indicators of cold stress include feather ruffling, rigid posture, trembling, huddling and distress vocalisations.

m) Vocalisation

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

3. Body condition

Poor body condition may indicate *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 may indicate disease or the presence of irritants such as dust and ammonia. High ammonia levels may also cause corneal burns and eventual blindness. Abnormal eye development 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 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, including infections, infestations and metabolic disorders

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 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), equipment, environmental conditions (e.g., 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 these rates and evaluating their causes ~~of morbidity and mortality~~ can be useful aids in diagnosing and remediating *animal welfare* problems.

9. Performance

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) layer pullet growth rate, which measures average daily mass gain per layer pullet ~~and *flock* uniformity~~;

b) layer pullet *flock* uniformity, which measures the range in weight of the *flock*;

c~~b~~) layer 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~~d) laying hen feed conversion, which measures quantity of *feed* consumed by a *flock* relative to the unit of egg production;

~~d~~e) egg production, which measures the number, size and weight of eggs per hen laying housed;

~~e~~f) 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*, 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~~ ~~a~~*Animal welfare* problems may arise in any system if there are ~~problems~~ issues with one or more of these factors ~~are lacking~~.

Articles 7.Z.5. to 7.Z.29. provide recommendations for layer pullets and laying hens.

Each recommendation includes a list of relevant outcome-based criteria or measurables derived from Article 7.Z.3. and, when appropriate, other criteria or measurables. The suitability of some of these criteria or measurables should be determined in accordance with the system in which the 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 their motivated behaviours, as well as health, environmental factors, and animal management capability. They should also be maintained to avoid injury or discomfort. Layer pullet 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.

Outcome-based measurables ~~include~~: body condition, 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, culling and morbidity rates, nesting, perching, performance, 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 ~~layer pullet~~ rearing system should pre-adapt ~~these birds~~ layer pullets for the intended laying hen production system [Aerni *et al.*, 2005].

“The rearing system should pre-adapt layer pullets for the intended laying hen production.”

Outcome-based measurables ~~include~~: dust bathing, feeding and drinking behaviours, foraging behaviour, incidence of diseases, *infections*, *infestations* and metabolic disorders, injurious feather pecking and cannibalism, injury rate and severity, locomotory and comfort behaviours, mortality, culling and morbidity rates, nesting, perching, performance, 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 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, injury rate and severity, locomotory and comfort behaviours, mortality rate, culling and morbidity rates, nesting, perching, performance, plumage condition, resting and sleeping, social behaviour, and spatial distribution.

Article 7.Z.8.

Nutrition

Layer pullets and laying hens should be fed a diet appropriate to their age, production stage, production system 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 pathogenic 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, 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, promote good health and allow the performance of behaviours, such as comfort and locomotory behaviours. Changes of flooring types from layer pullet to laying 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 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*.

Outcome-based measurables ~~include~~: dust bathing, foot problems, foraging behaviour, incidence of diseases, *infections*, *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*, *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*, *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*, *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.

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~~ standing 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 pullets 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. Good rearing conditions can prepare layer pullets and laying hens for outdoor access [Bari *et al.*, 2020].

Outcome-based measurables ~~include~~: fear behaviour, foot problems, foraging behaviour, incidence of diseases, *infections*, *infestations* and metabolic disorders, injury rate and severity, locomotory and comfort behaviours, mortality, culling and morbidity 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; extreme 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 problems with the system ~~can~~ be detected and corrected before they cause an *animal welfare* problem.

Outcome-based measurable ~~include~~: mortality, culling and morbidity rates, performance, spatial distribution, temperature and relative humidity, thermoregulatory behaviours, and water and *feed* consumption.

Article 7.Z.16.

Air quality

Ventilation, housing design and equipment, 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].

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, temperature, and relative humidity, and thermoregulatory behaviours.

Annexe 15 (contd)

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 moulting is practised, during which 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 behaviours, 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 cause 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, 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 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 nesting areas during lay [Shi *et al.*,2019a; Shi *et al.*, 2019b],

– 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, culling and morbidity rates, plumage condition, and vocalisation.

Article 7.Z.20.

Moulting

Induced moulting 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~~ water at all times [Anderson, 2015] and adequate periods of light. 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, 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, mortality, 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 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 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 15 (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*, *infestations* and metabolic disorders, injury rate and severity, mortality, culling 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, and performance.

Article 7.Z.24.

Euthanasia of individual layer pullets or laying hens

Individual layer pullets or laying hens may be euthanised. Techniques used should be performed, in accordance with Chapter 7.6.

Reasons for euthanasia include:

– bone fractures or other injuries,

– diagnostic purposes,

– disaster management,

– emaciation,

– rapid deterioration of a medical condition for which treatment has been unsuccessful,

– severe pain that cannot be alleviated.

The decision to euthanise a layer pullet or a laying hen 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 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, 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 evacuation procedures and 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,* 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*. Emergency *killing* procedures should be a part of the plan and be in accordance with the methods recommended in Chapter 7.6.

Annex 15 (contd)

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

Article 7.Z.27.

Competencies of personnel

Animal handlers should have the ability, knowledge and competencies necessary to maintain the welfare and health of the layer pullets and laying hens.

All people responsible for layer pullets and laying hens should have received appropriate training and be able to demonstrate that they are competent to carry out their responsibilities, which should include the assessment of 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, 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~~: 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~~: 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 16

CHAPTER 8.Y.

INFECTION WITH ANIMAL TRYPANOSOMES OF AFRICAN ORIGIN

EU position

The EU supports the adoption of this new chapter.

Article 8.Y.1.

General provisions

1) *Infection* with a~~A~~nimal 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~~ animal production. ~~Some trypanosomes of African origin (*i.e.* T~~*rypanosoma brucei gambiense*~~,~~ and *T. brucei rhodesiense*~~)~~ can 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~~ may occur 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~~ subgenera *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*s of susceptible animals with *T. evansi* ~~or~~ and *T. equiperdum* ~~is~~ are covered by Chapter 8.X. and Chapter 12.3., respectively.

6) Other trypanosomes including *T. uniforme*, *T. godfreyi* and *T. suis*, which are rarely reported~~,~~ 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~~ owing 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 and collagen;

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, there has been no *case* in the country or *zone* and:

      i) *surveillance* in accordance with Articles 8.Y.~~13~~7. to 8.Y.~~16~~10. has been in place in the entire country; or

      ii) ~~there has been no *case* of *infection* with animal trypanosomes of African origin in the country, or *zone* or *compartment*.; or~~ the absence of competent *vectors* has been demonstrated by a *surveillance* programme in accordance with Chapter 1.5. and Article 8.Y.9.

   ~~c~~) ~~the absence of competent *vectors* has been demonstrated by a *surveillance* programme in accordance with Chapter 1.5. and Article 8.Y.9.~~

A country or *zone* free from *infection* with animal trypanosomes of African origin ~~neighbouring~~ adjacent to an infected country or *zone* should include a *zone* in which *surveillance* is conducted in accordance with Articles 8.Y.~~13~~7. to 8.Y.~~16~~10.

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 from *vector* attacks 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~~ including *vector* control or ~~*vector*~~ protection from *vector* attacks 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*;

Annex 16 (contd)

3) did not transit through an *infected zone* during transportation to the *place of shipment* or were protected from *vectors* or any source of animal trypanosomes of African origin by the application of effective *biosecurity* 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;

Annex 16 (contd)

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:~~

Annex 16 (contd)

~~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~~7. to 8.Y.~~16~~10. 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* concerned and adapt the *surveillance* strategies for defining their status to the local conditions. There is considerable latitude available to Member Countries to justify their status at an acceptable level of confidence.

Although *surveillance* in *wildlife* presents challenges that may differ significantly from those in domestic *animals*, ~~W~~*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, reporting 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~~ animal owners and keepers and other stakeholders who have regular contact with susceptible animals ~~and workers, who have regular contact with susceptible animals,~~ as well as *veterinarians* or *veterinary paraprofessionals*~~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~~ adjacent 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~~ were to occur at a predetermined minimum ~~rate~~ expected *prevalence*. 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~~ with 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 consider the movement history of the *animals* being sampled when interpreting the results.

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, suspected *cases* of *infection* with animal trypanosomes of African origin detected by clinical *surveillance* should always be confirmed by ~~diagnosis must rely on~~ direct or indirect laboratory tests that confirm the presence of trypanosomes.

Annex 16 (contd)

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 parasites 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 parasites~~ic~~ 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~~ Owing 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~~ detect 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 the absence of competent *vectors* ~~tsetse flies~~ may support the claim of freedom from *infection* with animal trypanosomes of African origin ~~that are cyclically transmitted~~.

The most effective way of gathering *vector surveillance* data should consider the biology and behavioural characteristics of the local *vector* species and include traps, fly rounds, sticky targets or other collection tools. ~~*Vector surveillance* should be based on scientific sampling techniques.~~ The choice of the number and type of collecting tools to be used and the frequency of their use should be made by considering 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 17

CHAPTER 9.4.

INFESTATION WITH *AETHINA TUMIDA* (SMALL HIVE BEETLE)

EU position

The EU in general supports the adoption of this revised article. However, we reiterate that a smaller radius also increases the likelihood of a SHB entering a region that is not under surveillance, possibly delaying detection. Therefore, the EU recommends that the reduction of radius is compensated by increased surveillance in the region in question to mitigate risk of both undetected presence of SHB and suboptimum preparation (inspections, packaging etc.) of the consignments.

[…]

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~~ immediately prior to packing, ~~and show~~ with 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

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

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 cages or the whole consignment of bees immediately after the packing with fine mesh through which a live beetle cannot enter.

[…]

Annex 18

CHAPTER 10.4.

INFECTION WITH HIGH PATHOGENICITY AVIAN INFLUENZA VIRUSES

EU position

The EU commends the OIE for this revision of the important chapter on avian influenza. The EU fully supports the new focus on HPAI in commercial poultry, while not neglecting relevant LPAI strains. We welcome the balanced and risk-based approach of this chapter and its trade facilitating direction. We are confident that this revised chapter will contribute to safe, smooth international trade and look forward to it being implemented by all OIE member countries. The EU therefore supports the adoption of this revised chapter.

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.

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*~~ domestic 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 international trade of *poultry commodities* in response to such *notifications*, or to other information on the presence of any non-notifiable influenza A virus in 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 avian influenza viruses *risks* and the specific *biosecurity* and management measures to address them~~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 establishments* 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 periods*) 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*.

Annex 18 (contd)

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 4d) 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 4d) 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 4d) 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:

Annex 18 (contd)

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.

Annex 18 (contd)

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, but ~~and currently~~ it is not possible to predict ~~whether and~~ which viruses will mutate or when ~~this~~ these mutations 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~~ is notifiable as an *emerging disease* in accordance with Article 1.1.4.

3) The detection, in domestic ~~and~~ or *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.

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*;

Annex 18 (contd)

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.

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Annex 19

CHAPTER 10.5.

INFECTION WITH ~~AVIAN MYCOPLASMOSIS (*MYCOPLASMA GALLISEPTICUM*)~~ (AVIAN MYCOPLASMOSIS)

EU position

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

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 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 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~~;

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~~ a serological test and an agent identification test for avian mycoplasmosis with negative results, ~~on two occasions,~~ ~~respectively~~ 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*:

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.

Annex 20

CHAPTER 14.7.

INFECTION WITH PESTE DES PETITS RUMINANTS VIRUS

EU position

The EU supports the adoption of this revised 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 20 (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.;

Annex 20 (contd)

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, documentedary evidence (such as copies of national legislation, regulations and *Veterinary Authority* directives) that *vaccination* of selected populations is~~ compulsory in the target population and is practised in accordance with Chapter 4.18.;~~,~~

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*;

~~4~~6) ~~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.

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 21

CHAPTER 15.2.

INFECTION WITH CLASSICAL SWINE FEVER VIRUS

EU position

The EU supports the adoption of this revised chapter.

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.~~

A *notification* of *infection* of *wild* and *feral* pigs with CSFV does not affect the CSF status of a country or *zone* provided that the provisions of Article 15.2.2. are complied with. A Member Country should not impose bans on the international trade of domestic and *captive wild* pig *commodities* in response to such *notifications*.

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 may 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;~~

Annex 21 (contd)

~~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 1.6.9~~10. ~~Chapter 1.9., has been accepted by the OIE.~~

The country or ~~the~~ *zone* will be included in the list of countries or *zones* free from CSF in accordance with Chapter 1.6.

Retention on the list requires annual reconfirmation of 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~~ is considered as infected with CSFV when the requirements for acceptance as a ~~CSF~~ free country or *zone* are not fulfilled.

Annex 21 (contd)

Article 15.2.~~5~~4.

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~~ the areas outside the *containment zone* may be reinstated, irrespective of the provisions of Article 15.2.~~6~~5., once the *containment zone* ~~is clearly established~~ has been approved by the OIE. ~~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*, as described in point 7 of Article 4.4.7., 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.~~

Annex 21 (contd)

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)~~ and the *vehicles* and the *slaughterhouse/abattoir* ~~should be~~ have been 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 21 (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.~~10~~8.

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.~~11~~9.

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.~~26~~21. to 15.2.~~32~~26., demonstrated that no *case* of CSF occurred ~~in the past 12 months~~during 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

      iii~~ii~~) 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.

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

Annex 21 (contd)

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~~ii~~) ~~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~~ consignment for export has been dispatched from the *slaughterhouse/abattoir* ~~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.;~~

~~12) that which have been were subjected with favourable results to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre facility approved by the *Veterinary Authority* for export purposes., with favourable results and have been found free from any sign suggestive of CSF;.~~

~~2) from each of which a sample has been was collected and has been subjected to a virological test and a serological test for CSF, with negative results.~~

Article 15.2.~~16~~13.

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*:

Annex 21 (contd)

1) ~~have been~~ were prepared:

   a) exclusively from *fresh meat* meeting the conditions laid down in Article~~s~~ 15.2.~~14~~12.~~,~~or 15.2.~~14~~12bis.~~ 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 Article~~s~~ 15.2.~~14~~12.~~,~~or 15.2.~~14~~12bis.~~ or 15.2.15.~~;

OR

2) ~~have been~~ were processed in accordance with one of the processes in Article 15.2.~~23~~18. in ~~an establishment~~ a facility approved by the *Veterinary Authority* for export purposes~~ so as to ensure the destruction of the CSFV in conformity with one of the procedures referred to in Article 15.2.23.~~, and that ~~the necessary~~ appropriate precautions were taken after processing to avoid ~~contact~~ cross-contamination of the product with any source of CSFV.

~~Article 15.2.17.~~

~~**Recommendations for the importation of pig products not derived from fresh meat intended for use in animal feeding**~~

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

~~1) originated from domestic and *captive wild* pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or~~

~~2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSFV in accordance with Article 15.2.22., and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.~~

~~Article 15.2.18.~~

~~**Recommendations for the importation of pig products not derived from fresh meat intended for agricultural or industrial use**~~

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

~~1) originated from domestic and captive wild pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or~~

~~2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.~~

Article 15.2.~~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

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

Annex 21 (contd)

2) the swill ~~should be~~ is maintained under saturated steam conditions at a temperature of at least 121°C for at least 10 minutes at an absolute pressure of ~~3~~ 2 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% $Na2_2HPO4_4$ and 2.8% $Na3_3PO4_4$ (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, which should be reached throughout the product; ~~or~~

2) moist heat treatment for at least 30 minutes at a minimum temperature of 70°C, which should be reached throughout the product~~.~~;

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 [$Na~~2~~_2CO~~3~~_3$]) 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 [$Na~~2~~_2CO~~3~~_3$]).

~~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:~~

~~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~~ free status. This may be for the entire country or a *zone*. Guidance is also provided for Member Countries seeking recovery of ~~CSF~~ free status for the entire country or for a *zone* following an *outbreak* and for the maintenance of ~~CSF~~ free status.

Annex 21 (contd)

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~~ or *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~~e~~) 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~~ free 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~~a~~ 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.

Annex 21 (contd)

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*.

Annex 21 (contd)

The domestic and *captive wild* pig populations should undergo regular clinical, pathological, virological and serological examinations, planned and implemented according to the general conditions and methods described in ~~these recommendations~~ 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*~~ and 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) *establishments* that feed swill;

   ~~f~~g) areas with a high level of hunting activity, where animal dispersion and feeding as well as inappropriate disposal of waste can occur;

   ~~gh~~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~~