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

ANNEX 1

Original: English

September 2020

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

Paris, 1–10 September 2020

EU comment

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

A number of general comments on this report of the September 2020 meeting of the Code Commission are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report.

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

The OIE Terrestrial Animal Health Standards Commission (the Code Commission) held its meeting electronically from 1 to 10 September 2020. The list of participants is attached as **Annex 1**.

The Code Commission thanked the following Members for providing comments: Argentina, Australia, Brazil, Canada, Chile, China (People's Republic of), Chinese Taipei, Costa Rica, Cuba, Japan, Kazakhstan, Korea (Republic of), Malaysia, Mexico, New Caledonia, New Zealand, Norway, Panama, Singapore, South Africa, Switzerland, Thailand, United States of America (USA), the OIE Americas Region, the Member States of European Union (EU), the African Union Interafrican Bureau for Animal Resources (AU-IBAR) on behalf of African Member Countries of the OIE and the Comité Veterinario Permanente del Cono Sur (CVP) on behalf of Argentina, Bolivia, Brazil, Chile, Paraguay and Uruguay, Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA) - Federación de Avicultores de Centroamérica y El Caribe (FEDAVICAC), the International Coalition for Farm Animal Welfare (ICFAW), the International Egg Commission (IEC), the International Meat Secretariat (IMS), the International Embryo Technology Society (IETS) and other experts.

The Code Commission reviewed Member comments, which were submitted on time and supported by a rationale and amended relevant chapters of the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) where appropriate. **The Code Commission did not consider comments where a rationale had not been provided or that were difficult to interpret.** Due to the large volume of work, the Code Commission was not able to draft a detailed explanation of the reasons for accepting or not each of the comments received and focused its explanations on the major ones. Where amendments were of an editorial nature, no explanatory text has been provided. The Code Commission wished to note that not all texts proposed by Members to improve clarity were accepted; in these cases, it considered the text clear as currently written.

The amendments are presented in the usual manner by '<u>double underline</u>' and '~~strikethrough~~', and the chapters are annexed to this report. In **Annexes 5 to 16 and 18** amendments proposed at this meeting are highlighted with a coloured background to distinguish them from those proposed previously.

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

Members should note that texts in **Part A (Annexes 4 to 14)** of this report are circulated for Member comments and will be proposed for adoption at the 88th General Session in May 2021. **Part B (Annexes 15 to 25)** includes texts that are circulated for Members comments only.

Texts annexed to the report of the Code Commission's February 2020 meeting, that were to be proposed for adoption and were open for one additional round of comments will be proposed for adoption in May 2021. The Code Commission noted that these texts were the result of a thorough process of analysis of all comments received from members and experts, taking into account all positions that were duly argued. Consequently, most of them are not circulated again for comments in this report. Details on these texts are discussed under section 8 of this report. All these texts will be considered again by the code Commission in its February 2021 meeting.

The reports of meetings of *ad hoc* Groups and other related documents are attached for information in **Part C (Annexes 26 to 28)**.

All comments on relevant texts in **Part A** and **Part B** must reach OIE Headquarters **by 28 December 2020** for them to be considered by the Code Commission at its February 2021 meeting. Comments received after the due date will not be submitted to the Code Commission for its consideration. In addition, the Code Commission would like to highlight that comments should be submitted through the OIE Delegate of Member Countries or organisations which the OIE has a Cooperative Agreement with.

All comments and related documents should be sent by email to the OIE Standards Department at **TCC.Secretariat@oie.int**.

The Code Commission again strongly encourages Members to participate in the development of the OIE's international standards by submitting comments on this report. Members are also reminded that comments should be submitted as Word files rather than pdf files because pdf files are difficult to incorporate into the working documents of the Code Commission. Comments should be submitted as specific proposed text changes, supported by a structured rationale or by published scientific references. Proposed deletions should be shown using '~~strikethrough~~' and additions using 'double underline'. Members should not use the automatic 'track-changes' function provided by word processing software as such changes are lost in the process of collating submissions into the Code Commission's working documents. Members are also requested **not** to reproduce the full text of a chapter as this makes it easy to miss comments while preparing the working documents.

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1. Welcome from the Deputy Director General

Deputy Director General (International Standards and Science) Dr Matthew Stone welcomed the Code Commission and thanked its members for taking time from their busy schedules to support the work of the OIE, extending this thanks to their employers and national governments. He thanked the Commission for its support during the organisation's response, including the reports prepared to ensure OIE Members remain well briefed on the activities of the Specialist Commissions following the cancellation of the General Session for 2020. Dr Stone noted the OIE's ongoing adaptation of its work programmes to the restrictions imposed as a result of the COVID-19 pandemic, with many successful virtual expert meetings now having been held ensuring that the OIE's productive output has continued thanks to the hard work of

staff and the understanding and dedication of our expert community. Although the impacts of the global pandemic continue, and the scientific understanding of its root causes, mitigating and exacerbating factors is yet incomplete, the OIE continues its internal reflection on our role to support our members in the face of new priorities around emerging disease risk mitigation, resilience and preparedness. Concrete proposals in this respect will soon emerge, and we will look to the expert networks of our Members and partners for implementation support, and funding support from our resource partners. These activities will also engage the Specialist Commissions, and therefore need to be considered in work programme prioritisation. Dr Stone noted the call for nominations for the elections in 2021 for Specialist Commissions that was open at that time. He also provided the Commission with a summary of the performance evaluation process that all experts of Specialist Commissions would be participating in, as the concluding phase of the new Specialist Commission performance management system. This would result in a confidential report to OIE Council in February 2021.

2. Meeting with the Director General

Dr Monique Eloit, the OIE Director General, met with the Code Commission on 9 September 2020 and thanked its members for their continued support and commitment to achieving OIE objectives. She also thanked them for their flexibility, in particular developing new ways of working in preparation of this virtual meeting and for their contribution to the Commission's activity report as part of the 2020 adapted procedure for the World Assembly of the Delegates, both consequences of the COVID-19 pandemic.

The Code Commission thanked Dr Eloit for making time to meet with them 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 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 II**.

4. Cooperation with other Specialist Commissions

4.1. Scientific Commission for Animal Diseases

The OIE Secretariat informed the Code Commission of relevant ongoing activities of the Scientific Commission, in particular, the progress of two initiatives being developed by the OIE Secretariat; the Standard Operating Procedure for listing decisions for pathogenic agents of terrestrial animals, and the strategy to revise or develop case definitions of OIE-listed diseases for inclusion in disease-specific chapters.

The Code Commission provided feedback on both items and commended the comprehensive analysis undertaken to develop the plan regarding the revision or development of new case definitions. The Commission noted that it would be important to ensure that the work on case definitions is integrated into the planned revision or development of disease-specific chapters as described in the Commission's work programme.

The opinion of the Scientific Commission was sought for selected Member comments. The Code Commission wished to thank the Scientific Commission for this collaborative work. The Code Commission noted that opinions of the Scientific Commission on various issues discussed during this meeting would be considered at its February 2021 meeting.

4.2. Biological Standards Commission

The OIE Secretariat provided a brief update to the Code Commission on relevant activities of the Biological Standards Commission, including chapters in the *Terrestrial Manual* that are being revised as well as other items of interest.

In view of amendments that have been proposed to selected chapters of the *Terrestrial Manual*, the Code Commission agreed to review the corresponding chapters of the *Terrestrial Code* to ensure that the provisions will be aligned. The Commission noted that some of these chapters were already in its

work programme, but added new work items on Newcastle disease, leishmaniosis, paratuberculosis and avian infectious laryngotracheitis (see section 5 of this report).

The Code Commission also noted the comments of the Biological Standards Commission on the definition of a 'case' in the Glossary of the *Terrestrial Code* and agreed to review the definition as part of the work on case definitions (see item 4.1 of this report).

4.3. Aquatic Animals Health Standards Commission

Dr Etienne Bonbon and Dr Ingo Ernst, Presidents of the Code Commission and Aquatic Animals Commission, respectively, held a virtual meeting on 9 July to discuss aspects of the revision of the glossary definitions for Competent Authority (CA), Veterinary Authority (VA) and Veterinary Services (VS) in the glossary of the *Terrestrial Code*, that could have an impact on the OIE *Aquatic Animal Health Code* (*Aquatic Code*) and the definitions of these same or related terms in its glossary. The Presidents discussed the changes proposed to the current definitions in the *Terrestrial Code* glossary and considered the opinions expressed by the Aquatic Animals Commission at its last meeting and agreed on revised definitions to be presented for the consideration of both Specialist Commissions at their September 2020 meetings.

Both Presidents agreed that the revised definitions would be sent out for Member comments simultaneously, for the revision to be undertaken in parallel.

Further reference to this discussion, as well as the detail of the revision of the glossary definitions for Competent Authority (CA), Veterinary Authority (VA) and Veterinary Services (VS) can be found under item 7.1 of this report.

5. Code Commission's work programme

Comments were received from Australia, Israel, Kazakhstan, Switzerland, the United States of America, the EU, the Members of the OIE Americas region, and the IETS.

The Code Commission discussed ongoing priority topics on its work programme and pending issues with recently adopted chapters and considered comments and new requests received. The Commission noted that in general, few Members submit comments on the work programme, which outlines the work areas, current and planned, to be undertaken by the Commission. The Commission strongly encouraged Members to provide feedback as to whether they agree with the topics being proposed, as well as their level of prioritisation.

In response to a comment requesting information about progress on the revisions of Chapter 8.8, Infection with foot and mouth disease virus, and Chapter 4.4, Zoning and compartmentalisation, the Code Commission reported that these chapters had been progressed during this meeting (see items 7.4 and 6.3 of this report, respectively).

The Code Commission agreed with a comment requesting that a higher priority be given to the revision of Chapter 14.8, Scrapie, but noted that this had to be balanced with other ongoing priority topics. In response to a comment stressing the importance of finalising the revision of BSE chapter, the Commission noted that the revision is progressing and an updated revised chapter is being sent for a second round of comments in this report (see item 7.6 of this report).

In response to a comment regarding the proposed revision of Chapter 6.10, Responsible and prudent use of antimicrobial agents in veterinary medicine, the Code Commission referred Members to item 5.1.5. of this report.

The Code Commission acknowledged a comment requesting a change to the taxonomic name for 'Newcastle disease virus' in Chapter 10.9 and was informed that the *Terrestrial Manual* chapter for Newcastle disease was under revision and that this issue will be addressed as part of that work. The Commission agreed to include the revision of Chapter 10.9 in its work programme and will commence that work once the corresponding *Terrestrial Manual* chapter has been revised.

5.1. Ongoing priority topics (not by order of priority)

The OIE Secretariat updated the Code Commission regarding the progress of a number of ongoing priority topics that were discussed in previous meetings and for which no new or revised text was reviewed at this meeting. The Commission noted that some topics that were noted in its February 2020 report but for which there has been no significant progress will be considered by the Commission at future meetings as they continue being part of the Commission work programme.

5.1.1. Terminology: Definition of 'swill.'

Background

During its September 2019 and February 2020 meetings, the Code Commission noted that the term 'swill' should be defined and decided to include it in its work programme. The Commission had requested the OIE Secretariat to include this task within the work being conducted for the preparation of Guidelines on compartmentalisation for African swine fever that would involve expert consultation.

Update

During the *ad hoc* Group on African swine fever compartmentalisation, relevant information was gathered from the members of the *ad hoc* Group. This information highlighted that there are significant differences in the scope and definition for this term amongst countries, and in equivalent terms used in local legislative texts.

Noting these differences, the Code Commission considered that more precise scoping would be required to create a definition, and requested the OIE Secretariat and the Commission member leading this work to continue working on this matter and report back on the progress at its next meeting.

5.1.2. Control of Shiga toxin-producing *Escherichia coli* (STEC) in food-producing animals

Background

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

Update

The Code Commission was informed that the OIE Secretariat had participated in the FAO/WHO joint expert meeting that took place in June 2020. Although the meeting report had not yet been published, the Commission was informed that discussions during the expert meeting highlighted that there was little evidence of effective mitigation measures applicable during primary production specific for the control of STEC. In addition, there was potential for STEC contamination further along the food processing chain. Based on this information, the Code Commission agreed that a specific chapter to address the prevention, detection and control of STEC in beef cattle in the Terrestrial Code was not indicated. The Commission agreed to remove this item from its work programme.

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

Background

At its September 2019 meeting, the Code Commission had requested that an *ad hoc* Group be convened to revise Chapter 4.6, General hygiene in semen collection and processing centres,

and Chapter 4.7, Collection and processing of bovine, small ruminant and porcine semen, as well as provisions in relevant disease-specific chapters of the *Terrestrial Code* and the *Terrestrial Manual*, in order to resolve inconsistencies among the chapters and ensure that relevant texts reflect the latest scientific evidence and best practices regarding risk mitigation measures in the collection and processing of semen of animals. The *ad hoc* Group will also consider the inclusion of provisions to address equine semen in these chapters.

At its February 2020 meeting, the Code Commission considered the draft Terms of Reference for the *ad hoc* Group.

Update

The OIE Secretariat informed the Code Commission that the membership of the *ad hoc* Group was being finalised. The plan to convene the first meeting of this *ad hoc* Group in June 2020 had been postponed due to the COVID-19 pandemic.

The OIE Secretariat informed the Code Commission that it would resume the plan to launch the work of this *ad hoc* Group, but noted the challenges of convening a new *ad hoc* Group that must work electronically to undertake this complex work.

The OIE Secretariat drew to the attention of Members that the Terms of Reference and the meeting dates, once confirmed, will be uploaded onto the 'OIE calendar of *ad hoc* Groups' on the OIE website at:

https://app.smartsheet.com/b/publish?EQBCT=9e202fcc2c804db5aac7bbe7d55aadb7.

The Code Commission highlighted the importance of this priority topic for Members and requested to be informed of progress at its next meeting.

5.1.4. Revision of Collection and processing of *in vivo* derived embryos from livestock and equids (Chapter 4.8), and Collection and processing of oocytes and *in vitro* produced embryos from livestock and horses (Chapter 4.9)

Background

The Code Commission had previously considered amending Chapter 4.9, Collection and processing of oocytes and *in vitro* produced embryos from livestock and horses, to include provisions regarding risk mitigation measures for bovine viral diarrhoea (BVD) based on a proposal submitted by the IETS. At its September 2019 meeting, the Commission requested the OIE Secretariat to seek expert advice regarding the process to demonstrate that the bovine granulosa cells or co-culture cells used for *in vitro* culture were free from BVD virus, in order to develop appropriate risk mitigation measures for BVD regardless of the disease status of a country or zone (as there is no provision in the *Terrestrial Code* for countries or zones free from BVD).

In addition, the IETS had submitted two new requests.

Discussion

The OIE Secretariat informed the Code Commission that the consultation with IETS on the inclusion of provisions regarding risk mitigation measures for bovine viral diarrhoea (BVD) was still ongoing. The Commission requested the OIE Secretariat to continue the ongoing consultation and to include the new amendments proposed to Article 4.9.5 in the next draft amended text when presented to the Commission for its consideration.

The Code Commission also considered two new requests received from IETS, one to amend Chapter 4.8 to reclassify the category for Bluetongue in line with the updated IETS classification (see item 5.2.3 of this report); and the other to amend Article 4.9.5, Optional tests and treatments, (see item 5.2.4 of this report). The Commission agreed to add these two new requests to the ongoing work on this chapter. Before amending Chapter 4.8 with regards to

Bluetongue, the Code Commission requested the OIE Secretariat to consider, in consultation with the Biological Standards Commission, if this would also require changes in Chapter 3.1.3, Bluetongue (infection with bluetongue virus), of the *Terrestrial Manual*.

The Code Commission requested the OIE Secretariat to provide an update on the progress of this topic at its next meeting.

5.1.5. Updates on OIE AMR Working Group and Codex Alimentarius Task Force on AMR (in relation to the revision of Chapter 6.10 Responsible and prudent use of antimicrobial agents in veterinary medicine)

Background

At the February 2019 meeting of the Code Commission, comments were received requesting a review of Chapter 6.10, Responsible and prudent use of antimicrobial agents in veterinary medicine, given that this chapter had not been significantly reviewed for some time.

The Code Commission had requested the advice from the OIE Working Group on Antimicrobial Resistance, which met in October 2019. The Working Group recommended that amendments to Chapter 6.10 not be undertaken before the work at the TFAMR is finished to avoid duplication and inconsistencies given the similarity between the text in Chapter 6.10 and the discussion at the Codex Alimentarius Task Force on Antimicrobial Resistance (TFAMR).

Update

The OIE Secretariat informed the Code Commission that the Codex TFAMR has been working to develop a Code of Practice (COP) and Guidelines for integrated surveillance. The draft COP, which would be closely linked to Chapter 6.10 of the *Terrestrial Code*, is close to being finalised and will be presented for adoption at the CAC43 to be held from September to October this year.

Given the possibility that the Codex COP will be adopted soon, and the importance of ensuring relevant alignments between the COP and Chapter 6.10, the Code Commission agreed to defer this discussion to February 2021. Furthermore, the Commission encouraged Delegates of the OIE to actively engage in the ongoing discussion at the Codex TFAMR through the Codex focal points to ensure their views are reflected in the Codex COP.

The Code Commission requested the OIE Secretariat to provide an update on the progress of the Codex work at its next meeting.

5.1.6. Surra and dourine

Background

The Code Commission and the Scientific Commission had agreed that three separate chapters on animal trypanosomes with different coverage of trypanosomes species and host animals would be developed. In addition to the development of a new draft Chapter 8.Y, Infection with animal trypanosomes of African origin, a draft new Chapter 8.X, Surra, and a revised Chapter 12.3, Dourine, had been proposed and extensively discussed since 2015, in particular their respective coverage of susceptible species. Both Commissions had also agreed that notwithstanding the diagnostic issues, the scope of Chapter 8.X should address surra of multiple species including horses and that the scope of Chapter 12.3 should remain as dourine of equids.

In February 2018, the Scientific Commission and the Code Commission had agreed to put Chapters 8.X and 12.3 on hold in light of the ongoing discussions related to Chapter 8.Y, Infection with animal trypanosomes of African origin.

In its February 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 Member comments.

In February 2020, the Code Commission, together with the Scientific Commission, agreed to consider comments received on the new Chapter 8.Y, Infection with animal trypanosomes of African origin, before progressing work on the other two chapters.

Update

The Code Commission reviewed the new comments received on the new Chapter 8.Y (see item 6.5 of this report), and considered that, after two rounds of comments, no objections had been submitted by Members to the proposed chapters in terms of coverage of trypanosomes species and host animal species.

Given the progress seen on the new Chapter 8.Y, Infection with animal trypanosomes of African origin, the Code Commission, therefore, decided to continue the work on the new Chapter 8.X and the revision of Chapter 12.3 and will circulate new draft chapters after its February 2021 meeting.

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

Background

In February 2020, the Code Commission considered a request received from the World Health Organization (WHO) to update Chapter 8.5, Infection with *Echinococcus granulosus*, and Chapter 15.4, Infection with *Taenia solium* (Porcine cysticercosis), as well as the corresponding chapters in the *Terrestrial Manual*, in view of recent developments in the area of vaccines and vaccination.

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

Update

The OIE Secretariat informed the Code Commission that the Biological Standards Commission considered this request at its February 2020 meeting, and wished to note the following:

– The *Terrestrial Manual* Chapter 3.9.5, Cysticercosis (including infection with *Taenia solium*), has been updated to include the vaccine information proposed by WHO experts, and will be proposed for adoption in May 2021.

– The *Terrestrial Manual* Chapter 3.1.6, Echinococcosis (infection with *Echinococcus granulosus* and with *E. multilocularis*), has been updated to include the vaccine information proposed by the WHO and will be reviewed by the Biological Standards Commission in the September 2020 meeting.

Given these amendments being proposed in the relevant chapters of the *Terrestrial Manual*, the Code Commission requested the OIE Secretariat to prepare amended versions of Chapters 8.5 and 15.4, as proposed by the WHO experts, for its consideration at its February 2021 meeting, taking into consideration the changes included in the *Terrestrial Manual*, and in consultation with relevant experts, if necessary.

5.1.8. Provisions regarding importation of honey

Background

At the February 2019 meeting of the Code Commission, a comment was received that enquired whether a re-evaluation of the risks associated with the importation of honey is planned. The

Commission requested the OIE Secretariat to assess the need to work on the provisions regarding honey, including a possibility to create a Glossary definition for 'honey', and report back to the Commission at its next meeting.

Update

The Code Commission discussed this issue and agreed that it could potentially be addressed by revising Chapter 4.15, Official health control of bee diseases. The Commission asked the OIE Secretariat to explore this option and to consult the Codex Alimentarius regarding definitions on honey and related processes.

5.1.9. Slaughter of animals (Chapter 7.5) and Glossary Part B ('slaughter', 'euthanasia', 'stunning', 'death', 'pain', 'distress' and 'suffering')

Background

The OIE *ad hoc* Group on the Revision of Chapter 7.5, Slaughter of animals, and Chapter 7.6, Killing of animals for disease control purposes, held physical meetings in April and November 2018, and June 2019, and most recently via video conference between April and July 2020 to progress work on a comprehensive review of Chapters 7.5 and 7.6. The objective of this review was to resolve inconsistencies in the methods used in the slaughter of animals, and the killing of animals for disease control purposes; to propose amendments to ensure that the text reflects current scientific knowledge; and to review the structure of both chapters.

At its February 2020 meeting, the Code Commission requested that the *ad hoc* Group be reconvened to consider Member comments received on the new proposed structure for Chapter 7.5 and some preliminary comments of the articles corresponding to animals arriving freely to the slaughterhouse, circulated in its September 2019 meeting report, and to continue its work to finalise the revised Chapter 7.5. The *ad hoc* Group was also requested to consider comments on the revised definitions related to the revision of these two chapters.

Discussion

Comments on the revised definitions were received from Argentina, Australia, Canada, New Caledonia, Norway, Singapore, Switzerland, the United Kingdom, the United States of America, and the EU.

The OIE Secretariat updated the Code Commission that the OIE *ad hoc* Group had met virtually on many occasions between April and July 2020, amended the draft articles for animals arriving freely to the slaughterhouse taking into account Member comments, and progressed in the development of articles for animals arriving in crates to the slaughterhouse. Unfortunately, despite the extensive efforts made by the *ad hoc* Group to progress this work while meeting virtually, they were unable to complete the draft chapter or consider all Member comments on the proposed definitions.

The Code Commission thanked the *ad hoc* Group for its commitment to completing this work and discussed the value of reviewing the *ad hoc* Group work in its current state of development. The Commission agreed not to review the *ad hoc* Group's work at this meeting but rather requested that the *ad hoc* Group be reconvened to finalise the revision of Chapter 7.5 and start the revision of Chapter 7.6, and at the same time finalise the revision of the related definitions to these two chapters and submit a report for the Commission's consideration at its February 2021 meeting.

5.1.10. Infection with Rift Valley fever virus (Chapter 8.15)

Comments were received from China (People's Republic of), New Caledonia, New Zealand, Switzerland, Thailand, the United States of America, the EU and AU-IBAR.

Background

Proposed amendments to Chapter 8.15 were first circulated in the Code Commission's February 2019 report to clarify the obligations of Members to notify when there is an epizootic of Rift Valley fever (RVF) in an endemic country or zone. The revised Chapter 8.15, Infection with Rift Valley fever virus, was circulated for the third time for Member comments in the February 2020 Code Commission meeting report.

Discussion

The Code Commission acknowledged the comments received on Chapter 8.15 and deferred its discussion to its February 2021 meeting given that selected comments on surveillance had been sent to the Scientific Commission for its opinion.

5.2. New requests/proposals

5.2.1. Request received to draft a chapter on Camelpox

The Code Commission noted a request submitted by a Member to develop a new chapter on Camelpox in the *Terrestrial Code* to provide recommendations for international trade.

The Code Commission agreed to consider this item to be included in its work programme and requested the OIE Secretariat to seek further information from experts on camelid diseases about the current situation of the disease and the value of such recommendations, as well as information about any other work currently being undertaken.

5.2.2. Trichomonosis (Chapter 11.11): Request received to update the recommended tests for importation of bulls.

The Code Commission considered a query received from a Member regarding the appropriate tests for trichomonosis for the importation of bulls. The topic is discussed under item 7.8 of this report.

5.2.3. Revision of Collection and processing of *in vivo* derived embryos from livestock and equids (Chapter 4.8) to reclassify the category for Bluetongue

The OIE Secretariat informed the Code Commission of a request received from the IETS to amend Article 4.8.14 of the *Terrestrial Code*, in line with the recent change in the categorisation of Bluetongue under the IETS embryo categorisation system relating to disease risks in *in vivo* derived bovine embryos.

The Code Commission thanked the IETS for its close collaboration with the OIE and the support in keeping the OIE standards up to date with current relevant scientific evidence.

The Code Commission agreed to incorporate this request regarding Bluetongue in its work programme, noting that relevant disease-specific chapters of the *Terrestrial Code* and *Terrestrial Manual* should also be reviewed in parallel. It requested the OIE Secretariat to group this issue with other pending issues to be considered for the revision of Chapters 4.8 and 4.9 of the *Terrestrial Code* and to prepare for the discussion at its next meeting (see item 5.1.4 of this report).

5.2.4. Revision of Collection and processing of oocytes and *in vitro* produced embryos from livestock and horses (Chapter 4.9) to amend Article 4.9.5 on optional tests and treatments

The OIE Secretariat informed the Code Commission of a request and supporting rationale received from the IETS to amend Article 4.9.5 on optional tests and treatments.

The Code Commission agreed to incorporate this request in its work programme, and requested the OIE Secretariat to group this issue with other pending issues to be considered for the revision of Chapters 4.8 and 4.9 of the *Terrestrial Code* and to prepare for the discussion at its next meeting (see item 5.1.4 of this report).

5.2.5. Revision of the Glossary definition for 'disinfection'

The OIE Secretariat informed the Code Commission of a request received from a Member to amend the Glossary definition for 'disinfection' in the Glossary, to allow 'fallowing' to be covered as a disinfection method.

The Code Commission acknowledged that there is evidence to support this proposal and agreed to take this into consideration when undertaking the planned revision of Chapter 4.14, General recommendations on disinfection and disinsection, which was already included in its work programme.

The Code Commission also noted that a newly revised Chapter 4.3, Disinfection of aquaculture establishments and equipment, of the *Aquatic Code* was adopted in 2017 and should be considered when undertaking the revision of Chapter 4.14.

5.2.6. Revision of Article 4.7.4 on Conditions applicable to testing of boars

The OIE Secretariat informed the Code Commission of a request received from a Member to amend Article 4.7.4 to provide more clarity with respect to testing of boars for brucellosis.

The Code Commission agreed that there were some inconsistencies and a lack of clarity for brucellosis as well as some other diseases and wished to note that these issues will be addressed as part of the work to review and revise Chapters 4.6 and 4.7 (see item 5.1.3 of this report). The Commission requested the OIE Secretariat to ensure this request regarding brucellosis be addressed in this work.

5.3. Follow-up revisions of recently adopted chapters

5.3.1. Outstanding issues regarding Chapter 8.14 Infection with rabies virus

The last revised version of Chapter 8.14, Infection with rabies virus, was adopted in 2019. At the time of adoption, the President of the Code Commission noted that additional work would be considered in the near future.

The Code Commission reviewed the pending issues on this chapter and the progress made by the Scientific Commission and the *ad hoc* Group on rabies regarding the provisions for the importation of dogs from infected countries or zones and agreed to discuss the revision of Chapter 8.14, Infection with rabies virus, at this meeting (see item 7.2 of this report).

5.4. Prioritisation of items in the work programme

Based on a range of considerations presented above, and the progress of different topics discussed during this meeting (see sections 6 to 8 of this report) as well as the coordination with other Specialist Commissions (see section 4 of this report), the Code Commission updated its work programme and revised the order of items in each section to reflect the current level of prioritisation. In addition, the Code Commission decided to include the items presented below.

- Revision of Glossary definition for 'case'
- New Glossary definition for 'swill'
- Revision of Chapter 5.11 Model veterinary certificate for international movement of dogs, cats and ferrets originating from countries considered infected with rabies
- Revision of Chapter 8.13 Paratuberculosis
- Revision of Chapter 10.3 Avian infectious laryngotracheitis
- Revision of Chapter 10.9 Infection with Newcastle disease virus

- Revision of Chapter 10.11 Trichomonosis
- Development of a new chapter on infection of dromedary camels with Middle East respiratory syndrome coronavirus
- Development of a new chapter on leishmaniosis.

The updated work programme is presented as **Annex 3** for Member comments.

EU comment

The EU thanks the OIE for having taken into consideration its previous comments and supports the revised work programme of the Code Commission.

6. Texts proposed for adoption in May 2021

The Code Commission considered comments received on the following new and revised texts previously circulated for Members comments and its responses are presented below. Items discussed under this section are proposed for adoption at the 88th General Session in May 2021.

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

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

Infection with *Mycobacterium tuberculosis* complex

The Code Commission recalled that in the report of its February 2020 meeting it had invited Members to provide any new scientific evidence to the OIE regarding the possibility and impact of transmission of *Mycobacterium tuberculosis* from animals to humans or other animals, to inform its decision as to whether or not *M. tuberculosis* should be listed. The Code Commission noted that a Member had provided some scientific evidence, which was referred to the Scientific Commission for consideration. Pending the feedback from the Scientific Commission, no change is proposed to the listed disease 'Infection with *Mycobacterium tuberculosis* complex'.

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

The Code Commission acknowledged a comment in support of amending the name of the pathogenic agent for contagious bovine pleuropneumonia and informed that the amendment would be proposed for adoption once the corresponding chapter in the *Terrestrial Manual* has been updated (in reference to a discussion in the report of the February 2020 meeting).

Infection with animal trypanosomes of African origin (*T. vivax*, *T. congolense*, *T. simiae* and *T. brucei*)

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

Infection of dromedary camels with Middle East respiratory syndrome coronavirus

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

Revised Articles 1.3.1, 1.3.2 and 1.3.9 are presented as **Annex 4** for Member comments and are proposed for adoption at the 88th General Session in May 2021.

EU comment

The EU supports the proposed changes to these articles.

6.2. Quality of Veterinary Services, Evaluation of Veterinary Services and new chapter on Veterinary Services (Chapters 3.1, 3.2 and 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 twice for comments, the first time in the report of the Code Commission September 2019 meeting and the second time in its February 2020 report.

General comments

The Code Commission considered proposals made by OIE Headquarters to refer to 'wildlife', 'zoonoses' and 'emerging diseases' in the texts of Chapter 3.X, 3.1 and 3.2, in response to infection with SARS-CoV-2 and in consideration of other emerging diseases and spill over events from wildlife to other animals and humans.

The Code Commission agreed to include some of these proposed additions where appropriate. However, it highlighted that the Glossary definition of 'animal' includes wildlife, and that the term 'animal diseases' inherently includes 'zoonoses' and 'emerging diseases'. Thus the Commission was of the view that there was no need for the systematic addition of 'including wildlife' whenever those terms were used. If considered ambiguous by Members, the Commission could consider revising the Glossary definition for 'animal', noting that this could entail consequential amendments across the *Terrestrial Code*.

For responses to comments relating to the definitions of 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services', refer to item 7.1 of this report.

New chapter on Veterinary Services (Chapter 3.X)

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

Article 3.X.1

In the first paragraph, the Code Commission agreed with a comment to add 'national' when referring to trade noting that Veterinary Services are not only responsible for ensuring safe international trade but also safe national trade.

In the same paragraph, the Code Commission agreed with a comment to include 'health' after wildlife as the point should also cover wildlife health and not just wildlife protection. Taking into account the proposal made by the OIE Headquarters in response to the recent infection with SARS-CoV-2, it proposed to add 'in a One Health approach' at the end of the last sentence given that a One Health approach is an important concept that is referred to in Chapter 3.1.

Quality of Veterinary Services (Chapter 3.1)

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

Article 3.1.2

In point 6 of Article 3.1.2, the Code Commission did not agree with a comment that the text does not effectively communicate the principle that veterinary science is made up of a range of scientific disciplines. The Commission was of the view that the original text is clear and concise and refers to 'implement their activities on a scientific basis', without specifying which expertise is needed. Furthermore, there is no universal definition of veterinary science, so the reference would be imprecise.

The Code Commission also did not agree with the second part of the comment to have a separate statement on economics and social sciences. The rationale provided by the Member was that although these are important considerations, there may be some debate that economics and social sciences are not 'true sciences'. The Commission explained that the text highlights some fields contributing to the activities of Veterinary Services, independent of whether or not these are considered 'true sciences'.

In response to a comment from OIE Headquarters to include a new point on collaboration to highlight existing links between the role of the Veterinary Services, wildlife health and risks of emerging zoonoses, the Code Commission partially agreed, and proposed a new point on 'intersectoral collaboration', and kept the explanatory text broad and high level, without scoping it to wildlife.

Article 3.1.3

In the second paragraph, the Code Commission replaced 'Competent Authorities' with 'governmental authorities' in response to a comment that there are other relevant agencies outside of the Competent Authority, e.g. law enforcement agencies, which may also be involved.

In point 8, the Code Commission did not agree with a comment to include text on multisectoral preparedness and response mechanisms as it considered this to be too detailed. However, the Commission agreed to include this point in parenthesis as an example of the activities for which formal external coordination mechanisms would apply.

Article 3.1.4

The Code Commission did not agree with a comment to include an additional point on access to private sector-based Veterinary Service providers, since this article provides provisions related mainly to personnel and resources covered by the official budget. The Commission noted that the engagement of the private sector is covered in Article 3.1.6. Furthermore, point 8 of the same article elaborates on procedures for the Veterinary Services to access personnel and other resources, which could include private sector providers.

Article 3.1.5

In point 3, the Code Commission did not agree with a comment to delete 'quality' after 'sufficient' and to add 'of the appropriate standard' after 'veterinary clinical services'. It explained that the point concerns both the quality and quantity of veterinary clinical services, and there was no need to elaborate on the quality or quantity needed since the last part of the sentence describes what these should be sufficient for, i.e. 'to meet the needs of animal owners'. The same explanation would apply to other comments on the 'quality' of veterinary clinical services.

Article 3.1.6

In the first paragraph, the Code Commission agreed with a proposal from OIE Headquarters to include wildlife managers and researchers in the list of examples.

Article 3.1.7

In point 1, the Code Commission agreed with a proposal from OIE Headquarters to include 'known and emerging' before 'diseases' and mention of 'wildlife' to highlight these points.

Article 3.1.8

In point 2, the Code Commission agreed with a proposal from OIE Headquarters to add 'including slaughter associated with live animal markets' to emphasise that live animal markets should also be subject to procedures for ante-mortem and post-mortem inspection. However, it did not agree with a comment to include a new point on 'management of risks from animal sales and slaughter associated with public markets, especially when many animal species, including wildlife are involved' as it considered this to be too detailed for the purposes of this article.

In the same point, the Code Commission proposed to replace 'and zoonoses' with 'including zoonoses' to clarify that animal diseases includes zoonoses.

Article 3.1.9

In point 2, the Code Commission partially agreed with a comment to rephrase the second sentence for better readability and proposed amendments to split the existing sentence. It agreed that surveillance and control of antimicrobials apply to both antimicrobial use and development and spread of antimicrobial resistant pathogens with the text as written.

Article 3.1.10

In the first sentence of the second paragraph, the Code Commission agreed with a comment to add 'implementing' before 'antimicrobial resistance surveillance'. The Commission also agreed to add 'as well as for associated research' at the end of the sentence.

In the last sentence, the Code Commission agreed with a comment and replaced 'overseas' with 'abroad'.

Article 3.1.12

In point 4, the Code Commission did not agree with a comment to add 'including wildlife' for the reasons given under general comments above.

Evaluation of Veterinary Services (Chapter 3.2)

Comments were received from Switzerland and the EU.

Article 3.2.3

In point 2, the Code Commission partially agreed with a comment to include a reference to the importance of independence and added the sentence 'The Competent Authorities should consider the principle of independence when carrying out self-evaluations'. It did not agree to include prescriptive information on the appointment of independent bodies, noting that there are many ways to ensure independence.

Revised new Chapter 3.X, and revised Chapters 3.1 and 3.2 are presented as **Annexes 5, 6 and 7** for Member comments and are proposed for adoption at the 88th General Session in May 2021.

EU comment

The EU thanks the OIE and in general supports the proposed changes to these chapters. One comment is inserted in the text of Annex 5.

6.3. Zoning and compartmentalisation (Articles 4.4.6 and 4.4.7)

Comments were received from Australia, Canada, New Caledonia, New Zealand, Switzerland, the United States of America, the EU and the OIE Americas Region.

Background

During the last revision of Chapter 4.4, Zoning and compartmentalisation that was adopted in 2018, some Members had requested an update regarding the status of the proposal 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 when an increased risk is considered to be temporary. At that time, the Code Commission, in consultation with the Scientific Commission, agreed to not address these comments 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 its inclusion in the *Terrestrial Code*.

The proposed revised texts for Articles 4.4.6 and 4.4.7 were circulated for Member comments for the first time in the report of the Code Commission February 2020 meeting.

Discussion

The Code Commission noted a request to develop separate chapters on the concept of zoning and compartmentalisation to improve clarity. The Commission informed Members that there is already Chapter 4.5 on the application of compartmentalisation and that the development of a new chapter on the application of zoning is included on the work programme of the Commission.

Article 4.4.6

In the second paragraph, the Code Commission did not agree with a comment to add text regarding temporality of a protection zone with a defined maximum duration of time. It reaffirmed that the maximum duration should be specified only for diseases for which the OIE grants official recognition of animal health status, noting the new concept of protection zone presented in this draft article should be applicable to any disease.

In the same paragraph, the Code Commission did not agree with a comment to merge the first two sentences as it considered the separate sentences as written provide more clarity.

For the previous fourth paragraph regarding increased surveillance, the Code Commission agreed with a comment to move this paragraph down as the new fifth paragraph, for better clarity and flow of the article. In this paragraph, the Commission did not agree with a comment to delete 'and the rest of the country or zone' as it considered these words should be retained for clarity.

In the new fourth paragraph, the Code Commission did not agree with a comment to replace 'these measures' by 'the measures implemented in the protection zone and the rest of the country or zone' because 'these measures' means the biosecurity and sanitary measures that are described in the preceding paragraph.

In the new sixth paragraph, the Code Commission did not agree with a comment to add 'outside the protection zone' after 'the rest of the country or zone' as it considered the text clear as written, noting that 'the rest' means outside. The Commission noted a comment to request that a protection zone transition to a containment zone if a case occurred in the protection zone. In response to this comment, the Commission agreed to add text regarding the 'subsequent' establishment of a containment zone at the end of this paragraph. Furthermore, the Commission agreed to move the text regarding the scenario where vaccination was implemented from the paragraph and to create a separate paragraph to improve readability.

In the last paragraph, the Code Commission did not agree with a comment that the current text may cause misunderstanding that OIE approval is required under all circumstances. Nevertheless, the Commission introduced three indents and also proposed minor amendments to the text to improve clarity.

Article 4.4.7

In point 1, the Code Commission did not agree with a comment to replace 'all' by 'one or several' highlighting that what matters here is not the number of outbreaks but the fact that all epidemiologically linked outbreaks are included in a containment zone. If epidemiologically linked outbreaks occur at distances making it impossible to have one containment zone, it would mean the disease is not contained.

In point 3, under the third indent, the Code Commission did not agree with a comment to add 'controlling or' before 'eradicating' as it considered that eradication can only be achieved by control measures against the disease, which was already implied with 'emergency control strategy aimed at eradicating disease'. It added that although not always feasible, in the context of a containment zone the measures should have the objective of eradicating the disease.

In point 4(a), the Code Commission did not agree with a comment to replace 'two incubation periods' by 'two infective periods'. While the Commission acknowledged that 'two infective periods' is used in Chapter 12.1, Infection with African horse sickness virus, due to its specificity, it agreed that it is the incubation period that should be considered for effective establishment of a containment zone, which is always preceded by stamping-out or killing of the last detected case. Incubation periods are used in post control surveillance to verify the absence of transmission of the pathogenic agent. The Commission also noted that infective period is, by definition, often hard to define and it can be lifelong. Notwithstanding, the Commission agreed to add 'unless otherwise specified in the disease-specific chapter' in the chapeau of point 4 to allow for different conditions depending on specific characteristics of some diseases.

In point 4(b), the Code Commission welcomed a proposal from some Members regarding the naming of two different zones that make up a containment zone, and agreed to use 'an inner zone' and 'an outer zone' for the clear differentiation of the two zones.

In point 5, the Code Commission did not agree with a comment to add 'for diseases for which the OIE grants official recognition of animal health status' in the first sentence as it considered this principle would be applicable to any disease. In the same point, the Commission did not agree with a comment to add a new sentence that allows for science- and risk-based agreements between Members to enable continued trade between geographically distant areas which are to be considered by trading countries to remain free from the disease. The Commission reminded Members that the provisions in the *Terrestrial Code* are general principles and in the situation described in this point, the free status of the rest of the country or zone is suspended irrespective of bilateral agreements. Moreover, the trade provisions are provided in disease-specific chapters irrespective of bilateral agreements, taking into account the animal health status of the exporting country or zone.

In point 7, the Code Commission did not agree with a comment to add 'that is epidemiologically related to the outbreak' before 'for which the containment zone was established' on the basis of a necessity to explicitly allow for the continued point-source introductions which could occur with infection with high pathogenicity influenza (HPAI) viruses and other diseases. While noting that such a situation could theoretically take place for some specific diseases, the Commission questioned the practicality and feasibility to establish and manage multiple containment zones in the same area that correspond to different sources for the same disease.

Revised articles 4.4.6 and 4.4.7 are presented as **Annex 8** for Member comments and are proposed for adoption at the 88th General Session in May 2021.

EU comment

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

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

Comments were received from Australia, Canada, China (People's Republic of), Ecuador, Honduras, Guatemala, Israel, Japan, Mexico, Norway, South Africa, Switzerland, the United Kingdom, the United States of America, the EU, the OIE Americas Region, OIRSA-FEDAVICAC, ICFAW and IEC.

Background

The new Chapter 7.Z, Animal welfare and laying hen production systems, is the last chapter to be developed on animal production systems based on the prioritised list developed by the former OIE Animal Welfare Working Group. The first draft was developed by the *ad hoc* Group on Animal welfare and laying hen production systems (in 2016) and was circulated for comments on three occasions in September 2017, 2018 and 2019.

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

During this commenting period, some comments were similar to those previously submitted. Where comments had been addressed previously, the Code Commission did not respond again but rather encouraged Members to refer to previous reports that included its rationale to these comments. The Commission encouraged Members to refer to its past reports and relevant *ad hoc* Group reports as they include detailed information about previous revisions as well as the rationale.

As noted in the report of its February 2020 meeting, the Code Commission only considered comments of significance that had not been submitted previously.

Discussion

The Code Commission did not agree with the comments proposing to continue discussing the revised chapter to include regional or particular production system specifications because it considered that the current text is already flexible enough to be used in different contexts.

The Code Commission did not agree with a comment to include more details regarding what is considered a 'motivated behaviour', as considered that the introduction in point 2 of article 7.Z.3 was sufficient, and also noted that this was already discussed in its February 2020 meeting report, where the Commission explained the reasons not to qualify behaviours as 'highly', 'strongly' and 'complex' in the text because these were qualitative terms difficult to interpret.

However, to allow for more flexibility, the Commission strengthened the text around the explanation of the outcome-based criteria (or measurables) articles of the draft, rather than amending the specific recommendations. This would ensure that all Members could implement the chapter irrespective of their level of development of animal welfare measures for laying hens and layer pullets.

The Code Commission agreed with comments to add the term 'layer' before 'pullets' and 'hens' where relevant to ensure consistency throughout the chapter.

The Code Commission did not agree to include the word 'may' in the list of measurables in the recommendation's articles, as they wished to infer that there could be other measurables and that this was not a complete list. Nevertheless, the Commission decided to modify the way lists of criteria are introduced by deleting the word 'include', and by using the terminology from Article 7.Z.3 'may be useful indicators'.

The Code Commission agreed in principle with the comment to consider including more welfare measures, but it considered that the addition of more measures so close to the proposed adoption was not feasible as it did not want to make significant changes at this time in order to be able to propose the draft chapter for adoption in May 2021.

Article 7.Z.3

The Code Commission did not agree to replace the wording 'outcome-based measurables' with 'outcome-based measures', as the intended meaning is assumed to be a specific criterion that could be measured. However, the Commission agreed that consistency of the use of these terms throughout this chapter as well as all chapters in Section 7 was important. The Commission requested the OIE Secretariat to review all relevant chapters and evaluate the work needed to apply the use based on Article 7.1.4 and report back to the February 2021 Code Commission meeting.

The Code Commission agreed with the proposal to delete the examples given in the first paragraph of this article as it was an oversight from the February review of the draft.

The Code Commission did not agree to delete point 1, regarding 'Beak condition', as it is considered an important animal welfare aspect to be measured, and not only a consequence of an operation.

In point 2, the Code Commission did not agree with the proposed way of using the word 'normal' in some of the behaviour measurables (criteria), as this is already explained in the introductory part of point 2.

The Code Commission did not agree to add the term 'when applicable' at the beginning of the sentence introducing the list of measurables as the last paragraph of the introduction of this article already mentions that other measures may be used if defined on the basis of science and used in the right context.

In point 2(a), the Code Commission did not agree to delete the words 'motivated behaviour'. As explained in the report of the February 2020 meeting:

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

The *ad hoc* Group and the Code Commission decided to emphasise the importance of this concept in this section of the revised chapter, to allow for more flexibility in the implementation of the 'recommendations' part of the chapter.

In point 2(g), the Code Commission did not agree to delete the words 'is a motivated', because it is considered important to qualify the behaviour 'nesting' in this section.

In point 2(j), the Code Commission agreed to include a missing reference to the list and reminded Members that the list of references will be deleted after adoption.

In point 6, the Code Commission did not agree to delete 'metabolic disorders' from the subtitle of this point but decided to add the word 'including' to highlight the fact that even if metabolic disorders do not have a transmissibility component, they can be considered as important diseases.

In point 8, the Code Commission agreed to include the term 'rates' in the second sentence but rephrased the sentence to improve readability.

In point 9, the Code Commission agreed to add the measure of performance 'layer pullet flock uniformity', under a new bullet point (b) because of the importance of having a measure specific to flock uniformity. Also, and to improve the text and to avoid repetition, the Code Commission deleted the last part of bullet point (a), 'and flock uniformity'.

In point 11, the Code Commission did not agree to include the term 'rate' in the subtitle as it considered that the criterion measured how layer pullets and laying hens consume feed and water rather than the amount consumed.

Article 7.Z.4

The Code Commission did not agree with the proposal to add a new sentence at the end of the first paragraph regarding the adaptation of layer pullet and laying hens to their environment, as it considered that the concept was already covered in the first part of that paragraph. The Commission agreed to remove the term 'management', add 'animal welfare' and replace 'are lacking' with 'there are problems with' to improve the readability.

Article 7.Z.6

The Code Commission did not agree to add a new sentence at the end of the first paragraph regarding the provision of conditions similar to the ones that would be offered in the intended layer housing system. It considered that by adding this new sentence, it would not allow for enough flexibility in the measures to be used to preadapt the layer pullet and laying hens to the housing and production systems. The Commission recalled that this comment was already addressed in the report its February meeting.

Article 7.Z.7

The Code Commission did not agree with the comment to add text regarding the possibility to have enough space for the expression of locomotory and comfort behaviours, as it considered the proposed wording was vague, and that the current text was adaptable enough.

Article 7.Z.8

The Code Commission agreed to include the term 'pathogenic' in the last sentence of the first paragraph, to distinguish it from microorganisms that may not be pathogenic.

Article 7.Z.9

The Code Commission agreed to delete the words 'locomotion of' in the first sentence as it agreed that they were now redundant following the wording added to this paragraph at the February 2020 meeting, which captured this concept.

Article 7.Z.10

The Code Commission did not agree with the comment proposing to combine the two first sentences and rephrase as 'when dust bathing areas are provided, they should have friable and dry substrate' as it considered that the change would restrict the meaning and not provide additional information to the current text which is considered clear as written.

The Code Commission did not agree to replace the word 'When' by 'if' in the same paragraph, as this paragraph should be written as a recommendation. The Commission did not agree with a similar comment submitted for Article 7.Z.11.

Article 7.Z.14

In the third paragraph of this article, the Code Commission agreed to replace 'stagnant' by 'standing' when describing 'water' that should be minimised in outdoor areas. In the same paragraph, the Commission did not agree with the proposal to add a new sentence regarding the provision of enrichment material to prepare the laying hens for outdoor access. However, the Commission redrafted the proposed text, to emphasise the good conditions that need to be provided in the rearing period to prepare layer pullet and laying hens to outdoor areas conditions. The Commission also agreed to consider this point in a future revision of the chapter and requested the OIE Secretariat to note this point for future revisions. The Commission did not agree with a comment to add a new sentence on the need for laying hens to have enough feather cover to be in completely outdoor systems, as it is already mentioned at the beginning of the first paragraph.

Article 7.Z.15

The Code Commission decided to add 'relative' to humidity as it is the correct measure that affects the thermal environment. The Commission recalled that even though this criterion is not described in Article 7.Z.3, it is consistent with Article 7.1.4, and corresponds to a resource-based measure.

Article 7.Z.16

To be consistent with the changes made in Article 7.Z.15, the Code Commission added the term 'relative' to 'humidity' as it is the appropriate measure that affects the air quality.

Article 7.Z.19

The Code Commission did not agree to add a new sentence clarifying the timing and extent of the partial beak removal when other methods to manage injurious feather pecking failed. The Commission considered that the current revised text is flexible enough and that this method should be considered as a final course of action rather than a routine one.

The Code Commission agreed to add a bullet point 'providing nesting areas during lay' following newly published research showing the importance of this concept for the welfare of layers.

Article 7.Z.20

The Code Commission partially agreed with the proposal to modify the wording of the first and third sentences of the first paragraph of this article. The Commission agreed to include the words 'and adequate periods of light' but did not agree with the proposal to add 'which can be mitigated by proper management' in the first sentence as it considered the current text to be clear as written.

Article 7.Z.26

The Code Commission agreed with the comment on the difficulties to implement evacuation procedures in some contexts, for example, in a sanitary one. Therefore, due to the importance of this concept, the Commission did agree to add 'evacuation procedures and', but at a different place in the text to make it more flexible, while keeping the possibility to implement this kind of measure in emergency situations.

The revised new Chapter 7.Z, Animal welfare and laying hen production systems, is presented as **Annex 9** for adoption at the 88th General Session in May 2021.

EU comment

The EU thanks the OIE for its work on the revision of this draft new chapter but regrets that its key comments submitted previously have not been addressed despite solid scientific evidence in support.

The EU will not support the adoption of this chapter unless the comments inserted in the text of Annex 9 have been taken into account.

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

Comments were received from Brazil, Switzerland, Mexico, New Caledonia, the United States of America, the EU and AU-IBAR.

Background

In its September 2019 meeting, the Code Commission agreed to amend Article 1.3.1 to add 'Infection with animal trypanosomes of African origin (*T. vivax, T. congolense, T. simiae* and *T. brucei*)' to the diseases, infections and infestations listed by the OIE and circulated a new Chapter 8.Y, Infection with animal trypanosomes of African origin, for Member comments. The Code Commission reiterated that the decision agreed by the Code Commission and the Scientific Commission was that three separate chapters on animal trypanosomes with different coverage of trypanosomes species and host animals would be developed and that a new draft Chapter 8.Y would be developed first.

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

Discussion

Article 8.Y.1

In points 1 and 4, 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, as other vectors can also

transmit the pathogenic agents. The Commission reminded Members that this point had been extensively discussed by the *ad hoc* Group on Animal trypanosomes of African origin, who agreed to focus the definition of the disease on the pathogenic agents and not on the vectors. Nevertheless, the Commission requested the Secretariat to seek further expert advice on this point to be considered in its February 2021 meeting. The Commission amended the text of point 1 for clarity.

In point 4, the Code Commission did not agree with a comment requesting to amend the wording and explained that this point refers to the 'incubation period' of the disease, i.e. 'infection with animal trypanosomes of African origin', and not to the infective period. The Commission reminded Members that the infective period of this disease can be lifelong.

Article 8.Y.2

In point 2, the Code Commission agreed with a comment that 'lanolin' could be considered as a safe commodity given that it was a derivative of wool which is included in the list of safe commodities in Article 8.Y.2. Nevertheless, the Commission decided not to add lanolin to Article 8.Y.2 as it considered that, as wool is a safe commodity, it was implicit that 'lanolin' could be considered as safe. The Commission explained that, for practical reasons, it is not possible to include all products that are exclusively derived from commodities already listed as safe.

In point 3, the Code Commission agreed with a comment to modify the wording to 'gelatine and collagen' given that the production of collagen, whether by acid, alkaline or enzymatic hydrolysis, includes a thermal step that ensures elimination of vegetative pathogens. This addition is also consistent with other *Terrestrial Code* chapters.

In point 5, the Code Commission did not agree with a comment to merge points 5 and 6. The Commission reminded Members that 'meat' would only be considered safe when derived from animals that passed ante- and post-mortem inspections, whereas all 'meat products' should be considered safe. The Commission had included these two entries in the list to clarify this difference.

In point 7, in response to a comment, the Code Commission reminded Members that the *ad hoc* Group on Animal trypanosomes of African origin had considered that there was a remote but not negligible risk of the presence of the pathogenic agent in raw hides and skins, and therefore hides and skins could not be considered safe commodities.

Article 8.Y.3

In point 3, the Code Commission agreed to include a new point 3(c) to cover the possibility of a country or zone to be recognised as free from infection with animal trypanosomes of African origin when the absence of competent vectors has been demonstrated by a surveillance programme. The Commission noted this is the case in several other vector-borne disease-specific chapters of the *Terrestrial Code*.

In the last paragraph, the Code Commission agreed to replace 'neighbouring to' with 'adjacent to' for consistency with other chapters of the *Terrestrial Code*. This was also applied to the second paragraph of Article 8.Y.9.

Article 8.Y.5

In point 2, the Code Commission did not agree with a comment to add text at the end of the current sentence about the need for these measures to be applied in conjunction with measures applied to positive animals (i.e. treated, slaughtered, or killed and appropriately disposed of). The Commission explained that this was already covered by point 1, since animals linked to a confirmed case and reacting positively to a test should be considered as cases, and therefore, these two points should be considered together as presented in the current text.

In point 2, the Code Commission agreed with a comment on the need to clarify the wording referring to the protection of animals against vectors and agreed to replace 'vector protection' by 'protection from vector attacks', for consistency with other vector-borne disease-specific chapters of the *Terrestrial Code* (e.g. African horse sickness).

In point 5, the Code Commission agreed with a comment to delete 'may', as biosecurity measures for trypanosomes of African origin should always consider including protection against vector attack.

Article 8.Y.6

In point 3, the Code Commission agreed with a comment and amended the text for clarity.

Article 8.Y.7

In the first paragraph, the Code Commission agreed with editorial comments and replaced the references by 'Articles 8.Y.7 to 8.Y.10'.

In the second paragraph, the Code Commission did not agree with a comment to delete the paragraph as the Commission considered it was important to explain the goals of the surveillance, and to specify that it is not intended only for disease freedom. The Commission also emphasised that this text is especially relevant for this disease as the surveillance strategies would vary considerably between countries and with different epidemiological situations. The Commission did not agree with a comment to delete the first sentence of the third paragraph for the same reasons.

In the last paragraph, the Code Commission partially agreed with a comment to delete the last sentence but moved it to the beginning of the paragraph for better flow.

Article 8.Y.8

In point 1(c), the Code Commission agreed with a comment to add 'reporting' as it considered that it is a critical component of a surveillance system.

In point 2(a), the Code Commission agreed with a comment to amend the wording for clarity, and to ensure consistency with other chapters as well as to better reflect the involvement of veterinarians and veterinary paraprofessionals in the early warning system.

Article 8.Y.9

In the fifth paragraph, the Code Commission partially agreed with a comment and, in line with the language of Chapter 1.4, replaced 'rate' with 'expected prevalence'. The rest of the text of the paragraph was considered consistent with other chapters of the *Terrestrial Code*.

In points 1 and 2, the Code Commission agreed with a comment and amended the wording of both points to remove redundancies.

In point 6, in the second paragraph, the Code Commission amended the text for consistency with the changes introduced in Article 8.Y.3 to cover the possibility for a country or zone to be recognised as free from infection with animal trypanosomes of African origin when the absence of competent vectors has been demonstrated by a surveillance programme.

Article 8.Y.10

The Code Commission did not agree with a comment requesting to move the content of this article to Article 8.Y.5, as this is the standard structure used for disease-specific chapters of the *Terrestrial Code*.

In response to a comment on the wording of points 1, 2 and 3, the Code Commission reminded Members that the convention for the *Terrestrial Code* is not to repeat 'and' at the end of each point of a list. When items are listed and separated by commas, they are all considered necessary. On the contrary, when alternatives are proposed, they are separated explicitly by 'or'.

Revised new Chapter 8.Y is presented as **Annex 10** for Member comments and proposed for adoption at the 88th General Session in May 2021.

EU comment

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

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

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

Background

At its February 2020 meeting, the Code Commission proposed amendments to Article 9.4.5 following a comment to modify points 2 and 3 of Article 9.4.5 concerning the timing of inspection prior to export and area freedom from the occurrence of infestation with *Aethina tumida*. The revised article has been circulated for Member comments for the first time in the report of the Code Commission February 2020 meeting.

The Commission thanked the OIE Reference Laboratory experts who provided advice on the comments received.

Discussion

In point 2, the Code Commission agreed with a comment that the timing of inspection should be specific and proposed to replace 'on the day of packing' with 'immediately prior to packing'. The Commission considered that this also addressed another comment on the packing of queens into queen cages immediately after inspection.

In the same point, the Code Commission did not agree with a comment to delete 'hives or' before 'colonies', and to add 'as well as the hive' after 'inspected' as it did not agree with the rationale provided that a hive is just the box where the colony lives.

In point 3, several comments were received on the appropriate geographical radius where no apiary has been subject to any restrictions associated with the occurrence of infestation with *A. tumida*. The Code Commission noted the advice of the OIE Reference Laboratory experts that there is no published data to support a specific radius. On the other hand, the Commission noted that empirical evidence from an infected Member showed that the disease had not spread through exportation despite using a smaller restriction area, as long as the other risk mitigation measures recommended in the article were also applied. Therefore, the Commission proposed to retain the proposed recommendation of a 50 km radius.

In point 6, the Code Commission agreed with a comment to include 'cages or the whole' before 'consignment of bees' to prevent the infestation or contamination of the cages. The Commission partially agreed with a comment from the same Member and proposed to add 'immediately after the packing' to align with point 2.

In the same point, the Code Commission did not agree to add 'adult' before 'beetle' as it considered that this would not provide any additional value.

Revised Article 9.4.5 is presented as **Annex 11** for Member comments and is proposed for adoption at the 88th General Session in May 2021.

EU comment

The EU thanks the OIE for having taken some of its comments into account. However, we reiterate our concern over one of the changes to this chapter as proposed. A comment is inserted in the text of Annex 11.

6.7. Infection with avian influenza viruses (Chapter 10.4) [together with Diseases, infections and infestations listed by the OIE (Article 1.3.6) and Glossary definition for 'poultry']

Infection with avian influenza viruses (Chapter 10.4)

Comments were received from Argentina, Belize, Canada, China (People's Republic of), Chinese Taipei, Costa Rica, Ecuador, Japan, New Caledonia, Switzerland, the United States of America, the OIE Americas Region, the EU and the International Poultry Council (IPC).

Background

A comprehensive review of Chapter 10.4, Infection with avian influenza viruses, was undertaken by the *ad hoc* Group on Avian influenza between 2017 and 2019. The revised chapter had been circulated for Member comments on three occasions and was proposed for adoption in the May 2020 General Session. Due to the postponement of the 88th General Session, the revised text was proposed for an additional round of comments in the report of the Code Commission February 2020 meeting noting that only substantive comments that had not been submitted before would be considered.

The revised Glossary definition for 'poultry' and the revised Article 1.3.6, which were presented as Annex 5 and 13, respectively, at the report of the Code Commission February 2020 meeting, were not further amended at this meeting, therefore these texts are not presented in this report as, in line with the guidance described in the report of the February 2020 meeting, Members are not invited to submit new comments in this occasion. Revised text will be presented in the report of the February 2021 meeting as proposed for adoption at the 88th General Session in May 2021.

Discussion

General comments

The Code Commission did not agree with a comment requesting that this chapter should remain as 'Infection with avian influenza viruses' so that all H5 and H7 subtypes, including low pathogenicity avian influenza (LPAI), should be notified to the OIE. The Commission stressed that this issue had been extensively discussed during previous meetings and encouraged Members to thoroughly review the relevant Commission's reports and *ad hoc* Group reports for the detailed rationales provided.

In response to a comment requesting that the current title of the chapter not be amended because of the inclusion of some guidance on LPAI in this chapter, the Code Commission reiterated that, even if some monitoring of LPAI is necessary, the objective of this chapter was to mitigate animal and public health risks posed by the listed disease 'Infection with high pathogenicity avian influenza viruses', and this should be reflected in the title as in other places in the *Terrestrial Code*.

The Code Commission noted a comment requesting the development of a procedure to determine 'LPAI having proven natural transmission to humans associated with severe consequences' as well as another comment made for Article 10.4.1 stating that notification of such events of zoonotic LPAI is undefinable and unfeasible. The Commission pointed out that decisions regarding these specific LPAI should be made based on the gathered data at an appropriate point in time, but while that decision is pending, Members can respond to the event by considering it as 'emerging disease' as described in the Glossary and Chapter 1.1 of the *Terrestrial Code*. Nevertheless, the Commission requested that the comment be referred to the Biological Standards Commission for its consideration in revising the corresponding chapter in the *Terrestrial Manual*.

Furthermore, the Code Commission informed Members that criterion 4) a) of Article 1.2.2 should be considered met if there is clear scientific evidence (e.g. peer-reviewed publications, official reports, grey literature) that the pathogenic agent is zoonotic, and the disease causes severe consequences in humans. The public health impact of the disease should be taken into consideration at the population level, and not only at the individual level (e.g. according to WHO-DALYs). One single occurrence of disease in humans is not sufficient to consider the criterion as met.

The Code Commission did not agree with a comment to 'develop provisions for safe trade of live birds in terms of LPAI', as the current text already takes into account the LPAI risk posed by live birds: trade provisions for live birds and hatching eggs include requirements for parent flocks regarding avian influenza in general, thus including LPAI.

In response to a comment saying that the OIE should keep collecting and analysing information on the occurrence of LPAI to allow for better preparation for future zoonotic events, the Code Commission noted that the OIE/FAO Global network of expertise on animal influenza (OFFLU) is exchanging scientific data and biological materials (including AI virus strains) within this network for analyses and continues to share this information with the wider scientific community.

Article 10.4.1.

In point 3, in the second sentence, the Code Commission did not agree with a comment to add 'and transmission' after 'virulence' as it considered that this was clear as currently presented.

In point 3, in the third sentence, the Code Commission did not agree with a comment to replace 'domestic and captive' with 'domestic or captive' as this accurately reflects the disease name listed in the revised Article 1.3.6.

In point 4, in the first sentence, the Code Commission agreed with a comment to replace 'infection of poultry or captive wild birds' with 'infection of domestic or captive wild birds' noting that this provision applies to all domestic birds including poultry. In the second sentence, the Code Commission did not agree with a comment to add 'or on the trade of birds other than poultry' after 'poultry commodities' as while HPAI is defined as the infection of poultry for the purposes of this chapter, including disease status, there could be specific situations where importing countries could justify restricting the trade of live birds other than poultry, in response to notifications of infection with HPAI viruses described in the previous sentence.

In the same point, in the same sentence, the Code Commission noted a comment requesting clarification as to what is meant by 'or to other information on the presence of any influenza A virus in birds' and explained that this corresponds to point 1 of Article 1.1.6 of the *Terrestrial Code*. Nevertheless, it proposed to add 'non-notifiable' before 'influenza' for clarity. In the same point, the Commission did not agree with a comment to add 'other than poultry, including wild birds' at the end of the sentence, explaining that birds here means all birds, including both poultry and other birds that are not poultry.

The Code Commission did not agree with a suggestion to reinstate the existing point 5 of Article 10.4.1 as it considered this to be clear as currently presented.

Article 10.4.1bis

The Code Commission did not agree with a comment to include a recommendation, in this article, on the need to avoid contact with any source of HPAI virus on the basis that such recommendation is included in some of the articles that address the trade of commodities. The Commission stressed that the commodities listed in this article should be considered safe per se, noting that the risk of cross-contamination after the production not only concerns safe commodities but also other commodities. The Commission noted that as stated in the general provisions of Article 2.2.1 (point 3 in the fourth paragraph) 'it is expected that any other steps in the treatment, processing and subsequent handling of the animal product do not jeopardise its safety'.

In point 3, the Code Commission did not agree with a comment to add 'that are not intended for feeding poultry' at the end as well as to add a new article on trade recommendations for poultry products for poultry feed, claiming that treatments of poultry feed may not always be effective in inactivating the pathogenic agent. The Commission considered that it is implicit that necessary treatments have been appropriately applied as per industry standards in each country, and added that re-contamination of *Salmonella*, which was given as an example of insufficient treatment in the comment, is not relevant here.

Article 10.4.2

In the fourth indent, the Code Commission partially agreed to a proposal to improve clarity regarding the awareness programme, and proposed amendments accordingly.

Article 10.4.2ter

In the first paragraph, the Code Commission did not agree with a comment to replace the paragraph with a completely new text that includes a reference to Article 4.4.7 as it noted that this paragraph is used consistently in other disease-specific chapters in the *Terrestrial Code*.

In the third paragraph, the Code Commission noted a comment requesting to delete the second sentence for consistency with the revised Chapter 15.2, Infection with classical swine fever virus, but agreed not to delete it as it considered it useful and stated that it would instead review the corresponding text in Chapter 15.2 at its February 2021 meeting.

In response to a comment requesting to include provisions for the occurrence of non-epidemiologically-related cases due to possible repeated point-source introductions from wildlife, the Code Commission advised Members to refer to its response to a similar comment made for point 7 of Article 4.4.7 (see item 6.3 of this report).

Article 10.4.2quater

The Code Commission did not agree with a comment to replace '28 days (i.e. two flock-level incubation periods)' with 'three months' reminding Members that the 28-day period is the minimum period and Members could use a longer period, if needed. It also encouraged Members to refer to the relevant part of the previous *ad hoc* Group reports on this point.

Articles 10.4.11 and 10.4.13

The Code Commission did not agree with a comment to include a new point for precautions to avoid contact with any source of HPAI viruses in these two articles. It reiterated that it is implicit that measures to avoid contamination are in place and highlighted that these provisions are for the importation from a country, zone or compartment free from HPAI.

Article 10.4.20

In point 1, the Code Commission noted a comment requesting consistency between the *Terrestrial Code* and the *Terrestrial Manual* on the potential mutation, and proposed amendments to the text accordingly.

In point 3, the Code Commission agreed with a comment to replace 'domestic and captive' with 'domestic or captive' because, unlike its response to the comment made for point 3 of Article 10.4.1 (see above), this was not a citation of the disease name listed in the revised Article 1.3.6 and the use of 'or' is correct here in terms of grammar.

Article 10.4.21

In point 2(b), the Code Commission did not agree with a comment to replace 'clinical inspection, or serological and virological testing' with 'clinical inspection, and serological and virological testing' as it is noted that these options should be implemented 'as relevant'.

Article 10.4.22

In point 1, in the sixth paragraph, the Code Commission did not agree with a comment to delete 'or indirect' as it considered indirect contacts can be and have been a cause of the spread of infection. Moreover, the Commission stressed that this article is about surveillance, for which all possible pathways should be considered.

Article 10.4.22ter

The Code Commission did not agree with a comment suggesting to add a sentence 'Such monitoring system may be applied for enabling early detection of the occurrence of LPAI naturally transmitted to humans associated with severe consequences in domestic and captive wild birds'. It considered that the suggested text is not relevant in this context, as early detection of zoonotic AI in humans would be achieved by the public health sector. The Commission, however, noted that Members could make the effective use of information obtained from the monitoring system in collaboration with the public health sector.

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

'Infection of domestic and captive wild birds with low pathogenicity avian influenza viruses having proven natural transmission to humans associated with severe consequences'

The Code Commission noted a comment requesting to clarify what category of birds are included under 'domestic birds' and explained that domestic birds can be either poultry or other birds that are not poultry, but they are not wild or feral birds.

Glossary definition for 'poultry' (in relation to item 6.2. Glossary Part A)

The Code Commission did not agree with a comment stating that the current definition for 'poultry' is concise and clear, and thus the proposed amendments are not necessary. The Commission encouraged the Member to refer to the previous discussions on the amended definition, including the issue around 'backyard poultry' that are available in previous *ad hoc* Group reports and the Commission's reports. It stressed that different types of birds and a variety of purposes are covered in the proposed revised definition because of their respective epidemiological significance.

The Code Commission noted a comment querying whether the text regarding the definition for 'poultry' in Chapter 10.9, Infection with Newcastle disease virus, would be removed once the revised definition was adopted together with Chapter 10.4. The Commission stated that, in line with current practice, if the revised definition was adopted in the Glossary, any other definitions for poultry described in other chapters would be deleted.

The Code Commission did not agree with a comment to add 'including' or reinstate 'as well as' before 'fighting cocks' as it considered it unnecessary and the sentence grammatically correct and clear as written.

The Code Commission did not agree with a comment suggesting the addition of a separate definition for 'birds' as it considered it unnecessary given that the term 'birds' is used in line with the standard dictionary meaning, while a Glossary definition for 'poultry' is required as it is specific to the *Terrestrial Code*.

The Code Commission did not agree with a comment to delete 'any' before 'commercial animal products' as it considered that the deletion of 'any' did not address the concern raised by the Member that 'commercial animal products' could be interpreted in a variety of ways.

The Code Commission did not agree with a comment to delete 'or indirect' and reiterated that the infection can also be spread through indirect contacts.

In addition, the Code Commission did not agree with a comment requesting to delete 'provided that they have no direct or indirect contact with poultry or poultry facilities', emphasising that direct or indirect contact had been causes for the spread of the infection, and if such contacts were confirmed, the birds should be considered poultry and any HPAI event in those birds would indeed affect the country or zone status.

The revised Chapter 10.4, Infection with avian influenza viruses, is presented as **Annex 12** for Member comments and is proposed for adoption at the 88th General Session in May 2021. As this text has already undergone extensive consultation, Members are requested to only submit comments on the new amendments proposed in this version shown as highlighted text.

EU comment

The EU thanks the OIE for taking into consideration our previous comments. We support the proposed changes to this chapter.

6.8. Infection with avian mycoplasmosis (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 with proposed amendments to Chapter 3.3.5, Avian mycoplasmosis (*Mycoplasma gallisepticum*, *M. synoviae*), of the *Terrestrial Manual*.

The Commission thanked the OIE Reference Laboratory experts who provided advice on Member comments received.

Discussion

The Code Commission proposed to amend the title of this chapter to 'Infection with *Mycoplasma gallisepticum* (avian mycoplasmosis)' for consistency with the naming approach being used in disease-specific chapters, i.e. infection with pathogenic agent X, while keeping the former name in parenthesis.

Article 10.5.2

In points 3(a) and 3(b), the Code Commission agreed with the advice of OIE Reference Laboratory experts to delete 'with negative results on at least the last two tests' noting that it is not possible to reliably eliminate *Mycoplasma gallisepticum* from an infected flock. When testing is performed at flock level at the prescribed age intervals, all results should be negative in order to maintain the status as a flock free from avian mycoplasmosis.

Article 10.5.3

In point 3, a comment was received to replace 'agent identification test' with 'serological test'. The Code Commission noted the inputs of the OIE Reference Laboratory experts that a serological test alone is not enough to confirm that the birds are negative for avian mycoplasmosis and an agent identification test is necessary at the end of the quarantine period. The Commission concurred with the experts and proposed amendments to indicate that a serological test was required at the beginning of the quarantine period to detect any previous exposure, and an agent identification test at the end of the quarantine period to take into account the possibility that birds might have been treated with antibiotics to mask infection.

Revised Chapter 10.5 is presented as **Annex 13** for Member comments and is proposed for adoption at the 88th General Session in May 2021.

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. One comment is inserted in the text of Annex 13.

6.9. Infection with equine influenza (Article 12.6.6)

Comments were received from Mexico, Switzerland, the United States of America and the EU.

Background

At its February 2019 meeting, the Code Commission had proposed amendments to Article 12.6.6 based on the results of work coordinated by an OIE Reference Laboratory for equine influenza. The revised article has been circulated three times for Member comments, most recently in the report of the Code Commission February 2020 meeting.

Discussion

In point 2, the Code Commission proposed to delete 'came from a country, zone or compartment not known to be free from EI' as this was considered redundant.

In point 3, the Code Commission agreed with a comment that highlighted that international surveillance programmes should monitor antigenic drift among equine influenza viruses, as referenced in Chapter 3.5.7 of the *Terrestrial Manual*, and noted that each year the Expert Surveillance Panel (ESP) for Equine Influenza makes recommendations for suitable vaccine strains. The Commission reminded Members that the *Terrestrial Manual* should be referred to for standards for vaccines.

In the last sentence of the last paragraph, the Code Commission agreed with a comment to include 'prior to' before 'shipment' to clarify that the sample should be collected within the four days prior to shipment and not after shipment.

Revised Article 12.6.6 is presented as **Annex 14** for Member comments and is proposed for adoption at the 88th General Session in May 2021.

EU comment

The EU supports the proposed changes to this chapter.

7. Texts circulated for comments

The Code Commission discussed the following new and revised texts, including the consideration of comments received for the texts previously circulated for Members comments. Its considerations and responses are presented below. Items discussed under this section are presented for Member comments.

7.1. Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'

Background

In September 2018, the Code Commission agreed to revise the Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' in the *Terrestrial Code* following Member requests and the feedback from the *ad hoc* Group that revised the PVS Tool in 2018. The Commission proposed amendments to these definitions and the revised definitions were circulated for Member comments in the report of its September 2018 meeting. At its February 2019 meeting, the Commission requested that the *ad hoc* Group on Veterinary Services review these comments and propose amendments as appropriate.

The *ad hoc* Group proposed new amendments and those amended definitions were further revised by the Code Commission, the Scientific Commission and the Biological Standards Commission in September 2019, as well as by an internal OIE Headquarters Group that considered possible impacts on different OIE activities such as the OIE PVS Pathway. The Aquatic Animals Commission also discussed the proposed draft definitions at its February 2020 meeting, to discuss how the Aquatic Animals Commission could amend the corresponding definitions in the *Aquatic Code* and to identify any potential conflicts these amendments may generate for the *Aquatic Code*.

Given the importance of aligning these definitions, as appropriate, in the *Aquatic* and *Terrestrial Codes* to avoid confusion by Members when implementing these *Codes*, the Presidents of the Code Commission and the Aquatic Animals Commission met in July 2020 to discuss these proposed revisions and potential issues for alignment that had been identified. The Presidents agreed on revised proposals that were aligned in both *Codes*, and agreed that these should be presented for the consideration of both Commissions at the September 2020 meetings. The Presidents noted that the definitions should be concise and clearly describe the link between one government authority and the OIE, but they should also provide flexibility to reflect the different administrative arrangements within Members.

The Presidents also agreed that given the importance of these definitions in both *Codes*, the amended definitions should be presented in the September 2020 reports of the Code Commission and the Aquatic Animals Commission respectively so that Members can consider all proposed amendments when preparing comments.

Discussion

The Code Commission had internal exchanges with the *ad hoc* Group and considered the draft amendments proposed by the *ad hoc* Group together with the suggestions further developed by the two Presidents. The text below describes the Code Commission's consideration of the amendments proposed by the *ad hoc* Group including some Member comments. The Commission noted that the *ad*

hoc Group, given the common nature of the comments received, did not provide individual responses, but provided detailed rationale supporting the modifications being proposed.

'Competent Authority'

The Code Commission agreed with the *ad hoc* Group that this term is widely understood, and commonly defined and used in other international standards, as well as in national and regional regulations. However, it agreed that it was useful to include a specific OIE definition in the context of the *Terrestrial Code.*

The Code Commission recognised that in many countries, more than one governmental authority is responsible for implementing standards of the *Terrestrial Code*, either because they do not necessarily cover all standards or they do not do it in the whole country, and that this should be reflected in the definition. The Commission agreed that the definition should be simple and that detailed recommendations should be provided in the relevant articles of the *Terrestrial Code*, for example details relevant to veterinary legislation are provided in Article 3.4.5, Competent Authorities, of Chapter 3.4, Veterinary Legislation.

'Veterinary Authority'

The Code Commission highlighted the importance of this term in the context of the *Terrestrial Code*, as it was vital to clarify the responsibility of a Member to the OIE and other Members regarding the development and application of OIE international standards. The Commission explained that given the possible existence of one or more Competent Authorities in a country, a single Veterinary Authority is needed to coordinate and ensure standards are implemented in the whole country, as well as to represent the Member internationally. The Commission agreed with the *ad hoc* Group that this was important for compliance with current *Terrestrial Code* provisions such as disease notification obligations, and when submitting comments on proposed amendments to *Terrestrial Code* or demonstrating compliance with international trade.

Although the Code Commission recognised the vital role of OIE Delegate to ensure this function, it agreed that it was not pertinent to include a 'single person' in a definition as his/her nomination could depend on many factors.

'Veterinary Services'

The Code Commission agreed that this term does not refer to a defined governmental structure, but rather to a combination of individuals and organisations; too many to warrant being individually listed in the definition. The Commission agreed with the *ad hoc* Group that the purpose of this definition in the *Terrestrial Code* was to address a broad range of actors that are responsible at some stage and level for the implementation of OIE standards and are not necessarily part of the governmental authorities, as is the case for many standards that involve complex chains of responsibilities to be appropriately implemented.

The Code Commission agreed to include the word 'individuals' to ensure that private veterinarians, veterinary paraprofessionals and others, could be covered under the definition even when not belonging to a given organisation.

The Code Commission concurred with the *ad hoc* Group that the definition should capture both delegated official activities and broader regulated activities, such as disease notification and surveillance, and considered that with the clearer definition being proposed for Competent Authority, the current reference to the Veterinary Authority within the definition was no longer appropriate. The Commission noted that the chain of command and reporting would be determined by each Member's legislation.

The Code Commission noted that the Aquatic Animals Commission was also circulating revised amendments to these terms, for use in the *Aquatic Code*, and encouraged Members to review both Commission reports to ensure alignment of comments, as appropriate.

The revised Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' are presented as **Annex 15** for Member comments.

EU comment

The EU in general supports the proposed changes to the Glossary. One comment is inserted in the text of Annex 15.

7.2. Infection with rabies virus (Chapter 8.14)

Background

The last revised version of Chapter 8.14, Infection with rabies virus was adopted in 2019. At the time of adoption, the President of the Code Commission noted that there had not been sufficient time to address pending work of the chapter in view of the urgency and importance of the Zero by 30 initiative (the global strategic plan to end human deaths from dog-mediated rabies by 2030).

These pending issues concerned the divergent views expressed by Members, the Code Commission, the Scientific Commission, and the *ad hoc* Group on Rabies regarding the provisions for vaccination, testing and shipment of animals (current Article 8.14.7), and the provisions on the risk mitigation measures for the importation of mammals outside of the Orders *Carnivora* and *Chiroptera* (current Articles 8.14.8 and 8.14.10). The Code Commission had requested the OIE Secretariat to seek further expert advice before considering revisions of these articles.

In addition, the Code Commission and the Scientific Commission had agreed to seek advice from the Working Group on Wildlife on the relevance of including specific provisions on the control of rabies in wildlife, including oral vaccination.

In February 2020, the Scientific Commission reviewed the report of the *ad hoc* Group on Rabies that met in October 2019, which, among other tasks, reviewed the scientific evidence regarding the safety of importation of dogs from one month after the date of rabies vaccination, and proposed draft text to amend the current provisions in Chapter 8.14. The Scientific Commission reviewed and endorsed a concept paper (Annex 15 of the Scientific Commission's February 2020 meeting report) that provided scientific evidence on the safety of importation of dogs from infected countries or zones from one month after the date of rabies vaccination.

At the request of the Code Commission in its February 2020 meeting, the *ad hoc* Group on the Revision of Chapter 7.7, Stray dog population control, which met from April to July 2020, proposed a new draft article on how to implement rabies vaccination programmes in Chapter 8.14.

Discussion

The Code Commission considered the position paper prepared by the *ad hoc* Group on Rabies and the views of the Scientific Commission regarding the safety of importation of dogs from infected countries or zones from one month after the date of rabies vaccination.

The Code Commission noted that the scientific evidence presented referred only to dogs and therefore agreed to add a new Article 8.14.6bis on recommendations for the importation of dogs from countries or zones infected with rabies virus, based on that evidence. The Commission consequently amended the title of Article 8.4.7 to remove dogs from the scope of the article.

The Code Commission also considered the new text providing guidance on how to implement rabies vaccination programmes proposed by the *ad hoc* Group on the Revision of Chapter 7.7. The Commission agreed with the proposal to include such recommendations in Chapter 8.14 but requested the OIE Secretariat to amend the text in compliance with the formatting and style of the *Terrestrial Code* and to seek the opinion of the Scientific Commission before proposing these amendments to Members.

The Code Commission also requested the OIE Secretariat to consult subject matter experts and the OIE Wildlife Working Group, as relevant, to progress the other pending issues to be taken into consideration for this revision.

The new Article 8.14.6bis and the revised Article 8.4.17, are presented as **Annex 16** for Member comments.

EU comment

The EU cannot support the proposed changes to this chapter. The rationale is provided in Annex 16.

7.3. Stray dog population control (Chapter 7.7)

Background

In September 2018, the Code Commission agreed to revise the Chapter 7.7, Stray dog population control, to ensure it was aligned with the OIE Global Strategy to end human death due to dog-mediated rabies by 2030. An *ad hoc* Group on the Revision of Chapter 7.7, Stray dog population control, was first convened in November 2019 to review current recommendations that address the monitoring and evaluation of stray dog control schemes and responsible dog ownership. It discussed additional recommendations that could support the Global Strategy, and developed a draft chapter structure. At its February 2020 meeting, the Commission reviewed the report of the *ad hoc* Group and requested the Group be reconvened to continue its work taking into consideration the Commission's feedback.

The *ad hoc* Group on the revision of Chapter 7.7, Stray dog population control, met via video conference between April and July 2020.

Discussion

The Code Commission considered the *ad hoc* Group's report and thanked its members for their hard work and acknowledged the challenges that working virtually posed to progress work on a heavily revised chapter.

During its meetings, the *ad hoc* Group considered the Commission's feedback regarding the structure of the chapter, the rationale for changing the title of the chapter, as well as the focus on animal welfare (i.e. moving animal health related topics to the Chapter 8.14, Infection with rabies virus), and the replacement of the term 'stray dogs' by 'free roaming dogs'. For more information on these clarifications, the Commission encouraged Members to refer to the *ad hoc* Group report presented as **Annex 26**.

The Code Commission agreed that the draft revised Chapter 7.7, Stray dog population control, should be renamed 'Dog population management' and agreed to circulate the new draft chapter for Member comments.

The revised Chapter 7.7, Stray Dog population control, is presented as **Annex 17** for Member comments.

EU comment

The EU welcomes and in general supports the revision of Chapter 7.7. Comments are inserted in the text of Annex 17.

The report of the ad hoc Group on the Revision of Chapter 7.7 Stray dog population control is presented as **Annex 26**.

7.4. Infection with foot and mouth disease virus (Chapter 8.8)

Chapter 8.8, Infection with foot and mouth disease virus

Comments were received from Australia, Canada, China (People's Republic of), Japan, New Caledonia, New Zealand, Singapore, South Africa, Switzerland, Chinese Taipei, Thailand, the United States of America, the OIE Americas Region, the EU, AU-IBAR and the Comité Veterinario Permanente del Cono Sur (CVP).

Background

Chapter 8.8, Infection with foot and mouth disease virus, was last circulated for Member comments in February 2017. Comments were received from Members but the Code Commission deferred its discussion on the chapter pending the proposed changes to Chapter 4.4, Zoning and compartmentalisation. Since that time, amendments have been proposed by the *ad hoc* Group on alternatives for surveillance for demonstration of freedom from foot and mouth disease (FMD) and the Scientific Commission in response to selected Member comments on shortening the recovering status period (from six to three months) when emergency vaccination without stamping out is applied. The *ad hoc* Group report was attached to the report of the Scientific Commission of September 2018 meeting.

Discussion

The Code Commission highlighted that in addition to the work described above (under Background), there is also other ongoing work that will need to be addressed in Chapter 8.8, including harmonisation of text relating to status recognition for alignment with Chapter 14.7, Infection with peste des petits ruminants virus, and 15.2, Infection with classical swine fever virus, and the development of provisions for game meat and small ruminants, which are being developed by the *ad hoc* Group on FMD in consultation with the Scientific Commission. These proposed amendments will be presented in a future circulation of Chapter 8.8.

General comments

The Code Commission noted a comment from a Member that Chapter 8.8 has been progressively revised to promote vaccination instead of eradicating FMDV by stamping-out. In response to the Member's concern that efforts to achieve global freedom from FMD may be undermined by provisions on the international trade of commodities from countries infected with FMDV or free from FMD where vaccination is practised, the Commission noted that a stepwise Progressive Control Pathway (http://www.fao.org/eufmd/global-situation/pcp-fmd/en/) had been developed for countries to move towards obtaining official freedom from FMD and expressed that in the future there could be a possibility for the chapter to refer to an eventual call for global eradication.

The Code Commission acknowledged comments requesting clarification of the term 'bovine' and agreed that this should be defined for the purposes of Chapter 8.8. Nonetheless, as the terms 'bovids' and 'bovines' are used with specific definitions for different disease-specific chapters and that the term 'bovine' is used in several articles of Chapter 8.8, the Code Commission requested the OIE Secretariat to propose a definition for the purposes of this chapter, in consultation with relevant experts as necessary, for discussion at its next meeting in February 2021.

The Code Commission noted comments that requested clarification on the use of the terms 'case', 'transmission', 'case with clinical signs' in the chapter, and proposed that these definitions be reviewed together with the Scientific Commission at their next joint meeting.

Article 8.8.1

The Code Commission agreed with a comment to include the heading 'General provisions'.

In point 6, the Code Commission did not agree with a comment to insert text on the duration of the carrier state of all susceptible animals as it considered this too detailed for a chapter of the *Terrestrial Code*. The Code Commission did not agree with a comment to remove 'limited' before 'period of time', noting the opinion of the Scientific Commission that the carrier status does not last longer than 28 days in the majority of cases and is hence 'limited'.

In the first sentence of the same point, the Code Commission agreed to add 'after infection' after '28 days' for clarity.

In the last sentence of the same point, the Code Commission agreed with a comment to add 'from this species' after 'transmission' for clarity. However, it did not agree with a comment that the risk of transmission of FMDV from African buffalos to cattle is significant and therefore did not accept the comment to amend the last sentence of point 6. The Commission recalled the opinion of the Scientific Commission (in September 2017 report) that FMDV transmission from African buffalo to domestic ruminants was rare.

In point 7, a comment was received that the terms 'case', 'transmission', 'case with clinical signs' were confusing, and not used consistently throughout the chapter. The Code Commission acknowledged this comment and proposed to delete point 7 as it considered that this point did not provide any additional value. The case definition for FMDV is already covered in point 3 of this article and the corresponding surveillance recommendations are described in Articles 8.8.40 to 8.8.42. Notwithstanding, the Commission acknowledged that these terms need to be reviewed (see 'General Comments' above).

Article 8.8.1bis (new article)

The Code Commission considered Member proposals on commodities to be included in the list of safe commodities for FMD and drafted a new Article 8.8.1bis.

1. UHT milk and derivatives thereof

   Members had proposed to add 'UHT milk and derivatives' as a safe commodity based on existing provisions in Article 8.8.25. The Code Commission considered that 'UHT' is an industrial standardised heat treatment process which is sufficient to inactivate FMDV and therefore meets the general provisions of Chapter 2.2, Criteria applied by the OIE for assessing the safety of commodities. The Code Commission thus proposed to include 'UHT milk and derivatives thereof' to the list of safe commodities.

   The Code Commission agreed that Articles 8.8.35 and 8.8.36 had to be amended to reflect the addition of UHT milk as a safe commodity.

2. Meat in hermetically sealed containers with a F_0 value of 3 or above

   Based on the current Article 8.8.31 which describes heat treated canning as a procedure that has been demonstrated to inactivate FMDV, the Code Commission accepted the proposal to add canned meat products as a safe commodity, but amended the description to 'meat in hermetically sealed container with a F_0 value of 3 or above' for consistency with other disease-specific chapters of the *Terrestrial Code*, which use this standard terminology.

3. Meat and bone meal, and blood meal

   The proposal from Members stated that meat and bone meal, and blood meal are obtained through a sterilisation process of the by-products of slaughter with a temperature sustained over a period of time (using dry or wet methods), and that such a process reaches a temperature for a sufficient period of time for the inactivation of FMDV as detailed in Article 8.8.26. Therefore, the Code Commission agreed with the proposal to include 'meat and bone meal, and blood meal' as a safe commodity, and consequently deleted Article 8.8.26.

4. Gelatine

   The proposal from Members provided a definition of gelatine and described processes used based on the Gelatine Manufacturers of Europe (GME). The Code Commission agreed that the standard manufacturing protocols involved in the production of gelatine would inactivate the FMDV, and thus proposed to include 'gelatine'.

5. *In vivo* derived bovine embryos collected, processed and stored in accordance with Chapter 4.8

The Code Commission agreed that the current Article 8.8.17 recognised *in vivo* derived embryos as a safe commodity and thus added '*In vivo* derived bovine embryos collected, processed and stored in accordance with Chapter 4.8'. The Commission thus proposed to delete Article 8.8.17.

The Code Commission did not agree with the proposal of Members to include 'fresh boneless ruminant meat' as a safe commodity as additional risk mitigation measures, as described in Article 8.8.22 are required. However, the Code Commission requested the OIE Secretariat to seek advice on the existence of globally standardised industrial processes, not specifically directed at addressing the risk of FMD, which could ensure the absence or inactivation of FMDV in boneless bovine meat from a potentially infected animal. **Article 8.8.2**

In point 4(d), the Code Commission did not agree to include 'and risk material' after 'other products'. However, it added the words 'and fomites' for consistency with other disease-specific chapters.

In the third sentence of point 4(e), the Code Commission agreed with a comment to add 'vaccinated' before 'animals' to reinforce that paragraph 4(e) is referring to vaccinated animals. It also agreed with a comment to add 'direct' before 'slaughter' for consistency with the wording used in Articles 8.8.8, 8.8.9 and 8.8.9bis.

In the same point, the Code Commission did not agree with a comment to replace 'favourable' with 'negative', noting that 'favourable results' is the standard term used in the *Terrestrial Code*.

A comment was received to delete the seventh paragraph, with the rationale that an incursion with African buffaloes that are potentially infected with FMDV should not allow a country to retain its FMD free status. The Code Commission recalled that this was discussed by the *ad hoc* Group on FMD that met in June 2016. It also noted the Scientific Commission's opinion that the presence of African buffaloes should not lead to the suspension of an officially recognised FMD free status except in the case of FMDV transmission to the domestic cattle. The Code Commission considered the proposal of the Scientific Commission to apply a containment zone to manage the threat of African buffaloes. However, in view of the recent updates to Chapter 4.4, Zoning and compartmentalisation, and proposed amendments to Article 4.4.6 (see item 6.3 of this report), the Code Commission considered that a protection zone would be more appropriate to accommodate the risk posed by African buffaloes. Therefore, the Commission deleted this paragraph, but proposed to include the sentence 'In the case of an incursion of stray African buffaloes, a protection zone according to Article 4.4.6 should be established to manage the threat and maintain the free status of the rest of the country' to the end of this article.

In the second indent of the eighth paragraph, the Code Commission, in agreement with the Scientific Commission, did not agree with a comment to delete the word 'domestic'. In some zoological collections, domestic animals are part of the collection and they should be effectively separated. Animals in the zoological collection should also be effectively separated from other domestic animals outside of the zoological collection.

In the same indent, the Code Commission did not agree with a comment to add 'and up to six years (for African buffalo)' after '12 months', noting the explanation from the Scientific Commission that surveillance for 12 months should be sufficient for detecting potential carriers.

In the tenth paragraph, the Code Commission did not agree with a comment to include mention of the necessity to distinguish the status of the protection zone from the rest of the country or zone as it considered this to be implicit in the proposal for the proposed revised Article 4.4.6 (see item 6.3 of this report). The Code Commission proposed further changes to this paragraph to align with the proposed changes to Article 4.4.6 (see item 6.3 of this report).

Article 8.8.3

In point 2, the Code Commission noted a comment seeking clarification on the requirement for no case in the last two years and no transmission during the past 12 months. The Code Commission noted the explanation of the Scientific Commission that in this point, 'no case' referred to the absence of 'clinical' cases of FMD during the past two years and proposed to add 'with clinical signs' after 'case' for clarity. However, the Code Commission proposed to review the use of these terms with the

Scientific Commission, as they might be confusing. The Code Commission also deleted the word 'evidence' as it considered this to be redundant since this sentence is about declaring the absence of cases or transmission based on documented evidence.

In point 3(a), the Code Commission accepted a comment to move 'to detect clinical signs of FMD has been implemented' after 'surveillance' for clarity. In the same point, the Commission proposed to delete 'no evidence of' as the preceding sentence in point 3 already refers to supplying documented evidence.

In reference to the recommendations of the Scientific Commission from September 2017, the Code Commission amended the time requirements in point 3. The Code Commission also modified 'two years' to '12 months' in point 2(b) in line with these changes.

In point 3(a)(i), a question was received as to what sort of animals were considered as unvaccinated given that vaccination is practised. The Code Commission noted the response by the Scientific Commission that based on the epidemiology of FMD in the country, it might be decided to vaccinate only a defined subpopulation of animals, such as one species. Other subpopulations such as sentinel animals, newborns or other species might also not be vaccinated.

Regarding a comment on moving the seventh paragraph to Article 8.8.2, the Code Commission agreed with the Scientific Commission to leave this paragraph in Article 8.8.3 considering it refers to a country or zone where vaccination is practised.

In the first sentence of the same paragraph, the Code Commission agreed with a comment to add 'and is recognised by the OIE as such' after 'practised', and to add 'an application and' before 'a plan' for clarity. The Code Commission also agreed with the changes proposed by the Scientific Commission to the second sentence.

In the second sentence of the same paragraph, comments were received as to whether a country must wait for OIE's approval before embarking on emergency vaccination. The Code Commission noted the opinion of the Scientific Commission provided its September 2017 report, and recalled that this paragraph is applicable in the case a Member wishes to change its status from free without vaccination to free with vaccination, not as a response to an emergency but to a change in the control strategy. The commission explained that, emergency vaccination could be implemented in response to either an outbreak, in which case provisions in Article 8.8.6 on containment zone would apply; or in response to an increased risk of FMD, for which they may implement a protection zone in accordance with Article 4.4.6.

In the eighth paragraph, the Code Commission proposed further changes to this paragraph to align with the proposed changes to Article 4.4.6 (see item 6.3 of this report). With this change, some Member comments to the original text were no longer relevant. The Commission did not agree with a comment to replace 'remains unchanged' with 'is reinstated'.

Article 8.8.4

The Code Commission agreed with a comment to include compartment free from FMD in Articles 8.8.13, 8.8.14, 8.8.15, 8.8.18, 8.8.19 and made the corresponding amendments to these articles.

In response to a question on whether the use of germplasm from vaccinated animals in compartments or zones free from FMD with vaccination would result in the loss of status of FMD free without vaccination, the Code Commission, in agreement with the Scientific Commission, noted that this will not be the case if this was done in accordance with the relevant articles in this chapter (refer to point 2(e) of this article).

In the first paragraph, the Code Commission did not agree with a comment to replace 'biosecurity plan' with 'biosecurity management system' as 'biosecurity plan' is a defined term used in the *Terrestrial Code*, including in the Chapter 4.5, Application of compartmentalisation.

In point 2(b), the Code Commission proposed to delete 'evidence of' before 'infection' and replaced the word 'found' by 'detected'.

In the third paragraph, a comment was received that the level of surveillance required is beyond the capacity of most compartments where wildlife is present in the vicinity, as it would be difficult to detect sub-clinical infection in wildlife since their movement cannot be effectively controlled. The Code Commission noted the view of the Scientific Commission that one of the critical elements of risk mitigation is to ensure that FMDV incursion does not occur, which implies that adapted biosecurity measures have to be maintained and adequate surveillance in place to detect if an incursion has occurred. The Code Commission proposed to add 'or transmission' after 'case' to address this point but recognised that the definitions of 'case' and 'transmission' need to be further clarified and that this work is planned for its next meeting, in collaboration with the Scientific Commission.

The Code Commission did not agree with a comment to add 'the approval should be suspended if FMD occurs within a 10-kilometre radius of the compartment at any time' to the end of the paragraph as this would contradict the objective of compartmentalisation, which is to allow the maintenance of a specific free health status for a subpopulation through the implementation of an adequate biosecurity plan, while infection is still occurring in the area. The approval of the compartment should be given when no case occurs, but subsequently, if the biosecurity plan is correctly applied, cases can occur outside the compartment without affecting the health status of the compartment.

Article 8.8.4bis

The Code Commission, in agreement with the Scientific Commission, did not agree with a comment to delete Article 8.8.4bis. The Code Commission noted the view of the Scientific Commission that stricter provisions for surveillance and biosecurity measures would be in place in compartments to ensure the early detection of infection and absence of undetected infection. The establishment of such compartments would support bilateral trade agreements and allow access to regional and international markets. The rationale is also included in the report of the June 2016 meeting of the *ad hoc* Group on FMD.

In the first sentence of the first paragraph, a comment was received to replace 'free country or zone where vaccination is practised' to 'free country or zone where vaccination is not practised' with the rationale that there is no purpose to establish a compartment free from FMD where vaccination is practised within a zone or country free from FMD where vaccination is practised. The Code Commission in agreement with the Scientific Commission, did not agree with this comment as establishing a compartment free from FMD with vaccination in a country or zone with the same status is a practice used by countries to ensure the continuity of trade from the compartment via bilateral trade agreements, in case of an outbreak in the country or zone, outside the compartment. Indeed, compartments should have additional biosecurity measures to ensure its safety and integrity and are established mainly for the purpose of bilateral trade.

In point 2(a), the Code Commission, in agreement with the Scientific Commission, did not agree with a comment to replace 12 months with 2 years, noting the clarification by the Scientific Commission that 12 months should be sufficient as additional biosecurity and risk mitigation measures are required.

In point 2(b), the Code Commission proposed to replace 'no evidence of infection with' with 'no transmission of'.

In point 2(d), the Code Commission did not agree with a comment to refer to the specific articles for the movement of animals, semen, embryos and animal products.

In the last paragraph, the Code Commission added 'or transmission' for consistency with Article 8.8.4. The Code Commission again did not agree with a comment to add 'the approval should be suspended if FMD occurs within a 10-kilometre radius of the compartment at any time' to the end of the paragraph for the reason given above.

Article 8.8.6

The Code Commission accepted proposed amendments to this article from the Scientific Commission and the OIE Secretariat to ensure consistency and minimise duplication with Article 4.4.7 but proposed further modifications to align with proposed changes to Article 4.4.7 (see item 6.3 of this report), as well as to harmonise with other disease-specific chapters, as relevant.

Article 8.8.7

In points 1(c) and 3(a), the Code Commission proposed to include the recommendations from the *ad hoc* Group August 2018 meeting report on Alternative surveillance and recovery periods. The Commission also considered that the work of the *ad hoc* Group addressed a comment that questioned the waiting period of three months.

Article 8.8.8

The Code Commission acknowledged a comment on the use of terminology 'case', 'infection' and 'with clinical signs' and agreed this would be addressed in future work as noted above.

Article 8.8.9bis

The Code Commission did not agree with comments to merge Articles 8.8.9bis and 8.8.11bis, explaining that these articles have different objectives. Article 8.8.9bis concerns the maintenance of status of a free zone where vaccination is not practised, even if animals from a zone where vaccination is practised are introduced for direct slaughter. Whereas, Article 8.8.11bis refers to the requirements for certification when importing animals for direct slaughter (from a country or zone where vaccination is practised). Furthermore, unlike in Article 8.8.9bis, the FMD status of the destination, i.e. importing country or zone, is irrelevant in Article 8.8.11bis. In the *Terrestrial Code*, articles on export certification provide risk mitigation measures that are not linked with the status of the importing country.

In point 4, the Code Commission agreed with a comment to insert 'the animals' before 'were not exposed' for clarity.

The Code Commission did not agree with a comment to add a new point 5 to include details regarding ante- and post-mortem inspections of the animals and the destruction or treatment of the head, including the pharynx, tongue and associated lymph nodes, noting that this aspect goes beyond the necessary requirements for allowing movement. Furthermore, these provisions are already addressed in Article 8.8.2.

Article 8.8.10

In point 2, the Code Commission agreed with a comment to move the reference to compartments earlier in the sentence. This was applied throughout the text, where relevant.

Article 8.8.11

In points 3 and 4, a comment requested including when the tests should be done in relation to shipment. The Code Commission agreed with the proposal of the Scientific Commission that 14 days is a reasonable time to obtain results after sampling prior to shipment and proposed to add 'on samples collected not earlier than 14 days before the shipment'.

Article 8.8.11bis

The Code Commission did not agree with a comment that Article 8.8.11bis is a subsection of Article 8.8.11 and to combine both articles as they addressed different commodities.

The Code Commission did not agree with a comment to add a new point 5 to include details regarding ante- and post-mortem inspections of the animals and the destruction or treatment of the head, including the pharynx, tongue and associated lymph nodes, for the reason given above under 'Article 8.8.9bis'.

Article 8.8.12

In point 2, the Code Commission did not agree with a comment to only retain this point if Article 8.8.31bis is expanded to include requirements aimed at avoiding cross-contamination of swill after treatment. The Commission explained that articles on inactivation are concerned with specifying the parameters for inactivation and not subsequent cross-contamination, which is also the case for all commodities, even when complying with specific risk mitigation measures, and need not be specified in the *Terrestrial Code* articles.

In the same point, the Code Commission did not agree with a comment to delete 'not complying with Article 8.8.31bis' and to have a blanket statement prohibiting the feeding of swill. The Commission explained that swill feeding in compliance with Article 8.8.31bis, and combined with other measures described in this article would provide the necessary safety.

Article 8.8.13 (proposed to be merged with Article 8.8.14)

The Code Commission agreed with a comment to merge Articles 8.8.13 and 8.8.14. In merging the two articles, the Code Commission considered that the risk of FMDV in fresh and frozen semen would be the same and there was therefore no justification for the additional requirement for donor animals of frozen semen to show no clinical signs of FMD for the 30 days following semen collection if this was not required of donor animals of fresh semen.

In the title of the article, the Code Commission deleted 'compartments free from FMD' and added 'or compartments' after 'zones' for improved readability. This change was also applied to other article titles, where relevant.

In point 1(c), the Code Commission proposed to delete 'where none of the animals had a history of infection with FMDV' as it considered this was more relevant to Chapters 4.6, General hygiene in semen collection and processing centres, and 4.7, Collection and processing of bovine, small ruminant and porcine semen.

Article 8.8.22

In point 2, regarding a query as to why bovines and water buffaloes are not subjected to any test prior to slaughter, unlike the requirement for pigs, the Code Commission noted the explanation from the Scientific Commission that the decrease in pH in the carcass of pigs is not sufficient to inactivate the virus, which was the reason why the new Article 8.8.22bis was introduced.

Article 8.8.22bis

In point 1, the Code Commission agreed with a comment to delete 'points 1 to 6 of' as this was considered redundant.

Article 8.8.24 and 8.8.25

With the proposed addition of Article 8.8.1bis, the Code Commission added '(other than those defined in Article 8.8.1bis)' after 'milk and milk products'.

Article 8.8.31bis

In response to comments questioning the scientific evidence that supported the inactivation procedures for FMDV in swill, the Code Commission reiterated that this article was introduced for consistency with other disease-specific chapters such as Chapter 15.1, Infection with African swine fever virus and based upon long-standing practices and field experience that showed the inactivation of virus in swill. The Commission highlighted that there is ongoing work on developing a definition for 'swill' in its work programme (see item 5.1.1 of this report).

Article 8.8.35

As a consequence of the addition of UHT milk to the list of safe commodities in Article 8.8.1bis the Code Commission proposed to delete point 1 of article 35 for consistency.

Article 8.8.36

Following the addition of UHT milk to the list of safe commodities in Article 8.8.1bis, the Code Commission acknowledged that if the commodity is considered safe, it is for all usages, including animal feeding, and consequently proposed to delete point 3 of article 36 for consistency.

Article 8.8.40

The Code Commission agreed with the proposal of the *ad hoc* Group on Alternative surveillance and recovery periods to add two new points 7 and 8.

Article 8.8.42

The Code Commission proposed to delete Figures 1 - 3 in line with its position to remove diagrams and illustrations from the *Terrestrial Code*. However, it requested the OIE Secretariat to see how these diagrams could be updated to reflect new developments in the chapter and whether they could be made available on the OIE website as guidance for Members.

Revised Chapter 8.8 is presented as **Annex 18** for Member comments.

EU comment

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

Comments are inserted in the text of Annex 18.

7.5. Rinderpest (Chapter 8.16)

Background

At its September 2018 meeting, the Code Commission agreed to undertake a thorough review of Chapter 8.16, Infection with rinderpest virus, in response to Member requests and to update the chapter to better clarify the definitions of 'case' and 'suspected case', the reporting obligations of countries when a suspected case is detected, and measures to be taken should there be a re-emergence.

In previous discussions, the Code Commission agreed with the Scientific Commission and OIE Headquarters that in this post-eradication era, the priority should be the maintenance of global freedom from rinderpest, and its prompt recovery should there be a re-emergence. To this end, the structure of the chapter and trade provisions should be compatible and aligned with this objective. Both Commissions thus agreed with the proposal to limit trade provisions from infected countries to safe commodities.

Discussion

The Code Commission considered the report of the *ad hoc* Group on Rinderpest that was convened in March 2020 to undertake this work and also wished to thank the *ad hoc* Group for its work.

The Code Commission considered the draft revised chapter prepared by the *ad hoc* Group on Rinderpest. The Commission agreed with the proposal to divide the chapter into two sections, one containing general provisions relevant in the era of global freedom, and another including provisions relevant in the event of re-emergence.

The Code Commission agreed with the proposal by the *ad hoc* Group to include a gradation in the level of suspicion for rinderpest, i.e. 'potential case', 'suspected case' and 'case', and actions to be taken in the event of suspicion or confirmation that will facilitate early detection and response to a re-emergence. The Commission highlighted that given the global freedom status of rinderpest, unlike

other OIE listed diseases, infections and infestations, a suspected case of rinderpest must be immediately notified to the OIE.

The Code Commission reminded Members that in previous discussions with the Scientific Commission and OIE Headquarters, it was agreed that in the event of the confirmation of rinderpest in a country, the entire country will be considered infected. The Code Commission also noted that this was consistent with the current Chapter 8.16. Therefore, for consistency the Commission amended the draft text to remove references to 'infected zone', as infection status should be defined only at the level of the country. Nonetheless, the Commission explained that in the event of confirmation of rinderpest, Members may apply zoning for the purposes of disease control, including the establishment of a containment zone.

The Code Commission noted that due to the extensive nature of the amendments made, the revised chapter is being presented as clean text only.

The revised Chapter 8.16 is presented as **Annex 19** (clean version) for Member comments.

EU comment

The EU in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 19.

The report of the *ad hoc* Group on Rinderpest is attached as **Annex 27** for Member information.

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

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

Background

In February 2018, the Code Commission and the Scientific Commission had agreed on an in-depth review of Chapter 11.4, Bovine spongiform encephalopathy (BSE). The OIE convened three *ad hoc* Groups between July 2018 and March 2019: i) BSE risk assessment, which met twice, ii) BSE surveillance, which met once, and iii) a joint BSE risk assessment and surveillance *ad hoc* Group, which met once. The Code Commission, at its September 2019 meeting, reviewed the four *ad hoc* Group reports and the opinion of the Scientific Commission regarding the revised draft chapter, and circulated the revised chapter for comments for the first time.

In February 2020, the Code Commission considered all comments and while it addressed some comments it also identified comments that needed further expert advice and requested that the joint *ad hoc* Group be reconvened to address these comments.

In June 2020, the joint *ad hoc* Group on BSE risk assessment and surveillance was convened to address the comments for Chapter 11.4 that had been referred from the Code Commission and to refine the draft revised Chapter 1.8, Application for official recognition by the OIE of free status for bovine spongiform encephalopathy, to ensure alignment with Chapter 11.4.

Discussion

The Code Commission commended the joint *ad hoc* Group on BSE risk assessment and surveillance on its comprehensive and quality work and thanked its members for their continued commitment to this priority topic.

The rationales for the amendments that the Code Commission had proposed in February 2020 as well as the amendments it proposed at this meeting in response to the text proposed by the *ad hoc* Group are presented below. The Commission highlighted that for amendments made by the *ad hoc* Group that the Commission agreed with, the rationale is provided in the *ad hoc* Group report (Annex 28).

The Commission also emphasised the importance of referring to the June 2020 *ad hoc* Group report and the previous four *ad hoc* Group reports for detailed explanations of much of this work.

Chapter 11.4, Bovine spongiform encephalopathy

Article 11.4.1

In point 1, the Code Commission discussed whether and how atypical BSE should be addressed in this chapter recalling the relevant discussions on this point in the past. Recognising the difficulties of strictly applying the criteria in Article 1.2.2 to atypical BSE and that there are still gaps in scientific knowledge regarding atypical BSE, the Commission agreed to keep atypical BSE as an OIE listed disease. Nevertheless, the Commission recognised that this was an interim solution and that this issue would need to be revisited in the future when any relevant evidence becomes available.

In point 2, the Code Commission noted comments that the use of 'a bovid' is not consistent with point 1 where BSE is described as a disease of cattle, and proposed an amendment for clarity, noting that cattle is defined in point 3 for the purposes of this chapter.

In point 4, the Code Commission noted reservations regarding the new definition for 'protein meal' in the chapter, and reminded Members that the rationale for this proposal was provided in the report of the *ad hoc* Group on BSE risk assessment and surveillance that met in March 2019. In addition, the Commission explained that once the revised chapter is adopted, it will review the use of terms 'meat-and-bone meal' and 'greaves' throughout the *Terrestrial Code* and consider where these terms should be replaced by 'protein meal'.

For the second last paragraph, the Code Commission did not agree with a comment to add 'other than ruminant feeds that may be contaminated with BSE agents' after 'commodities' as it did not consider that the proposal enhanced the existing text and also noted that there is no trade provision for 'contaminated feed' in this chapter.

Article 11.4.1bis

In point 1, the Code Commission did not agree with a comment to add 'derived from cattle' at the end of this point, as it considered that it was clear in the first paragraph that all the commodities listed under safe commodities are derived from cattle. Notwithstanding, the Commission added 'derived from cattle' in the first paragraph for clarity.

In point 2, in response to a comment querying whether references to both the *Terrestrial Code* and the International Embryo Technology Society (IETS) should be included, the Code Commission clarified that the reference to the relevant chapters of the *Terrestrial Code* is sufficient, noting that the relevant chapters such as Chapter 4.8, Collection and processing of *in vivo* derived embryos from livestock and equids, include references to the IETS.

In point 4, the Code Commission agreed with the *ad hoc* Group's rationale for the inclusion of gelatine and collagen as safe commodities. It encouraged Members to refer to the relevant part of the June 2020 *ad hoc* Group report.

For the deleted point 6, the Code Commission agreed with comments that tallow derivatives would be made from tallow that complied with the requirements in point 5, and therefore proposed to add 'and derivatives made from this tallow' at the end of point 5. It also stressed that tallow derivatives are used in many commercial products and have a greater importance in international trade, therefore including explicitly the derivatives of tallow in the text is appropriate, while this is usually not the case for safe commodities currently included in the *Terrestrial Code*, where it is implicit.

In point 7, the Code Commission agreed with the *ad hoc* Group to include 'foetal blood' as a safe commodity.

Article 11.4.2

After careful consideration of the latest *ad hoc* Group report and its proposed amendments, the Code Commission noted that the BSE risk described in the draft revised chapter was primarily referring to the risk of recycling BSE agents in a country, zone or compartment, not necessarily the risk of BSE posed by the entire cattle population of the country. While the Commission did not disagree with this new approach, it highlighted that this fundamental shift regarding the interpretation of BSE risk should be well communicated to Members due to its relevance regarding trade provisions of this chapter (see relevant sections below) and the consequent application for international veterinary certificates.

In point 1, in the first paragraph, the Code Commission did not agree with a comment to replace 'in accordance with' with 'as described in' as it did not consider that the proposal improved the existing text.

With respect to some comments suggesting improved definition of the steps of the risk assessment to prevent confusion with the terminology in Chapter 2.1, Import risk analysis, the Code Commission agreed with the proposed text by the *ad hoc* Group. It further noted that the flowchart of risk assessment steps (Figure 1 of the June 2020 *ad hoc* Group report) should be placed somewhere on the OIE website for Members' information once the revised chapter is adopted.

In response to a comment seeking to reinstate the two points on 'ongoing awareness programme' and 'compulsory notification and investigation', the Code Commission proposed to include in point 2 a reference to Article 11.4.18, which captures both aspects under point 1 as pillars to support the credibility of the surveillance programme.

Article 11.4.3

In the chapeau paragraph, the Code Commission did not agree with a comment to add 'the Member Country has demonstrated through documented evidence that' after 'if' noting that documented evidence in support of points 2 to 4 should be provided as part of the application for disease status recognition whereas point 1 highlights that the risk assessment should include documented evidence.

The Code Commission agreed with the ad hoc Group's proposed amendments to point 1. It also noted that the Group had proposed to change 'likelihood' to 'risk' in this article and agreed to the proposal. The Commission noted that the use of 'likelihood' or 'risk' had been reviewed throughout the chapter and amended where relevant.

In response to a comment to reinstate provisions applicable to feed and birth cohort animals when an indigenous case of classical BSE is identified, the Code Commission reminded Members that the *ad hoc* Group on BSE risk assessment that met in July 2018 concluded that, based on 16-year surveillance data, the complete destruction of all cohort animals would not provide a significant gain in risk reduction. The Commission did not agree to reinstate the text.

The Code Commission acknowledged a comment requesting to revise the form for the annual confirmation of BSE risk status to ensure alignment with this revised chapter, and requested the OIE Secretariat to address this matter.

Article 11.4.3bis

The Code Commission agreed with the *ad hoc* Group's proposed amendments to address some Member comments for clarity and consistency.

In response to a comment to clarify that the provision proposed in this article will also be applicable to cases confirmed before the adoption of the revised Chapter 11.4, the Code Commission clarified that revised chapters become effective from the day of adoption.

Deleted previous Article 11.4.6

The Code Commission extensively discussed the rationale for the *ad hoc* Group's proposed deletion of the previous Article 11.4.6 and merging the negligible and controlled risk into Article 11.4.7, noting that this relates to the issue of the concept of risk status that the Commission had pointed out in

Article 11.4.2 above and has significant implications on the rest of the trade provisions. After extensive discussions, the Commission agreed to present the *ad hoc* Group's proposal for Member comments. The proposal would allow for two different subpopulations within a country, zone or compartment recognised as either negligible or controlled risk, based on the date of birth of the cattle relative to the period when the risk of BSE agents being recycled in the cattle population had been demonstrated to be negligible.

Article 11.4.7

In response to comments requesting to reinstate the requirements regarding animal identification, the Code Commission agreed that BSE concerns the lifespan of an animal and animal identification enables the Veterinary Authorities to trace the origin of animals for the purpose of the effective control, and amended the text accordingly.

Article 11.4.8

In point 2, the Code Commission did not agree with a comment to reinstate the provision that cattle selected for export were born at least two years after the likelihood of the BSE agents being recycled was demonstrated to be negligible, as it considered it too stringent and prescriptive considering the reality of risk and the current global situation on BSE. The Commission also encouraged Members to refer to the report of the *ad hoc* Group on Risk assessment and surveillance that met in March 2019 for details on the rationale for this amendment.

Deleted previous Article 11.4.9

For consistency with the reasoning applied to the previously deleted Article 11.4.6, the Code Commission agreed with the *ad hoc* Group's proposal to delete previous Article 11.4.9. The Commission's response to some Member comments received for the previous Article 11.4.9 are presented in the following section for Article 11.4.10.

Article 11.4.10

In point 1, the Code Commission did not agree with a comment to replace 'came from' with 'were born in and have always been a resident in' as it considered that the existing text is clear regarding risk mitigation.

On the same point, the Code Commission did not agree with a comment to add 'and' at the end, as this is not the convention used in the *Terrestrial Code*.

The Code Commission did not agree with a comment to reinstate the previous provision which provided recommendations for the importation from negligible BSE risk countries where there has been an indigenous case. The Commission agreed with the *ad hoc* Group that met in March 2019 that it was no longer relevant to provide such recommendations given that the revised Article 11.4.3 clearly defines the conditions related to the occurrence of an indigenous case.

The Code Commission did not agree with a comment to delete point 3 as it considered it consistent with the trade provisions for live animals, for fresh meat and for meat products.

Article 11.4.11

Regarding a comment requesting guidance on how a Member could comply with point 2, the Code Commission acknowledged that it may be difficult to certify that the cattle from which the meat was derived have never been fed with ruminant protein meal. However, the Commission agreed that it was not impossible and that including provisions for this product was necessary.

Article 11.4.12

The Code Commission agreed with the *ad hoc* Group's proposed amendments to this article and its responses to Member comments requesting to retain the requirements for countries with negligible

BSE risk status where there has been an indigenous case (see relevant section of the June 2020 *ad hoc* Group report).

Article 11.4.13

Following the same logic as expressed above regarding risks posed by cattle subpopulations in controlled or negligible risk countries, the Code Commission agreed with the *ad hoc* Group's proposed amendments to this article.

Article 11.4.14

The Code Commission extensively discussed the amendments proposed by the *ad hoc* Group to this article and made some additional amendments to further explain the approach the Group had chosen with respect to the concept of BSE risk status.

The Code Commission noted the *ad hoc* Group had considered that the risk status of a country, zone or compartment is determined by the risk of BSE agent being recycled and thus, trade recommendations should take into account the risk posed by different subpopulations within a given status. While recognising that this approach appears to be different from the current perception of the risk status of a country, zone or compartment and that it might undermine efforts of some Members to reach negligible risk status, the Commission considered the approach was technically correct from the perspective of risk. The Code Commission, however, found the amendments to this article proposed by the *ad hoc* Group did not completely follow the logic of this approach, since the non-negligible risk posed by a 'sub'-population in a country, zone or compartment having a negligible risk status was not considered for commodities in this article. The Code Commission, therefore, proposed further amendments to address this point, except for cattle-derived protein meal, or any commodities containing such products, where the Code Commission agreed with the *ad hoc* Group, as the risk of cross-contamination was higher and such differentiation of sub-populations within controlled risk country was not possible.

In addition, the Commission noted that the last paragraph was no longer needed because risks posed by the 'sub'-populations in both negligible and controlled status are now considered in the revised text.

In point 1, the Code Commission did not agree with comments to reinstate 'tonsils', noting that the *ad hoc* Group had concluded that the restriction applicable to tonsils should be removed. The Commission reminded Members to refer to the rationale provided in the report of the *ad hoc* Group that met in March 2019.

Article 11.4.16bis

In line with the amendment to point 5 of Article 11.4.1bis, the Code Commission reinstated the previously deleted Article 11.4.18 on recommendations for the importation of tallow derivatives (other than as defined as safe commodities) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices, as Article 11.4.16bis.

Article 11.4.17

In response to a comment to include the levels of risk reduction associated with specific processing parameters, the Code Commission recalled that the parameters for effective BSE infectivity reduction are currently defined but empirical. It therefore encouraged Members to provide further evidence to consider including alternative techniques in this chapter.

In response to a comment to retain the terms 'meat-and-bone meal' and 'greaves' due to the ease of reference from the World Customs Organization (WCO) Harmonization System Code, the Code Commission noted that the new term 'protein meal', which had been proposed by the *ad hoc* Group that met in March 2019, could be a good replacement for both 'meat-and-bone meal' and 'greaves' because there is no clear difference between the two. The Commission was of the view that once the new definition for 'protein meal' is adopted in the Glossary of the *Terrestrial Code*, it could be a consideration for the WCO.

Article 11.4.18

The Code Commission agreed with the *ad hoc* Group's proposed texts and its responses to Member comments.

Chapter 1.8, Application for official recognition by the OIE of free status for bovine spongiform encephalopathy

The Code Commission agreed with the proposed amendments to the draft Chapter 1.8 proposed by the *ad hoc* Group.

The revised Chapter 11.4, Bovine spongiform encephalopathy, and the revised Chapter 1.8, Application for official recognition by the OIE of free status for bovine spongiform encephalopathy, are presented as **Annex 20** and **Annex 21** respectively, for Member comments.

EU comment

The EU thanks the OIE for the latest version of the revised Chapters 11.4. and 1.8. Comments are inserted the text of Annexes 20 and 21.

The report of the June 2020 meeting of the OIE *ad hoc* Group on BSE risk assessment and surveillance is attached as **Annex 28** for Member information.

7.7. Theileriosis (Chapters 11.10 and 14.X)

Background

The revised Chapter 11.10, Infection with *Theileria annulata*, *T. orientalis* and *T. parva* and the new Chapter 14.X, Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi*, were first circulated in September 2017, following the work of the *ad hoc* Group on Theileriosis that met in February 2017.

At the Code Commission's February 2018 meeting, in response to some Member comments which questioned the listing of some *Theileria* spp., the review of comments was put on hold while expert advice was sought regarding listing.

At its September 2019 meeting, the Code Commission was informed that *Theileria lestoquardi*, *T. luwenshuni*, *T. uilenbergi* and *T. orientalis* (Ikeda and Chitose) had been assessed by experts against the criteria for listing in accordance with Chapter 1.2 and were found to meet the criteria for listing (refer to Annex 19 of the Scientific Commission's February 2019 meeting report).

Given that these pathogenic agents were found to meet the criteria for listing, the Code Commission, at its September 2020 meeting, agreed to recommence work on these draft chapters and considered Member comments that had been received in February 2018.

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

Comments were received from Australia, China (People's Republic of), New Caledonia, New Zealand, South Africa, Switzerland, Thailand, the EU and AU-IBAR.

Discussion

In response to comments questioning the listing of *T. orientalis* (Chitose and Ikeda), the Code Commission highlighted that the inclusion of *T. orientalis* (Chitose and Ikeda) in the chapter had been supported by the Scientific Commission, the *ad hoc* Group on Theileriosis and the experts who had undertaken the assessments against the criteria for listing.

In response to a comment requesting to have one chapter on theileriosis across species, the Code Commission reiterated that given the host specificity of the different *Theileria* spp., maintaining

separate chapters would allow their management in different species, including surveillance easier for Members.

In response to a comment on species-specific diagnostic tests, the Code Commission noted that the Biological Standards Commission had agreed to review and update the corresponding disease-specific chapters of the *Terrestrial Manual* once suitable validated tests are available.

Article 11.10.1

In agreement with the Scientific Commission, the Code Commission did not agree with a comment to consider *T. orientalis* in the chapter without specifying the genotype, as only *T. orientalis* Ikeda and *T. orientalis* Chitose satisfied the listing criteria. The Commission also noted that this point is well described in the article.

Article 11.10.3

In point 1(c), a comment was received that questioned whether all ticks are to be targeted by the surveillance programme, as it would be difficult to demonstrate the total absence of ticks in a country or zone for a period of two years. The Code Commission agreed with the Scientific Commission that this referred to competent tick vectors, and thus added the word 'competent' before 'tick vectors'.

In point 2, in response to a comment on the involvement of non-tick vectors in the mechanical transmission of *T. orientalis*, the Code Commission requested the OIE Secretariat to seek further expert advice.

Article 11.10.5

In point 3, the Code Commission agreed with a comment to remove reference to the time periods for treating the animal with an acaricide as there are some acaricide products that allowed long-term protection against ticks. It also agreed with a comment to include a reference to the efficacy of the acaricide used in view of tick resistance, and proposed to include 'the efficacy of which has been confirmed in relation to the area of origin of the animals, at the entrance of the isolation zone and then at regular intervals' before 'according to manufacturer's instructions', and 'allowing continuous protection against ticks until their shipment' at the end of the sentence.

In point 4, in response to a comment requesting to use the same test schedule as that used in Chapter 12.1, Infection with African horse sickness virus, i.e. testing is conducted at least 25 days after entry to the isolation establishment, the Code Commission requested the OIE Secretariat to seek expert advice on the appropriate test schedule to be applied at the beginning and end of the quarantine period.

Article 11.10.6

The Code Commission did not agree with a comment to delete Articles 11.10.6 and 11.10.7 and to move these commodities to Article 11.10.2 on safe commodities. In response to the rationale provided by the Member that there are no measures in place for the trade in hides, skins and trophies for other tick-borne disease chapters like heartwater, bovine anaplasmosis and bovine babesiosis, the Commission explained that the lack of mention of hides, skins and trophies in these other chapters did not mean that these commodities were 'safe', but rather that their safety has not been assessed. Furthermore, these chapters have not been updated for some time and the inclusion of articles on safe commodities is still a work in progress across the disease-specific chapters of the *Terrestrial Code*. The Commission agreed with the Scientific Commission that treated skins and hides might qualify as safe commodities but that would not be the case for untreated commodities as they might still contain infected ticks and pose a risk. The Commission invited Members to submit data on standardised treatments that could assure the safety of hides, skins and trophies as per Chapter 2.2, Criteria applied by the OIE for assessing the safety of commodities, as such evidence could be used to assess the safety of these commodities.

Article 11.10.7

The Code Commission agreed with a comment to delete 'wild' from the title, agreeing that trophies from susceptible domestic or feral ruminants, as well as wild susceptible ruminants should be included.

Revised Chapter 11.10 is presented as **Annex 22** for Member comments.

EU comment

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

Chapter 14.X, Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi*

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

The Code Commission noted that there is no recommendation for diagnostic tests for *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* in the *Terrestrial Manual.* Given that this would have an impact on the case definition and appropriate diagnostic tests to be recommended in the chapter, the Code Commission agreed not to progress further work on this chapter until the Biological Standards Commission can provide advice on the development of recommended diagnostic tests for these *Theileria* spp. in the *Terrestrial Manual.* The Commission requested the OIE Secretariat to seek advice from the Biological Standards Commission as to how to address this gap.

7.8. Trichomonosis (Chapter 11.11)

The Code Commission was informed that a Member had asked for clarification regarding the appropriate tests for trichomonosis for the importation of bulls given that the recommendations in the disease-specific chapters of the *Terrestrial Code* and *Terrestrial Manual* are different. The Code Commission thanked the Reference Laboratory experts for Trichomonosis for their inputs as to the appropriate tests to be recommended in the *Terrestrial Code*.

The experts clarified that real-time PCR is the appropriate test, and thus proposed amendments to Articles 11.11.2 to 11.11.4 to replace microscopy and cultural examination with an 'agent identification test'. The Code Commission also requested the OIE Secretariat to ensure that recommendations on diagnostic tests for trichomonosis in Chapter 4.7 are reviewed as part of the proposed work to review Chapter 4.7.

Revised Chapter 11.11 is presented as **Annex 23** for Member comments.

EU comment

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

7.9. Contagious equine metritis (Chapter 12.2)

Background

At its February 2019 meeting, the Code Commission agreed to amend Chapter 12.2, Contagious equine metritis, to include requirements for the temporary movement of horses. In addition, given that this chapter had not been reviewed for some time, the Commission requested a comprehensive revision be undertaken.

An electronic expert consultation was conducted between September and December 2019 and its report, including the draft revised chapter, was endorsed by the Scientific Commission at its February 2020 meeting. The full report of this consultation was annexed to the Scientific Commission's February 2020 meeting report.

Discussion

The Code Commission considered the report of the electronic expert consultation and the draft revised chapter.

The Code Commission reviewed the revised chapter and proposed amendments to the text for clarity and consistency with other chapters in the *Terrestrial Code*. In addition, the Commission wished to highlight the following points.

Article 12.2.1

The Code Commission agreed with the proposal from the experts to specify that this chapter deals not only with the occurrence of clinical or asymptomatic infection of the mare caused by *T. equigenitalis* but also with the presence of *T. equigenitalis* on the genital mucous membrane surface in the stallion. The Commission noted that this was a very specific case and that this particular reference to the presence of the pathogenic agent on the genital mucous membrane surface (not entering and developing or multiplying in the body) was needed to avoid inconsistency with the glossary definition for '*infection'*.

The Code Commission highlighted that this article defines the incubation period only for mares as they are the only ones potentially showing clinical signs, but it also defines the infective period for 'horses', meaning females and males, of all categories. The Commission explained that this is a consequence of the point explained above regarding the definition of the scope of this chapter, as uncastrated males, although not 'infected', can also harbour the pathogenic agent on their genital mucosa and be 'infective'.

The Code Commission supported the approach proposed to manage the provisions for the temporary importation of horses. The Commission recognised that the general provisions included in Article 12.7.1 defining the concept of 'temporary importation' for the purpose of this chapter provided a clear framework to differentiate it from a regular importation where the horse remains permanently in, and has a direct relation with the health status of the importing country. The Commission explained that this approach allowed for the definition of different measures for both situations, in a manner that can also be applied to other horse disease-specific chapters.

Article 12.2.2

The Code Commission acknowledged the discussion noted in the *ad hoc* Group report regarding the inclusion of 'geldings' in the list of safe commodities in Article 12.2.2. The Commission discussed the different risk management implications that such a decision would imply recognising the important movement this category of animals has both internationally and at country level.

The Code Commission noted that the *ad hoc* Group referred to some studies that found geldings to be carriers of *T. equigenitalis*, nevertheless there was no clear evidence of their capacity to transmit the disease nor about their epidemiological significance. Taking this into account, and considering the criteria applied by the OIE for assessing the safety of commodities as defined in Chapter 2.2 of the *Terrestrial Code*, notably point 1 of Article 12.2.2, the Commission decided to include 'geldings' in the list of safe commodities.

Article 12.2.3

The Code Commission noted that the *ad hoc* Group had proposed a new article for the 'Establishment free from infection with *T. equigenitalis*', but the Scientific Commission, in its February 2020 meeting report, referred to provisions for 'compartment freedom'.

The Code Commission agreed with the proposal and the rationale provided by the *ad hoc* Group and agreed that managing this disease at establishment level is the appropriate way of managing risks, and is also achievable in practical terms. The Commission reminded Members that compartmentalisation principles could be implemented by countries, but taking into account the epidemiology of the disease, the Commission agreed that full compliance with Chapter 4.4 and 4.5 should not be considered mandatory to secure the health status of horses in this case.

The Code Commission noted that due to the extensive nature of the amendments made, the revised chapter is being presented as clean text only.

Revised Chapter 12.2 is presented as **Annex 24** for Member comments.

EU comment

The EU in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 24.

7.10. Equine piroplasmosis (Chapter 12.7)

Background

At its February 2019 meeting, the Code Commission agreed to amend Chapter 12.7, Equine piroplasmosis, to include requirements for the temporary movement of horses. In addition, given that this chapter had not been reviewed for some time, the Commission requested for a comprehensive revision be undertaken.

An electronic expert consultation was conducted between September and December 2019 and its report, including the draft revised chapter, was endorsed by the Scientific Commission at its February 2020 meeting.

In addition, during the OIE-International Horse Sport Confederation (OIE-IHSC) Technical Committee in March 2020, the IHSC representatives requested that the Code Commission consider the possible interference of antiparasitic treatments with testing for equine piroplasmosis before the importation of horses and provided scientific evidence on the use of imidocarb dipropionate.

Discussion

The Code Commission considered the report of the electronic expert consultation and the draft revised chapter and proposed amendments to the draft chapter for clarity and consistency with other chapters in the *Terrestrial Code*.

The Code Commission agreed with the *ad hoc* Group on not including *T. haneyi* at current time, because of uncertainty as to whether *T. haneyi* meets the criteria for inclusion on the OIE List.

The Code Commission supported the approach proposed to manage the provisions for the temporary importation of horses. The Commission recognised that the general provisions included in Article 12.7.1 defining the concept of 'temporary importation' for the purpose of this chapter provided a clear framework to differentiate it from a regular importation, where the horse remains permanently in, and has a direct relation with the health status of the importing country. The Commission explained that this approach allowed for the definition of different measures for both situations, in a manner that can also be applied to other horse disease-specific chapters.

The Code Commission discussed the request from the IHSC and considered the possibilities to include provisions regarding the interference of antiparasitic treatments with testing before the importation of horses. The Commission agreed that this is a very important issue for the international movement of horses that could bring additional risks to free countries. Nevertheless, they recognised that it could be a challenge for Veterinary Authorities to certify requirements related to the absence of such treatments, as it would be difficult to have adequate evidence of compliance. The Commission noted that the value of different diagnostic tests in drug-treated animals was already covered for some tests in Chapter 3.5.8, Equine Piroplasmosis, of the *Terrestrial Manual*, and agreed to request the opinion of the Biological Standards Commission on this issue.

Revised Chapter 12.7 is presented as **Annex 25** for Member comments.

EU comment

The EU in general supports the proposed changes to this chapter. One comment is inserted in the text of Annex 25.

8. Other texts proposed for adoption in the report of the Code Commission's February 2020 meeting (adoption postponed to May 2021)

The Code Commission considered all comments received on the texts proposed for adoption in the report of the Code Commission's February 2020 meeting (adoption postponed to May 2021). For efficiency, the Commission only addressed, in this meeting, those chapters where substantial comments had been received and for those for which it considered that the input of the Scientific Commission was required.

Based on this approach, only the new Chapter 7.Z, Animal welfare and laying hen production systems, and the revised Chapter 10.4, Infection with avian influenza viruses, were further amended after consideration of the comments received. These revised chapters are presented for Member comments and are being proposed for adoption at the 88th General Session in May 2021 (see items 6.4 and 6.6 of this report).

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

The Code Commission considered the comments received on Articles 14.7.3, 14.7.7, 14.7.24 and 14.7.34, and deferred its discussion to 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.

The Code Commission will address all comments received, together with the advice of the Scientific Commission, at its February 2021 meeting.

– **Infection with classical swine fever virus (Chapter 15.2)**

The Code Commission considered the comments received on Chapter 15.2, and deferred its discussion to 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.

The Code Commission will address all comments received, together with the advice of the Scientific Commission, at its February 2021 meeting.

The Code Commission considered the comments received on the other texts that were proposed for adoption in the report of the Code Commission's February 2020 meeting and agreed to defer its discussion until its February 2021 meeting. These texts are:

– User's Guide
– Glossary Part A ('epidemiological unit', 'captive wild [animal]', 'feral [animal]' and 'wild [animal]')
– Animal health surveillance (Article 1.4.3)
– Notification of diseases, infections and infestations, and provision of epidemiological information (Chapter 1.1)
– Procedures for self-declaration and official recognition by the OIE (Chapter 1.6)
– Veterinary legislation (Chapter 3.4)
– New chapter on official control programmes for listed and emerging diseases (Chapter 4.Y).

The Commission wished to note that all responses to comments received and the corresponding amended texts (incorporating any revisions resulting from these considerations) will be presented in the February 2021 meeting report as proposed for adoption in May 2021.

9. Other updates

9.1. Update on Guidelines on compartmentalisation for African swine fever

The Code Commission was informed of the work of the *ad hoc* Group on Compartmentalisation for African swine fever (ASF) that was convened in March 2020 to contribute to the development of practical guidelines on compartmentalisation for ASF. A representative of the Code Commission also participated in that meeting.

These guidelines will incorporate the general principles outlined in the *Terrestrial Code* and also provide specific guidance for the application and validation of compartmentalisation in support of OIE Members with the objective of minimising the impact of ASF and ensuring business continuity.

The Guidelines, consisting of the main document plus tools and examples, is currently being prepared for publication which is planned for November 2020. The Guidelines will be made available on the OIE website.

The Code Commission noted that the report of the *ad hoc* Group is annexed to the September 2020 report of the Scientific Commission.

9.2. Wildlife health management framework concept note

The OIE Secretariat updated the Code Commission on the OIE Headquarters work to develop a wildlife health management framework, including the development of a concept note. The Code Commission reviewed the concept note presented for information to the Specialists Commissions, and that has been annexed to the September 2020 report of the Scientific Commission.

The Code Commission acknowledged the work done by the OIE Headquarters and the OIE Wildlife Working Group and recognized the risks that the close interaction between wildlife, domestic animals and humans could pose to animal and human health. The Commission highlighted the importance of considering these issues with a One health approach and emphasised the urgent need of ensuring complementarity between the different actors involved in addressing them.

The Code Commission agreed on the value of strengthening the role of Veterinary Services in improving wildlife health management and on the need to establish priorities and assess the needs of Members at an early stage.

The Code Commission noted that the *Terrestrial Code* already considers wildlife as a key component of animal health management, notably for its potential role as a reservoir for a number of diseases, but also because the impact on wildlife is a specific criterion for listing an OIE disease, and that it is addressed explicitly in both horizontal and disease-specific chapters. The Commission agreed that, if needed, new elements could be considered for inclusion in existing chapters or by developing new ones. However, such inclusions should only be considered on the basis of scientific evidence and a risk analysis to ensure their relevance and sustainability.

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

10. Date of next meeting

The next meeting will be held from 2 to 11 February 2021.

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…/Annexes

Annex 4

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY THE OIE

EU comment

The EU supports the proposed changes to these 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 1.3.9.

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 5

DRAFT CHAPTER 3.1.

QUALITY OF VETERINARY SERVICES

EU comment

The EU in general supports the proposed changes to this chapter. One comment is inserted in the text below.

Article 3.1.1.

General considerations

The quality of *Veterinary Services* depends on ethical, organisational, legislative and technical factors.

Compliance with standards of quality is critical for *Veterinary Services* to meet their animal health, *animal welfare*, and veterinary public health objectives, and is important for the establishment and maintenance of trust in *international trade*.

Veterinary Services should conform to the fundamental operating principles in Article 3.1.2., regardless of the political, economic or social situation of their country.

The key components of a country's *Veterinary Services* are presented in Articles 3.1.3 to 3.1.12. Four components are focused on governance aspects: Policy and Management, Personnel and Resources, the Veterinary Profession, and Stakeholders; and six components are focused on technical aspects: Animal Health, Animal Production Food Safety, Veterinary Medicinal Products, Laboratories, Animal Welfare and International Trade.

This chapter should be read in conjunction with other chapters in the *Terrestrial Code*, relevant chapters of the *Terrestrial Manual* with regards to quality of *laboratories*, diagnosis and vaccines, as well as relevant Codex Alimentarius texts.

Article 3.1.2.

Fundamental operating principles

Veterinary Services should comply with the following interrelating principles to ensure the quality of their activities:

1. Professional judgement

   The personnel should have the relevant qualifications, expertise and experience to give them the competence to make sound professional judgements.

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.

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

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

This component should comprise the following specific elements:

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

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

3) Capability to perform *risk analysis* and cost-benefit analysis to define and adapt policies and programmes.

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

5) Quality management systems with quality policies, procedures and documentation suited to the *Veterinary Services*' activities, including procedures for information sharing, complaints and appeals and for internal audits.

6) Information management systems for collecting data to monitor and evaluate *Veterinary Services*' policies and activities and to perform *risk analysis*.

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

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

EU comment

The EU queries whether the same change should be made in point 8 above as in the 2nd

paragraph of this article, i.e. to replace "Competent Authorities" with "<u>other governmental authorities</u>".

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

Article 3.1.4.

Personnel and resources

Veterinary Services should be appropriately staffed, including *veterinarians*, *veterinary paraprofessionals* or other personnel, with appropriate competencies through initial and continuing education to allow for their functions to be undertaken effectively and efficiently.

Veterinary Services should have functional and well-maintained physical resources, adequate operational resources for their ongoing and planned activities, and access to extraordinary resources to respond effectively to emergency situations or new emerging issues.

This component should comprise the following specific elements:

1) A core of full-time civil service employees with qualified *veterinarians* and *veterinary paraprofessionals*.

2) Formal, consistent and merit-based recruitment and promotion procedures.

3) Job descriptions, formal performance assessment and management procedures for *veterinarians*, *veterinary paraprofessionals* and other personnel that are defined and being implemented.

4) Personnel remuneration, sufficient to minimise the risk of conflicts of interest and to preserve independence.

5) *Veterinarians*' and *veterinary paraprofessionals'* education, knowledge, skills and practices, standardised and sufficient to perform relevant activities of the *Veterinary Services*.

6) *Veterinary paraprofessionals* are adequately supervised by *veterinarians*.

7) All personnel have access to <u>professional development, including</u> continuing education programmes that are reviewed and updated as necessary.

8) Established procedures for *Veterinary Services* to access personnel and other resources, including in emergencies.

9) Access to suitable physical resources at all levels (national, state/provincial and local), including, but not limited to, functional buildings, furniture, equipment, communications, information technology, transport and cold chain, which are maintained or renewed as necessary.

10) Access to sufficient operational resources for planned and continued activities, as well as for new or expanded operations, including but not limited to, contracts, fuel, per diem, vaccines, diagnostic reagents, personal protective equipment and other consumables.

Article 3.1.5.

The veterinary profession

Veterinarians and *veterinary paraprofessionals* are an essential component of *Veterinary Services*, whether as part of governmental authorities or as private service providers.

The *Veterinary Statutory Body* should regulate *veterinarians* and *veterinary paraprofessionals* to effectively and independently maintain educational and professional standards <u>relevant to their role</u>s, including ~~for both~~ official tasks<u>,</u> ~~and~~ veterinary clinical services <u>and other veterinary tasks as appropriate</u>. 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 5 (contd)

This component should comprise the following specific elements:

1) An independent *Veterinary Statutory Body*, legally responsible and adequately resourced for:

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

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

   c) setting minimum standards of professional conduct and competence of registered *veterinarians* and *veterinary paraprofessionals* and ensuring that these standards are met and maintained;

   d) investigating complaints and applying disciplinary measures.

2) Independence of the *Veterinary Statutory Body* is ensured through transparent governance and funding arrangements including an elected, representative council or equivalent, and financial arrangements for the collection and management of registration fees.

3) Sufficient quality veterinary clinical services are available ~~of sufficient quality~~ to meet the needs of animal owners, including their access to essential animal disease and injury diagnosis and treatment.

Article 3.1.6.

Stakeholders

A range of individuals or organisations have an interest or concern in the activities of the *Veterinary Services*, for example livestock farmers, processors, traders, feed manufacturers, *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 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~~ion~~ in collaborative joint programmes with producers or other stakeholders.

The OIE has produced guidelines for both public and private sectors to help advocate for, develop and implement public private partnerships in the veterinary domain.

This component should comprise the following specific elements:

1) Good governance relevant to all stakeholder engagement is in place to ensure compliance with Article 3.1.2, incorporating transparency and effective monitoring and evaluation.

2) Ongoing, targeted and effective communication with stakeholders in accordance with Chapter 3.3.

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

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

Annex 5 (contd)

Article 3.1.7.

Animal health

Veterinary Services should organise and implement programmes to prevent, control or eradicate animal diseases, and should be able to identify *animals* to trace and control their movements.

Veterinary Services should organise and implement an effective animal health surveillance system and be prepared to respond effectively to sanitary emergencies.

This component should comprise the following specific elements:

1) Effective surveillance for the early detection, monitoring and reporting of 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) An updated list of *notifiable diseases* that includes relevant *listed diseases*.

3) Use of the formal procedures for self-declaration and official recognition by the OIE for both disease freedom and disease control programmes, in accordance with Chapter 1.6.

4) Emergency management, including preparedness and response planning, a legal framework, and access to the human, physical and financial resources to respond rapidly to sanitary emergencies in a well-coordinated manner, including for disposal and *disinfection* in accordance with Chapters 4.13. and 4.14.

5) *Official control programmes* for priority diseases with scientific and risk-based evaluation of their efficacy and efficiency, in accordance with the relevant chapters of the *Terrestrial Code*.

6) A programme for managing the risks to animal health from germplasm, including the collection, processing and distribution of semen, oocytes or embryos, in accordance with the relevant chapters in Section 4.

7) A programme for the official health control of bee diseases, in accordance with Chapter 4.15.

8) A programme for managing the risks to animal and public health from animal *feed*, including feeding animal materials to susceptible ~~livestock~~ *animals*, in accordance with Chapter 6.4.

9) A system for *animal identification*, *animal traceability* and movement control for specific animal *populations* as required for traceability or disease control, in accordance with Chapters 4.1. and 4.2.

Article 3.1.8.

Animal production food safety

Veterinary Services should contribute to assuring the safety of food of animal origin for domestic and export markets as part of a food safety system, with effective coordination of official controls between relevant *Competent Authorities*.

This component should comprise the following specific elements:

1) Regulation, inspection, authorisation, ~~and~~ supervision and auditing of establishments and processes for production and processing of food of animal origin (*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) 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 5 (contd)

3) Regulation and implementation of controls on animal *feed* safety covering processing, handling, storage, distribution and use of both commercial and on-farm produced animal *feed* and *feed ingredients*, including risks such as microbial, physical, chemical and toxin contamination.

4) A residue monitoring programme for veterinary medicines (e.g. antimicrobials and hormones), chemicals, pesticides, radionuclides, heavy metals, etc. and the capacity to respond appropriately to adverse findings.

5) Identification and traceability of products of animal origin for the purposes of food safety, animal health or trade, in accordance with Chapter 6.2.

6) Procedures for corrective actions ~~or~~ and for proportional and dissuasive sanctions in response to regulatory non-compliance to mitigate risks to the safety of food of animal origin for export or domestic markets in accordance with Article 6.2.3.

7) Preparedness and response planning to manage food or *feed* safety incidents of animal origin.

Article 3.1.9.

Veterinary medicinal products

Veterinary Services should regulate all *veterinary medicinal products* such as veterinary medicines, biologicals and medicated *feed*, in order to ensure their quality and safety, as well as their responsible and prudent use, including *monitoring* antimicrobial use and antimicrobial resistance, and minimising the associated risks.

This article should be read in conjunction with the *Terrestrial Manual*, which set standards for the production and control of vaccines and other biological products.

This component should comprise the following specific elements:

1) Effective regulatory and administrative control, in accordance with Article 3.4.11., including communications and compliance programmes for:

   a) the market authorisation of *veterinary medicinal products*, including registration, import, manufacture, quality control, and reducing the risk from illegal imports;

   b) responsible and prudent use of *veterinary medicinal products*, including the labelling, distribution, sale, dispensing, prescription and administration of these products.

2) *Risk management* and *risk communication* for antimicrobial use and antimicrobial resistance, based on *risk assessment*. This includes *surveillance* and control of the use of antimicrobials and the development and spread of antimicrobial resistant pathogens in animal production and, ~~animal origin~~ food products 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.

Articles 3.1.10.

Laboratories

Veterinary Services should have access to quality *laboratory* diagnosis through a sustainable network of *laboratories*, capable of accurately identifying and reporting *infections* and *infestations* or other relevant *hazards*.

Veterinary Services require *laboratory* services for purposes such as early detection, measuring disease prevalence and progress with control, assessing the ~~*veterinary medicinal products*~~ quality and ~~protection~~ effectiveness of *veterinary medicinal products*, 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* Quality Management Systems and proficiency testing programmes, in accordance with the *Terrestrial Manual*.

Article 3.1.11.

Animal welfare

Veterinary Services should implement policies, legislation and programmes in accordance with Section 7.

This component should comprise the following specific elements:

1) *animal welfare* programmes, supported by suitable legislation, with appropriate stakeholder and public awareness and compliance inspection activities;

2) communication, consultation and coordination with stakeholders.

Article 3.1.12.

International trade

Through the implementation of OIE standards, *Veterinary Services* play a critical role in ensuring the safety of *international trade* of *commodities* and *veterinary medicinal products*, while avoiding unjustified barriers.

Veterinary Services should implement risk-based measures for import and export following relevant provisions in the *Terrestrial Code* and in accordance with Chapter 5.3. Quality of *Veterinary Services* is essential for these measures to be recognised and trusted.

This component should comprise the following specific elements:

1) *Sanitary measures* developed and implemented in accordance with Chapter 2.1. and other relevant chapters of the *Terrestrial Code*.

2) Effective implementation of *official veterinary controls* to prevent the entry of diseases and other *hazards* through effective border inspection and quarantine operations, in accordance with Chapter 5.6.

3) Effective application of relevant animal health measures at or before departure for exports, during transit through the country, and on arrival for imports, in accordance with Chapters 5.4., 5.5. and 5.7.

4) Effective development and implementation of international veterinary certification for *animals*, animal products, services and processes for export under their mandate, in accordance with *importing country* requirements and relevant chapters in Section 5.

5) Effective development, implementation and maintenance of equivalence and other types of sanitary agreements with trading partners, where applicable, in collaboration with national stakeholders, and in accordance with Chapter 5.3.

6) Regular and timely official notification to the OIE, WTO, trading partners and other relevant organisations of changes in animal disease status, regulations and *sanitary measures* and systems, in accordance with the procedures established by these organisations, including Chapters 1.1. and 1.3.

Annex 5 (contd)

7) Where applicable, effective implementation and maintenance of disease-free *zones*, *compartments* or other high health status *subpopulations* for the purposes of trade, in collaboration with producers and other stakeholders, and in accordance with relevant chapters in Sections 4 and 5.

8) Active participation in the OIE and Codex Alimentarius standard setting processes.

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Annex 6

DRAFT CHAPTER 3.2.

EVALUATION OF VETERINARY SERVICES

EU comment

The EU thanks the OIE and supports the proposed changes to this 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 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 intends to conduct an evaluation of another Member Country's *Veterinary Services* should give them notice in writing. This should define the purpose and scope of the evaluation and detail the information required.

5) Prior to the evaluation, the parties should agree on the objective, scope and approach of the evaluation, including any financing and confidentiality requirements ~~of confidentiality~~.

6) The evaluation should be conducted in accordance with the Fundamental Operating Principles set-out for *Veterinary Services* in Article 3.2.2 in a timely and efficient manner, ensuring the level of evaluation activity is undertaken only to the extent necessary.

7) The evaluation should start with a review of available information including existing PVS Pathway or other reports, analysis of publicly available or previously provided information, or historical performance such as relating to safe trade or transparency.

8) The outcome of the evaluation conducted by another Member Country should be provided in writing to the evaluated country as soon as possible. The evaluation report should detail any findings which affect trade prospects. The Member Country which conducts the evaluation should clarify any points of the evaluation on request, and provide the opportunity for the evaluated country to clarify or respond to the findings before the production of the final evaluation report.

9) The use of the OIE PVS Tool is encouraged.

Article 3.2.5.

Evaluation of the Veterinary Services of a Member Country by OIE experts, under the auspices of the OIE

1) The OIE has established procedures for the evaluation of the *Veterinary Services* of a Member Country using the OIE PVS Tool, following a voluntary request from the Member Country.

2) The report of such an evaluation belongs to the *Veterinary Authority* of the Member Country. The OIE encourages Member Countries to make their reports publicly available.

3) Member Countries are encouraged to use these reports in a transparent way to achieve some or all of the objectives listed in Article 3.2.2.

4) Support for further use of the evaluation report in national planning and targeted capacity building is available from the OIE as part of its PVS Pathway.

Annex 7

DRAFT CHAPTER 3.X.

INTRODUCTION TO RECOMMENDATIONS ON VETERINARY SERVICES

EU comment

The EU supports the proposed changes to this 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. The veterinary domain covers a broad scope of possible activities. Section 3 focuses on aspects of the *Veterinary Services* that enable the OIE standards to be met even when under the responsibility of one or more *Competent Authorities.*

Member Countries should implement the OIE standards across their whole territory and should meet their obligations at the international level through representation by their respective OIE Delegate. The *Veterinary Authority,* including the OIE Delegate, should coordinate with other *Competent Authorities* to ensure international standards and responsibilities are met.

Veterinary Services have responsibility for implementing the activities necessary for the Member Country to comply with OIE standards. These activities can be delivered by a combination of individuals or organisations, public or private that are responsible to one or more *Competent Authorities*. *Veterinary Services* also include the personnel of the *Competent Authorities* themselves. The term *Veterinary Services* refers to the combination of a number of separate actors, with different organisational affiliations.

Section 3 provides standards to assist the *Veterinary Services* of Member Countries in meeting their objectives of improving terrestrial animal health and *animal welfare* and veterinary public health, as well as to establish and maintain confidence in their *international veterinary certificates*.

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Annex 8

CHAPTER 4.4.

ZONING AND COMPARTMENTALISATION

EU comment

The EU thanks the OIE and supports the proposed changes to this 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. The *protection zone* can be established within or outside a *free zone* or within a free country. Based on the results of a *risk assessment*, more than one *protection zone* may be established.

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

~~Increased *surveillance*, in accordance with Chapter 1.4. and the relevant disease-specific chapter, should be implemented in the *protection zone* and the rest of the country or *zone*, including *surveillance* of *wildlife* and *vectors* as relevant.~~

In addition to the general considerations in Article 4.4.2. and the principles in Article 4.4.3., t~~T~~hese measures should include intensified movement control, ~~and *surveillance* and specific~~ *animal identification* and *animal traceability* to ensure that *animals* in the *protection zone* are clearly distinguishable from other populations. *Vaccination* of susceptible *animals* in accordance with Chapter 4.18. may also be applied.

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 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 *vaccination*, the *animal health status* of the rest of the country or *zone* is not affected.

Regarding diseases for which the OIE grants official recognition of *animal health status*:

- a *protection zone* is considered as effectively established when the conditions described in this article and in the relevant disease-specific chapters have been applied and documented evidence is submitted to and was accepted by the OIE;

- ~~. A~~a *protection zone* established on a temporary basis should be limited to less than 24 months from the date of its approval by the OIE;

- if a Member wishes to make the *protection zone* permanent, the process for official recognition by the OIE should be followed 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 inside or outside the *containment zone*.

3) Establishment of a *containment zone* should be based on a rapid response, prepared in a contingency plan, and that includes:

   – appropriate control of movement of *animals* and other *commodities* upon declaration of suspicion of the specified disease;

   – epidemiological investigation (trace-back, trace-forward) after confirmation of *infection* or *infestation*, demonstrating that the *outbreaks* are epidemiologically related and all contained within the defined boundaries of the *containment zone*;

   – a *stamping-out policy* or another effective emergency control strategy aimed at eradicating the disease;

   – *animal identification* of the susceptible population within the *containment zone* enabling its recognition as belonging to the *containment zone*;

   – increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* demonstrating no occurrence of *infection* or *infestation*;

   – *biosecurity* and *sanitary measures*, including ongoing *surveillance* and control of the movement of *animals*, other *commodities* and fomites within and from the *containment zone*, consistent with the *listed disease*-specific chapter, when there is one, to prevent spread of the *infection* or *infestation* from the *containment zone* to the rest of the country or *zone*.

4) A *containment zone* is considered as effectively established when the following is demonstrated, 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 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 4a) or in the ~~*protection*~~ outer *zone* where no *outbreaks* had occurred as ~~defined~~ described in point 4b), the rest of the country or *zone* is considered infected.

Annex 9

DRAFT CHAPTER 7.Z.

ANIMAL WELFARE AND LAYING HEN PRODUCTION SYSTEMS

EU comment

The EU thanks the OIE for its work on the revision of this draft new chapter but regrets that its key comments submitted previously have not been addressed despite solid scientific evidence in support.

The EU will not support the adoption of this chapter unless the comments inserted in the text below have been taken into account.

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.

In this context, we would like to inform the OIE that the European Food Safety Authority (EFSA) has been mandated to update its scientific opinion on the welfare of laying hens within the context of an ongoing Fitness Check of the EU animal welfare acquis. The EFSA opinion is expected to be published by end of 2022.

Article 7.Z.1.

Definitions

For the purposes of this chapter:

Laying hens: means sexually mature female birds of the species *Gallus gallus domesticus* kept for the commercial production of eggs for human consumption. Breeding hens are not included.

End-of-lay hens: means laying hens at the end of their productive lives.

Layer pullets: means female birds of the species *Gallus gallus domesticus* raised for commercial layer production purposes from hatch until the onset of sexual maturity.

Article 7.Z.2.

Scope

This chapter provides recommendations for the *animal welfare* aspects of commercial laying hen production systems. It covers the production period from the arrival of *day-old birds* onto the pullet-rearing farm through to the removal of end-of-lay hens from the laying production facilities. 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 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 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 pullet and hen areas of the poultry house [Jones, 1996; Waiblinger *et al*., 2006].

c) Feeding and drinking behaviour

Changes in feeding or drinking behaviour may indicate management problems, including inadequate spaces for, or inappropriate placement of, feeders or drinkers, dietary imbalances, poor *feed* or water quality, or *feed* contamination [Garner *et al.*, 2012; Thogerson *et al.*, 2009a; Thogerson *et al.*, 2009b]. *Feed* and water intake is often reduced when pullets or hens are ill. *Feed* or water intake may also change as a result of heat stress [Lara ~~L. J.~~ & Rostagno, 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 pullets and hens select a site for resting or sleeping [EFSA, 2015]. Reduced perching behaviour in the *flock* may indicate problems with environmental factors, such as inadequate perch or poor space design, injuries or pullet rearing experience [Janczak and Riber, 2015; Gunnarsson *et al.*, 1999].

i) Resting and sleeping

Sleep is an adaptive state that allows animals to recover from daily stress, conserve energy and consolidate memory [Siegel, 2009]. Layer pullets and laying hens display synchronised resting and sleeping behaviours, which can be disrupted by light intensity, photoperiod, environmental or social factors [Malleau *et al*., 2007; Alvino *et al.*, 2009].

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), 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 measures ~~s~~ that can be used include:

a) layer pullet growth rate, which measures average daily mass gain per 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 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 *animal welfare* problems may arise in any system if there are problems 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 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 for the intended laying hen production system [Aerni *et al.*, 2005].

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.

EU comment

The EU requests an amendment of the second sentence of the paragraph above as follows:

"~~Providing s~~Sufficient space for the expression of locomotory and comfort behaviours

that contribute to good musculoskeletal health and plumage condition ~~is desirable~~ should be provided."

Justification

Considering the substantive scientific evidence, supporting that insufficient space allowance impairs hens to express priority behaviours the EU requests that the term "[is] desirable" be replaced with "should [be provided]". Indeed, it is necessary to provide sufficient space for the expression of (species specific) locomotory and comfort behaviours.

References

Opinion of the scientific panel on animal health and welfare on a request from the Commission related to the welfare aspects of various systems of keeping laying hens (Question N EFSA-Q-2003-092) EFSA Journal (2005) 197, 1-23,

Report of the Scientific Veterinary Committee, Animal Welfare Section on the Welfare of Laying Hens, Brussels, 30 October 1996.

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 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*.

EU comment

The EU requests an amendment of the above sentence as follows:

"~~When substrate is~~ Substrate should be provided~~, it should~~ to 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".

Justification

The substrate allows dust bathing and some other motivated behaviours such as foraging, pecking and scratching as already described in Article 7.Z.3.2.

References

EFSA Journal (2005) 197, 1-23. The welfare aspects of various systems of keeping laying hens

De Jong, I.C. and Blokhuis, H.J. The welfare of laying hens, Proceedings of the XII European Poultry Conference, Verona, Italy, 12-14 sept 2006

Hens are highly motivated to access litter for dust bathing, and showed very strong preference of hens for dust bathing in peat moss (there was no preference to stay on a certain substrate in general, but the efforts and the total expenditure to take a dust bath in peat moss were high).

De Jong *et al*. (2007), Applied Animal Behaviour Science 104 (2007) 24-36.

Matthews, L.R., Temple,W., Foster, T.M.,Walker, A.W., McAdie, T.M., 1995. Comparison of the demand for dustbathing substrates by layer hens. In: Rutter, S.M., Rushen, J., Randle, H.D., Eddison, J.C. (Eds.), Proceedings of the 29th International Congress of the ISAE, Conference Universities' Federation of Animal Welfare, Exeter, pp. 11–12.

"Hens have been found to work for access to a range of additional resources including pecking, scratching and dust bathing substrates, perches (particularly prior to nightfall), additional space and nestboxes." And: "Modified or enriched cages allow for these activities, as well as perching, and, potentially dust bathing, but do not allow full expression of exploratory or comfort behaviours. Free-range systems, percheries and other types of colony housing provide opportunities for all of the above, although at high stocking densities social competition and limited space may restrict performance of these behaviours for certain birds."

Cooper, J.J., Albentosa, M.J., 2003. Behavioural priorities of laying hens. Avian Poultry Biol. Rev. 14, 127–149.

Outcome-based measurable ~~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.

EU comment

The EU requests an amendment of the above sentence as follows:

"Access to substrate that encourages foraging behaviour ~~activity is desirable~~ <u>should be provided</u>. ~~When provided,~~ <u>F</u>oraging areas should be designed and positioned to encourage synchronised behaviour, prevent undue competition and not cause damage or injuries."

Justification and reference as above:

DAWKINS, M. S. 1989. TIME BUDGETS IN RED JUNGLEFOWL AS A BASELINE FOR THE ASSESSMENT OF WELFARE IN DOMESTIC-FOWL. Applied Animal Behaviour Science, 24, 77-80

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.

EU comment

The EU requests an amendment of the above sentence as follows:

"Access to nesting areas ~~is desirable~~ should be provided. ~~When provided~~ ~~n~~Nesting areas should be built of suitable materials, and designed and positioned to encourage nesting, prevent undue competition and not cause damage or injuries.

Justification

Hens deprived of nests show higher levels of corticosterone and signs of stress than hens with access. Therefore, providing adequate numbers of nesting areas is deemed relevant in that context.

References

EFSA Scientific Opinion on the welfare aspects of various systems of keeping laying hens http://www.efsa.europa.eu/en/efsajournal/pub/197

Cooper, J. J., & Appleby, M. C. (1995). Nesting behaviour of hens: effects of experience on motivation. Applied Animal Behaviour Science, 42(4), 283-295.

Kruschwitz, A., Zupan, M., Buchwalder, T., & Huber-Eicher, B. (2008). Nest preference of laying hens (Gallus gallus domesticus) and their motivation to exert themselves to gain nest access. Applied animal behaviour science, 112(3), 321-330.

Alm, M., Tauson, R., Holm, L., Wichman, A., Kalliokoski, O., & Wall, H. (2016). Welfare indicators in laying hens in relation to nest exclusion. Poultry science, 95(6), 1238-1247.

COOPER, J. J. & APPLEBY, M. C. 2003. The value of environmental resources to domestic hens: A comparison of the work-rate for food and for nests as a function of time. Animal Welfare, 12, 39-52.

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

Outcome-based measurables ~~include~~: incidence of diseases, *infections*, *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].

EU comment

The EU requests an amendment of the above sentence as follows:

"Access to perches ~~is desirable.~~ should be provided.~~When provided~~ Perches should be built of suitable materials, designed, elevated and positioned to encourage perching by all layer pullets and laying hens, prevent undue competition, minimise keel bone deformation, foot problems or other injuries, and to ensure stability during perching. In

the absence of designated perches, other structures such as platforms, grids or slats that are perceived by the pullets and hens as elevated and that do not cause damage or injuries, may be a suitable alternative. ~~When provided,~~ Perches or their alternatives should be made available from an early age, be easy to clean and maintain, and be positioned to minimise faecal fouling [Hester, 2014; EFSA, 2015]".

Justification

Resting and perching are important aspects of pullet and hen welfare. Perch design and hygiene are important to avoid damage to the foot pad. All pullets and hens should be able to perch at the same time.

Scientific evidence exists demonstrating how perches should be positioned to reduce the risk of keel bone problems, pecking and aid navigation.

Further, the change to "desirable" is inconsistent with other guidance in the chapter: Art 7.Z.5. recognises that "Houses, outdoor areas and accessible equipment should be designed after considering the opportunities for layer pullets and laying hens to perform motivated behaviours".

Nesting and perching are recognised as motivated behaviours. It is therefore appropriate that the chapter maintains wording that they should be provided.

References

EFSA Scientific Opinion on the welfare aspects of various systems of keeping laying hens http://www.efsa.europa.eu/en/efsajournal/pub/197

The EFSA report states: "laying hens have a high behavioural priority to lay their eggs in a nest site that is suitable to them and to perform nest building behaviour."

The report's recommendations reflect the importance they attach to certain key behaviours. The recommendations include:

"Housing systems should provide the possibility for hens to carry out activities which are behavioural priorities.

An adequate number of discrete enclosed individual or group nests should be provided.

They should be placed so that birds can easily gain access to them.

Litter appropriate for foraging and dust-bathing should be provided in all systems and should be managed in such a way that it is friable and is readily accessible to all birds.

Perch material, design and position should be an important consideration when selecting a housing system for laying hens. Perches should be raised above the level of the floor."

EFSA Scientific Opinion Scientific Opinion on welfare aspects of the use of perches for laying hens https://www.efsa.europa.eu/en/efsajournal/pub/4131

Appleby, Michael C., and Barry O. Hughes. "Welfare of laying hens in cages and alternative systems: environmental, physical and behavioural aspects." World's Poultry Science Journal 47.2 (1991): 109-128. This paper states "Foot and claw damage are often a major problem in cages, with lesions, fissures and hyperkeratosis on the feet and with twisted, broken or overgrown claws (Tauson, 1980). These problems are affected by the thickness of the floor wire […]".

LAYWEL, 2006. Welfare implications of changes in production systems for laying hens. Deliverable 7.1: Overall strengths and weaknesses of each defined housing system for laying hens, and detailing the overall welfare impact of each housing system

The above LayWel report, produced for the European Commission states "normal nesting is a behavioural priority essential for good laying hen welfare".

The same LayWel report, produced for the European Commission states that: "perching, dustbathing and foraging are also very important parts of the normal behavioural repertoire."

Weeks, C.A. and Nicol, C.J., 2006. Behavioural needs, priorities and preferences of laying hens. World's Poultry Science Journal, 62(2), pp.296-307. This review of multiple studies concluded: "Access to a nest site is a high-ranking priority for laying hens, preferred over food at this time."

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Donaldson, C. J. and N. E. O'Connell (2012). "The influence of access to aerial perches on fearfulness, social behaviour and production parameters in free-range laying hens." Applied Animal Behaviour Science 142(1-2): 51-60.

Outcome-based measurables ~~include~~: foot problems, injurious feather pecking and cannibalism, 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, 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.

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 9 (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.

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.

Annex 9 (contd)

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Annex 10

CHAPTER 8.Y.

INFECTION WITH ANIMAL TRYPANOSOMES OF AFRICAN ORIGIN

EU comment

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

Article 8.Y.1.

General provisions

1) Animal trypanosomes of African origin is a disease complex caused by several protozoan parasites of the genus *Trypanosoma*, transmitted mainly cyclically by the genus *Glossina* (tsetse flies), but also mechanically by several biting flies (*e.g.* tabanids, *Stomoxys* spp). The disease can be caused by many different trypanosomes and can affect various mammals such as horses, donkeys, camels, goats, sheep, pigs, dogs, cats and non-human primates. ~~From the socio-economic point of view~~ The disease ~~is~~ has a ~~particularly~~ significant socio-economic impact ~~deleterious~~ ~~in~~ on cattle production. ~~Some trypanosomes of African origin (*i.e.* *T. brucei gambiense*,~~ 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 although ~~they~~ this may not always be detected ~~be evidenced~~ using routine testing methods.

3) For the purposes of this chapter, 'susceptible animals' means domestic and *wild animals* from the following families: bovidae, suidae, equidae, camelidae, canidae, felidae and non-human primates.

4) For the purposes of the *Terrestrial Code*, *infection* with animal trypanosomes of African origin is defined as an *infection* of susceptible animals with one or more Salivarian trypanosomes of the subgenus *Duttonella* (only *T. vivax*), *Nannomonas* (only *T. congolense* and *T. simiae*) and *Trypanozoon* (*T. brucei sspp* excluding *T. evansi* and *T. equiperdum*), hereafter referred to as 'pathogenic agent'.

5) *Infection*~~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 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:

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

      ii) there has been no *case* of *infection* with animal trypanosomes of African origin in the country~~,~~ or *zone* ~~or *compartment*~~.; or

   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. to 8.Y.16.

Article 8.Y.4.

Compartment free from infection with animal trypanosomes of African origin

The establishment and bilateral recognition of a *compartment* free from *infection* with animal trypanosomes of African origin should follow the provisions laid down in this chapter and in Chapters 4.4. and 4.5.

Susceptible animals in the free *compartment* should be protected against the *vectors* by the application of an effective *biosecurity* management system.

Article 8.Y.5.

Recovery of free status

Should a *case* of *infection* with animal trypanosomes of African origin occur in a previously free country or *zone*, its status may be recovered after the following:

1) infected *animals* have been isolated and then immediately treated, slaughtered, or killed and appropriately disposed of;

2) *animals* in contact with infected *animals* have been put immediately under ~~*vector-*~~protection 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 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 10 (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;

2) the semen used for the production of embryos complied with the provisions of Article 8.Y.7. or Article 8.Y.8.;

3) the embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.

Article 8.Y.10.

Recommendations for importation from countries or zones infected with animal trypanosomes of African origin

For *in vivo* derived embryos and for *in vitro* produced embryos

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

1) the donor females:

a) were kept in isolation in a *vector*-protected *collection centre* for at least 90 days prior to the collection;

b) were subjected, with negative results, to an agent identification test and an ELISA test for antibody detection adapted to the epidemiological situation on samples collected at entrance to the *vector*-protected *collection centre* and at least 90 days after the first test;

c) showed no clinical signs of *infection* with animal trypanosomes of African origin on the day of collection;

2) the semen used for the production of embryos complied with the provisions of Article 8.Y.7. or Article 8.Y.8.;

3) the embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.

Article 8.Y.11.

Recommendations for importation from countries, zones or compartments free from infection with animal trypanosomes of African origin

For meat

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

1) were kept since birth in a free country, *zone* or *compartment* or were imported from a free country, *zone* or *compartment*;

2) have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 8.Y.12.

Recommendations for importation from countries or zones infected with animal trypanosomes of African origin

For meat

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

1) comes from *animals* which have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results; and

2) either:

a) has been kept at a temperature lower than + 4°C for a minimum period of five days; or

~~b) has been subjected to any procedure of equivalent efficacy recognised by the *Veterinary Authority*.~~

Article 8.Y.~~13~~7.

Introduction to surveillance

Articles 8.Y.~~13~~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* 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~~*w*ildlife 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 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 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 animal trypanosomes of African origin should be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated.

The results of random or targeted surveys are important in providing reliable evidence that no *infection* with animal trypanosomes of African origin is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results considering the movement history of the *animals* being sampled.

An active programme of *surveillance* of susceptible populations to detect evidence of *infection* with animal trypanosomes of African origin is essential to establish the *animal health status* of a country or *zone*.

1. Clinical surveillance

   Clinical *surveillance* aims to detect clinical signs of *infection* with animal trypanosomes of African origin in susceptible animals, particularly during a newly introduced *infection*. However, neither clinical nor post-mortem signs of *infection* with animal trypanosomes of African origin are pathognomonic. Therefore, 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 10 (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 parasite at the subgenus level;

c) confirm active *infection* after positive serological results.

3. Molecular techniques

Molecular techniques increase the sensitivity of the detection of active *infections*. They can also be applied to identify the parasite and to better characterise the genotype of circulating 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 to cross reactions with *T. evansi, T. equiperdum, T. cruzi* and *Leishmania* spp, the presence of these pathogenic agents should be considered when interpreting the results of the serological *surveillance* system.

c) Serological *surveillance* can be used to:

i) demonstrate individual or population freedom;

ii) evidence subclinical or latent *infection* by animal trypanosomes of African origin;

iii) determine by seroprevalence the magnitude of *infection* by animal trypanosomes of African origin in the host population.

d) Positive test results can have ~~four~~ different possible causes:

i) ~~active~~ *infection*;

ii) antibodies from previous *infection* (after effective treatment or self-cure);

iii) maternal antibodies;

iv) cross reactions with *T. evansi, T. equiperdum, T. cruzi* and *Leishmania* spp.

5. Sentinel animals

Sentinel *surveillance* may provide evidence of freedom from *infection* or provide data on *prevalence* and *incidence* as well as the distribution of disease or *infection*. Sentinel *surveillance* may consist of:

a) the identification and regular testing of one or more of sentinel animal units of known health or immune status in a specified geographical location to detect the occurrence of *infection* with animal trypanosomes of African origin;

b) the investigation of clinical suspect *cases* targeting highly susceptible animals such as dogs, donkeys or horses.

6. Vector surveillance

This point should be read in conjunction with Chapter 1.5.

For the purposes of this chapter, *vector surveillance* aims at determining different levels of *risk* by identifying the ~~various *vector* species~~ presence and abundance of various *vector* species in an area or by demonstrating the absence of *vectors*.

Demonstration of absence of 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 consider the size and ecological characteristics of the area to be surveyed.

When sentinel *animals* are used, *vector surveillance* should be conducted at the same locations.

Article 8.Y.~~16~~10.

Additional surveillance procedures for recovery of free status

In addition to the general conditions described in this chapter, a Member Country seeking recovery of country or *zone* free status, including a *containment zone* established in accordance with Article 4.4.7., should show evidence of an active *surveillance* programme to demonstrate absence of *infection* with animal trypanosomes of African origin.

Populations under this *surveillance* programme should include:

1) *establishments* in the proximity of the *outbreak*;

2) *establishments* epidemiologically linked to the *outbreak*;

3) *animals* moved from or used to re-populate affected *establishments*.

Annex 11

CHAPTER 9.4.

INFESTATION WITH *AETHINA TUMIDA* (SMALL HIVE BEETLE)

[…]

EU comment

The EU thanks the OIE for having taken some of its comments into account. However, we reiterate our concern over one of the changes to this chapter as proposed. A comment is inserted in the text below.

Article 9.4.5.

Recommendations for the importation of individual consignments containing a single live queen bee, accompanied by a small number of associated attendants (a maximum of 20 attendants per queen)

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

1) the bees come from *apiaries* situated in a country or *zone* free from *A. tumida*;

OR

2) the bees come from hives or colonies which were inspected ~~immediately prior to dispatch~~ ~~on the day of~~ 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

EU comment

The EU reiterates its previous comment regarding its preference for keeping of the 100 km radius. Reduction of the radius increases the risk that *A. tumida* circulates in the area surrounding the honeybee colonies producing the queens, when it is otherwise circulating beyond that circle. We consider that any reduction of the number of kilometres should not merely be based on empirical evidence from one member, but on clear scientific evidence on how far small hive beetle can fly or be transported by the wind. In lack of such, status quo should remain.

Indeed, the European Food Safety Authority, in its 2015 scientific opinion on survival, spread and establishment of the small hive beetle, described the effect of radius on the probability of SHB to escape the surveillance zone. According to the 'distance-only' model used, the median probability that an outbreak would spread beyond a surveillance zone with a radius of 100 km is 0.027 (0.95 credible interval (CI) 0.019–0.041), while reducing the radius of the surveillance zone to 50 km increases this probability to 0.053 (0.95 CI 0.037–0.08). Furthermore, the probabilities of escape for simulations of the 'distance-only' model were estimated to be 0.126 (0.95 CI 0.055–0.20)

and 0.0003 (95 CI 0–0.005) at 50 km and 100 km, respectively. The conclusion of EFSA was the following:

"When choosing the radius for the surveillance zone, it is necessary to balance two competing factors. A smaller radius might allow more intensive surveillance and, hence, increase the likelihood of detecting infested apiaries within the surveillance zone. It could also make controls on movements within the zone more feasible. However, a smaller radius also increases the likelihood of a SHB escaping the surveillance zone into a region that is not under surveillance, possibly delaying detection."

Reference: EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), 2015. Scientific opinion on the survival, spread and establishment of the small hive beetle (*Aethina tumida*). EFSA Journal 2015;13(12):4328, 77 pp. (see section 3.5.1. on p. 41, https://www.efsa.europa.eu/en/efsajournal/pub/4328).

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 12

CHAPTER 10.4.

INFECTION WITH HIGH PATHOGENICITY AVIAN INFLUENZA VIRUSES

EU comment

The EU thanks the OIE for taking into consideration our previous comments. We support the proposed changes to this 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 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 12 (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.

Annex 12 (contd)

Article 10.4.11.

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

For eggs for human consumption

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

1) the eggs for human consumption were produced and packed in a country, *zone* or *compartment* free from high pathogenicity avian influenza;

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

Article 10.4.12.

Recommendations for the importation of egg products from poultry

Regardless of the high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) the egg products are derived from eggs which meet the requirements of Article 10.4.11.; or

2) the egg products have been processed to ensure the inactivation of high pathogenicity avian influenza viruses, in accordance with Article 10.4.18.;

AND

3) the necessary precautions were taken to avoid contact of the egg products with any source of high pathogenicity avian influenza viruses.

Article 10.4.13.

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

For fresh meat of poultry

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

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

2) which were slaughtered in an approved *slaughterhouse/abattoir* in a country, *zone* or *compartment* free from high pathogenicity avian influenza and were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., with favourable results.

Article 10.4.14.

Recommendations for the importation of meat products from poultry

Regardless of the high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) the *meat products* from *poultry* are derived from *fresh meat* which meets the requirements of Article 10.4.13.; or

2) the *meat products* from *poultry* have been processed to ensure the inactivation of high pathogenicity avian influenza viruses in accordance with Article 10.4.19.;

AND

3) the necessary precautions were taken to avoid contact of the *meat products* from *poultry* with any source of high pathogenicity avian influenza viruses.

Article 10.4.15.

Recommendations for the importation of poultry products not listed in Article 10.4.1bis. and intended for use in animal feeding, or for agricultural or industrial use

Regardless of the high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) these *commodities* were obtained from *poultry* which originated in a country, *zone* or *compartment* free from high pathogenicity avian influenza and that the necessary precautions were taken to avoid contamination during processing with any source of high pathogenicity avian influenza viruses;

OR

2) these *commodities* have been processed to ensure the inactivation of high pathogenicity avian influenza viruses using:

   a) moist heat treatment for 30 minutes at 56°C; or

   b) heat treatment where the internal temperature throughout the product reached at least 74°C; or

   c) any equivalent treatment that has been demonstrated to inactivate avian influenza viruses;

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of high pathogenicity avian influenza viruses.

Article 10.4.16.

Recommendations for the importation of feathers and down from poultry not listed in Article 10.4.1bis.

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

1) these *commodities* originated from *poultry* as described in Article 10.4.13. and were processed in a country, *zone* or *compartment* free from high pathogenicity avian influenza; or

2) these *commodities* have been processed to ensure the inactivation of high pathogenicity avian influenza viruses using one of the following:

   a) fumigation with formalin (10% formaldehyde) for 8 hours;

   b) irradiation with a dose of 20 kGy;

   c) any equivalent treatment which has been demonstrated to inactivate avian influenza viruses;

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of high pathogenicity avian influenza viruses.

Annex 12 (contd)

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.

Annex 12 (contd)

There is an increased recognition of the value of the application of sequencing technologies and phylogenetic analyses to determine routes of introduction, transmission pathways and epidemiological patterns of *infection*. When avian influenza viruses are detected, Member Countries should apply these technologies, when possible, to enhance the evidence used to develop specific *surveillance* strategies and control activities.

A *monitoring* system for low pathogenicity avian influenza viruses in *poultry* should be in place for the following reasons:

1) ~~Some~~ H5 and H7 low pathogenicity avian influenza viruses have the potential to mutate into high pathogenicity avian influenza viruses, 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 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*;

c) *poultry* used to re-populate affected *establishments*;

d) any *establishments* where preventive depopulation has been carried out.

Article 10.4.22bis.

Surveillance of wild bird populations

Passive *surveillance*, i.e. sampling of birds found dead, is an appropriate method of *surveillance* in *wild* birds because *infection* with high pathogenicity avian influenza can be associated with mortality in some species. Mortality events, or clusters of birds found dead should be reported to the local *Veterinary Authorities* and investigated, including through the collection and submission of samples to a *laboratory* for appropriate tests.

Active *surveillance,* i.e. sampling of live *wild* birds, may be necessary for detection of some strains of high pathogenicity avian influenza viruses that produce *infection* without mortality in *wild* birds. Furthermore, it increases knowledge of the ecology and evolution of avian influenza viruses.

Surveillance in *wild* birds should be targeted towards times of year, species and locations in which *infection* is more likely.

Surveillance in *wild* birds should be enhanced by raising awareness, and by active searching and *monitoring* for dead or moribund *wild* birds when high pathogenicity avian influenza has been detected in the region. The movements of migratory water birds, in particular ducks, geese and swans, should be taken into account as a potential pathway for introduction of virus to uninfected areas.

Article 10.4.22ter.

Monitoring of low pathogenicity avian influenza in poultry populations

Outbreaks of low pathogenicity avian influenza viruses can be managed at the *establishment* level; however, spread to other *poultry establishments* increases the risk of virus mutation, particularly if it is not detected and managed. Therefore, a *monitoring* system should be in place.

Monitoring the presence and types of low pathogenicity avian influenza viruses can be achieved through a combination of clinical investigation when *infection* is suspected because of changes in production parameters, such as reductions in egg production or *feed* and water intake, and active serological and virological *surveillance*, which can be supported by the information obtained by the *surveillance* system for high pathogenicity avian influenza.

Serological and virological *monitoring* should aim at detecting clusters of infected *flocks* to identify spread between *establishments*. Epidemiological follow-up (tracing forward and back) of serologically positive *flocks* should be carried out to determine whether there is clustering of infected *flocks* regardless of whether the seropositive birds are still present at the *establishment* or whether active virus *infection* has been detected. Hence, *monitoring* of low pathogenicity avian influenza will also enhance early detection of high pathogenicity avian influenza.

Annex 13

CHAPTER 10.5.

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

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. One comment is inserted in the text below.

Article 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.

EU comment

The EU welcomes the amendments proposed in point 3 above, specifying that a serological test should be done at the beginning of the quarantine period. However, there is a risk that antibiotics are administered to the birds during the quarantine period that must be taken into account. Indeed, such treatment could mask an ongoing infection acquired shortly before entering the quarantine station, leading to false negative results in the agent identification test performed at the end of the quarantine period. We would therefore like to suggest that, instead of the test combination proposed above, <u>both</u> a serological and an agent identification test are performed at the <u>end</u> of the quarantine period, as follows:

"3) were kept in a quarantine station for the 28 days prior to shipment and were subjected to <u>a serological test for avian mycoplasmosis with negative results at the beginning of the 28-day period and</u> a serological test and an agent identification test for avian mycoplasmosis with negative results~~, 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 14

CHAPTER 12.6.

INFECTION WITH EQUINE INFLUENZA VIRUS

EU comment

The EU supports the proposed changes to this chapter.

Editorial comment: the article number at the top of the text should not be deleted (i.e. "Article 12.6.6." should not be presented as strike-through).

[...]

~~Article 12.6.6.~~

Recommendations for the importation of domestic equids for unrestricted movement

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

1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its *vaccination* status should be included in the veterinary certificate;

OR

2) ~~came from a country, *zone* or *compartment* not known to be free from EI,~~ were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and

3) were ~~immunised~~ vaccinated in accordance with the recommendations of the manufacturer with a vaccine complying with the standards described in the *Terrestrial Manual* and considered effective against the epidemiologically relevant virus strains, ~~between 21 and 90 days before shipment either with a primary course or a booster; information on their *vaccination* status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12.~~ in accordance with one of the following procedures:

   a) between 14 and 90 days before shipment either with a primary course or a booster; or

   b) between 14 and 180 days before shipment, if they are older than four years of age, ~~previously~~ having received up to the date of this pre-shipment *vaccination*, at least four doses of ~~the same~~ vaccine at intervals not greater than 180 days.

Information on the *vaccination* status should be included in the *international veterinary certificate* or the passport in accordance with Chapter 5.12. as relevant.

~~For additional security, c~~Countries that are free ~~of~~ from EI or undertaking an eradication programme may also request that the domestic equids were ~~tested negative for EIV by~~ subjected to an agent identification test for EI described in the *Terrestrial Manual* with negative results, conducted on samples collected on two occasions, ~~at 7 to 14 days~~ four to six days after commencement of pre-export isolation and ~~less than 5~~ ~~prior to~~ within four days ~~before of~~ prior to shipment.

[...]

Annex 15

GLOSSARY

EU comment

The EU in general supports the proposed changes to the Glossary. One comment is inserted in the text below.

COMPETENT AUTHORITY

means ~~the *Veterinary Authority* or other~~ a Governmental Authority of a Member Country ~~having the responsibility and that has competence for ensuring or supervising~~ having responsibility in the whole or part of the territory for the implementation of ~~animal health and *welfare* measures, international veterinary certification and other~~ ~~any~~ certain standards ~~and recommendations~~ of ~~in~~ the *Terrestrial Code* ~~and in the OIE *Aquatic Animal Health Code* in the whole territory, which are not under the competence of the *Veterinary Authority*~~.

VETERINARY AUTHORITY

means the Governmental Authority of a Member Country~~, comprising the OIE Delegate, *veterinarians*, other professionals and paraprofessionals,~~ having the primary responsibility in the whole territory ~~and competence~~ for coordinating ~~ensuring or supervising~~ the implementation of ~~animal health, and *animal welfare* and veterinary public health measures, international veterinary certification and other~~ the standards ~~and recommendations~~ of ~~in~~ the *Terrestrial Code* ~~in the whole territory~~.

VETERINARY SERVICES

means the combination of ~~the~~ governmental and non-governmental individuals and organisations that perform activities to implement ~~animal health, and *animal welfare* and veterinary public health measures and other~~ the standards ~~and recommendations~~ of ~~in~~ the *Terrestrial Code* ~~and the OIE *Aquatic Animal Health Code* in the territory. The Veterinary Services are under the overall control and direction of the *Veterinary Authority*. Private sector organisations, *veterinarians*, *veterinary paraprofessionals* or aquatic animal health professionals are normally accredited or approved by the *Veterinary Authority* to deliver the delegated functions~~.

EU comment

The EU suggests mentioning organisations first, then individuals (for the definition to read "… governmental and non-governmental organisations and individuals …"). Indeed, VS are more commonly organisased in governmental or non-governmental organisations, than at individual level.

Edited definitions in clean text:

COMPETENT AUTHORITY

means a Governmental Authority of a Member Country having responsibility in the whole or part of the territory for the implementation of certain standards of the *Terrestrial Code*.

VETERINARY AUTHORITY

means the Governmental Authority of a Member Country having the primary responsibility in the whole territory for coordinating the implementation of the standards of the *Terrestrial Code*.

VETERINARY SERVICES

means the combination of governmental and non-governmental individuals and organisations that perform activities to implement the standards of the *Terrestrial Code*.

Annex 16

CHAPTER 8.14.

INFECTION WITH RABIES VIRUS

EU comment

The EU cannot support the proposed changes to this chapter.

The proposed changes concern the waiting period after the 30-day blood sampling and subsequent antibody titration test prior to the international movement of the dog. This waiting period is presently at least 3 months after the blood sampling. The new Article 8.14.6bis. proposes to reduce this waiting period from the current three months to 30 days.

This amendment is based on a concept paper endorsed by the OIE Scientific Commission for Animals Diseases at its February 2020 meeting that, according to the SCAD, "*provides scientific evidence on the safety of shipment of dogs from infected countries or zone after one month from date of rabies vaccination, and commended its scientific quality. The Commission also acknowledged that a reduction in the post-titre waiting period from the current 3 months may reduce incentives for illegal movement*" (https://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/SCAD/A_SCAD_Feb2020.pdf, p. 5).

This concept paper (Annex 15 of the above SCAD meeting report, p. 71-78) has been assessed by the EURL for rabies (ANSES, France). The main conclusion of the EURL for rabies is that:

"*It should be noted that several papers have been cited in this report, which did not correspond to specific studies in link with the question raised here whereas some other major papers were not considered. It is also important to note that the report does not contain any new study on the pathogenicity of rabies in natural conditions. Moreover, the authors used data from published papers (in particular the paper of Cho* et al.*, 1989) which cannot be used so easily as done in the document (see above the details). The report contains many mistakes and the limitations and bias of the interpretations are not mentioned. Certain conclusions are indeed not correct because based on insufficient or not appropriate data, hence neither the data analysis nor the content of the discussions are sufficiently rigorous and convincing for allowing a change in the current regulation*".

Therefore, the EU would request that additional scientific evidence is provided to support the proposed change.

The full report of the EURL for rabies is appended to this Annex 16.

Article 8.14.6bis.

Recommendations for importation of dogs from countries or zones infected with rabies virus

Veterinary Authorities should require the presentation of an *international veterinary certificate* complying with the model of Chapter 5.11. attesting that the dogs:

1) showed no clinical sign of rabies the day prior to or on the day of shipment;

2) were permanently identified and their identification number stated in the certificate;

3) and either:

a) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the *Terrestrial Manual* and were subjected, not less than 30 days and not more than 12 months prior to shipment, to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5 IU/ml;

or

b) were kept in a *quarantine station* for six months prior to shipment.

Article 8.14.7.

Recommendations for importation of ~~dogs,~~ cats and ferrets from countries or zones infected with rabies virus

Veterinary Authorities should require the presentation of an *international veterinary certificate* complying with the model of Chapter 5.11. attesting that the animals:

1) showed no clinical sign of rabies the day prior to or on the day of shipment;

2) were permanently identified and their identification number stated in the certificate;

3) and either:

a) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the *Terrestrial Manual* and were subjected not less than 3 months and not more than 12 months prior to shipment to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5 IU/ml;

or

b) were kept in a *quarantine station* for six months prior to shipment.

21 August 2020

OPINIONS ON THE ANNEX 15 OF THE MEETING REPORT OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES (PARIS, 3–7 FEBRUARY 2020)

Introduction

The report provided in the Annex 15 of the Report of the meeting of the OIE Scientific Commission for Animal Diseases held in Paris on 3–7 February 2020 concerns the waiting period prior to the pet movement.

Currently, in the OIE Terrestrial Code, the pets should be subjected not less than 3 months and not more than 12 months prior to shipment to an antibody titration with a positive result (≥ 0.5 IU/mL). According to the regulation (EU) N° 576/2013, the serological test must be carried out on a sample collected at least 30 days after the date of vaccination and not less than three months before the date of movement.

The report proposes to reduce this waiting period prior to the movement from three months, according to the OIE Terrestrial Code, to 30 days.

The UK has maintained its rabies-free status since 1922, initially by a six-month quarantine and since 2000 by a combination of the Pet Travel Scheme and quarantine. The advisory group on quarantine (Kennedy 1998), following recommendations by OIE (OIE, 1997), proposed a six-month delay for dogs and cats to re-enter the UK after primary vaccination ("immunological quarantine"). This was implemented to prevent the possible import of an animal that had been infected before it was vaccinated (Fooks and McElhinney 2000). Since January 2012, pets being imported from "unlisted" countries have to be vaccinated, blood tested a month later, and following a further three-month wait in the country of origin, they may enter the UK with the appropriate certification. Between 1993 and 2000, many rabies free countries have alleviated their quarantine measures and adopted a scheme requiring a vaccination followed by a serological control and a waiting period prior to the animal movement (Wasniewski et al., 2019).

The waiting period between vaccination and import is crucial (Wilsmore et al., 2006), because vaccination does not prevent disease developing in already infected animals: Blancou et al. (1989) demonstrated that vaccination in an already infected animal does not significantly alter the clinical picture or development time of the disease. Therefore, it is possible that an animal infected prior to rabies vaccination would continue to incubate the disease despite developing a significant antibody titre (Fooks and McElhinney 2000). The risk that an animal is incubating disease at the time of vaccination is the same as the risk that an unvaccinated animal is incubating disease when it is imported, thus, the overall risk is very sensitive to the waiting period. It is also very sensitive to compliance with requirements (e.g. shorter than required wait, incorrect or no vaccination, falsified test result) (Wilsmore et al., 2006).

On request of the European Commission, this document is an analysis of the Annex 15 (pages 71 – 78) of the Report of the meeting of the OIE Scientific Commission for Animal Diseases.

Rationale 1

First bullet point : The study mentioned in 2017 was conducted by Wallace on dogs under one year of age only. It confirmed previous older papers (e.g. Sage et al., 1993, Sugiyama et al., 1997, Cliquet et al., 2003, Mansfield et al., 2004) demonstrating on large populations of dogs, whatever their ages, that the best period for measuring rabies neutralizing antibodies is not one week after primary vaccination, it is around 30 days following primary vaccination, which corresponds to the peak of VNA. This does not contribute to the discussion, as this report does not deal with the period of the blood sampling after vaccination.

Figure 1: The 3 graphs, allowing to compare Type A and Type B risks according to vaccination, antibody production and waiting period are unclear, we do not understand what the 3 graphs are demonstrating. Furthermore, we do not know which data were used to build them: either the data obtained by Wallace et al (2017) as mentioned in the first bullet point (p.75) or the data from the Table 1 as mentioned in the Rationale 2 (p.76) or maybe both of them.

No definition was given on what is Type A risk and Type B risk, so it is difficult to understand. Is it the definition given in the Rationale 2? If we consider the definitions given in Rationale 2, it is absolutely unclear for us as the Type B definition is the same than for the Type A, i.e. the animal is infected prior to the primary vaccination but does not develop an immune response and succumbs to rabies. For this Type B, no problem, the animal tested is not eligible for movements as it is below the 0.5 IU/mL level, so we do not understand this definition. In Rationale 1, the Type B risk concerns only unvaccinated dogs receiving a RABV challenge. There is no reference to a vaccination step after the challenge, contrary to the definition given in Rationale 2. The case of an animal infected after vaccination has not been considered (it was considered in the EFSA document).

Second bullet point (named Type A risk): The paper of Cho (1989) was designed to investigate the post-exposure treatments of dogs. All the study of Cho was done by injecting to dogs a human diploid cell vaccine for human use. The reference to 34 dogs is not correct, it was 32 dogs. Moreover, out of the 32 dogs, 16 received HRIG (human immunoglobulins) and vaccine, mimicking a post-treatment after infection. Obviously, these dogs do not correspond to the current immunization protocols, hence these 16 dogs have not to figure in the Table 1. Only 8 experimental dogs could be possibly considered here, which were infected, then vaccinated with a human vaccine into the femoral muscle of the leg at different times after infection (6 different times, from 6 hours to 90 days) for a total of 8 dogs, meaning that the number of dogs for each time was quite low). The dogs all died between 12 and 15 days, and we do not know at which times was given the vaccine. Furthermore, the VNA were measured by using the mouse neutralization test (MNT). The use of different serologic tests in the results of the Table 1 makes much more complicated the analysis. In particular, the MNT is quite different from the *in vitro* SNT.

It should be noted that the titles of the Table 1 are incorrect as it reports data of 11 unvaccinated dogs (and not 10) and of vaccinated dogs as well. Furthermore, in addition to ELISA and RFFIT, the MNT was used and not mentioned.

Third bullet point (named Type B risk) : here it seems that the Type B concerns only unvaccinated dogs. This underlines a problem of data consistency in this report as in Rationale 2, the Type B risk concerns animal vaccinated after a RABV challenge.

The antibody production of unvaccinated animals is fewly documented, except in some experimental studies such as those of Fekadu and Manickam, by using the data of the control groups. The dogs die

within a short time following rabies antibody production, which is quite low (not robust as written in the report), as seen in the paper of Manickam. In this last paper, the dog that succumbed to the infection despite rabies antibody production died 18 days and not 7 as mentioned in the report (it makes a difference) after a blood sampling done at D14; it should be noted that the blood sampling D28 as well as D7 were negative. It should also be mentioned that we do not know if the 4 dogs survived to rabies, the authors mention in their paper that the dogs were "sacrificed 90-day post-challenge" and "they survived the 90 days of observation". Some dogs of this study died after a long time, i.e. D40, D46 and D58.

Fourth bullet point (Figure 2): In the caption of the Figure 2, it is mentioned that the data were obtained from 27 and 5 studies (32 studies), representing 490 dogs (217+273), whereas in the Fourth bullet point, it is mentioned that the data were aggregated from 203 dogs, across 30 studies. Moreover, there is no clear legend describing the 3 graphs (a, b and c). Some words concerned the graph b only. The most important information to retain is that around 5% of unvaccinated dogs were alive after 30 days after exposure and still incubated the disease. We have no idea if these dogs produced rabies antibodies and when they died exactly after rabies exposure.

Rationale 2

First paragraph : the authors resume in two sentences the risk assessment studies (Goddard et al., 2012 and EFSA, 2006). In these studies, different approaches were used, with infected countries grouped in different categories according to the rabies risk. In the EFSA report, the Type B definition was not the one which is given by the authors (which is the same than for the Type A), the Type B of the EFSA report corresponded to a vaccinated animal infected during the waiting time (therefore after vaccination).

Second paragraph : here again the study of Cho is mentioned. The data discussed here concern one dog succumbing to rabies 20 days post-vaccination, up to 14 after a positive antibody response. This dog, as mentioned in Rationale 1 (see above), is part of a group of dogs infected experimentally with rabies and receiving HRIG (20 IU/kg) and a human vaccine. We cannot interpret these data in the frame of this discussion as the protocol is completely different, the authors were investigated a model of post-exposure treatment for dogs, looking for the effect of HRIG in combination or not with a human vaccine in previously infected dogs.

Third paragraph : we would be interested to see how the Figure 1 was done in view of the data recorded in the Table 1, which reports many different studies, most of them being not appropriate here. Indeed, the only data to be considered in this Table 1 which are in line with the subject of this discussion are those corresponding to the 8 dogs of the study of Cho (dogs quoted as Cv, they are the last ones of the Table 1). However these dogs were vaccinated by using a human vaccine, injected into the femoral muscle, and the titration of rabies antibodies were undertaken by an old technique (MNT) which lacks of precision, this test is no longer recommended.

Fourth paragraph : it should be noted that the data of Cho et al., which are extensively described here (in fact they are the only ones to approximately correspond to the question raised here, however only the 8 experimental dogs, with all the limitations already mentioned above) where not used in the modeling methods done by Goddard et al. and also by Have et al. (EFSA report, 2006).
The incubation period of 38-day corresponds to strong scientific data gathered in natural conditions and also with experimentally infected dogs (Jones et al. 2005) (at least 10 papers, including the review book named "Kennedy report" with an extensive review of the literature, in which the paper of Cho was not included)

Discussion

The waiting time following vaccination has been established to reduce risk by an amount related to the distribution of rabies incubation period. The incubation period (the time from initial viral exposure at first demonstration of clinical signs) is dependent upon viral dose, route and strain as well as the site of inoculation. Concentrated inoculum of virus produces a short period of incubation and a rapid course of the disease (EFSA, 2006). In experimental dogs, high infectious doses of virus are generally used, shortening the incubation period. The true incubation period of rabies in naturally infected dogs is very difficult to define as there is no knowledge on the true date of infection (Goddard et al., 2012). Fekadu (1988 and 1993) published data showing incubation periods from a week to several months. This expert explained that long incubation periods may be observed in naturally infected animals as a result of very small doses of inoculated rabies virus (as also Tierkel et al., 1949). It should be noted that the mean period of 38 days, calculated by Jones et al. (2005), has a standard deviation of 45 days. During the risk assessment done with data collection, the authors (Jones et al., 2005) mentioned that generally, shorter incubation periods were found in experimentally infected dogs (less than 70 days) whereas dogs issued from quarantine dying of rabies had longer periods of incubation (2-234 days). The waiting time of 4 months after vaccination was therefore chosen in consideration of all information available. Indeed, it appears that there is justification for a shorter than six months wait between serological test and import (Wilsmore et al., 2006). Moreover, the minimum four-month waiting period, as stipulated in EU regulations, is greater than the reported range of incubation periods and should ensure that an animal infected before vaccination would develop clinical disease before the four-month period elapses (Wilsmore et al., 2006).

The authors of the document explained (page 71) a recent change in the legislation of Hawaii. They omitted to mention a major point, which is that in a primary vaccinated pet, at least two rabies vaccinations must be done and there must be an interval of one month (30 days) or more between the two required vaccinations. A minimum waiting period after the most recent rabies vaccination as well as a successful FAVN rabies antibody test before arriving in Hawaii is performed at 30 days. This regulation is more severe than those proposed by the authors of this report as animals must be boosted to be authorized to move at least two months following the first vaccination. Recent deep risk assessment studies not mentioned in the report were performed in Japan (Kwan et al., 2017; Takahashi et al., 2008, for review Cliquet et al., 2018). The recent study of Kwan et al., 2017 suggested to reduce the waiting time from six to four months after vaccination and to reduce the number of vaccination required (two vaccinations were compulsory), highlighting the efficiency of the current system using a four month waiting time following vaccination.
For animal movements out of an area with non-negligible risk, the EFSA recommended the usefulness of a booster vaccination for a better risk reduction as an additional required measure in combination with a waiting period of more than 100 days (EFSA 2006, https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2007.436).

The authors did not mention a recent paper (Ribadeau Dumas et al., 2017), reporting during 2001–2013 a total of 21 animal rabies cases attributed to pets in Western Europe from rabies-enzootic countries. Of 19 transported rabid pets, 8 (42%) had no rabies vaccination, pet passport, or health certificate. Only 6 were vaccinated. Most vaccinated pets did not comply with recommended age for vaccination (>12 weeks of age) or time between vaccination, serologic analysis, and transport. Generally, people willing to fraud do not vaccinate their dogs (https://www.anses.fr/fr/content/avis-et-rapport-de-lanses-relatif-%C3%A0-%C2%AB-l%E2%80%99interpr%C3%A9tation-des-r%C3%A9sultats-de-titrages-des, Klevar et al., 2015; Rota Nodari et al., 2017).

It should be noted that several papers have been cited in this report, which did not correspond to specific studies in link with the question raised here whereas some other major papers were not considered. It is also important to note that the report does not contain any new study on the pathogenicity of rabies in natural conditions. Moreover, the authors used data from published papers

(in particular the paper of Cho et al., 1989) which cannot be used so easily as done in the document (see above the details). Cats have not been considered in this study, the incubation period commonly described is 9 days to 6 months (Jones et al., 2002; Jones et al., 2005). The report contains many mistakes and the limitations and bias of the interpretations are not mentioned. Certain conclusions are indeed not correct because based on insufficient or not appropriate data, hence neither the data analysis nor the content of the discussions are sufficiently rigorous and convincing for allowing a change in the current regulation.

If a need for alleviating the current regulation is required, an expert group, including expert epidemiologists, mandated to conduct a risk assessment could investigate one or different possible scenarios to provide scientific evidence for policy decisions relating to rabies. Adopting a scheme of a double vaccination in primary vaccinated animals (in the past it was recommended to boost primo-vaccinated animals) could probably be one of the alternatives, allowing to slightly reduce the waiting time.

Dr Florence Cliquet

Dr Marine Wasniewski

This report reflects the views of the authors and not necessarily those of Anses

Annex 17

CHAPTER 7.7.

DOG POPULATION MANAGEMENT

EU comment

The EU welcomes and in general supports the revision of Chapter 7.7.

Comments are inserted in the text below.

Article 7.7.1.

Introduction

Dog Population Management (DPM) refers to the holistic approach that aims to improve the welfare of dogs, reduce problems they may present and create harmonious co-existence with people and their environment. Dogs are present in every human society around the world and valued for the range of roles they fulfil. However, they can present public health and safety and animal health and *animal welfare* issues, especially when free to roam.

DPM is an integral part of effective and sustainable rabies control programmes and control of other zoonoses. Recognising that mass culling is ineffective and may be counterproductive, reducing dog population size is not an effective means of reducing rabies *prevalence* [WHO, 2018].

EU comment

The EU would like to propose the following revision:

"DPM is an integral part of effective and sustainable rabies control programmes and control of other zoonoses. Recognising that mass culling is ineffective and may be counterproductive, reducing dog population size by killing is not an effective means of reducing rabies *prevalence."*

Justification

Reducing dog population size by castration is effective but killing is not.

"The Effectiveness of Dog Population Management: A Systematic Review".
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6940938/

Although all methods decreased population size, fertility control had the greatest effect in both observational studies [68,69,83,84] and modelling studies [69,85,86,87,88,89,90]. Fertility control decreases dog population size by preventing births, therefore allowing a reduction of numbers as natural deaths occur. This is in contrast with culling and sheltering, which reduce the population size through the removal of individuals, either through death or the moving of dogs into a shelter population. When fertility control was combined with other methods, such as movement restriction and sheltering, synergistic effects were reported [89]. By increasing the rate of fertility control and restriction status of dogs, this would both reduce the opportunities for reproduction and therefore potentially reduce the birth rate even greater than if fertility control had been used alone. Culling, by increasing the death rate of a population, may cause a rapid reduction in population numbers [85,88]. The culling method has been criticised as ineffective at reducing populations over longer periods of time [88]. This was supported by modelling studies that directly compared fertility control and culling. These papers

found that, although culling resulted in an initial decrease in dog population size (e.g., a five-year period [88]), fertility control was more effective at reducing the population size over longer periods of time (e.g., a 20-year period) [85,88].

However, DPM can contribute to rabies control by reducing population turnover, therefore supporting maintenance of herd immunity within a vaccinated dog population. The components of turnover most relevant for rabies are the reduction in the birth of unwanted puppies that would be at risk of remaining unvaccinated, and improving welfare and life expectancy of vaccinated dogs.

Reproduction control as part of DPM also reduces breeding behaviours which may increase the *risk* of rabies transmission due to increased contact rates between dogs.

Promotion of *responsible dog ownership* as part of DPM can strengthen owner motivation, knowledge and therefore behaviour in caring for their dogs, including timely rabies *vaccination* of *owned dogs* to maintain immunity.

The OIE recognises the importance of managing dog populations without causing unnecessary animal suffering.

Article 7.7.2.

Scope

The scope of this chapter is to provide recommendations for the management of dog *(Canis lupus familiaris)* populations to improve human health and safety, animal health and *animal welfare* and to minimise their potential negative socio-economic and environmental impacts. The recommendations will also assist Members in the implementation of zoonotic disease control programmes such as *infection* with rabies virus in accordance with Chapter 8.14.

Article 7.7.3.

Guiding principles

Building upon the guiding principles described in Chapter 7.1., the following apply:

– DPM has direct benefits to public health and safety, and animal health and welfare.

– Dogs are domesticated species and therefore dependent on human communities, thus there is an ethical responsibility to ensure their health and welfare even in the absence of ownership.

– Recognising diversity of stakeholders in the management of dog populations, it is crucial to clarify roles and responsibilities.

– Dog ecology is linked with human activities. Therefore, effective management of dog populations should be accompanied by changes in human behaviour, including promotion of *responsible dog ownership.*

– Acknowledging that the *owned dog* population is a common source of free-roaming dogs, DPM programmes should consider all dogs.

– Understanding local dog population dynamics and community attitudes is a key element to determine whether and how DPM programmes might contribute to rabies control and which tools would be most successful.

– Considering that sources and drivers of free-roaming dogs and management goals differ across communities, DPM should be individually tailored at local and national level.

– DPM programmes should be designed to be sustainable, evaluated and refined.

Article 7.7.4.

Definitions for the purpose of this chapter

DPM programme means a combination of DPM measures that enhance the care of dogs and influence dog population dynamics to sustainably improve dog health and welfare, public health and safety, environment and related economic benefit and costs.

Rabies means dog-mediated rabies.

Free roaming dog means any *owned dog* or unowned dog that is without direct human supervision or control.

Article 7.7.5.

DPM programme objectives

DPM programmes may include the following objectives:

– promote and establish *responsible dog ownership*;

– improve health and welfare of dog populations;

– reduce number of *free-roaming dogs* to a manageable level;

– stabilise the dog population by reducing turnover;

– reduce *risks* to public health and safety including dog bites, zoonotic *diseases* including rabies and traffic accidents;

– contribute towards eradicating dog-mediated human rabies by 2030;

– reduce nuisance free roaming dogs may cause (e.g., environmental impact, negative publicity directed at governments, tourism disincentives);

– prevent harm to livestock and other animals;

– prevent dog illegal trade and trafficking.

Article 7.7.6.

Roles and responsibilities

As a cross-sectoral subject, DPM requires a high level of engagement and collaboration between *Competent Authorities* responsible for animal health and welfare, food safety and public health, in line with the One Health approach.

DPM activities performed by *Veterinary Services* or other *Competent Authorities* should be integrated to the greatest extent possible with the activities of all other responsible agencies.

Articles 7.7.7. and 7.7.8. describe the roles and responsibilities that different organisations may play in the planning and implementation of DPM programmes, at the national and local level.

Article 7.7.7.

Competent Authority for dog population management

The development and implementation of DPM occur at the local level through specific DPM programmes, whose success requires a supportive and enabling environment created by the *Competent Authority* at the national level. As DPM is relevant to several governmental agencies and various stakeholders, a multi-sectorial group should establish governance and coordinate actions across governmental agencies and programmes, including those focusing on zoonotic diseases where dogs play a role, such as rabies.

1. Governance

   DPM should be identified as the responsibility of a *Competent Authority*, which may be the *Veterinary Authority*. National level action plans provide the details of actions which support the implementation of DPM programmes and coordinate with other action plans, such as those focused on dog-related zoonoses. These plans are led by this *Competent Authority* and developed in collaboration with the multi-sectorial group.

2. Legislation

Implementation of DPM programmes requires the support of a suitable regulatory framework (see Article 7.7.9.). Further secondary regulations provide adaptations to suit local requirements.

3. Enforcement

The *Competent Authority* can support enforcement of legislation through guidelines on enforcement procedures/practices, training, and funding of enforcement agencies, and defining penalties.

4. Funding

To establish sustainable DPM with long-lasting impacts, the *Competent Authority* and multi-sectorial group should establish a policy and legislative basis for sufficient funding of national action plans and DPM Programmes. The One Health concept provides strength to the argument for increasing the priority of DPM across the animal health, environmental, and public health sectors.

5. Training and support

Training of professionals including *veterinarians* and providing accessibility to appropriate drugs at local, national or regional level led by the *Competent Authority* would support achievement of minimum standards across DPM Programmes. The *Competent Authority* should support DPM through national level communication and education initiatives.

EU comment

The EU would like to propose the following revision:

"Training of professionals including veterinarians ~~and providing accessibility to appropriate drugs at local, national or regional level~~ led by the Competent Authority would support achievement of minimum standards across DPM Programmes."

Justification:

Only veterinarians should have access to drugs. Furthermore, it is not clear which drugs are meant: for chemical sterilisation and/or for euthanasia.

Article 7.7.8.

Other organisations involved in dog population management

The following may have a role in the development of DPM programmes [Paolini *et al.*, 2020]:

1. Veterinary Authority

The *Veterinary Authority* plays a lead role in preventing zoonotic diseases and ensuring *animal welfare* and should be involved in DPM, coordinating its activities with other relevant *Competent Authorities*.

2. Veterinary Services

Veterinary Services should play an active role and coordinate their activities with relevant *Competent Authorities* and may be responsible for the organisation, implementation, and supervision of DPM Programmes.

3. Other governmental agencies

The responsibilities of governmental agencies will depend on the *risk* being managed and the objective or nature of the DPM measures implemented.

a) Public health

The ministry or other governmental agencies responsible for public health, would normally play a leadership role and may have legislative authority in dealing with zoonotic diseases and regarding

other human health *risks* (e.g., free-roaming dogs on roads; dog bites).

b) Environmental protection

Environmental protection governmental agencies may take responsibility for problems associated with free-roaming dogs when they present a *hazard* to the environment (e.g., control of *feral* dogs in national parks; prevention of predation to *wildlife* or transmission of diseases to *wildlife*) or where a lack of environmental controls encourage dogs to roam.

c) Education

The Ministry of Education can play a key role in promoting *responsible dog ownership* and dog bite prevention programmes at school level.

d) Local authorities

In many countries, local authorities are responsible for the implementation of DPM programmes and the enforcement of legislation relating to dog ownership (e.g., *registration* and *identification*, *vaccination*, leash laws, animal abandonment). This should be done with the support and enabling environment created by the *Competent Authority.*

EU comment

The EU notes that according to the new definition of Competent Authorities as proposed in Annex 15 of the Code Commission report, local authorities are included in the definition of Competent Authorities. Point d) above should be revised accordingly, by replacing "local authorities" with "local Competent Authorities", and "Competent Authority" with "Central Competent Authority".

4. Civil Society

The responsibilities of civil society stakeholders will depend on their involvement with the DPM measures implemented.

a) Dog owners

When a person takes on the ownership of a dog, there should be an immediate acceptance of responsibility for that dog, and for any offspring it may produce, for the duration of its life or until a subsequent owner is found. The owner responsibilities should include providing for the health and welfare of the dog and mitigating negative impacts on public health and the environment, in accordance with Article 7.7.17.

b) Dog breeders and sellers

Dog breeders and sellers have the same responsibilities as dog owners and in addition should comply with the recommendations in accordance with Article 7.7.15.

5. Advisory group

The development of a DPM programme should also benefit from the support of an advisory group, which should include *veterinarians*, experts in dog ecology, dog behaviour and zoonotic diseases, and representatives of relevant stakeholders (local authorities, human health services or authorities, environmental control services or authorities, non-governmental organisations and the public).

Article 7.7.9.

Regulatory framework

DPM legislation is a key element for the sustainability and efficiency of DPM Programmes. It can ensure that DPM is carried out with respect to *animal welfare* guiding principles (see Chapter 7.1.).

Regulations related to the following areas, may support successful DPM Programmes; these may be found in a DPM regulatory framework or other regulatory frameworks:

– Owners' obligations regarding the principles of *responsible dog ownership*, including *animal welfare*;

– *animal welfare* obligations of authorities;

– *registration* and *identification* of dogs in a centralised database;

– authorisation and licensing of dog breeders and sellers;

– authorisation and licensing of dog shelters, rehoming centres and holding facilities;

– licensing practice of veterinary medicine, including surgery;

– licensing preparation, use and sales of *veterinary products*;

– preventive and medical measures against rabies and other zoonotic diseases;

– dog movements and trade at international and national level;

– waste management.

This regulatory framework must be designed with both incentive measures for compliance and penalties for non-compliance.

Article 7.7.10.

Assessment, monitoring and evaluation

DPM programmes should be regularly evaluated and adapted to improve effectiveness and to respond to changes in wider context that influence dog population dynamics. This requires an evidence base from data collected through initial assessment and continued *monitoring* using objective methods.

Recognising the different needs of communities and the multi-sectorial roles in DPM, this should be conducted with involvement of advisory groups and relevant authorities.

Competent Authorities should support assessment, monitoring and evaluation by:

– Developing training and tools to help with implementing assessment and *monitoring*;

– Providing the budget of DPM programmes including the costs for *monitoring* activities;

– Establishing standardised indicators with feasible and repeatable methods of measurement that can be used across locations and over time, to support subsequent evaluations and compare performance between different DPM programmes. It should be expected that DPM programmes will also use and benefit from their own context-specific indicators and methods of measurement;

– Encourage the use of *monitoring* data for evaluation, learning and subsequent adaptation of DPM programmes.

Article 7.7.11.

DPM programme development

Developing a DPM programme requires an evidence-based approach. Areas for assessment that provide this evidence should include:

1) Review of the current regulatory framework and evaluation of the efficiency and effectiveness of DPM control measures used historically and currently.

2) Identification of the priority issues related to dogs from the perspective of all relevant stakeholders. The resolution of these issues will form the objectives of DPM programmes. Establishing baselines and *monitoring* methods for indicators reflecting each objective allows for later evaluation of efficiency and effectiveness. Identifying which dogs are associated with priority issues may include *owned dogs*.

3) Exploration of dog population dynamics in the whole dog population (not limited to the current free-roaming dog population) to identify the sources of free-roaming dogs:

   – *owned dogs* that roam freely;

   – dogs that have been lost or abandoned, including puppies resulting from uncontrolled breeding of *owned dogs*;

   – unowned dogs that reproduce.

4) Identify peoples' knowledge, attitudes and practices of dog care and responsibility over *owned dogs* and unowned dogs. Further, citizens' attitudes towards potential control measures should be explored. This information can be used to ensure the DPM programme acceptability to local communities and effectiveness at changing human behaviours.

5) Estimating dog population size and demography

   Dog population size estimates can help with planning DPM programmes. Accuracy of estimates is typically improved with more time-consuming methods. Where resources are limited, a rough estimate may be sufficient at the outset. This estimate may be refined by *monitoring* population coverage achieved by the implementation of measures and comparing this to the number of dogs receiving these measures (e.g., rabies *vaccination* and sterilisation in 'Catch, Neuter and Return').

   For evaluation of DPM programme effectiveness, *monitoring* changes in population trends (e.g., changes in the density of free-roaming dogs on public streets, proportion of lactating females and presence of puppies) may be sufficient rather than investing in repeated estimates of population size.

   Methods to estimate population size may also measure demographic factors such as age, sex, sterilisation and reproductive status (lactation and pregnancy in females) to allow for refinement of estimates to sub-populations of relevance.

   Available methods for population size estimates include the following:

   – *Owned dogs*: Dog *registration* databases, household questionnaires (to estimate proportion of dog owning households and mean number of dogs per dog owning household), post-*vaccination* campaign coverage and animal ownership surveys as part of human census.

   – Free-roaming *owned dogs*: Household questionnaires including questions or visible inspection of whether *owned dogs* are confined or allowed to roam unsupervised.

   – All free-roaming dogs, including both owned roaming and unowned:

     Direct observation of free-roaming dogs during surveys along routes through public streets at peak roaming time; capturing of these data can provide the mean free roaming dogs per km of street surveyed. This can be extrapolated by the estimated total street length within the defined area to estimate the total number of free-roaming dogs on the street at the time of survey; some free roaming dogs will not have been visible during the survey and so this is an underestimate of the total free roaming dog population.

EU comment

The EU would like to suggest the following revision of the first sentence and adding the following new paragraph:

"Direct observation of free-roaming dogs during surveys along <u>chosen</u> routes through public streets at peak roaming time; capturing of these data can provide the mean free roaming dogs per km of street surveyed."

"<u>-Surveys in special zones could be used in a complementary way, as free-roaming dogs often gather at feeding sites</u>."

Justification

According to Pal (1995) study (on feral dogs) or Sen Majumder et al. (2014) study on stray dogs, food spots are gathering groups of dogs. However, looking at methods used by authors, surveys along routes have proven to be a reliable technique.

e.g. Pal (1995): "Preliminary observations were made from January to February 1994 in order to facilitate the recognition of area residents, routes in the study area and to identify the locations of individuals. Further observations were made from March 1994 to February 1998 to collect data on abundance, breeding behaviour, mortality and immigration. Data were collected by conducting daily tours along the fixed routes. The routes were travelled on foot or by bicycle between 06.00 h and 08.00 h, when dogs were most active (Daniels 1983, Font 1987). The dogs were censused by enumeration."

Mark-resight is a method that aims to estimate population size considering that not all animals are visible to direct observation on a survey. This is achieved by first marking dogs with temporary marks such as paint, or photographs for individual recognition, or using marks applied as part of control measures, such as collars or paint applied during *vaccination* and ear notches or tags applied during neutering in Catch, Neuter and Return programmes. Then noting the proportion of marked and unmarked dogs during subsequent surveys. Mark-resight methods rely on assumptions that may not hold true in dog populations, such as equal resighting probability in marked and unmarked dogs, lack of immigration/emigration and no or measurable mark loss.

EU comment

The EU would like to suggest the following revision of this paragraph:

"Mark-resight is a method that aims to estimate population size considering that not all animals are visible to direct observation on a survey. This is achieved by first marking dogs with temporary marks such as paint, or photographs for individual recognition, or using marks applied as part of control measures, such as collars or paint applied during *vaccination* and ear notches or tags may be applied for rapid identification in long-term during neutering in Catch, Neuter and Return programmes."

Justification

***Ear notches or tags* are questionable from an animal-welfare perspective.**

Some studies show that ear tags can lead to inflammation, infection or loss of the tags: https://www.researchgate.net/publication/233564066_A_Comparison_of_Commonly_Used_Ear_Tags_on_the_Ear_Damage_of_Sheep

https://pubmed.ncbi.nlm.nih.gov/10390799/

Furthermore, the identification of numerous individuals remains difficult with ear notches as a coding system, or implies several cuts on both ears. This system may not be the best for identification. However, it can be used as a rapid assessment of whether the dog has been neutered or not (e.g. Identification methods for dogs and cats Guidance for WSPA staff and member societies providing positive/negative points of using marking).

Mark-resight is a relatively resource intensive method as compared to direct observation which may limit the extent of the area that can be feasibly surveyed.

Mark-resight and direct observation may be done concurrently in a sample of areas to estimate the proportion of free roaming dogs visible during direct observation. This proportion can be used to correct the data regarding those dogs missed during direct observation over a larger geographical area.

Article 7.7.12.

Monitoring and evaluation

Monitoring aims to check the progress of DPM programme measures against targets and support performance management. It should allow for regular adjustments of implementation of measures and collect data on indicators of objectives. It should also include *monitoring* of costs associated with measures and costs or savings relating to objectives to support cost-benefit analysis.

Evaluation is a periodic assessment of progress using data collected through *monitoring*, usually carried out at milestones to assess whether the DPM programme is achieving the desired objectives and to adapt the DPM programme to improve effectiveness and efficiency. Where methods of *monitoring* are equivalent, evaluation can compare effectiveness and efficiency across DPM programmes.

Indicators are the measurable signs of objectives. Indicators of DPM objectives may include:

– *Owned dog* population size, demographics and whether they are receiving *responsible dog ownership* (can include their *vaccination* status, sterilisation, *registration*, identification, level and method of confinement and how they were acquired).

– Free-roaming dog population density, demography (age, sex, sterilisation, lactating females, and puppies) and welfare (e.g., body condition score and presence of a skin problem) recorded by direct observation of free-roaming dog on surveys along standardised routes.

EU comment

The EU would like to suggest adding the following paragraph:

"- Dog population movements from owned dogs to free-roaming dogs (based on investigations and monitoring);"

Justification:

Following Boitani & Ciucci (1995) publication, feral dogs' populations seem to be maintained from stray dogs' populations. The question would be whether stray dogs' populations reproduce themselves from stray dogs only, or from owned dogs that wander and roam and could reproduce with stray dogs. Such knowledge could help to better understand the evolution of stray dogs' populations.

– *Prevalence* of zoonotic diseases in both the animal and human population; for example, Chapter 8.14. and Chapter 8.5.

– Knowledge, attitudes and practices of communities relating to the free-roaming dog population, and dog owner knowledge, attitudes and practices of *responsible dog ownership*.

– Adoption or reuniting facility performance including intake, adoption rates, welfare state of dogs in their care, mortality and *euthanasia* rate.

– Dog bites reported to health centres or number of rabies post-exposure prophylaxis provided to the exposed individuals or the cost incurred by the public health authorities for provision of post-exposure prophylaxis.

– Number and nature of complaints about dogs to local government authorities.

– Compensation costs relating to dog-related damages to people, livestock, or property.

Article 7.7.13.

Recommendations for DPM measures

The recommendations for DPM measures in Articles 7.7.14. to 7.7.24. should be implemented in accordance with the national context and local circumstances. A combination of the following measures should be used for a successful DPM programme.

– *Registration* and *identification* of dogs

– Commercial dog breeding and sale

EU Comment

The EU would like to propose the following revision:

- Regulation of c~~C~~ommercial dog breeding and sale

Justification

Commercial dog breeding and sale itself is no measure for a DPM program. It should be clarified what is meant here.

– Control of national and international (export and import) dog movements

– Promoting *responsible dog ownership*

– Reproductive control

– 'Catch, Neuter and Return'

– Reuniting and adoption

– Access to veterinary care

– Environmental controls

– Education in safe dog-human interaction.

Article 7.7.14.

Registration and identification of dogs

Outcomes of *registration* and identification of dogs include the following:

– supports enforcement of legislation through proof of ownership;

– improves success rate in reuniting lost dogs to their owners;

– enables traceability in commercial breeding and sale;

– encourages responsible ownership behaviours;

– support for an animal health programme, e.g., mandatory rabies *vaccination* and traceability.

These outcomes require widespread adoption of *registration* and *identification*.

EU comment

The EU would like to propose the following revision:

"Registration and identification of dogs as a DMP measure

~~Outcomes of r~~Registration and identification of dogs ~~include the following~~ is an important DPM measure because it:

– supports enforcement of legislation through proof of ownership;

– improves success rate in reuniting lost dogs to their owners;

– enables traceability in commercial breeding and sale;

– encourages responsible ownership behaviours;

– support for an animal health programme, e.g., mandatory rabies vaccination and traceability.

~~These outcomes require widespread adoption of registration and identification~~."

Justification:

Applicable only if there is a need for DPM measures.

Widespread adoption of identification and registration of dogs is only necessary if there are populations of free roaming dogs that need to be managed. This should be clarified. In countries where such a problem does not exist, it is sufficient if identification and registration of dogs is done on a voluntary basis by the owners.

Competent Authorities should ensure that a centralised database is established for dog *registration* to allow for reuniting of identified dogs with registered owners across the territory. *Competent Authorities* should ensure there is an enforcement system in place with the capacity to deliver appropriate methods of identification to all dogs (such as microchipping or Quick Response tags [QR tags])), read identification when a dog is found (using scanners or other devices) and access the *registration* database to retrieve owner details.

EU comment

The EU would like to propose the following revision:

"<u>As a DPM measure</u> Competent Authorities should ensure that a ~~centralised~~ database is established for dog registration to allow for reuniting of identified dogs with registered owners across the territory."

Justification:

Revision proposed in the context of the previous comment. No need to specify the type of a database. For example, in some countries regional databases are used.

Owners need to be informed and able to access identification services and the *registration* system both initially to enter each dog, to update contact information, when there is a change of ownership or the dog dies.

EU comment

While regulations on registration and identification of dogs may indeed support DPM programmes (as mentioned in Article 7.7.9.), registration of dogs in a central database should not be mandatory as that would go beyond what is necessary. Furthermore, this should not necessarily be under the responsibility of the central Competent Authority. Indeed, depending on the purpose and the country concerned, there may already be registration of dogs at local level for tax purposes, mandatory identification of dogs for international travel purposes, or voluntary national dog registration under the responsibility of the private sector or NGOs for the purpose of reuniting with the owner etc. There should be no duplication of what already exists, nor should the recommendations of this chapter be too prescriptive (e.g. as regards access of owners to databases). Therefore, the article above needs to be thoroughly revised.

Article 7.7.15.

Commercial dog breeding and sale

Outcomes of regulating commercial breeding and sale include:

– protection of dog health and welfare,

– avoidance of abandonment,

– transparency in dog breeding and sales.

Competent Authorities should require mandatory *registration* of all breeders and sellers. For commercial breeders and sellers, where the number of litters produced per year exceeds a threshold set by regulations, a further requirement for licensing can be imposed, including the requirement for inspection before trade can begin.

Advertisements for dog sales should be required to carry the *registration* or licence number of the breeder and seller.

To ensure dogs traceability, the breeder should be established through identification and *registration* as the first owner.

The seller should ensure *registration* details of the dog are updated with those of the first buyer following transfer of ownership.

EU Comment

The EU would like to propose the following revision:

"Regulation of c~~C~~ommercial dog breeding and sale as a DPM measure

~~Outcomes of r~~Regulating commercial breeding and sale ~~include~~ as a DPM measure aim:

- **protection of dog health and welfare,**
- **avoidance of abandonment,**
- **transparency in dog breeding and sales.**

This can be achieved by ~~*Competent Authorities* should require~~ mandatory *registration* of all breeders and sellers. For commercial breeders and sellers, where the number of litters produced per year exceeds a threshold set by regulations, a further requirement for licensing may ~~can~~ be imposed, including the requirement for inspection before trade can begin.

~~Advertisements for dog sales should be required to carry the *registration* or licence number of the breeder and seller.~~

~~To ensure dogs traceability, the breeder should be established through identification and *registration* as the first owner.~~

~~The seller should ensure *registration* details of the dog are updated with those of the first buyer following transfer of ownership."~~

Justification

Applicable only if there is a need for DPM measures.

Measures concerning commercial dog breeding may support DPM programmes but they should not be mandatory. Depending on the country, concerned lighter and/or different measures may be more appropriate, especially if there is no need for DMP.

Regulations of breeding practices should include limits on number of litters, minimum breeding age to protect the health and welfare of dam, good health of both parents and avoidance of selective breeding that leads to inherited diseases and extreme conformations. Regulations of both breeders and sellers should also outline specific requirements for accommodation, veterinary care, husbandry, puppy socialisation and habituation to their environment, minimum puppy age before leaving the dam and training of staff. Sales of puppies or adult dogs should be limited to adults and sales from exhibitions or from the street should be banned.

Article 7.7.16.

Control of national and international (export or import) dog movements

International movements of dog (import and export) should comply with trade measures, import or export procedures and veterinary certification according to Chapters 5.11., 7.2., 7.3., 7.4. and 8.14.

Movement of dogs within a country should be under the responsibility of the owner with the following outcomes:

– reducing the *risk* of contagious diseases spread,

– protecting public health and safety,

– protecting *wildlife* and livestock.

EU comment

The EU would like to propose adding the following:

"<u>- protecting dog welfare.</u>"

Justification:

Protecting dog welfare during transport is another important consideration to be respected.

Article 7.7.17.

Promoting responsible dog ownership

1) Owning a dog is a choice and should result in a mutually beneficial relationship. The benefits of dog ownership come with responsibilities. Promoting *responsible dog ownership* through education and enforcement of national and local regulations is a core component of a DPM programme to achieve the following outcomes:

   – improve the health and welfare of dogs;

   – support the human-animal bond;

   – minimise the *risk* that dogs pose to the community;

   – reduce the number of dogs allowed to roam.

2) Education on *responsible dog ownership* (for the currently *owned dog* and any offspring it produces for its lifetime or until the responsibility is passed to the next owner) should address the following elements:

   – providing appropriate care to ensure the welfare of the dog and any offspring according to the dog's five welfare needs (suitable environment, suitable diet, housed with or apart from other animals, ability to exhibit normal behaviour and protected from pain, suffering, injury, and disease) in order to meet the internationally recognised "five freedoms" (see point 2 of Article 7.1.2.);

EU comment

The EU would like to suggest adding the following:

"<u>- training owners to detect fear, stress and aggression related behaviours of their dogs;</u>"

Justification:

It is known that owners have to be trained to detect fear and stress signs from dogs (e.g. Bloom & Friedman, 2013): experienced or non-experienced persons looking at photos representing different emotions of dogs have difficulties to distinguish fear and stress. Since fear and stress may lead to aggression, it is important that owners can detect fear and stress signs to reduce aggressions. In the same way, detecting aggression signs can reduce bites.

   – encouraging appropriate behaviours, reducing unwanted behaviours (including dog bites) and supporting the dog's ability to cope with its environment through attention to socialisation and training;

EU comment

The EU would like to suggest adding "positive" before training:

"- encouraging appropriate behaviours, reducing unwanted behaviours (including dog bites) and supporting the dog's ability to cope with its environment through attention to socialisation and <u>positive</u> training;"

Justification:

It is known that positive reinforcement is important for a better quality of the relationship between the owner and the dog. On the contrary, punishment increases aggression (e.g. Haverbeke et al. 2008 on dogs belonging to the Belgian army).

- *registration* and identification of dogs (see Article 7.7.14.);
- access to veterinary care (see Article 7.7.21.);
- preventing negative impacts of dogs on the community, via pollution (e.g., faeces and noise), *risks* to human health through bites or traffic accidents and *risks* to other dogs, *wildlife*, livestock and another companion animal species;
- control of dog reproduction (see Article 7.7.18.);
- arranging for the care of the dogs when the owner is unable to do so.

3) Achieving sustained and widespread responsible ownership requires an understanding of barriers and motivations for responsible behaviour and taking action to address these. This will likely require a combination of legislation, public awareness and enforcement, behaviour change campaigns, formal education in schools and encouragement through the building of social expectations. It may also be necessary to improve availability and accessibility to resources supporting responsible ownership, such as veterinary care, identification and *registration* services and measures for control of zoonotic *diseases*.

Article 7.7.18.

Reproductive control

1) Outcomes of controlling reproduction in dogs include the following:
   - prevents the birth of unwanted puppies;
   - helps address the imbalance between reproduction and demand for dogs;
   - reduces the size of free-roaming dog population.

2) Efficient use of reproduction control does not require limiting overall population size. To ensure best use of resources, focus should be on controlling reproduction of females most likely to be the source of unwanted and free-roaming dogs.

3) Methods of controlling reproduction will require direct veterinary input to individual animals. Involvement of both private and public veterinary sectors may be required to meet demand for services. Subsidisation of sterilisation programmes by government or other organisations may be considered to encourage uptake. The control of reproduction in *owned dogs* is essentially the responsibility of owners and should be incorporated into promotion of responsible ownership (see Article 7.7.17.).

4) Methods for controlling reproduction in dogs include:
   - surgical sterilisation;

EU comment

The EU would like to propose replacing "sterilisation" with "castration":

"– surgical ~~sterilisation~~ <u>castration (female and male)</u>;"

Justification:

With castration the reproductive organ of the animal is taken away, which changes the way the animal behaves. In females, the ovaria are /should be removed; so 'castration' would be the terminology to use. The same is valid also for males who are /should be castrated.

– non-surgical sterilisation or contraception, including chemical and immunological approaches;

– separation/confinement of female dogs during oestrus from unsterilised males.

5) Surgery has the primary advantage of being permanent. Surgical sterilisation must be carried out by a *veterinarian* and must include good surgical technique, a good standard of asepsis, appropriate anaesthesia and proactive, multi-modal pain management maintained throughout and adjusted to the individual animal as needed. This requires *monitoring* during and post-operatively for the whole recovery period. It requires suitably trained *veterinarians* and *veterinary paraprofessionals* and access to appropriate drugs and equipment. *Competent Authorities* are responsible for ensuring access to training and drugs to ensure surgical sterilisation can be performed safely.

EU comment

The EU would like to propose replacing *"sterilisation"* with *"castration"* in the text below:

"Surgery has the primary advantage of being permanent. Surgical ~~sterilisation~~ castration must be carried out by a *veterinarian* and must include good surgical technique, a good standard of asepsis, appropriate anaesthesia and proactive, multi-modal pain management maintained throughout and adjusted to the individual animal as needed."

Justification:

Same as above, with castration the reproductive organ of the animal is taken away, which changes the way the animal behaves. In females, the ovaria are /should be removed; so 'castration' would be the terminology to use. The same is valid also for males who are /should be castrated.

6) Castration of male dogs is generally preferred over vasectomies, as unlike castration, vasectomy does not reduce sex hormone levels and therefore has no mechanism to reduce sex-specific behaviours, such as roaming, territory marking and fighting (Houlihan, 2017; McGreevy *et al.*, 2018). Females may be surgically sterilised by ovariohysterectomy, ovariectomy, hysterectomy or tubal ligation. Tubal ligation and hysterectomy are not recommended as the female will be under ovarian hormonal influences and will continue to show sexual behaviour.

EU comment

The EU would like to propose deleting the word "generally" from the first sentence:

"Castration of male dogs is ~~generally~~ preferred over vasectomies, as unlike castration, vasectomy does not reduce sex hormone levels ~~and therefore has no mechanism~~. However, castration effects to reduce sex-specific behaviours, such as roaming, territory marking and fighting cannot be generalised, and castration is suggested to increase fear in dogs (Houlihan, 2017; McGreevy *et al.*, 2018). A case-by-case analysis should be applied to decide whether to gonadectomise dogs or not."

Justification:

By removing "generally" the message becomes more straight forward and concrete.

The 2 studies quoted there do not state that gonadectomy decreases roaming, territory marking and fighting systematic gonadectomy should definitely be discussed. There is no obvious arguments to propose that.

→ Houlihan 2017 promotes a case-by-case analysis, and not systematic gonadectomy

In a joint statement, the American College of Theriogenologists and Society for Theriogenology assert that companion animals not intended for breeding should be spayed or neutered, although the decision must be made on a case-by-case basis and take into consideration the pet's age, breed, sex, intended use, household environment, and temperament. Developing recommendations for an informed case-by-case assessment requires an evaluation of the risks and benefits of gonadectomy, including potential effects on neoplasia, orthopedic disease, reproductive disease, behavior, longevity, and population management as well as the risks of anesthetic and surgical complications. However, many factors other than neuter status play an important role in these outcomes, including breed, sex, genetics, lifestyle, and body condition. Potential consequences for an individual animal must also be weighed with the necessity of managing unwanted pet populations. Because of the aforementioned variables, there currently is no single recommendation regarding gonadectomy that would be appropriate for all dogs. The information reported here summarizes the currently available literature involving risks and benefits that might be considered when making a recommendation about gonadectomy of dogs and the optimal age for performing the procedure.

→ McGreevy et al. 2018 show that gonadectomy decreases indoor urine marking and howling when left alone. In contrast, gonadectomy is suspected to increase fear and stranger-directed aggression, behaviours that we do not want to increase for roaming dogs.

The beneficial effects of gonadectomy are underpinned by the need to reduce the number of unwanted companion animals. Thousands of dogs are euthanased in shelters and pounds annually in many developed countries [36,37,38,39]. However, shelters are inundated by dogs that are most commonly surrendered because they display undesirable behaviours [40] So the current findings present the paradox that castration may reduce the number of unwanted dogs but may also increase the likelihood of problem behaviours that reduce the appeal of the castrated dogs and make them more vulnerable to being surrendered. Responsible pet ownership does not end with having one's pet gonadectomised. Rearing dogs and managing them in ways that meet their behavioural needs and enrich the bonds they share with their owners must be given priority as a form of preventive care. The challenges that owners face and the role of unwanted behaviours in jeopardising the human-dog bonds should not be underestimated by simple, broad-scale policies.

7) Any chemicals or drugs used in controlling reproduction should be shown to have appropriate safety, quality and efficacy for the function required and used in accordance with the manufacturer's recommendations and *Competent Authority*'s regulations. In the case of non-surgical sterilant and contraceptives in the research phase, trials may need to be completed before use.

Article 7.7.19.

'Catch, Neuter and Return'

'Catch, Neuter and Return' provides an approach to controlling the reproduction of unowned dogs as a source of *free roaming dogs*. This is not a stand-alone solution to DPM and must be used in combination with other measures addressing other sources of *free-roaming dogs*. It can be considered a method of managing the current free roaming dog population *in situ* on the streets and hence an alternative to removal for reuniting and adoption (see Article 7.7.20.).

In collaboration with local community, identified unowned dogs are caught, provided with health care (including rabies *vaccination*), evaluated for adoption, if adoption is not feasible, sterilised, and released to their local community at or near the place of capture. This method is more likely to be accepted in the situation where the presence of *free-roaming dogs* is widespread and well tolerated by the local community.

EU comment

The EU would like to propose the following revision:

"In collaboration with local community, identified unowned dogs are caught, provided with health care (including rabies *vaccination*), evaluated for adoption, ~~if adoption is not feasible, sterilised,~~ castrated and released to their local community at or near the place of capture."

Justification:

The recommendation should be to castrate the dog as explained above. Moreover, it is important to reduce sex hormone levels, to reduce sex-specific behaviours.

This method is not applicable in all situations and may be illegal in countries or regions where legislation prohibits the abandonment of dogs. Problems caused by dogs, such as noise, faecal pollution, bite injuries and traffic accidents, would not be alleviated as dogs are returned to the local community and their movements are not restricted. Consideration should be given to the *risk* that 'Catch, Neuter and Return' could encourage abandonment of unwanted dogs. In the situation where many free-roaming dogs are owned, a DPM programme that focuses on neutering and responsible ownership may be more appropriate.

It is recommended that before adopting this approach, a cost-benefit analysis is conducted. Factors such as the monetary costs, impact on culture of ownership and public safety should be assessed as well as the benefits for *disease* control and *animal welfare* as well as any societal benefits.

If this measure is implemented, the *Competent Authority* should ensure the following are addressed:

– engaging local communities to understand, support, design and be an active part of 'Catch, Neuter and Return' activities and *monitoring* of released dogs, in particular in the case of dogs cared for by the community;

– use of humane methods for catching, transporting and holding dogs;

– correct surgical technique with a good standard of asepsis, anaesthesia and analgesia, followed by post-operative care (see Article 7.7.18.);

– *disease* control may include *vaccination* (e.g., rabies) and treatments and testing for *diseases* (e.g., leishmaniasis) followed, as appropriate by treatment or *euthanasia* of the dog;

– 'catch, neuter and return' is not suitable for all dogs and should be applied on an individual basis. Health assessment and behavioural observation may be used to assess if dogs are suitable for release; if not suitable for release or adoption, *euthanasia* should be considered;

– permanent marking (e.g., tattoo or microchip) to indicate that the animal has been sterilised; individual identification also allows for tracking of *vaccination* status and treatment history. A visible identification (e.g., collar, tag or ear notch) may also be used to prevent unnecessary recapture;

EU comment

The EU would like to suggest the following revision:

"- permanent marking (e.g., tattoo or microchip) to indicate that the animal has been sterilised; individual identification also allows for tracking of *vaccination* status and treatment history. A visible identification (e.g., collar, or in case of long-term or rapid sighting tag or ear notch) may also be used cautiously to prevent unnecessary recapture;"

Justification

Same justification as above that ear notches or tags are questionable from an animal-welfare perspective. Some studies show that ear tags can lead to inflammation, infection or loss of the tags: e.g. https://www.researchgate.net/publication/233564066_A_Comparison_of_Commonly_Used_Ear_Tags_on_the_Ear_Damage_of_Sheep;

https://pubmed.ncbi.nlm.nih.gov/10390799/

Furthermore, identification of numerous individuals remains difficult with ear notches as a coding system, or imply several cuts on both ears. This system may not be the best for identification. However, it can be used as a rapid assessment of whether the dog has been neutered or not (e.g. Identification methods for dogs and cats Guidance for WSPA staff and member societies providing positive/negative points of using marking).

– the dog should be returned to a place that is as near as possible to the place of capture;

– the behaviour and welfare of dogs after release should be monitored and action taken if required.

Article 7.7.20.

Reuniting and adoption

Free roaming dogs can be removed to housing facilities for reuniting with their owners or adopted. This addresses only the current free roaming population and not the source of these dogs, hence must be used in combination with other measures to prevent replacement of removed dogs. Evidence collected about dogs and dog owner practices during DPM programme development must confirm that reuniting and adoption is probable and achievable before developing reuniting and adoption facilities. Without sufficient adoptive homes or systems for reuniting, facilities quickly fill to capacity creating an ineffective and expensive measure. The *Competent Authority* should ensure capture, transport, and holding of dogs is done humanely.

Dogs that are removed from a community may be reunited with the owner or adopted. There should be provision for holding the dogs for a reasonable period to allow for reuniting with the owner and, as appropriate, for rabies observation. Reuniting and adoption provide an opportunity to promote responsible ownership and good animal health care (including rabies *vaccination* and sterilisation). The suitability of dogs should be assessed and matched with available owners. The effectiveness of adoption may be limited by the number of adoptive homes.

EU comment

The EU would like to propose the following additional text at the end of the paragraph above:

"Adoption within the same local area or country should be preferred to minimize the stress in association with transportation of the dogs as well as to reducing the risk of spreading zoonotic and other pathogens to new areas."

Justification:

It is to prefer that dogs for adoption is translocated to adoptive homes in the same local area or country to reduce the stress in association with long and exhausting transports and to minimize the risk of spreading pathogens with the dogs to previous free areas.

Dogs that are removed from a community may be too numerous or may be unsuitable for adoption. If acceptable to the local community, 'Catch, Neuter and Return' may provide an alternative approach (see Article 7.7.19.). If *euthanasia* of these unwanted animals is the only option, the procedure should be conducted in accordance with Article 7.7.27.

Article 7.7.21.

Access to veterinary care

Access to veterinary care delivered by *veterinary services* positively impacts animal health, *animal welfare*, and public health through provision of preventive and therapeutic veterinary care to dogs in a community. Increased interactions with *veterinary services* provide additional opportunities to educate dog owners on *responsible dog ownership* (see Article 7.7.17.). From a DPM perspective, the prevention of disease, treatment of illness and injury, and *euthanasia* to end suffering where treatment is not feasible, potentially reduces abandonment of sick or injured dogs.

Veterinary care should be part of DPM programmes and contribute to disease control by creating healthier populations of dogs with reduced population turnover. Herd immunity for rabies control is supported by DPM through improvement in the survival of vaccinated dogs and reducing birth of unvaccinated puppies through surgical sterilisation. Guidance on implementing dog rabies *vaccination* campaigns is provided in Chapter 8.14.

Preventive veterinary care is central to zoonotic disease control and *surveillance*. DPM programmes should encompass or align with all disease control measures relevant to dogs. This includes rabies *vaccination* for controlling dog-mediated rabies (see Chapter 8.14.) and deworming for *Echinococcus granulosus* (see Chapter 8.5).

Veterinary services should identify 'at *risk*' populations of dogs that do not have reliable access to basic veterinary care. *Competent Authorities* should facilitate access to veterinary care. Potential solutions may include subsiding costs and organising outreach *veterinary services*.

Article 7.7.22.

Environmental controls

Actions should be taken to exclude dogs from uncontrolled sources of food (e.g., rubbish dumps and *abattoirs* and installing animal-proof rubbish containers). Chapter 8.5. provides additional recommendations on environmental controls for the prevention and control of *Echinococcus granulosus*. Environmental control should be linked to other DPM measures, to avoid *animal welfare* problems from a sudden reduction in food sources.

Article 7.7.23.

Education in safe dog-human interaction

The most effective means of reducing *prevalence* of dog bites are education in safe interaction with dogs and owner responsibility for training and managing dogs as part of *responsible dog ownership* (see Article 7.7.17.). Young children are the group at highest *risk* for dog bites. Public education programmes focussed on appropriate dog-directed behaviour have been demonstrated to be effective in reducing dog bite *prevalence* and these programmes should be encouraged. *Competent Authorities* should seek advice from dog behaviour experts in developing dog safety education programmes.

Education programmes on appropriate bite treatment, and when necessary post-exposure prophylaxis, for all age groups is encouraged.

Article 7.7.24

Specific consideration for dog population management activities

Articles 7.7.25. to 7.7.27. are recommendations for activities that may be required as part of the implementation of the above measures:

– Dog capture and handling;

– Dog housing;

– *Euthanasia.*

Euthanasia of dogs, used alone, is not effective for DPM. If used, it should be done humanely (see Article 7.7.27.) and implemented in combination with other measures as part of a DPM programme.

Article 7.7.25.

Dog capture and handling

Humane capture and handling aim to prevent animal suffering and distress. It can also bring other benefits, including reduced injuries to handlers, easier handling of dogs in future and modelling positive handling to owners and public.

Competent Authorities should develop appropriate legislation and training to promote humane handling and enforce regulations against cruel methods, including the use of tongs and uncovered wire loops. *Animal welfare* and operator safety outcomes are improved when the personnel conducting capture and handling have a complete understanding of, and proficiency in, the capture and handling method to be used.

Competent Authorities and *veterinary services* should ensure their staff and volunteers expected to handle dogs have received rabies pre-exposure *vaccination* and are provided with clear protocols for treating injuries, including dog bites.

The least aversive method of capture and handling should be used to minimise harm and discomfort. Further, handlers should strive to make the handling experience as positive as possible from the perspective of the dog; this includes looking for ways to reward the dog during handling.

Handlers should use minimum *restraint* to provide the dog with opportunities to exert choice and control, so that they cope better with the handling.

Article 7.7.26.

Dog housing

Competent Authorities should develop minimum standards for the housing (physical facilities) and care of dogs to ensure the physical, mental and social needs of dogs are met. Enforcement of standards are supported by licensing and inspection of facilities (Barnard *et al.*, 2014). The following minimum standards should be considered:

a) Facilities

- sustainable finances to cover ongoing running costs;
- site selection: access to drainage, waste disposal, water and electricity are essential and environmental factors such as noise and pollution should be considered;
- kennel size, design and occupancy taking exercise and expected length of stay into account and providing sufficient area for dogs to separate the functions of eating or drinking, resting, urinating and defecating;
- disease control measures including isolation and *quarantine station*;
- maximum capacity of the facility.

b) Management

- provision of adequate fresh water and nutritious food;
- regular hygiene and cleaning;
- routine inspection, handling and exercise of the dogs;
- *monitoring* of physical and behavioural health and provision of required veterinary treatments under veterinary supervision, including routine and preventive veterinary care and *euthanasia*;
- policies and procedures to respect the maximum capacity for the facility and action when this is reached, assessment of dog health and behaviour, animal care, intake, treatment, adoption, sterilisation and *euthanasia*;
- provision of sufficient numbers of appropriately skilled staff and training of staff in safe, appropriate and positive handling of dogs;

– record keeping, animal identification, and reporting to the *Competent Authority*.

EU comment

The EU would like to suggest adding the following:

"- <u>respect the 'five freedoms' principles</u>. (see Chapter 7.1. Article 7.1.2. Guiding principles for animal welfare)."

Justification:

Making a reference to respect the internationally recognised 'five freedom' principles is important in the context of minimum housing standards.

c) <u>Assessment</u>

Dog housing performance may be assessed using the following measurables:

– body condition score, skin condition, disease *incidence*, injuries and mortality, reaction to humans and conspecifics;

EU comment:

The EU would like to suggest adding

"<u>-respect of behavioural needs and evaluation of emotional state</u>;"

Justification:

The emotional state needs to be positive. Following the five freedoms, the respect of behavioural needs and natural behaviours, is essential. Since a positive emotional state is essential for animal welfare (Anses, 2018, definition of animal welfare), evaluating whether or not a dog is in a positive emotional state is essential to respect its welfare.

– housing must provide adequate space appropriate to the age, size, weight, and breed of the dog, and that allows the dog to engage in normal body movements, including the ability to sit, stand up, turn about freely, or lie recumbent in a natural position, stretch, move their head, hold tail erect while standing, comfortably eat, drink, urinate and defecate;

EU comment:

The EU would like to suggest the following revision:

"housing must provide adequate space appropriate to the age, size, weight, and breed of the dog, and that allows the dog to engage in normal body movements, including the ability to sit, stand up, turn about freely, or lie recumbent in a natural position, stretch, move their head, hold tail erect while standing, <u>to move sufficiently</u> ~~comfortably eat, drink, urinate~~ and <u>provide sufficient area for dogs to separate the functions of eating or drinking, resting, urinating and defecating</u> ~~defecate~~;"

Justification:

Consistency with the better text in point a) of Article 7.7.26.

– hygiene, cleaning, drainage and housing materials should prevent an excessive accumulation of faeces and food waste, to prevent soiling of dogs in the enclosure, reduce disease *hazards*, insects, pests and odours;

– ventilation should allow dogs to comfortably maintain normal body temperature and provide good air quality;

– protection from harmful extremes of temperature, air movement, moisture, light and other climatic elements to ensure proper health and well-being of the dog.

Article 7.7.27.

Euthanasia

Euthanasia of dogs, used alone, is not effective for DPM. If used, it should be done humanely and implemented in combination with other measures as part of a DPM programme to achieve effective long-term management. Reducing dog population size is not an effective means of reducing the number of rabies cases [WHO, 2018].

As a process, *euthanasia* involves pre-*euthanasia* and handling procedures, *euthanasia* methods and agents, confirmation of *death*, and carcass disposal. When *euthanasia* is practised, the general principles in the *Terrestrial Code* should be applied, with the emphasis on using practical methods which achieve the most rapid, painless, and distress free-*death* possible while ensuring operator safety. *Euthanasia* should be conducted under the supervision of a *veterinarian*. To ensure *animal welfare* and operator safety, the personnel conducting *euthanasia* should have a complete understanding of, and proficiency in, the *euthanasia* method to be used.

a) Restraint

When a dog needs to be restrained for any procedure, including *euthanasia*, this should always be done with full regard for operator security and *animal welfare*. Animal handling should also minimise distress experienced by the dog prior to loss of consciousness. Some *euthanasia* methods should be used in with prior sedation or anaesthesia to be considered humane. Regardless the *euthanasia* method used, pre-*euthanasia* sedation or anaesthesia should be used to minimise anxiety or facilitate safe *restraint*.

b) Euthanasia methods

The following are recommended methods of canine *euthanasia*:

– intravenous barbiturates,

– intraperitoneal barbiturates in small dogs or puppies,

– intravenous anaesthetic overdose,

– inhaled anaesthetic overdose in small dogs (not neonates).

If anesthetised:

– administration of barbiturates by alternate routes (intracardiac, intrarenal, intrahepatic, intraosseous).

If sedated:

– intravenous *euthanasia* specific formulation of embutramide, chloroquine and lidocaine;

– intravenous *euthanasia* specific formulation of embutramide, mebezonium and tetracaine.

Methods, procedures and practices that are unacceptable as primary methods of *euthanasia* on *animal welfare* grounds include air embolism, asphyxiation, burning, chloral hydrate, chloroform, cyanide, decompression, drowning, exsanguination, formalin, household products and solvents, hypothermia, insulin, neuromuscular blocking agents (magnesium sulphate, potassium chloride, nicotine, and all curariform agents), manually applied blunt force trauma to the head, rapid freezing, thoracic compression, strychnine, nitrous oxide, ether, kill-trapping, CO from engine fumes, CO_2 if the required concentration and flow rates are not regulated and monitored, free-bullet without proper anatomic placement at close range by highly trained personnel, penetrating captive bolt, electrocution if not already under general anaesthesia, *stunning* without secondary kill method.

c) Confirmation of death

For all methods of *euthanasia* used, *death* should be confirmed before animals are disposed of or left unattended.

A combination of criteria is most reliable in confirming *death*, including lack of pulse, breathing, corneal

reflex, and response to firm toe pinch; inability to hear respiratory sounds and heartbeat by use of a stethoscope; greying of the mucous membranes; and rigor mortis. None of these signs alone, except rigor mortis, confirms *death*. If an animal is not dead, another method of *euthanasia* should be performed.

d) Carcass disposal

Carcasses should be disposed of in a manner that complies with legislation. Attention should be paid to the *risk* of residues occurring in the carcass. Incineration is generally the safest way of carcass disposal (see Chapter 4.13.).

References [Note: references will be removed when the chapter is adopted.]

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Annex 18

CHAPTER 8.8.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

EU comment

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

Comments are inserted in the text below.

Article 8.8.1.

General provisions

1) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with foot and mouth disease virus (FMDV). Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contacts between them. Amongst *Camelidae*, only Bactrian camels *(Camelus bactrianus)* are sufficiently susceptible to have potential for epidemiological significance. Dromedaries *(Camelus dromedarius)* are not susceptible to *infection* with FMDV while South American camelids are not considered to be of epidemiological significance.

2) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the suborder *ruminantia* and of the family *suidae* of the order *Artiodactyla*, and *Camelus bactrianus* with FMDV.

3) The following defines the occurrence of *infection* with FMDV:

   a) FMDV has been isolated from a sample from an animal listed in point 2; or

   b) ~~viral~~ antigen or ~~viral~~ ribonucleic acid specific to FMDV has been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or

   c) antibodies to structural or non-structural proteins (NSP) of FMDV, that are not a consequence of *vaccination*, have been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.

4) Transmission of FMDV in a vaccinated *population* is demonstrated by change in virological or serological evidence indicative of recent *infection*, even in the absence of clinical signs.

5) For the purposes of the *Terrestrial Code*, the *incubation period* of FMD shall be 14 days.

6) *Infection* with FMDV can give rise to *disease* of variable severity and to ~~FMDV~~ transmission of FMDV. FMDV may persist in the pharynx and associated lymph nodes of ruminants for a variable but limited period of time beyond 28 days after infection. Such animals have been termed carriers. ~~However,~~ The only persistently infected species from which transmission of FMDV has been proven is the African buffalo *(Syncerus caffer)*. However, transmission from this species to domestic livestock is rare.

~~7)~~ ~~This chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of *infection* with, FMDV and transmission of FMDV in the absence of clinical signs.~~

~~8~~7) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.8.1bis.

Safe commodities

When authorising import or transit of the following *commodities, Veterinary Authorities* should not require any type of FMD-related conditions, regardless of the FMD status of the *exporting country* or *zone:*

1) UHT milk and derivatives thereof;

2) *meat* in hermetically sealed container with a F_0 value of 3 or above;

3) *meat* and bone meal and blood meal;

4) gelatine;

5) *in vivo* derived bovine embryos collected, processed and stored in accordance with Chapter 4.8.

Other *commodities* of susceptible species can be traded safely if in accordance with the relevant articles in this chapter.

Article 8.8.2.

~~FMD free~~ Country or zone free from FMD where vaccination is not practised

In defining a *zone* where *vaccination* is not practised the principles of Chapter 4.~~3~~4. should be followed.

Susceptible animals in the ~~FMD free~~ country or *zone* free from FMD, where *vaccination* is not practised should be protected by the application of *biosecurity* ~~measures~~ that prevents the entry of FMDV into the free country or *zone*.

Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*.

To qualify for inclusion in the list of ~~FMD free~~ countries or *zones* free from FMD, where *vaccination* is not practised, a Member Country should:

1) have a record of regular and prompt animal *disease* reporting;

2) send a declaration to the OIE stating that during the past 12 months, within the proposed ~~FMD~~ free country or *zone*:

   a) there has been no *case* of FMD;

   b) no *vaccination* against FMD has been carried out;

3) supply documented evidence that for the past 12 months:

   a) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. has been implemented to detect clinical signs of FMD and demonstrate no evidence of:

      i) *infection* with FMDV in unvaccinated animals;

      ii) ~~FMDV~~ transmission of FMDV in previously vaccinated animals when the ~~FMD~~ free country or *zone* where *vaccination* is practised is seeking to become one where *vaccination* is not practised;

   b) regulatory measures for the prevention and early detection of FMD have been implemented;

4) describe in detail and provide ~~supply~~ documented evidence that for the past 12 months ~~the following have been properly implemented and supervised~~:

   a) ~~in the case of a FMD free *zone*,~~ the boundaries of ~~the~~ any proposed ~~FMD~~ free *zone* have been established and effectively supervised;

   b) the boundaries and *biosecurity* ~~measures~~ of ~~a~~ any *protection zone*~~, if applicable~~ have been established and effectively supervised;

c) the system for preventing the entry of FMDV into the proposed ~~FMD~~ free country or *zone* has been established and effectively supervised;

d) the control of the movement of susceptible animals, their *meat* ~~and~~ other products, and fomites into the proposed ~~FMD~~ free country or *zone*, in particular the measures described in Articles 8.8.8.~~, 8.8.9. and~~ to 8.8.12. has been effectively implemented and supervised;

e) measures to prevent the introduction of ~~no~~ vaccinated animals ~~has been introduced,~~ except in accordance with Articles 8.8.8. ~~and~~ 8.8.9., 8.8.9bis., 8.8.11. and 8.8.11bis. have been effectively implemented and supervised. Any vaccinated animals introduced for direct *slaughter* were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results. For ruminants the head, including the pharynx, tongue and associated lymph nodes, was either destroyed or treated in accordance with Article 8.8.31.

The Member Country or the proposed free *zone* will be included in the list of ~~FMD free~~ countries or *zones* free from FMD, where *vaccination* is not practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE in accordance with the requirements in Chapter 1.1.

~~A country or *zone* free from FMD may maintain its free status despite an incursion of potentially infected African buffaloes provided that the *surveillance* programme substantiates the absence of transmission of FMDV.~~

Provided the conditions of point~~s 1 to 4~~ 3 ~~are~~ is fulfilled, the status of a country or *zone* will not be affected by applying official emergency *vaccination* to FMD susceptible animals in zoological collections in the face of a FMD threat identified by the *Veterinary Authorities*, provided that the following conditions are met:

– the zoological collection has the primary purpose of exhibiting animals or preserving rare species, has been identified, including the boundaries of the facility, and is included in the country's contingency plan for FMD;

– appropriate *biosecurity* measures are in place, including effective separation from other susceptible domestic *population*s or *wildlife*;

– the animals are identified as belonging to the collection and any movements can be traced;

– the vaccine used complies with the standards described in the *Terrestrial Manual*;

– *vaccination* is conducted under the supervision of the *Veterinary Authority*;

– the zoological collection is placed under *surveillance* for at least 12 months after *vaccination*.

In the event of the application for ~~the status of~~ a new ~~FMD~~ free *zone* ~~where *vaccination* is not practised to be assigned to a new *zone*~~ being adjacent to another ~~FMD~~ ~~free~~ *zone* of the same status ~~where *vaccination* is not practised~~, it should be stated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zone*s remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of animals between the *zones* of the same status in accordance with Chapter 4.3.

In the case of an incursion of stray African buffalo, a *protection zone* according to Article 4.4.6. should be established to manage the threat and maintain the free status of the rest of the country.

If Aa *protection zone* ~~used~~ is established, ~~to preserve the *status* of a free country or *zone* from a newly identified likelihood of introduction of FMDV~~ it should comply with Article 4.~~43~~.6. If *vaccination* is implemented in the *protection zone*, ~~this will not affect the freedom of the rest of the country or *zone*~~ the *animal health status* of the rest of the country or *zone* is not affected.

Article 8.8.3.

~~FMD free~~ Country or zone free from FMD where vaccination is practised

In defining a *zone* where *vaccination* is practised the principles of Chapter 4.3. should be followed.

Susceptible animals in the ~~FMD free~~ country or *zone* free from FMD where *vaccination* is practised should be protected by the application of *biosecurity* measures that prevent the entry of FMDV into the free country or *zone*. Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*.

Based on the epidemiology of FMD in the country, it may be decided to vaccinate only a defined *subpopulation* comprised of certain species or other subsets of the total susceptible *population*.

To qualify for inclusion in the list of ~~FMD free~~ countries or *zones* free from FMD where *vaccination* is practised, a Member Country should:

1) have a record of regular and prompt animal *disease* reporting;

2) send a declaration to the OIE stating that, based on the *surveillance* described in point 3, within the proposed ~~FMD~~ free country or *zone*:

   ~~a)~~ ~~there has been no case of FMD during the past two years;~~

   ~~b~~a) there has been no ~~evidence~~ of ~~FMDV~~ transmission of FMDV during the past 12 months;

EU comment

Editorial: the word "of" before "transmission" should be deleted in point 2a) above.

   b) there has been no *case* with clinical sign of FMD during the past 12 months;

3) supply documented evidence that:

   a) *surveillance* to detect clinical signs of FMD has been implemented in accordance with Articles 8.8.40. to 8.8.42. ~~has been implemented to detect clinical signs of FMD~~ for the past two years and demonstrates ~~no evidence of~~ that there has been no:

      i) *infection* with FMDV in unvaccinated animals for the past ~~two years~~ 12 months;

      ii) ~~FMDV~~ transmission of FMDV in vaccinated animals for the past 12 months;

   b) regulatory measures for the prevention and early detection of FMD have been implemented for the past ~~12 months~~ two years;

   c) compulsory systematic *vaccination* in the target *population* has been carried out to achieve adequate *vaccination* coverage and population immunity for the past 12 months ~~two years;~~

   d) *vaccination* has been carried out following appropriate vaccine strain selection for the past 12 months ~~two years;~~

4) describe in detail and ~~supply~~ provide documented evidence that for the past 12 months ~~the following have been properly implemented and supervised~~:

   a) ~~in case of FMD free zone,~~ the boundaries of the proposed ~~FMD~~ free *zone* have been established and effectively supervised;

   b) the boundaries and *biosecurity* ~~measures~~ of any *protection zone*~~,~~ ~~if applicable~~ have been established and effectively supervised;

   c) the system for preventing the entry of FMDV into the proposed ~~FMD~~ free country or *zone*, in particular the measures described in Articles 8.8.8., 8.8.9. and 8.8.12. has been established and effectively supervised;

   d) the control of the movement of susceptible animals and their products into the proposed ~~FMD~~ free country or *zone* has been effectively implemented and supervised.

The Member Country or the proposed free *zone* will be included in the list of ~~FMD free~~ countries or *zones* free from FMD where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE in accordance with the requirements in Chapter 1.1.

If a Member Country that meets the requirements of a ~~FMD free~~ country or *zone* free from FMD where *vaccination* is practised wishes to change its status to ~~FMD free~~ country or *zone* free from FMD where *vaccination* is not practised, it should notify the OIE in advance of the intended date of cessation of *vaccination* and apply for the new status within 24 months of the cessation. The status of this country or *zone* remains unchanged until compliance with Article 8.8.2. is approved by the OIE. If the dossier for the new status is not provided within 24 months then the status of the country or *zone* as being free with *vaccination* will be suspended. If the country does not comply with requirements of Article 8.8.2., evidence should be provided within three months that it complies with Article 8.8.3. Otherwise the status will be withdrawn.

If a Member Country that meets the requirements of a country or *zone* free from FMD where *vaccination* is not practised and is recognised by the OIE as such, wishes to change its status to country or *zone* free from FMD where *vaccination* is practised, it should provide the OIE with an application and a plan following the structure of the Questionnaire of Article 1.6.6~~., indicating the intended date of beginning of *vaccination*~~. The status as country or *zone* free from FMD where *vaccination* is not practised ~~of this country or *zone*~~ remains unchanged until the application and plan are approved by the OIE. As soon as recognised free with *vaccination* the country or *zone* will begin the *vaccination*. The Member Country should provide evidence within six months that it complies with Article 8.8.3. for this time period. Otherwise the status will be withdrawn.

~~If a country needs to define a *protection zone* l~~In accordance with Article 4.~~3~~4.6. ~~in response to an increased risk, including by the application of *vaccination*,~~ once a ~~the~~ *protection zone* has been approved by the OIE, the freedom of the rest of the country or *zone* remains unchanged.

In the event of the application for ~~the status of~~ a new ~~FMD free~~ free *zone* ~~where *vaccination* is practised to be assigned to a new *zone*~~ being adjacent to another ~~FMD~~ ~~free~~ *zone* of the same status ~~where *vaccination* is practised~~, it should be stated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of animals between the *zones* of the same status in accordance with Chapter 4.3.

Article 8.8.4.

~~FMD free~~ Compartment free from FMD where vaccination is not practised

A ~~FMD free~~ *compartment* free from FMD where *vaccination* is not practised can be established in ~~either a FMD free~~ any country or *zone* ~~or in an infected country or *zone*~~. In defining such a *compartment* the principles of Chapters 4.~~3~~4. and 4.~~4~~5. should be followed. Susceptible animals in the ~~FMD~~ free *compartment* should be separated from any other susceptible animals by the effective application of an ~~effective~~ *biosecurity plan* ~~management system~~.

EU comment

Editorial: it should be Chapter 4.4. and 4.5. (not 4.45.).

A Member Country wishing to establish a ~~FMD free~~ *compartment* free from FMD where *vaccination* is not practised should:

1) have a record of regular and prompt animal *disease* reporting and, if not ~~FMD~~ free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;

2) declare for the ~~FMD~~ free *compartment* that:

   a) there has been no *case* of FMD during the past 12 months;

   b) no ~~evidence of~~ *infection* with FMDV has been ~~found~~ detected during the past 12 months;

   c) *vaccination* against FMD is prohibited;

   d) no animal vaccinated against FMD within the past 12 months is in the *compartment*;

e) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;

f) documented evidence shows that *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation;

g) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;

3) describe in detail:

a) the animal *subpopulation* in the *compartment*;

b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out in accordance with point 1.

The *compartment* should be approved by the *Veterinary Authority*. The ~~first~~ approval should only be granted when no *case* or transmission of FMD has occurred within a 10 ~~ten~~-kilometre radius of the *compartment* during the ~~past~~ three months prior to the effective establishment of the *biosecurity plan*.

Article 8.8.4bis.

Compartment free from FMD where vaccination is practised

A *compartment* free from FMD where *vaccination* is practised can be established in either a free country or *zone* where *vaccination* is practised or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.~~3~~4. and 4.~~4~~5. should be followed. Susceptible animals in the free *compartment* should be separated from any other susceptible animals by the application of an effective *biosecurity plan*.

EU comment

Editorial: it should be Chapter 4.4. and 4.5. (not 4.45.).

A Member Country wishing to establish a *compartment* free from FMD where *vaccination* is practised should:

1) have a record of regular and prompt animal *disease* reporting and, if not free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;

2) declare for the free *compartment* where *vaccination* is practised that:

a) there has been no *case* of FMD during the past 12 months;

b) no ~~evidence of *infection* with~~ transmission of FMDV has been found during the past 12 months;

c) compulsory systematic *vaccination* is carried out using a vaccine that complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection. The *vaccination* coverage and population immunity are closely monitored;

d) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;

e) documented evidence shows that regular clinical, serological and virological *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation, so as to detect *infection* at an early stage with a high level of confidence;

f) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;

3) describe in detail:

a) the animal *subpopulation* in the *compartment*;

b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out according to point 1 and the *vaccination* plan;

c) implementation of points 2c), 2e) and 2f).

The *compartment* should be approved by the *Veterinary Authority*. The approval should only be granted when no *case* or transmission of FMD has occurred within a 10-kilometre radius of the *compartment* during the three months prior to the effective establishment of the *biosecurity plan*.

Article 8.8.5.

~~FMD infected~~ Country or zone infected with FMDV

For the purposes of this chapter, a ~~FMD infected~~ country or *zone* infected with FMDV is one that does not fulfil the requirements to qualify as either ~~FMD~~ free where *vaccination* is not practised or ~~FMD~~ free where *vaccination* is practised.

Article 8.8.6.

Establishment of a containment zone within a ~~FMD free~~ country or zone free from FMD

In the event of ~~limited~~ *outbreaks* within a ~~FMD free~~ country or *zone* previously free from FMD, including within a *protection zone*, with or without *vaccination*, a ~~single~~*containment zone*, which includes all epidemiologically linked *outbreaks*, may be established for the purpose of minimising the impact on the entire country or *zone* in accordance with Article 4.4.7.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit as soon as possible to the OIE, in addition to the requirements of Article 4.4.7. in support of the application, documented evidence that:

1) on suspicion, a strict standstill has been imposed on the suspected *establishments* and in the country or *zone* animal movement control has been imposed and effective controls on the movement of other *commodities* mentioned in this chapter are in place;

2) on confirmation, an additional standstill of susceptible animals has been imposed in the entire *containment zone* and the movement controls described in point 1 have been reinforced;

~~3) the definitive boundaries of the *containment zone* have been established after an epidemiological investigation (trace-back, trace-forward) has demonstrated that the *outbreaks* are epidemiologically related and limited in number and geographic distribution;~~

34) investigations into the likely source of the *outbreaks* have been carried out;

~~5 a *stamping-out policy*, with or without the use of emergency *vaccination*, has been applied;~~

~~6) no new *cases* have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.8.1. after the application of a *stamping-out policy* to the last detected *case*;~~

~~7) the susceptible domestic and *captive wild* animal populations within the *containment zone* are clearly identified as belonging to the *containment zone*;~~

48) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in place in the *containment zone* and in the rest of the country or *zone*;

59) measures that prevent the spread of FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place.

~~The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established.~~ The free status of the ~~these~~ areas outside the *containment zone* may be reinstated irrespective of the provisions of Article 8.8.7., once the *containment zone* has been approved by the OIE as complying with points 1 to 59 above. ~~*Commodities* from susceptible animals for *international trade* should be identified as to their origin, either from inside or outside the *containment zone*.~~

In the event of recurrence of *infection* with FMDV in unvaccinated animals or ~~FMDV~~ transmission of FMDV in vaccinated animals in the *containment zone*, established in accordance with point 4a) of Article 4.4.7., the

approval of the *containment zone* is withdrawn and the FMD status of the whole country or *zone* is suspended until the relevant requirements of Article 8.8.7. are fulfilled.

In the event of occurrence of *infection* with FMDV in unvaccinated animals or transmission of FMDV in vaccinated animals in the outer zone of a *containment zone* established in accordance with point 4a) of Article 4.4.7., the approval of the *containment zone* is withdrawn and the status of the whole country or *zone* is suspended until the relevant requirements of Article 8.8.7. are fulfilled.

The recovery of the ~~FMD~~ free status of the *containment zone* should be achieved within 12 months of its approval and follow the provisions of Article 8.8.7.

Article 8.8.7.

Recovery of free status ~~(see Figures 1 and 2)~~

1) When a FMD *case* occurs in a ~~FMD free~~ country or *zone* previously free from FMD where *vaccination* is not practised, one of the following waiting periods is required to regain this free status:

   a) three months after the disposal of the last animal killed where a *stamping-out policy*, without emergency *vaccination*, and *surveillance* are applied in accordance with Articles 8.8.40. to 8.8.42.; or

   b) three months after the disposal of the last animal killed or the *slaughter* of all vaccinated animals, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied; or

   c) six months after the disposal of the last animal killed or the last *vaccination*, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated animals, and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied. However, this requires a serological survey based on the detection of antibodies to non-structural proteins of FMDV to demonstrate no ~~evidence of *infection*~~ transmission of FMDV in the ~~remaining~~ vaccinated *population*. This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of *infection* in the non-vaccinated *population*, and absence of transmission in the emergency vaccinated *population* based on the provisions of point 7 of Article 8.8.40. ~~effectiveness of *vaccination* is demonstrated by a serological survey and serological *surveillance* for antibodies to nonstructural proteins is carried out in all vaccinated *herds* by sampling all vaccinated ruminants and their unvaccinated offspring, and a representative number of FMD susceptible animals of other species~~.

   The country or *zone* will regain ~~the~~ its free status ~~of FMD free country or *zone* where *vaccination* is not practised~~ only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

   The time periods in points 1a) to 1c) are not affected if official emergency *vaccination* of zoological collections has been carried out following the relevant provisions of Article 8.8.2.

   Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.8.2. applies.

2) When a ~~FMD~~ *case* of FMD occurs in a ~~FMD free~~ country or *zone* previously free from FMD where *vaccination* is not practised, the following waiting period is required to gain the status of ~~FMD free~~ country or *zone* free from FMD where *vaccination* is practised: six months after the disposal of the last animal killed where a *stamping-out policy* has been applied and a continued *vaccination* policy has been adopted, provided that *surveillance* is applied in accordance with Articles 8.8.40. to 8.8.42., and a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates no evidence of ~~FMDV~~ transmission of FMDV.

   The country or *zone* can gain the status of ~~FMD~~ free ~~country or *zone*~~ from FMD where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

   Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.8.3. applies.

3) When a *case* of *infection* with FMDV occurs in a ~~FMD free~~ country or *zone* previously free from FMD where *vaccination* is practised, one of the following waiting periods is required to regain this free status:

   a) six months after the disposal of the last animal killed where a *stamping-out policy*, with emergency *vaccination*, and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates no evidence of ~~virus~~ transmission of FMDV This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of *infection* in the non-vaccinated *population* and absence of transmission of FMDV in the vaccinated *population* based on the provisions of points 7 and 8 of Articles 8.8.40. as appropriate; or

   b) 12 months after the detection of the last *case* where a *stamping-out policy* is not applied, but where emergency *vaccination* and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates no evidence of ~~virus~~ transmission of FMDV.

   The country or *zone* will regain its free status only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

   When~~re~~ emergency *vaccination* is not applied, the above waiting periods do not apply, and Article 8.8.3. applies.

   ~~The country or *zone* will regain the status of FMD free country or *zone* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.~~

4) When a ~~FMD~~ *case* of *infection* with FMDV occurs in a ~~FMD free~~ *compartment* free from FMD, Article 8.8.4. or Article 8.8.4bis. applies.

5) Member Countries applying for the recovery of status should do so only when the respective requirements for the recovery of status are met. When a *containment zone* has been established, the restrictions within the *containment zone* should be lifted in accordance with the requirements of this article only when ~~the *disease*~~ FMD has been successfully eradicated within the *containment zone*.

   For Member Countries not applying for recovery within 24 months after suspension, the provisions of Article 8.8.2., Article 8.8.3. or Article 8.8.4. apply.

Article 8.8.8.

Direct transfer of FMD susceptible animals from an infected zone for slaughter in a free zone (whether vaccination is practised or not)

In order not to jeopardise the status of a free *zone*, FMD susceptible animals should only leave the infected *zone* if transported directly ~~to~~ for *slaughter* in the nearest designated *slaughterhouse/abattoir* under the following conditions:

1) no FMD susceptible animal has been introduced into the *establishment* of origin and no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;

2) the animals were kept in the *establishment* of origin for at least three months prior to movement;

3) FMD has not occurred within a 10-kilometre radius of the *establishment* of origin for at least four weeks prior to movement;

4) the animals ~~should be~~ are transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;

5) such a *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the infected *zone*;

6) *vehicles* and the *slaughterhouse/abattoir* ~~should be~~ are subjected to thorough cleansing and *disinfection* immediately after use.

The animals should have been subjected to ante- and post-mortem inspection within 24 hours before and after *slaughter* with no evidence of FMD, and the *meat* derived from them treated in accordance with point 2 of Article 8.8.22. or Article 8.8.23. Other products obtained from the animals and any products coming into contact with them should be treated in accordance with Articles 8.8.31. to 8.8.38. in order to destroy any FMDV potentially present.

Article 8.8.9.

Direct transfer of FMD susceptible animals from a containment zone for slaughter in a free zone (whether vaccination is practised or not)

In order not to jeopardise the status of a free *zone*, FMD susceptible animals should only leave the *containment zone* if transported directly ~~to~~ for *slaughter* in the nearest designated *slaughterhouse/abattoir* under the following conditions:

1) the *containment zone* has been officially established in accordance with the requirements in Article 8.8.6.;

2) the animals ~~should be~~ are transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;

3) such an *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the *containment zone*;

4) *vehicles* and the *slaughterhouse/abattoir* ~~should be~~ are subjected to thorough cleansing and *disinfection* immediately after use.

The animals should have been subjected to ante- and post-mortem inspection within 24 hours before and after *slaughter* with no evidence of FMD and the *meat* derived from them treated in accordance with point 2 of Article 8.8.22. or Article 8.8.23. Other products obtained from the animals and any products coming into contact with them should be treated in accordance with Articles 8.8.31. to 8.8.38. in order to destroy any FMDV potentially present.

Article 8.8.9bis.

Direct transfer of FMD vaccinated animals from a ~~free~~ zone free from FMD where vaccination is practised or not for slaughter in a free zone where vaccination is not practised

In order not to jeopardise the status of a free *zone* where *vaccination* is not practised, FMD vaccinated animals should only leave the *free zone* if transported directly for *slaughter* in the nearest designated *slaughterhouse/abattoir* under the following conditions:

1) no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;

2) the animals were kept in the country or *zone* of origin for at least three months prior to movement;

3) the animals are transported under the supervision of the *Veterinary Authority* in a *vehicle*, directly from the *establishment* of origin to the *slaughterhouse/abattoir*;

4) if transiting an infected *zone*, the animals were not exposed to any source of FMDV during transportation to the *place of shipment*.

Article 8.8.10.

Recommendations for importation from ~~FMD free~~ countries, ~~or~~ zones or compartments free from FMD where vaccination is not practised ~~or FMD free compartments~~ free from FMD

For FMD susceptible animals

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

1) showed no clinical sign of FMD on the day of shipment;

2) were kept since birth or for at least the past three months in a ~~FMD free~~ country, ~~or~~ *zone* or *compartment* free from FMD where *vaccination* is not practised ~~or a FMD free *compartment*~~ free from FMD;

EU comment

Editorial: the words "free from FMD" at the end of the sentence above should be deleted as they are redundant.

3) if transiting an infected *zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*~~.~~;

4) if previously vaccinated, comply with point 4 of Article 8.8.11.

Article 8.8.11.

Recommendations for importation from ~~FMD free~~ countries, ~~or~~ zones or compartments free from FMD where vaccination is practised

For domestic ruminants and pigs

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

1) showed no clinical sign of FMD on the day of shipment;

2) were kept since birth or for at least the past three months in a ~~FMD free~~ country, ~~or~~ *zone* or *compartment* free from FMD where *vaccination* is practised;

3) if not vaccinated were subjected to ~~a~~ virological and serological tests for FMD with negative results on samples collected not earlier than 14 days before the shipment;

4) if vaccinated were subjected to virological and NSP serological tests for FMD with negative results on samples collected not earlier than 14 days before the shipment;

5) if transiting an infected *zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*.

Article 8.8.11bis.

Recommendations for the importation from a ~~free~~ country, zone or compartment free from FMD where vaccination is practised

For vaccinated animals destined for slaughter

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

1) no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to shipment;

2) the animals were kept in the country, *zone* or *compartment* of origin since birth or for at least three months prior to shipment;

3) the animals were transported under the supervision of the *Veterinary Authority* directly from the *establishment* of origin in sealed *vehicles/vessels*;

4) if transiting an *infected zone*, the animals were not exposed to any source of FMDV during transportation to the *place of shipment*.

Article 8.8.12.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV, where an official control programme exists

For domestic ruminants and pigs

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

1) the animals showed no clinical sign of FMD on the day of shipment;

2) pigs have not been fed swill not complying with Article 8.8.31bis.;

3~~2~~) prior to isolation, the animals were kept in the *establishment* of origin:

a) for 30 days, or since birth if younger than 30 days, if a *stamping-out policy* is applied to control FMD in the *exporting country* or *zone*, or

b) for three months, or since birth if younger than three months if a *stamping-out policy* is not applied to control FMD in the *exporting country* or *zone*;

4~~3~~) the *establishment* of origin is covered by the *official control programme* and FMD has not occurred within it ~~the *establishment* of origin~~ for the relevant period as defined in points 2a) and 2b) above;

5~~4~~) the animals were isolated in an *establishment* for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic virological and serological tests for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period, and that FMD did not occur within a 10-kilometre radius of the *establishment* during that period, or the *establishment* is a *quarantine station*;

6~~5~~) the animals were not exposed to any source of FMDV during their transportation from the *establishment* to the *place of shipment*.

~~Article 8.8.13.~~

~~**Recommendations for importation from FMD free countries, or *zones* free from FMD where vaccination is not practised or FMD free compartments free from FMD**~~

~~For fresh semen of domestic ruminants and pigs~~

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

~~1) the donor males:~~

~~*a)* showed no clinical sign of FMD on the day of collection of the semen;~~

~~*b)* were kept for at least three months prior to collection in a FMD free country, or *zone* free from FMD where *vaccination* is not practised or FMD free *compartments* free from FMD;~~

~~*c)* were kept in an *artificial insemination centre* where none of the animals had a history of *infection* with FMDV;~~

~~2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.~~

Article 8.8.14.

Recommendations for importation from ~~FMD free~~ countries~~, or~~ zones or compartments free from FMD where vaccination is not practised or ~~FMD free compartments free from FMD~~

For fresh and frozen semen of domestic ruminants and pigs

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

1) the donor males:

   a) showed no clinical sign of FMD on the day of collection of the semen ~~and for the following 30 days~~;

   b) were kept for at least three months prior to collection in a ~~FMD free~~ country, ~~or~~ *zone* or *compartment* free from FMD where *vaccination* is not practised ~~or FMD free *compartments* free from FMD~~;

   c) were kept in an *artificial insemination centre*;

EU comment

In relation to point 1c) above, the EU queries for how long the donor males need to have been kept in the artificial insemination centre before collection. Indeed, it is not clear from the text whether a specific time period is required for that at all (as is the case for point 1b) i.e. 3 months).

2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.8.15.

Recommendations for importation from ~~FMD free~~ countries ~~or~~, zones or compartments free from FMD where vaccination is practised

For frozen semen of domestic ruminants and pigs

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

1) the donor males:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept for at least three months prior to collection in a ~~FMD free~~ country or *zone* free from FMD where *vaccination* is practised;

   c) either

      i) have been vaccinated at least twice~~,~~ with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;

      or

      ii) were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;

2) the semen:

   a) was collected, processed and stored in accordance with Chapters 4.5. and 4.6.;

   b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor ~~animals~~ males were kept showed any sign of FMD.

Article 8.8.16.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV

For frozen semen of domestic ruminants and pigs

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

1) the donor males:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept in an *artificial insemination centre* ~~where~~ to which no animal had been added in the 30 days before collection, and within a 10-kilometre radius of which, ~~that~~ FMD has not occurred ~~within a 10 kilometre radius of the *artificial insemination centre* for~~ in the 30 days before and after collection;

   c) either

      i) have been vaccinated at least twice~~,~~ with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;

      or

      ii) were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;

2) the semen:

   a) was collected, processed and stored in accordance with Chapters 4.5. and 4.6.;

   b) was subjected, with negative results, to a test for evidence of FMDV if the donor male has been vaccinated within the 12 months prior to collection;

   c) was stored in the country of origin for a period of at least one month following collection, and that during this period no animal on the *establishment* where the donor males were kept showed any sign of FMD.

~~Article 8.8.17.~~

~~**Recommendations for the importation of *in vivo* derived embryos of bovines cattle**~~

~~Irrespective of the FMD status of the *exporting country*, *zone* or *compartment*, *Veterinary Authorities* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of bovines cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in accordance with the relevant provisions of Chapters 4.7. and 4.9., as relevant.~~

Article 8.8.18.

Recommendations for importation from ~~FMD free~~ countries ~~or~~, zones or compartments free from FMD where vaccination is not practised ~~or FMD free compartments free from FMD~~

For *in vitro* produced embryos of bovines ~~cattle~~

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

1) the donor females:

   a) showed no clinical sign of FMD at the time of collection of the oocytes;

   b) were kept for at least three months prior to collection in a ~~FMD free~~ country or *zone* free from FMD where *vaccination* is not practised or ~~FMD free~~ *compartments* free from FMD;

2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16., as relevant;

3) the oocytes were collected, and the embryos were processed and stored in accordance with Chapters 4.8. and 4.9., as relevant.

Article 8.8.19.

Recommendations for importation from ~~FMD free~~ countries ~~or~~, zones or compartments free from FMD where vaccination is practised

For *in vitro* produced embryos of bovines ~~cattle~~

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

1) the donor females:

   a) showed no clinical sign of FMD at the time of collection of the oocytes;

   b) were kept for at least three months prior to collection in a ~~FMD free~~ country or *zone* free from FMD where *vaccination* is practised;

   c) either

      i) have been vaccinated at least twice~~,~~ with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;

      or

      ii) were subjected, not less than 21 days after collection, to tests for antibodies against FMDV, with negative results;

2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16., as relevant;

3) the oocytes were collected, and the embryos were processed and stored in accordance with Chapters 4.8. and 4.9., as relevant.

Article 8.8.20.

Recommendations for importation from ~~FMD free~~ countries ~~or~~, zones or compartments free from FMD where vaccination is not practised ~~or FMD free compartments free from FMD~~

For fresh meat or meat products of FMD susceptible animals

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

1) have been kept in a ~~FMD free~~ country or *zone* or *compartment* free from FMD, where *vaccination* is not practised ~~or FMD free *compartment* free from FMD,~~ or ~~which~~ have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;

EU comment

Editorial: it should be "country, zone or compartment".

2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 8.8.21.

Recommendations for importation from ~~FMD free~~ countries ~~or~~, zones or compartments free from FMD where vaccination is practised

For fresh meat and meat products of ruminants and pigs

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

1) have been kept in the ~~FMD free~~ country or *zone* or *compartment* free from FMD where *vaccination* is practised, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;

EU comment

Editorial: it should be "country, zone or compartment".

2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections ~~for FMD~~ with favourable results;

3) for ruminants the head, including the pharynx, tongue and associated lymph nodes, has been excluded from the shipment.

Article 8.8.22.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV, where an official control programme exists

For fresh meat of bovines cattle and water buffaloes *(Bubalus bubalis)* (excluding feet, head and viscera)

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

1) comes from animals which:

   a) have remained, for at least three months prior to *slaughter*, in a *zone* of the *exporting country* where bovines ~~cattle~~ and water buffaloes are regularly vaccinated against FMD and where an *official control programme* is in operation;

   b) have been vaccinated at least twice with the last *vaccination* not more than six months, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to *slaughter*;

   c) were kept for the past 30 days in:

      – a *quarantine station*; or ~~in~~

      – an *establishment*, within a ~~ten~~ 10-kilometre radius of which ~~and that~~ FMD has not occurred ~~within a 10 kilometre radius of the *establishment*~~ during that period~~, or the *establishment* is a *quarantine station*~~;

   d) have been transported, in a *vehicle* which was cleansed and disinfected before the bovines ~~cattle~~ and water buffaloes were loaded, directly from the *establishment* of origin or *quarantine station* to the approved *slaughterhouse/abattoir* without coming into contact with other FMD susceptible animals which do not fulfil the required conditions for export;

   e) have been slaughtered in an approved *slaughterhouse/abattoir*:

      i) which is officially designated for export;

      ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;

   f) were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2., with favourable results ~~have been subjected, with favourable results, to ante-mortem inspection within 24 hours of *slaughter* and to post-mortem inspections within 24 hours before and after *slaughter* with no evidence of FMD~~;

2) comes from deboned carcasses:

   a) from which the major lymphatic nodes have been removed;

b) which, prior to deboning, have been submitted to maturation at a temperature greater than + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was less than 6.0 when tested in the middle of both the longissimus dorsi muscle.

Article 8.8.22bis.

Recommendations for importation from countries or zones infected with FMDV, where an official control programme exists

For fresh meat of domestic pigs

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

1) the *meat* comes from animals complying with ~~points 1 to 6 of~~ Article 8.8.12.;

2) the animals were transported, in a *vehicle* which was cleaned and disinfected before the pigs were loaded, directly from the *establishment* of origin or *quarantine station* to the approved *slaughterhouse/abattoir* without coming into contact with other FMD susceptible animals that do not fulfil the conditions required for export, either during transport or at the *slaughterhouse/abattoir*;

3) the animals were slaughtered in an approved *slaughterhouse/abattoir*:

   a) which is officially designated for export;

   b) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;

4) the animals were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2., with favourable results;

5) the carcasses were not released earlier than 24 hours after *slaughter* and not before *Veterinary Authorities* have confirmed that FMD has not occurred in the *establishment* of origin.

Article 8.8.23.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV

For meat products of FMD susceptible animals

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

1) the entire consignment of *meat products* come from animals which have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections ~~for FMD~~ with favourable results;

2) the *meat products* have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.31.;

3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMDV.

Article 8.8.24.

Recommendations for importation from ~~FMD free~~ countries ~~or~~, zones or compartments free from FMD ~~where~~ whether vaccination ~~either~~ is practised or ~~is~~ not ~~practised or FMD free compartments~~ free from FMD

For milk and milk products (other than those defined in Article 8.8.1bis.) intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a ~~FMD free~~ country, *zone* or *compartment* free from FMD, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.

Article 8.8.25.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV, where an official control programme exists

For milk and milk products (other than those defined in Article 8.8.1bis.)

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

1) these products:

   a) originate from *establishments* which were not infected or suspected of being infected with FMD at the time of *milk* collection;

   b) have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.35. and in Article 8.8.36.;

2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

~~Article 8.8.26.~~

~~**Recommendations for importation from FMD infected countries or zones infected with FMDV**~~

~~For blood-meal and meat-meals from FMD susceptible animals~~

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

~~1)~~ ~~the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.;~~

~~2)~~ ~~the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.~~

Article 8.8.27.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV

For wool, hair, bristles, raw hides and skins from FMD susceptible animals

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

1) these products have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Articles 8.8.32., 8.8.33. and 8.8.34.;

2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMDV.

Veterinary Authorities should authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather such as wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 8.8.28.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV

For straw and forage

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

1) are free of grossly identified contamination with material of animal origin;

2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:

   a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ~~ten~~ 10 minutes,

   b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35-40% in a chamber kept closed for at least eight hours and at a minimum temperature of 19°C;

OR

3) have been kept in bond for at least four months before being released for export.

Article 8.8.29.

Recommendations for importation from ~~FMD free~~ countries~~or~~, zones or *compartments* free from FMD, ~~where~~ whether vaccination ~~either~~ is practised or ~~is not practised~~

For skins and trophies derived from FMD susceptible wildlife

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products are derived from animals that have been killed in ~~such~~ a country or *zone* free from FMD or which have been imported from a country, *zone* or *compartment* free from FMD.

Article 8.8.30.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV

For skins and trophies derived from FMD susceptible wildlife

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of FMDV in accordance with the procedures in Article 8.8.37.

Article 8.8.31.

Procedures for the inactivation of FMDV in meat and meat products

For the inactivation of FMDV present in *meat* and *meat products*, one of the following procedures should be used:

1. Canning

   Meat and *meat products* are subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate FMDV.

2. Thorough cooking

   Meat, previously deboned and defatted, and *meat products* are subjected to a heat treatment that results in a core temperature of at least 70°C for a minimum of 30 minutes.

   After cooking, they should be packed and handled in such a way they are not exposed to a source of FMDV.

3. Drying after salting

When *rigor mortis* is complete, the *meat* is deboned, treated with salt (NaCl) and 'completely dried'. It should not deteriorate at ambient temperature.

'Completely dried' is defined as a moisture protein ratio that is not greater than 2.25:1 or a water activity (Aw) that is not greater than 0.85.

Article 8.8.31bis.

Procedures for the inactivation of FMDV in swill

For the inactivation of FMDV in swill, one of the following procedures should be used:

1) the swill is maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or

2) the swill is maintained at a temperature of at least 121°C for at least ten minutes at an absolute pressure of 3 bar; or

3) the swill is subjected to an equivalent treatment that has been demonstrated to inactivate FMDV.

Article 8.8.32.

Procedures for the inactivation of FMDV in wool and hair

For the inactivation of FMDV present in wool and hair for industrial use, one of the following procedures should be used:

1) for wool, industrial washing, which consists of the immersion ~~of the wool~~ in a series of baths of water, soap and sodium hydroxide (~~soda~~ NaOH) or potassium hydroxide (~~potash~~ KOH);

2) chemical depilation by means of slaked lime or sodium sulphide;

3) fumigation with formaldehyde in a hermetically sealed chamber for at least 24 hours;

4) for wool, industrial scouring which consists of the immersion ~~of wool~~ in a water-soluble detergent held at 60-70°C;

5) for wool, storage ~~of wool~~ at 4°C for four months, 18°C for four weeks or 37°C for eight days.

Article 8.8.33.

Procedures for the inactivation of FMDV in bristles

For the inactivation of FMDV present in bristles for industrial use, one of the following procedures should be used:

1) boiling for at least one hour; or

2) immersion for at least 24 hours in a 1% aqueous solution of formaldehyde.

Article 8.8.34.

Procedures for the inactivation of FMDV in raw hides and skins

For the inactivation of FMDV present in raw hides and skins for industrial use, the following procedure should be used: treatment for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na_2CO_3).

Article 8.8.35.

Procedures for the inactivation of FMDV in milk and cream for human consumption

For the inactivation of FMDV present in *milk* and cream for human consumption, one of the following procedures should be used:

~~1) a process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]); or~~

~~2~~1) if the *milk* has a pH less than 7.0, a process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST])~~,~~; or

~~3~~2) if the *milk* has a pH of 7.0 or greater, the HTST process applied twice.

Article 8.8.36.

Procedures for the inactivation of FMDV in milk for animal consumption

For the inactivation of FMDV present in *milk* for animal consumption, one of the following procedures should be used:

1) the HTST process applied twice; or

2) HTST combined with another physical treatment, e.g., maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with desiccation~~, or~~.

~~3) UHT combined with another physical treatment referred to in point 2 above.~~

Article 8.8.37.

Procedures for the inactivation of FMDV in skins and trophies from susceptible wildlife ~~susceptible to the disease~~

For the inactivation of FMDV present in skins and trophies from susceptible *wildlife* ~~*wild animals* susceptible to FMD~~, one of the following procedures should be used prior to complete taxidermal treatment

1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed; or

2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher); or

3) soaking, with agitation, in a 4% (weight/volume) solution of sodium carbonate (Na_2CO_3) maintained at pH 11.5 or greater for at least 48 hours; or

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 pH less than 3.0 for at least 48 hours; wetting and dressing agents may be added; or

5) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na_2CO_3).

Article 8.8.38.

Procedures for the inactivation of FMDV in casings of ruminants and pigs

For the inactivation of FMDV present in casings of ruminants and pigs, the following procedures should be used: treating for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl, $a_w < 0.80$), or with phosphate supplemented salt containing 86.5% NaCl, 10.7% Na_2HPO_4 and 2.8% Na_3PO_4 (weight/weight/weight), either dry or as a saturated brine ($a_w < 0.80$), and kept at a temperature of greater than 12°C during this entire period.

Article 8.8.39.

OIE endorsed official control programme for FMD

The overall objective of an OIE endorsed *official control programme* for FMD is for countries to progressively improve the situation and eventually attain ~~FMD~~ free status. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined *subpopulations* only.

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.

For a Member Country's *official control programme* for FMD to be endorsed by the OIE, the Member Country should:

1) have a record of regular and prompt animal *disease* reporting in accordance with the requirements in Chapter 1.1.;

2) submit documented evidence of the capacity of the *Veterinary Services* to control FMD; one way of providing this evidence is through the OIE PVS Pathway;

3) submit a detailed plan of the programme to control and eventually eradicate FMD in the country or *zone* including:

   a) the timeline;

   b) the performance indicators for assessing the efficacy of the control measures to be implemented;

   c) documentation indicating that the *official control programme* for FMD is applicable to the entire country;

4) submit a dossier on the epidemiology of FMD in the country describing the following:

   a) the general epidemiology in the country highlighting the current knowledge and gaps and the progress that has been made in controlling FMD;

   b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all FMD *outbreaks* in order to reduce the incidence of FMD *outbreaks* and to eliminate ~~FMDV~~ transmission of FMDV in at least one *zone* in the country;

   c) the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;

5) submit evidence that ~~FMD *surveillance* is in place~~:

   a) FMD *surveillance* is in place, ~~taking into account provisions~~ in accordance with Chapter 1.4. and the provisions on *surveillance* of this chapter;

   b) it has ~~have~~ diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains;

6) where *vaccination* is practised as a part of the *official control programme* for FMD, provide:

   a) evidence (such as copies of legislation) that *vaccination* of selected *population*s is compulsory;

   b) detailed information on *vaccination* campaigns, in particular on:

      i) target populations for *vaccination*;

      ii) monitoring of *vaccination* coverage, including serological monitoring of population immunity;

      iii) technical specification of the vaccines used, including matching with the circulating FMDV strains, and description of the licensing procedures in place;

      iv) the proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;

7) provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.

The Member Country's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence, based on the provisions of Article 1.6.11., has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE 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 or an extension of the distribution of FMD that cannot be addressed by the programme.

Article 8.8.40.

General principles of surveillance

Articles 8.8.40. to 8.8.42. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Member Countries seeking establishment, maintenance or recovery of freedom from FMD at the country, *zone* or *compartment* level or seeking endorsement by the OIE of their *official control programme* for FMD, in accordance with Article 8.8.39. *Surveillance* aimed at identifying *disease* and ~~FMDV~~ *infection* with, or transmission of, FMDV should cover domestic and, where appropriate, *wildlife* species as indicated in point 2 of Article 8.8.1.

1. Early detection

A *surveillance* system in accordance with Chapter 1.4. should be the responsibility of the *Veterinary Authority* and should provide an early warning system to report suspected *cases* throughout the entire production, marketing and processing chain. A procedure should be in place for the rapid collection and transport of samples to a *laboratory* for FMD diagnosis. This requires that sampling kits and other equipment be available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to seek assistance from a team with expertise in FMD diagnosis and control.

2. Demonstration of freedom

The impact and epidemiology of FMD widely differ in different regions of the world and therefore it is inappropriate to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from FMD in the country, *zone* or *compartment* at an acceptable level of confidence should be adapted to the local situation. For example, the approach to demonstrating freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMDV should differ significantly from an approach designed to demonstrate freedom from FMD in a country or *zone* where African buffaloes *(Syncerus caffer)* provide a potential reservoir of *infection*.

Surveillance for FMD should be in the form of a continuing programme. Programmes to demonstrate no evidence of *infection* with, ~~FMDV~~ and transmission of, FMDV should be carefully designed and implemented to avoid producing results that are insufficient to be accepted by the OIE or trading partners, or being excessively costly and logistically complicated.

The strategy and design of the *surveillance* programme will depend on the historical epidemiological circumstances including whether ~~or not~~ *vaccination* has been ~~used~~ practised or not.

A Member Country wishing to substantiate FMD freedom where *vaccination* is not practised should demonstrate no evidence of *infection* with FMDV.

A Member Country wishing to substantiate FMD freedom where *vaccination* is practised should demonstrate that FMDV has not been transmitted in any susceptible *population*s. Within vaccinated *population*s, serological surveys to demonstrate no evidence of ~~FMDV~~ transmission of FMDV should target animals that are less likely to show vaccine-derived antibodies to nonstructural proteins, such as young animals vaccinated a limited number of times, or unvaccinated animals. In any unvaccinated *subpopulation*, *surveillance* should demonstrate no evidence of *infection* with FMDV.

Surveillance strategies employed for establishing and maintaining a *compartment* should identify the prevalence, distribution and characteristics of FMD outside the *compartment*.

3. OIE endorsed official control programme

Surveillance strategies employed in support of an OIE endorsed *official control programme* should demonstrate evidence of the effectiveness of any *vaccination* used and of the ability to rapidly detect all FMD *outbreaks*.

Therefore considerable latitude is available to Member Countries to design and implement *surveillance* to establish that the whole territory or part of it is free from ~~FMDV~~ *infection* with, and transmission of, FMDV and to understand the epidemiology of FMD as part of the *official control programme*.

The Member Country should submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors, including the role of *wildlife*, if appropriate, are identified and managed. This should include provision of scientifically based supporting data.

4. Surveillance strategies

The strategy employed to establish the prevalence of *infection* with FMDV or to substantiate freedom from ~~FMDV~~ *infection* with, or transmission of, FMDV may be based on randomised or targeted clinical investigation or sampling at an acceptable level of statistical confidence, as described in Articles 1.4.4. and 1.4.5. If an increased likelihood of *infection* in particular localities or species can be identified, targeted sampling may be appropriate. Clinical inspection may be targeted at particular species likely to exhibit clear clinical signs (e.g., bovines ~~cattle~~ and pigs). The Member Country should justify the *surveillance* strategy chosen and the frequency of sampling as adequate to detect the presence of ~~FMDV~~ *infection* with, or transmission of, FMDV in accordance with Chapter 1.4. and the epidemiological situation.

The design of the sampling strategy should incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing should be adequate to detect *infection* or transmission if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member Country should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the prevailing or historical epidemiological situation, in accordance with Chapter 1.4.

5. Follow-up of suspected cases and interpretation of results

An effective *surveillance* system will identify suspected *cases* that require immediate follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Samples should be taken and submitted for diagnostic testing, unless the suspected *case* can be confirmed or ruled out by epidemiological and clinical investigation. Details of the occurrence of suspected *cases* and how they were investigated and dealt with should be documented. This should include the results of diagnostic testing and the control measures to which the animals concerned were subjected during the investigation.

The sensitivity and specificity of the diagnostic tests employed, including the performance of confirmatory tests, are key factors in the design, sample size determination and interpretation of the results obtained. The sensitivity and specificity of the tests used should be validated for the *vaccination* or *infection* history and production class of animals in the target population.

The *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following-up positives to determine with a high level of confidence, whether or not they are indicative of *infection* or transmission. This should involve supplementary tests and follow-up investigation to collect diagnostic material from the original *epidemiological unit* and *herds* which may be epidemiologically linked to it.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral transmission includes but is not limited to:

– characterisation of the existing production systems;
– results of clinical *surveillance* of the suspects and their cohorts;
– description of number of, and protocol for, *vaccinations* performed in the area under assessment;
– *biosecurity* and history of the *establishments* with reactors;
– identification and traceability of animals and control of their movements;
– other parameters of regional significance in historic ~~FMDV~~ transmission of FMDV.

6. Demonstration of population immunity

Following routine *vaccination*, evidence should be provided to demonstrate the effectiveness of the *vaccination* programme such as adequate *vaccination* coverage and population immunity. This can help to reduce reliance on post-*vaccination* surveys for residual *infection* and transmission.

In designing serological surveys to estimate population immunity, blood sample collection should be stratified by age to take account of the number of *vaccinations* the animals have received. The interval between last

vaccination and sampling depends upon the intended purpose. Sampling at one or two months after *vaccination* provides information on the efficiency of the *vaccination* programme, while sampling before or at the time of revaccination provides information on the duration of immunity. When multivalent vaccines are used, tests should be carried out to determine the antibody level at least for each serotype, if not for each antigen blended into the vaccine. The test cut-off for an acceptable level of antibody should be selected with reference to protective levels demonstrated by vaccine-challenge test results for the antigen concerned. Where the threat from circulating virus has been characterised as resulting from a field virus with significantly different antigenic properties from the vaccine virus, this should be taken into account when interpreting the protective effect of population immunity. Figures for population immunity should be quoted with reference to the total of susceptible animals in a given *subpopulation* and in relation to the subset of vaccinated animals.

7. Additional measures for early recovery of free status without vaccination or early recovery of free status with vaccination in the area(s) where emergency vaccination has been applied but not followed by the slaughtering of all vaccinated animals

In addition to the general conditions described in this chapter, a Member Country seeking either recovery of status of a country or *zone* previously free from FMD where *vaccination* is not practiced, including a *containment zone*, or recovery of status of a country or *zone* previously free from FMD where *vaccination* is practiced, earlier than the six months as specified respectively under point 1c) of Article 8.8.7. or under point 3a) of Article 8.8.7. should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved when answering the relevant questionnaire in Chapter 1.11. by demonstrating compliance with either a) or b) and c) below, in the area(s) where emergency *vaccination* has been applied. It is advisable that countries should consider the different options for the recovery of a free status when control measures are first implemented at the onset of the *outbreak* in order to plan for the applicable requirements to be met.

a) The following serological surveys have been conducted in the area where emergency *vaccination* has been applied and have demonstrated the absence of *infection* in unvaccinated *animals* and the absence of transmission in emergency vaccinated *animals*:

i) for vaccinated ruminants, serological surveys using nonstructural protein tests to detect antibodies in all vaccinated ruminants and their non-vaccinated offspring in all *epidemiological units* (census serosurveillance);

ii) for vaccinated pigs and their non-vaccinated offspring, serological surveys using nonstructural protein tests to detect antibodies in all vaccinated *epidemiological units* with maximum 5% within *herd* design prevalence (95% confidence level);

iii) for non-vaccinated susceptible species that do not show reliable clinical signs, serological surveys with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level).

EU comment

In Articles 8.8.40. and 8.8.41. on surveillance, reference is made to animals of susceptible species that do not show reliable clinical signs, for which serological surveys should be conducted. While fully agreeing on that principle, from its own experience (FMD outbreak in the UK in 2007), the EU requests that this be extended to animals of susceptible species that do show reliable clinical signs but which are not subject to regular and frequent observation so that clinical signs could be missed. This would especially be relevant e.g. for extensive keeping of beef cattle.

b) The following *surveillance* components have been implemented in the area where emergency *vaccination* has been applied and have demonstrated the absence of *infection* in unvaccinated *animals* and the absence of transmission in vaccinated *animals*:

i) risk-based serological *surveillance* in vaccinated *herds* with stratification according to relevant factors such as proximity to known infected *herds*, region/*establishment* with numerous movement of animals, epidemiological links to infected *herds*, species, production management systems and *herd* size;

ii) random serological *surveillance* in vaccinated *herds* with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level) in each emergency *vaccination* area;

iii) intensified clinical and *slaughterhouse/abattoir surveillance*;

iv) for non-vaccinated susceptible species that do not show reliable clinical signs, serological surveys with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level);

EU comment

See comment above.

v) virological *surveillance* to investigate the status of vaccinated *herds* may also be conducted to contribute to additional confidence in demonstrating freedom.

c) Vaccine efficacy and *vaccination* effectiveness of the emergency *vaccination* deployed have been demonstrated by documenting the following:

i) Vaccine efficacy

– vaccine potency of at least 6PD50 or equivalent probability of protection and evidence of a good match between the vaccine strain and the field virus;

– evidence that the vaccine used can protect against the field strain that has caused the *outbreak*, demonstrated through the results of a heterologous challenge test or indirect serological assay (i.e., sera from vaccinated *animals* tested against the field virus). This should also establish the cut-off titre for protection to be used in the test for population immunity studies.

ii) Vaccination effectiveness

– objective and strategy of the emergency *vaccination* deployed;

– evidence of the timeliness of the emergency *vaccination* (start and completion dates);

– evidence of *vaccination* delivery including preservation of vaccine (e.g., cold chain) and at least 95% *vaccination* coverage achieved in the targeted and eligible *population*;

– evidence of high population immunity at *herd* and individual level through serological *surveillance*.

8. Additional measures for early recovery of free status with *vaccination* in the area outside of the area(s) where emergency *vaccination* has been applied.

In addition to the general conditions described in this chapter, a Member Country seeking recovery of status of a country or *zone* previously free from FMD where *vaccination* is practiced in the area outside of the area(s) where emergency *vaccination* has been applied, earlier than six months as specified under point 3a) of Article 8.8.7. should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved either by meeting the requirements listed in a) below or by demonstrating compliance with the requirements listed in b) and c) below, when answering the questionnaire in Article 1.11.2. or Article 1.11.4.

With regard to the *surveillance* requirements listed in b), it should be noted that clinical signs may not be apparent in the routinely vaccinated *population*. The expression of clinical signs would depend on the relationship between the virus strain used in the routine *vaccination* to the virus that caused the *outbreak*. For example, following an incursion of a new serotype it would be expected that the routinely vaccinated animals would show clinical signs if infected. In contrast, following an incursion of a serotype or strain covered by the vaccine it would be expected that most of the routinely vaccinated animals would be protected and therefore less likely to be infected and to show clinical signs if infected. Other factors such as *vaccination* coverage and timing of *vaccination* could influence the likelihood of *infection* and expression of clinical signs.

It is advisable that countries should consider the different options for the recovery of a free status when control measures are first implemented at the onset of the *outbreak* in order to plan for the applicable requirements to be met.

a) Establishment of a containment zone

A *containment zone* that includes all emergency *vaccination* area(s) has been established based on the provisions of Article 8.8.6. to provide assurance that FMD has not occurred in the area outside the emergency *vaccination* area(s).

b) The following *surveillance* components have been implemented in the area outside of the area(s) where emergency *vaccination* has been applied and have demonstrated the absence of *infection* in unvaccinated *animals* and the absence of transmission in vaccinated *animals*:

i) risk-based serological *surveillance* in vaccinated *herds* with stratification according to relevant factors such as proximity to the emergency *vaccination* area, region/*establishment* with numerous movement of *animals*, epidemiological links to infected *herds*, species and age, production management systems, *herd* size;

ii) random serological *surveillance* in vaccinated *herds* with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level);

iii) intensified clinical and *slaughterhouse/abattoir surveillance*;

iv) serological survey in non-vaccinated susceptible species that do not show reliable clinical signs with risk-based stratification according to factors such as proximity to the emergency *vaccination* area, region/*establishment* with numerous movement of *animals*, epidemiological links to infected *herds*, species, production management systems, *herd* size;

EU comment

See comment above.

v) virological *surveillance* to investigate the status of vaccinated *herds* may also be conducted to contribute to additional confidence in demonstrating freedom.

The efficacy of the routine vaccine against the virus that caused the *outbreak(s)* has been documented.

The entire investigative process should be documented within the *surveillance* programme.

All the epidemiological information should be substantiated, and the results should be collated in the final report.

Article 8.8.41.

Methods of surveillance

1. Clinical surveillance

Farmers and workers who have day-to-day contact with livestock, as well as *veterinary para-professionals*, *veterinarians* and diagnosticians, should report promptly any suspicion of FMD. The *Veterinary Services ~~Authority~~* should implement programmes to raise awareness among them.

Clinical *surveillance* requires the physical examination of susceptible *animals*. Although significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection may provide a high level of confidence of detection of *disease* if a sufficient number of clinically susceptible *animals* is examined at an appropriate frequency and investigations are recorded and quantified.

Clinical examination and diagnostic testing should be applied to clarify the status of suspected *cases*. Diagnostic testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive laboratory test results. Clinical *surveillance* may be insufficient in *wildlife* and domestic species that usually do not show clinical signs or husbandry systems that do not permit sufficient observations. In such situations, serological *surveillance* should be used. Hunting, capture and non-invasive sampling and observation methods can be used to obtain information and diagnostic samples from *wildlife* species.

EU comment

See comment above.

2. Virological surveillance

Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is mostly dependent upon clinical *surveillance* to provide samples. FMDV isolates should be sent regularly to an OIE Reference Laboratory.

Virological *surveillance* aims to:

a) confirm clinically suspected *cases*;

b) follow up positive serological results;

c) characterise isolates for epidemiological studies and vaccine matching;

d) monitor *population*s at risk for the presence and transmission of the virus.

3. Serological surveillance

Serological *surveillance* aims to detect antibodies resulting from *infection* or *vaccination* using nonstructural protein tests or structural protein tests.

Serological *surveillance* may be used to:

a) estimate the prevalence or substantiate freedom from ~~FMDV~~ *infection* with, or transmission of, FMDV;

b) monitor population immunity.

Serum collected for other purposes can be used for FMD *surveillance*, provided the principles of survey design described in this chapter are met.

The results of random or targeted serological surveys are important in providing reliable evidence of the FMD situation in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

Article 8.8.42.

The use and interpretation of serological tests (see Figure 3)

The selection and interpretation of serological tests should be considered in the context of the epidemiological situation. Test protocols, reagents, performance characteristics and validation of all tests used should be known. Where combinations of tests are used, the overall test system performance characteristics should also be known.

Animals infected with FMDV produce antibodies to both the structural proteins and the nonstructural proteins of the virus. Vaccinated *animals* produce antibodies mainly or entirely to the structural proteins of the virus depending upon vaccine purity. The structural protein tests are serotype specific and for optimal sensitivity one should select an antigen or virus closely related to the field strain expected. In unvaccinated *population*s, structural protein tests may be used to screen sera for evidence of ~~FMDV~~ *infection* with, or transmission of, FMDV or to detect the introduction of vaccinated *animals*. In vaccinated *population*s, structural protein tests may be used to monitor the serological response to the *vaccination*.

Nonstructural protein tests may be used to screen sera for evidence of *infection* or transmission of all serotypes of FMDV regardless of the *vaccination* status of the *animals* provided the vaccines comply with the standards of the *Terrestrial Manual* with respect to purity. However, although *animals* vaccinated and subsequently infected with FMDV develop antibodies to nonstructural proteins, the levels may be lower than those found in infected *animals* that have not been vaccinated. To ensure that all *animals* that had contact with FMDV have seroconverted, it is recommended that for each *vaccination* area samples for nonstructural protein antibody testing are taken not earlier than 30 days after the last *case* and in any case not earlier than 30 days after the last *vaccination*.

Positive FMDV antibody test results can have four possible causes:

– *infection* with FMDV;

– *vaccination* against FMD;

– maternal antibodies (maternal antibodies in bovines ~~cattle~~ are usually found only up to six months of age but in some individuals and in some other species, maternal antibodies can be detected for longer periods);

– non-specific reactivity of the serum in the tests used.

1. Procedure in case of positive test results

The proportion and strength of seropositive reactors should be taken into account when deciding if they are *laboratory* confirmed reactors or further investigation and testing are required.

When false positive results are suspected, seropositive reactors should be retested in the *laboratory* using repeat and confirmatory tests. Tests used for confirmation should be of high diagnostic specificity to minimise false positive test results. The diagnostic sensitivity of the confirmatory test should approach that of the screening test.

All *herds* with at least one ~~*laboratory* confirmed~~ reactor that has been confirmed in a *laboratory* should be investigated. The investigation should examine all evidence, which may include the results ~~of virological tests and~~ of any further serological tests ~~that might~~ used to confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to ~~FMDV~~ transmission of FMDV, as well as of virological tests. This investigation should document the status for each positive *herd*. Epidemiological investigation should be continued concurrently.

Clustering of seropositive results within *herds* or within a region should be investigated as it may reflect any of a series of events, including the demographics of the *population* sampled, vaccinal exposure or the presence of *infection* or transmission. As clustering may signal *infection* or transmission, the investigation of all instances should be incorporated in the survey design.

Paired serology can be used to identify ~~FMDV~~ transmission of FMDV by demonstrating an increase in the number of seropositive *animals* or an increase in antibody titre at the second sampling.

The investigation should include the reactor *animals*, susceptible *animals* of the same *epidemiological unit* and susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animals*. The *animals* sampled should be identified as such and remain in the *establishment* pending test results, should be ~~clearly identified,~~ accessible and should not be vaccinated during the investigations, so that they can be retested after an appropriate period of time. Following clinical examination, a second sample should be taken, after an appropriate time has lapsed, from the *animals* tested in the initial survey with emphasis on *animals* in direct contact with the reactors. If the *animals* are not individually identified, a new serological survey should be carried out in the *establishments* after an appropriate time, repeating the application of the primary survey design. If FMDV is not circulating, the magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample.

In some circumstances, unvaccinated sentinel *animals* may also be used. These can be young *animals* from unvaccinated dams or *animals* in which maternally conferred immunity has lapsed and preferably of the same species as in the positive sampling units. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the *animals* of the *epidemiological unit* under investigation for at least two *incubation periods*, ~~and~~ If there is no transmission of FMDV, they ~~should~~ will remain serologically negative ~~if FMDV is not circulating~~.

2. Follow-up of field and laboratory findings

If transmission is demonstrated, an *outbreak* is declared.

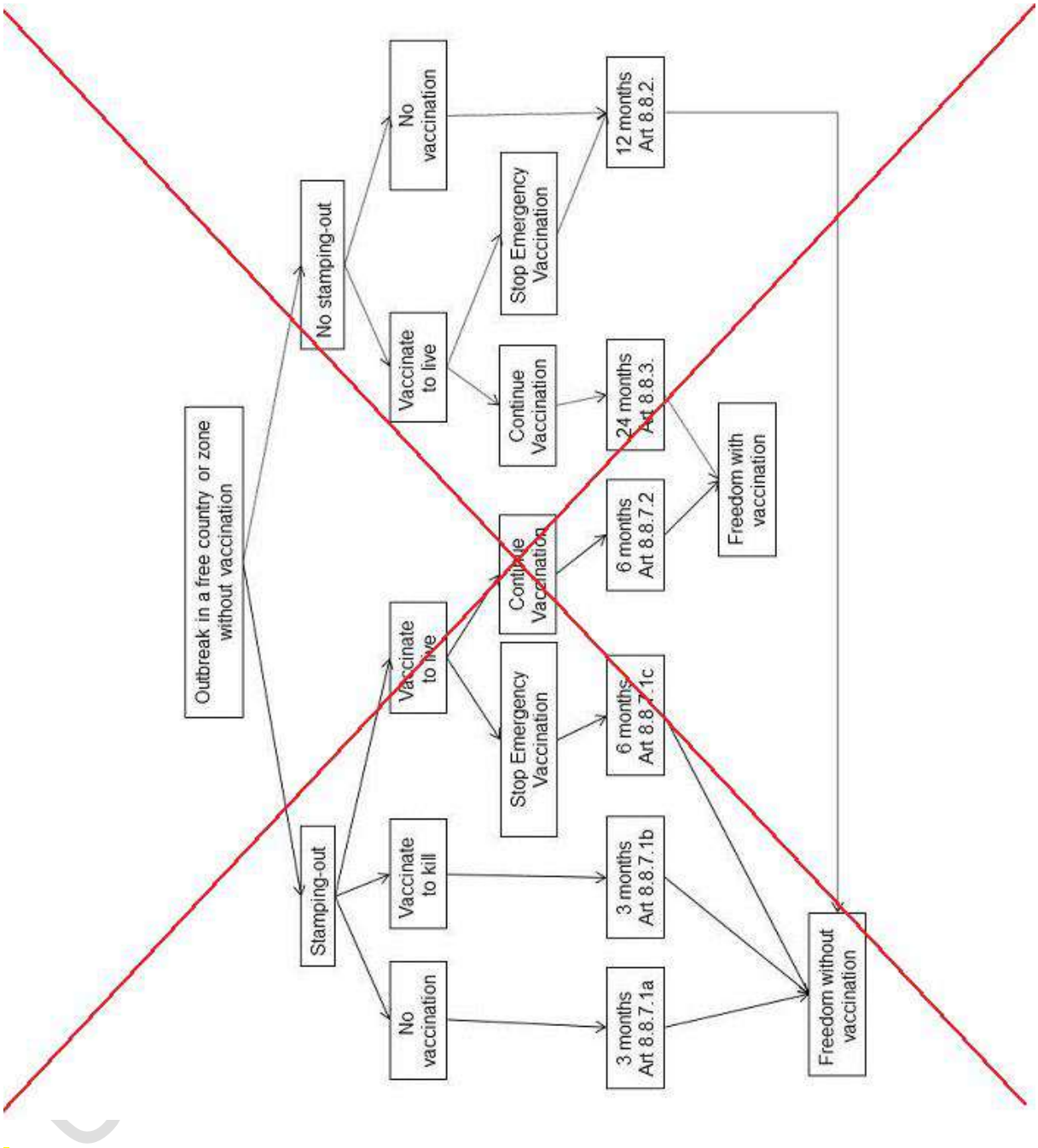
It is difficult to determine ~~T~~the significance of small numbers of seropositive *animals* in the absence of current FMDV transmission ~~is difficult to determine~~. Such findings may be an indication of past *infection* followed by recovery or by the development of a carrier state, in ruminants, or due to non-specific serological reactions. Antibodies to nonstructural proteins may be induced by repeated *vaccination* with vaccines that do not comply with the requirements for purity. However, the use of such vaccines is not permissible in countries or *zones* applying for an official status. In the absence of evidence of ~~FMDV~~ *infection* with, and transmission of, FMDV, such findings do not warrant the declaration of a new *outbreak* and the follow-up investigations may be considered complete.

However, if the number of seropositive *animals* is greater than the number of false positive results expected from the specificity of the diagnostic tests used, susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animals* should be investigated further.

Abbreviations and acronyms:	
ELISA	Enzyme-linked immunosorbent assay
VNT	Virus neutralisation test
NSP	Nonstructural protein(s) of foot and mouth disease virus (FMDV)
3ABC	NSP antibody test
SP	Structural protein of foot and mouth disease virus

Annex 18 (contd)

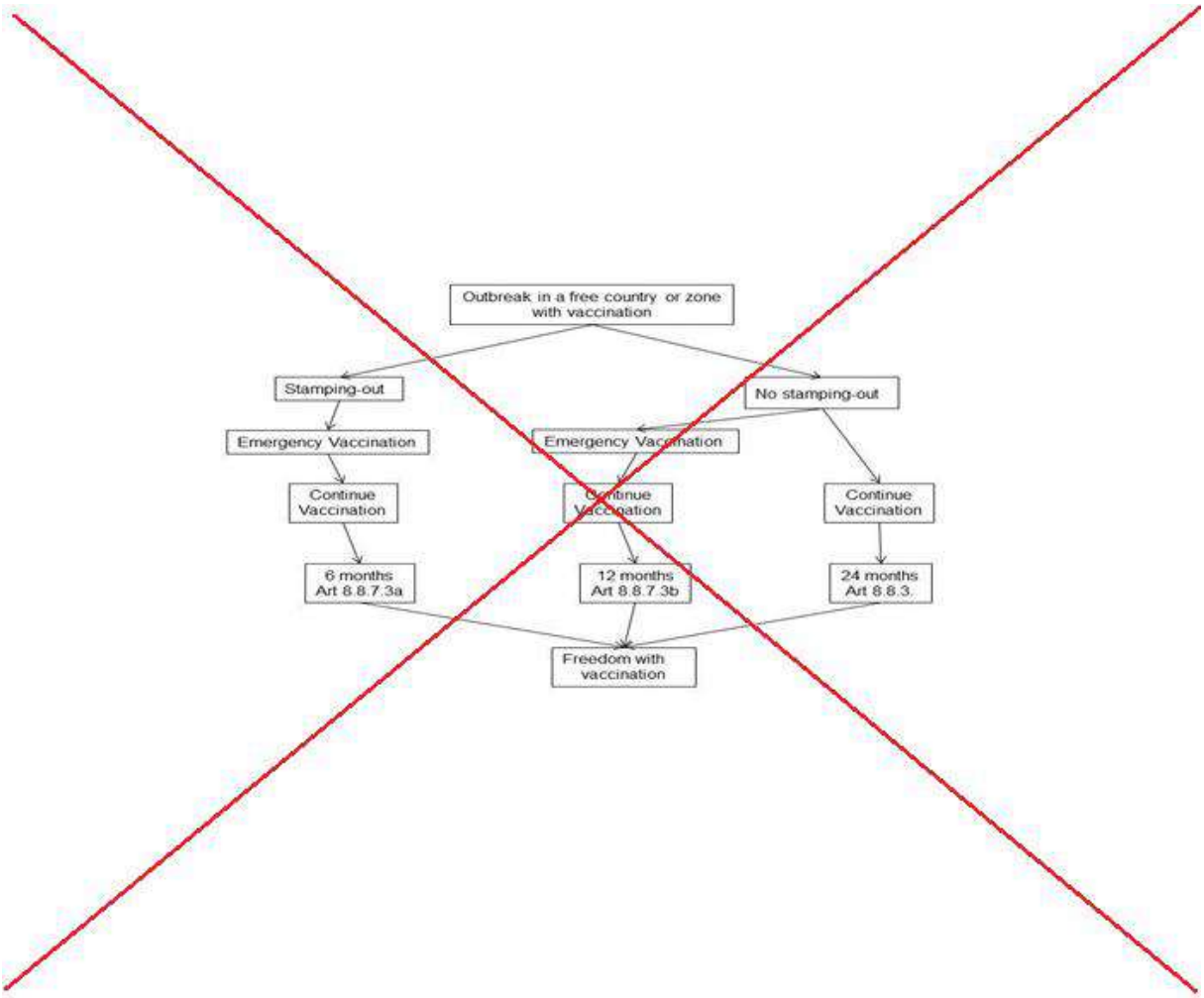
Fig. 1. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak of FMD in a previously free country or zone where vaccination is not practised



Waiting periods are minima depending upon outcome of *surveillance* specified in respective articles. If there are multiple waiting periods because of different control measures, the longest applies.

Annex 18 (contd)

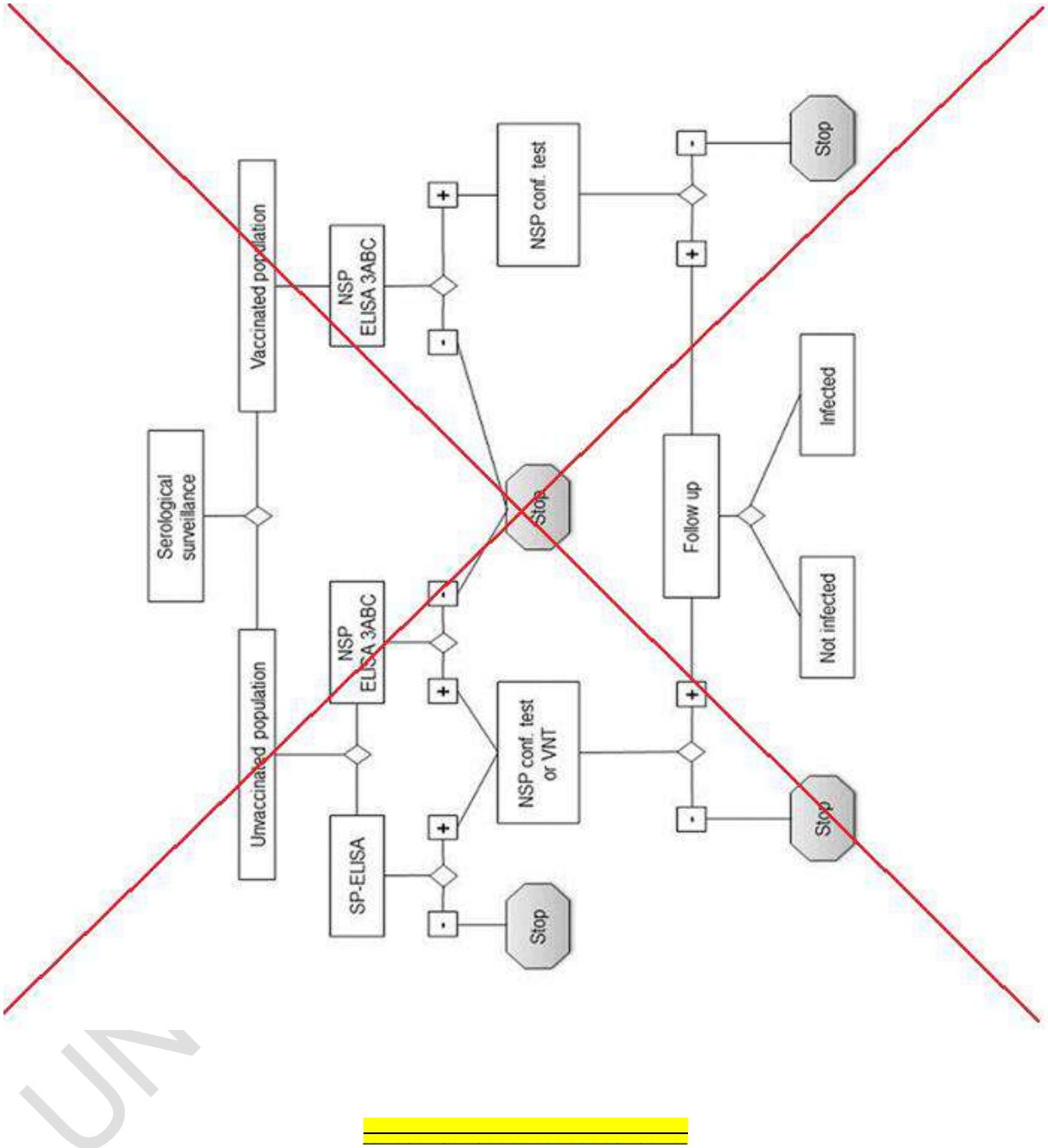
Fig. 2. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak of FMD in a previously free country or zone where vaccination is practised



Waiting periods are minima depending upon outcome of *surveillance* specified in respective articles. If there are multiple waiting periods because of different control measures, the longest applies.

Annex 18 (contd)

Fig. 3. Schematic representation of laboratory tests for determining evidence of infection with FMDV by means of serological surveys



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Annex 19

CHAPTER 8.16.

INFECTION WITH RINDERPEST VIRUS

EU comment

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

We note however that this draft chapter still requires significant work that should preferably be finalised as a matter of high priority in order for the global veterinary community to be well prepared in case of re-emergence of this animal disease.

In general, the EU would suggest not introducing sections in this chapter that divide large parts of the articles in the two scenarios, as that is not common practice in the Code and could result in confusion as to what is applicable when. In addition, that division is not very clear: on the one hand, Articles 8.16.1. and 8.16.2. would apply both during global freedom and in the event of re-emergence; in addition the latter is split between the two scenarios. On the other hand, point 1 of Article 8.16.5. strictly speaking does not necessarily fall within the second scenario, as the suspicion of re-emergence could well be ruled out. It would thus be simpler and clearer if instead, in Article 8.16.1. "General provisions", after the last paragraph of point 1), a sentence would be added stating that Articles 8.16.3. and 8.16.4. apply during global freedom, while Articles 8.16.5. to 8.16.13. apply in the event of re-emergence of rinderpest. As an alternative, wording could be added to the last paragraph of Article 8.16.5. indicating that Articles 8.16.3. and 8.16.4. no longer apply.

Further comments are included in the text below.

Article 8.16.1.

General provisions

1) The global eradication of rinderpest has been achieved and was announced in mid-2011 based on the following:

   a) Evidence demonstrating that there is no significant likelihood that rinderpest virus (RPV) remains in susceptible domesticated or *wildlife* host populations anywhere in the world.

   b) OIE Member and non-member countries have completed the pathway defined by the OIE for recognition of national rinderpest freedom and have been officially recognised by the OIE as free from *infection* with RPV.

   c) All *vaccinations* against rinderpest are banned and have ceased throughout the world. A ban on vaccination against rinderpest means a ban on administering any vaccine containing RPV or any components derived from RPV to any animal.

   However, RPV-containing material including live vaccines continue to be held in a number of institutions around the world and this poses a *risk* of virus re-introduction into susceptible animals. Therefore, manipulation of existing RPV-containing material, and synthesis or other forms of production of RPV-containing material, is forbidden unless authorised by the FAO and OIE.

EU comment

As regards "is forbidden unless authorised by the FAO and OIE", perhaps it would be useful to insert a footnote with the reference to the relevant OIE resolution.

As sequestration and destruction of virus stocks proceed, the *risks* of re-occurrence of *infection* are expected to progressively diminish. The possibility of deliberate or accidental release of virus demands continuing vigilance, especially in the case of those countries hosting an institution holding RPV-containing material.

This chapter takes into account the global freedom status of rinderpest and provides recommendations to prevent re-emergence of the disease, to ensure adequate *surveillance* and protection of livestock and to manage any re-emergence and facilitate recovery of global freedom from rinderpest.

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

a) Rinderpest is defined as an *infection* of susceptible animals with RPV, with or without clinical signs;

b) The following defines the occurrence of a *case* of *infection* with RPV,

i) RPV has been isolated from a susceptible animal or a product derived from that animal and identified; or

ii) viral antigen or viral RNA specific to RPV has been identified in samples from a susceptible animal; or

iii) antibodies to RPV have been identified in a susceptible animal with either epidemiological links to a confirmed or suspected *outbreak* of rinderpest, or showing clinical signs consistent with recent *infection* with RPV.

EU comment

The words "<u>that are not a consequence of vaccination</u>" should be inserted after "antibodies" in point iii) above. Indeed, depending on the country concerned and the year of cessation of vaccination, animals could still be alive that were vaccinated before global freedom.

c) The following defines a 'suspected case' of rinderpest:

i) a potential *case* for which other diseases compatible with 'stomatitis-enteritis syndrome' have been ruled out by clinical or laboratory investigation; or

EU comment

The term "case" in "potential *case*" in point i) above and point ii) below should not be italicised, as this is not the case in the definition of that term in point 3b) below (rightfully so as no reference to the glossary definition of "case" should be made).

ii) a potential *case* which has given a positive reaction in a diagnostic test for RPV conducted outside of an OIE Reference Laboratory for rinderpest; or

iii) the detection of RPV-specific antibodies in a susceptible animal with or without clinical signs.

EU comment

The words "<u>that are not a consequence of vaccination</u>" should be inserted after "antibodies" in point iii) above. Indeed, depending on the country concerned and the year of cessation of vaccination, animals could still be alive that were vaccinated before global freedom.

d) The *incubation period* for rinderpest shall be 21 days.

e) RPV-containing material means field and laboratory strains of RPV; vaccine strains of RPV including valid and expired vaccine stocks; tissues, sera and other material from animals known or suspected to be infected; laboratory-generated diagnostic material containing live virus, recombinant morbilliviruses (segmented or nonsegmented) containing unique RPV nucleic acid or amino acid sequences, and full length genomic material including virus RNA and its cDNA copies.

Subgenomic fragments of RPV genome (either as plasmid or incorporated into recombinant viruses) that cannot be incorporated into a replicating morbillivirus or morbillivirus-like virus are not considered to be RPV-containing material, neither are sera that have been either heat-treated to at least 56°C for at least two hours, or shown to be free from RPV genome sequences by a validated RT-PCR assay.

3) For the purposes of this chapter:

a) 'Susceptible animals' means domestic, *feral, captive wild* and *wild* artiodactyls.

b) A 'potential case' means a susceptible animal showing clinical signs consistent with 'stomatitis-enteritis syndrome' and where these signs cannot be ascribed to another disease compatible with 'stomatitis-enteritis syndrome' by epidemiological considerations or appropriate laboratory investigation.

The occurrence of a potential case should draw special attention if it is linked to identified risks such as proximity to facilities holding RPV-containing material.

c) 'Stomatitis-enteritis syndrome' is defined as fever with ocular and nasal discharges in combination with clinical signs of erosions in the oral cavity with diarrhoea, dysentery, dehydration or death or necropsy findings of haemorrhages on serosal surfaces, haemorrhages and erosions on alimentary mucosal surfaces and lymphadenopathy.

4) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.16.2

1. Safe commodities during global freedom

When authorising import or transit of the *commodities* of susceptible animals, *Veterinary Authorities* should not require any conditions related to rinderpest.

EU comment

Editorial: the word "the" before "commodities" should be deleted.

2. Safe commodities in the event of re-emergence of rinderpest

Regardless of the rinderpest status of the *exporting country*, *Veterinary Authorities* should not require any conditions related to rinderpest for:

a) semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather, e.g., wet blue and crust leather) which have been submitted to the usual chemical and mechanical processes in use in the tanning industry;

b) *meat products* in hermetically sealed containers with a F_0 value of 3 or above;

c) gelatine.

First section: applicable during global freedom

Article 8.16.3.

Ongoing surveillance post global freedom

All countries in the world, whether or not Member Countries of the OIE, have completed all the procedures necessary to be recognised as free from rinderpest *infection,* and annual re-confirmation of rinderpest absence is no longer required. However, rinderpest should still be notifiable in the whole territory and countries are still required to carry out general *surveillance* in accordance with Chapter 1.4. to detect rinderpest should it recur and to comply with OIE reporting obligations concerning the occurrence of unusual epidemiological events in accordance with Chapter 1.1. Countries should either maintain the capacity for local investigation of potential cases or have protocols in place to send samples from such cases to an OIE Reference Laboratory for routine checking. Countries should also maintain national contingency plans for responding to events suggestive of rinderpest including the checking of potential cases and the prompt identification of suspected cases.

EU comment

To avoid any confusion, the word "cases" before "to an OIE Reference Laboratory" in line 7 of the paragraph above should either be replaced with "potential cases" or "events".

The Global Rinderpest Action Plan (GRAP) complements all national and regional contingency plans and lays out the roles and responsibilities of all relevant stakeholders to prepare for, prevent, detect, respond and recover from a rinderpest *outbreak*. If needed, expertise from the region or continent, or international organisations may be requested to provide resources to help confirm or rule out if the potential case meets the definition for a suspected case of rinderpest.

EU comment

The EU suggests adding the words "<u>or represents a *case* of *infection* with rinderpest</u>" at the end of the paragraph above, as this could equally be useful for certain countries.

Article 8.16.4.

Annual update on RPV-containing material

Annual reports on RPV-containing material should be submitted to the OIE each year by the *Veterinary Authority* of a Member Country hosting an institution or institutions holding RPV-containing material using the online platform designated for such a purpose. A final report should be submitted to the OIE for each institution when all materials have been destroyed and no new activities are foreseen.

EU comment

For reasons of clarity, the EU suggests inserting the words "<u>RPV-containing</u>" before "materials" in the last line of the paragraph above. Furthermore, it should be clarified what is meant by "new activities".

Second section: applicable in the event of re-emergence of rinderpest

Article 8.16.5.

Response to a recurrence of rinderpest

1. <u>Procedures to be followed in the event of the suspicion of rinderpest</u>

   Any suspected case should be immediately notified to the *Veterinary Authority.*

   Veterinary Authorities shall immediately notify any suspected case to the OIE.

EU comment

While fully supporting the intended, for reasons of legal certainty, the EU suggests either:

- clarifying in the sentence above that the immediate notification is to be done based on point 1 of Article 1.1.2. (or on Article 1.1.6.), or

- amending Article 1.3.1. by adding "(including 'suspected case' of rinderpest)" after "Infection with rinderpest virus".

Indeed, a 'suspected case' of rinderpest is not a listed disease and thus does not fall under the notification obligation of Article 1.1.3. in combination with the current Article 1.3.1. and the proposed definitions in point 2) of Article 8.16.1. of the present text (nor

does it fall under the notification obligations of Article 1.1.4. as it does not constitute an emerging disease).

Furthermore, for clarity reasons, please insert "<u>of rinderpest</u>" as appropriate in both the first and second sentence of point 1) above.

Upon detection of a suspected case, the national contingency plan should be implemented immediately. If the presence of rinderpest cannot be ruled out, samples should be collected in accordance with the *Terrestrial Manual* and dispatched to one of the appointed OIE Reference Laboratories for rinderpest for confirmation and, if applicable, for molecular characterisation of the virus to facilitate identification of its source. A full epidemiological investigation should be conducted simultaneously to provide supporting information and to assist in identifying the possible source and spread of the virus.

EU comment

For clarity reasons, we suggest inserting the words "<u>or is confirmed by a national laboratory</u>" after "If the presence of rinderpest cannot be ruled out". That would clarify that samples should in any case be sent to an OIE Reference Laboratory for confirmation (as seems to be intended as per the third paragraph of point 2 below).

2. <u>Procedures to be followed after confirmation of rinderpest</u>

Veterinary Authorities shall immediately notify any *case* to the OIE.

EU comment

While in fact being redundant, the sentence above could be acceptable. We would however suggest adding the words "<u>in accordance with Article 1.1.3.</u>".

A *case* shall constitute a global emergency requiring immediate, concerted action for its investigation and elimination.

Immediately following the confirmation of the presence of RPV, viral RNA or antibody as described in Article 8.16.1., the appointed OIE Reference Laboratory for rinderpest should inform the country concerned, the OIE and the FAO, allowing the initiation of the response operations described in the GRAP.

When epidemiological investigation has indicated the extent of the infected area, zoning can be implemented for the purposes of disease control. In the event of a limited *outbreak*, a *containment zone* may be established in accordance with Article 8.16.8.

Emergency *vaccination* is acceptable only with rinderpest vaccines produced in accordance with the *Terrestrial Manual*. Vaccinated animals should always be clearly and permanently identified at the individual level.

Global rinderpest freedom is suspended and the sanitary measures for trade with the infected country or countries shall be those in Articles 8.16.12. and 8.16.13.

Article 8.16.6

Country free from rinderpest

In the event of re-emergence of rinderpest, all OIE Member Countries without a case will remain free from rinderpest. However, all OIE Member Countries will be asked to provide a *risk assessment* to the OIE and free status will be suspended if their *risk assessment* is not accepted by the OIE.

EU comment

For reasons of clarity, the word "case" in the paragraph above should be italicised. Furthermore, the words "<u>of *infection* with rinderpest virus</u>" should be added after the word "case".

Finally, it is not clear what exactly is meant by "risk assessment", i.e. what is expected of

member countries.

Some countries will be at heightened *risk*. In particular, countries meeting the conditions below would be regarded as being at heightened risk and should carry out appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs; this may be achieved through a *surveillance* programme in accordance with Article 8.16.11. in addition to ongoing *surveillance* in accordance with Article 8.16.3.:

EU comment

Please insert the words "with rinderpest virus" after the word "infection" in the paragraph above.

1) countries that are adjacent to a country infected with RPV; or

2) countries that have relevant epidemiological or ecological links through trade or animal movements to a country infected with RPV.

Article 8.16.7

Country infected with RPV

A country infected with RPV is one in which a *case* of rinderpest has occurred.

Article 8.16.8.

Establishment of a containment zone within a country previously free from rinderpest

In the event of a limited *outbreak* within a country previously free of rinderpest, a *containment zone* for the purposes of disease control and eradication can be established in accordance with Article 4.4.7. Notwithstanding the establishment of a *containment zone* for disease control and eradication, *international trade* in *commodities* of susceptible species from the entire country will be limited to the *safe commodities* listed in point 2 of Article 8.16.2. until free status is recovered.

EU comment

Please replace the word "can" by "may" in the paragraph above, in line with the wording in Article 4.4.7.

Article 8.16.9.

Recovery of free status for a country

Should a *case* of rinderpest occur, a country is considered infected with RPV until shown to be free in accordance with the procedures below.

The time needed to recover rinderpest free status of a country depends on the methods employed to achieve the elimination of *infection*.

One of the following waiting periods is applicable:

1) when a *stamping-out policy* has been applied:

   a) three months after the *disinfection* of the last affected *establishment* where a *stamping-out policy* without *vaccination* and targeted *surveillance* in accordance with Article 8.16.11. have been applied; or

   b) three months after the *disinfection* of the last affected *establishment* and the *slaughter* of all vaccinated animals, where a *stamping-out policy*, emergency *vaccination* and targeted *surveillance* in accordance with Article 8.16.11. have been applied; or

   c) 18 months after the *disinfection* of the last affected *establishment* and the last *vaccination*, where a *stamping-out policy*, emergency *vaccination* not followed by the *slaughter* of all vaccinated animals, and targeted *surveillance* in accordance with Article 8.16.11. have been applied;

2) when a *stamping-out policy* is not practised, the above waiting periods do not apply. Instead, the country must be in compliance with the requirements below:

a) have a record of regular and prompt animal disease reporting in accordance with Chapter 1.1.

b) send a declaration to the OIE stating that:

i) there has been no *case* of rinderpest during the past 24 months,

ii) no suspected case of RPV *infection* has been found during the past 24 months,

iii) no *vaccination* against rinderpest has been carried out during the past 24 months,

c) supply documented evidence that targeted *surveillance* for *infection* with RPV in accordance with Chapter 1.4. and Article 8.16.11. is in operation and that regulatory measures for the prevention and control of rinderpest have been implemented,

d) not have imported, since the cessation of *vaccination*, any animals vaccinated against rinderpest.

EU comment

The prospect of countries not applying a stamping-out policy in the event of re-emergence of rinderpest frankly is appalling. Even if it would be preferable for the EU to oppose the scenario of point 2 (and possibly also point 1c) in this chapter, we have to acknowledge that an efficient and rapid stamping-out policy sadly is not realistic in many countries around the world, for various reasons. Therefore, point 2 above could be supported by the EU – simply as there could otherwise be no path back to global freedom. However, we would suggest including wording in this article that would advocate for scenarios 1a) and 1b) over the others, and clearly state that scenario 2 should only be used as a last resort.

In the scenarios mentioned in points 1a), b) and c) and in point 2) above, the recovery of free status requires an international expert mission to verify the successful application of containment and eradication measures, as well as a review of documented evidence by the OIE. The country shall be considered free only after the submitted evidence has been accepted by the OIE.

Article 8.16.10.

Recovery of global freedom

The suspension of global freedom will be lifted when all countries infected with RPV have recovered freedom in accordance with Article 8.16.9.

Unless it is verified through an OIE expert mission that the conditions below are met for all countries having experienced an outbreak within 12 months of suspension, then global rinderpest freedom is lost and recovery of freedom would require an assessment of free status of all countries by the OIE. If the conditions below are met within 12 months, then global freedom will remain suspended, subject to periodic review by the OIE.

EU comment

In the absence of explicit articles in this chapter, as well as a Code chapter in Section 1 (on *Application for official recognition by the OIE of free status for rinderpest*) clearly describing the path to individual country freedom, recovery of global freedom will simply not be possible once it is lost, contrary to what is said in the paragraph above – at least based on the present draft revised chapter. A solution would be either to include all the necessary provisions in this chapter (preferred option for legal certainty and transparency), or to again refer to the relevant provisions of the 2010 version of the chapter (same as is the case now, see last paragraph of Article 8.16.7. https://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_rinderpest.htm).

1) The *outbreak* is limited to a country or *zone*, without any further *outbreaks* outside the ecosystem of the first *outbreak*.

2) The *outbreak* is handled in a prompt and efficient manner, with robust control measures including movement controls, which were rapidly implemented and were shown to be successful in mitigating the spread of rinderpest and reducing its incidence.

EU comment

Stamping-out policy as described in points 1a) and 1b) of Article 8.16.9. should be mentioned explicitly in point 2 above, as other scenarios described in Article 8.16.9. for recovery of free status cannot be described as prompt and efficient and would in any case not be completed within 12 months.

Article 8.16.11.

Surveillance for recovery of rinderpest free status

A country infected with RPV applying for recovery of rinderpest free status in accordance with Article 8.16.9. should provide evidence demonstrating effective *surveillance* in accordance with Chapter 1.4. and the points below.

1) The target for *surveillance* should be all populations of rinderpest susceptible species within the country. In certain areas some *wildlife* populations, such as African buffaloes, act as sentinels for rinderpest *infection*.

2) An awareness programme should be established for all animal health professionals including *veterinarians*, both official and private, and livestock owners to ensure that rinderpest's clinical and epidemiological characteristics and *risks* of its recurrence are understood. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any potential case.

3) Differing clinical presentations can result from variations in levels of innate host resistance (*Bos indicus* breeds being more resistant than *B. taurus*), and variations in the virulence of the attacking strain. In the case of sub-acute (mild) cases, clinical signs are irregularly displayed and difficult to detect. Experience has shown that syndromic *surveillance* strategies i.e., *surveillance* based on a predefined set of clinical signs (i.e., 'stomatitis-enteritis syndrome') are useful to increase the sensitivity of the system.

4) Given these differing clinical presentations, virological *surveillance* should be conducted in addition to clinical surveillance. A procedure should be established for the rapid collection and transport of samples from suspected cases to an appointed OIE Reference Laboratory for rinderpest.

5) Since rinderpest is an acute *infection* with no known carriers, serological *surveillance* should be conducted to detect mild *infections* that are not detected clinically. There are no serological means to differentiate animals infected with field virus from vaccinated animals. Consequently, serological surveys should target unvaccinated animals and young animals devoid of maternal antibodies.

Article 8.16.12.

Recommendations for importation of rinderpest susceptible animals and their products except safe commodities in point 2 of Article 8.16.2 from countries free from rinderpest

EU comment

The title does not read well. The words "except safe commodities in point 2 of Article 8.16.2" should be deleted as they are not really necessary; Article 8.16.2. is clear enough in itself.

1) For rinderpest susceptible animals, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the animals remained in a country free from rinderpest since birth or for at least 30 days prior to shipment. Animals must not transit through a country infected with RPV, in accordance with Chapter 5.7.

2) For *fresh meat* or *meat products* of susceptible animals, for *milk or milk products* from susceptible animals, and for all products of animal origin intended for use in animal feeding, for agricultural use or for industrial

use, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting the entire consignment of product is derived from animals that remained in a country free from rinderpest since birth or for at least 30 days prior to *slaughter* or harvesting of the product.

3) For semen and oocytes of susceptible animals, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

   a) the donor animals showed no clinical sign of rinderpest on the day of collection and had been kept in a country free from rinderpest for at least 30 days prior to collection;

   b) the semen and oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.6., 4.7. or 4.9., as relevant.

4) For *in vivo* derived embryos of susceptible animals, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

   a) the donor females showed no clinical sign of rinderpest on the day of collection and had been kept in a country free from rinderpest for at least 30 days prior to collection;

   b) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.8. and 4.10., as relevant.

Article 8.16.13.

Recommendations for importation from countries infected with rinderpest

In the event of re-emergence of rinderpest, only *safe commodities* in point 2 of Article 8.16.2. can be traded.

EU comment

The article above does not read well and should be redrafted.

Furthermore, in both the title and the text of the article, reference should be made to countries whose free status has been suspended in accordance with the first paragraph of Article 8.16.6. Indeed, trade restrictions for these countries are not contained anywhere in this chapter.

Annex 20

CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

EU comment

The EU thanks the OIE for the latest version of the revised Chapter 11.4. on bovine spongiform encephalopathy. The EU appreciates various evolutions reflected in the text since the initial draft of September 2019.

However, the EU wishes to submit a number of additional comments, inserted in the text below, that need to be addressed before the revised chapter is presented for adoption.

In addition, the EU wishes to highlight, in line with the position expressed on the proposed Chapter 1.8., that the 'period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible', will be a central information for the future implementation of this Chapter 11.4. by the OIE Members, if adopted. The EU is of the opinion that this information will definitely be as important and necessary as the BSE status of the countries. As a consequence, the EU considers of critical importance that total transparency is ensured on this information. Therefore, the EU respectfully requests that, for each country applying for a BSE status, that period is submitted to approval by the OIE Members, together with the BSE status itself, and published in the Resolution adopted at the general session annually.

Article 11.4.1.

General provisions

1) The recommendations in this chapter are intended to mitigate the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agents in cattle only. BSE manifests in two main forms: classical BSE and atypical BSE. Atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population. Oral exposure to contaminated *feed* is the main route of transmission of classical BSE. Given that cattle have been experimentally infected by the oral route with a low molecular weight type of atypical BSE (L-type BSE~~,~~), atypical BSE is also ~~potentially~~ considered capable of being recycled in a cattle population if cattle are orally exposed to contaminated *feed*.

2) BSE primarily affects cattle. Other animal species may be naturally and experimentally susceptible to BSE, but they are not regarded as being epidemiologically significant, particularly when feeding ruminants with ruminant-derived protein meal is not practiced.

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

~~1~~a) BSE is an invariably fatal neurological prion disease of cattle caused by PrP^{BSE}, including both classical (C-type BSE) and atypical strains (H- and L-type BSE~~).~~ for respectively having a protease-resistant PrP^{BSE} fragment of higher and lower molecular mass than classical BSE). The term 'BSE' includes both classical and atypical forms, unless otherwise specified.

~~2~~b) The occurrence of a BSE *case* is defined by the immunohistochemical (IHC) or immunochemical detection of PrP^{BSE} in brain tissue of a bovid of the species *Bos taurus* or *Bos indicus*, with discrimination between atypical and classical BSE strains based on the Western immunoblot banding pattern, as described in the *Terrestrial Manual*.

4) For the purposes of this chapter:

~~3~~a) 'Cattle' means ~~a~~ bovids of the species *Bos taurus* or *Bos indicus.*

~~4~~b) 'Protein meal' means any final or intermediate solid protein-containing product, obtained when animal tissues are rendered, excluding blood and blood products, peptides of a molecular weight less than 10,000 daltons and amino-acids.

5) When *commodities* are imported in accordance with this chapter, the BSE risk of the *importing country* or *zone* of destination is not affected by the BSE risk of the *exporting country*, *zone* or *compartment* of origin.

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

Article 11.4.1bis.

Safe commodities

When authorising the importation or transit of the following *commodities* derived from cattle, *Veterinary Authorities* should not require any conditions related to BSE, regardless of the BSE risk posed by the cattle population of the *exporting country*, *zone* or *compartment*:

1) *milk* and *milk products*;

2) semen and *in vivo* derived cattle embryos collected and handled in accordance with the relevant chapters of the *Terrestrial Code*;

3) hides and skins;

4) gelatine and collagen;

5) tallow with maximum level of insoluble impurities of 0.15% in weight and derivatives made from this tallow;

~~6)~~ ~~tallow derivatives;~~

EU comment

The EU thanks the OIE for restoring the currently applicable provisions on tallow, as requested by the EU in its December 2019 comments.

~~7~~6) dicalcium phosphate (with no trace of protein or fat~~).~~);

7) foetal blood.

Other *commodities* of cattle can be traded safely if in accordance with the relevant articles of this chapter.

Article 11.4.2.

EU comment

The EU notes that an effort has been made throughout the text to replace the word 'likelihood' by 'risk'. However, the word 'likelihood' remains in the first sentence of points a), b) an c) of this article. The EU suggests that these occurrences are also replaced by 'risk' to ensure a full consistency of the chapter.

~~The~~ General criteria for the determination of the BSE risk of the cattle population of a country, zone or compartment

EU comment

The EU notes that this title is not consistent with the first sentence of this article and of Article 11.4.3., both amended to introduce the notion of BSE risk of a country, etc.' instead of the 'BSE risk *of the cattle population* of a country, etc.). The EU is of the

opinion that this evolution is actually in line with the new proposed approach by which different sub-populations of cattle, with a different level of BSE risk, can be considered within a country.

The EU therefore suggests that the title is amended as follows:

'General criteria for the determination of the BSE risk ~~of the cattle population~~ of a country, zone or compartment'

~~The~~ Due to its etiological and epidemiological features, the BSE risk of ~~the cattle population of~~ a country, *zone* or *compartment* is determined on the basis of the following criteria:

1) a BSE *risk assessment*, in accordance with the provisions of ~~Chapter 1.8.~~the "Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy" that evaluates the ~~likelihood~~risk of BSE being recycled within the cattle population by identifying all potential factors associated with the occurrence of BSE and their historic perspective. Member Countries should review the *risk assessment* annually to determine whether the situation has changed.

   ~~A~~The *risk assessment* for the purpose of BSE, based on the framework provided by Article 2.1.4, consists of:

   a) Entry assessment

      ~~An~~The entry assessment evaluates the likelihood that the classical BSE agent has been introduced into the country, *zone* or *compartment* ~~via imported~~through the importation of the following *commodities*. in the preceding eight years:

      i) Cattle;

      ii) Ruminant-derived protein meal;

      iii) *Feed* (not intended for pets) that contains ruminant-derived protein meal;

      iv) Fertilizers that contain ruminant-derived protein meal;

      v) Any other *commodity* that either is or could be contaminated by *commodities* listed in Article 11.4.14.

   b) Exposure assessment

      ~~An~~The exposure assessment evaluates the likelihood of cattle being exposed to BSE during the preceding eight years, either through imported *commodities* or as a result of the presence of BSE agents in the indigenous cattle population of the country, *zone* or *compartment*.

      The first step in the exposure assessment involves an evaluation of livestock industry practices through a consideration of the impact of:

      i) Livestock industry practices on preventing cattle from being fed ruminant-derived protein meal, taking account of:

EU comment

The EU is of the opinion that unintentional exposure to ruminant-derived protein meal needs to be clearly considered together with intentional feeding of ruminant-derived protein meal, as it can also result in cross contamination.

In order to clarify that unintentional exposure to ruminant-derived protein meal is also part of the assessment, the EU proposes the following wording:

'i) Livestock industry practices on preventing cattle from being intentionally fed, or unintentionally exposed to, ruminant-derived protein meal, taking account of;'

- demographics of the cattle population and production systems;
- feeding practices;
- slaughtering and waste management practices;
- rendering practices;
- *feed* production, distribution and storage.

Depending on the outcome from this step, an evaluation of mitigation measures specifically targeting BSE may also need to be included through a consideration of the impact of:

ii) Specific risk mitigation measures on preventing cattle from being fed ruminant-derived protein meal, taking account of:

- the nature and scope of a *feed* ban on feeding ruminants with protein meal derived from ruminants;
- the fate of *commodities* with the greatest BSE infectivity (those *commodities* listed in point 1 of Article 11.4.14.);
- parameters of the rendering process;
- prevention of cross-contamination during rendering, *feed* production, transport, storage and feeding;
- awareness programme under the scope of the *feed* ban;
- monitoring and enforcement of the *feed* ban.

Depending on the outcome of the exposure assessment, a consequence assessment (in point c) below) may not be required.

c) Consequence assessment

~~A~~The consequence assessment evaluates the likelihood of cattle becoming infected ~~with~~ following exposure to the BSE agents together with the likely extent and duration of any subsequent recycling and amplification within the cattle population during the preceding eight years. The factors to be considered in the consequence assessment are:

i) age at exposure;

ii) production type;

iii) the impact of cattle industry practices or the implementation of BSE specific mitigation measures under a *feed* ban.

d) Risk estimation

The risk estimation combines the results and conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk that BSE agents have been recycled in the cattle population through the feeding of ruminant-derived protein meal, with indigenous *cases* arising ~~as a consequence~~;

EU comment

The EU is of the opinion that:

- ‘the feeding of ruminant-derived protein meal’ is too restrictive and does not cover the whole range of events that could result in the BSE agents being recycled;

- the addition of 'with indigenous cases arising' is not necessary and could even be confusing, particularly if no such case has been detected.

These two elements of the sentence appear to be unnecessary and should be deleted.

Furthermore, the EU considers that the outcome of the risk estimation should also indicate the 'period when the risk of BSE agents being recycled in the cattle population has been demonstrated to be negligible', as this will be a critical information for the implementation of the provisions of Articles 11.4.7., 11.4.10., 11.4.12., 11.4.13. and 11.4.14. This should be clearly stated in point d). Please see also the related EU comment on point 4) of Article 1.8.5.

The EU therefore suggests that subpoint d) is amended as follows:

'd) Risk estimation

The risk estimation combines the results and conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk that BSE agents have been recycled in the cattle population ~~through the feeding of ruminant-derived protein meal, with indigenous cases arising~~, and to precise the period when the risk of BSE agents being recycled in the cattle population has been demonstrated to be negligible;'

EU comment

Furthermore, the EU notes that the above description of the risk assessment constantly refers to the preceding eight years. It is not fully clear for the EU how the proposed system will actually apply in the case of an applicant country wishing to claim that the 'period when the risk of BSE agents being recycled in the cattle population has been demonstrated to be negligible' is more than eight years, e.g. the preceding fifteen years: will that country be expected to consider the preceding fifteen years when performing the risk assessment (entry assessment, exposure assessment, etc.) in order to justify the outcome of the risk estimation that the period is indeed fifteen years?

In addition, could the OIE confirm that when applying for the reconfirmation of the status in the following years, the country will only have to justify that the risk has remained negligible during the previous year and will not be expected to provide the relevant justifications for all of the preceding 16 years, then 17, etc.?

The EU would therefore appreciate receiving some clarification from the OIE on how the system will work in practice to ensure that the claimed period is properly justified, while simultaneously avoiding imposing a disproportionate administrative burden on the applicant countries.

2) the ongoing implementation of a *surveillance* programme for classical BSE in the cattle population in accordance with Article 11.4.18.;

3) the history of occurrence and management of BSE *cases*.

Article 11.4.3.

Negligible BSE risk

The BSE risk of ~~the cattle population of~~ a country, *zone* or *compartment* can be considered to be negligible if the following conditions for the cattle population are met for at least the preceding eight years:

1) A *risk assessment* as described in Article 11.4.2. that has identified all potential risk factors associated with the occurrence of BSE has been conducted, and the Member Country has demonstrated through documented evidence that the ~~likelihood~~risk of BSE agents being recycled in the cattle population has been negligible ~~as the result of:~~.

~~EITHER:~~

~~a) livestock industry practices ensuring that protein meal derived from ruminants has not been fed to ruminants;~~

~~OR~~

~~b) effective and continuous mitigation of each identified risk ensuring that protein meal derived from ruminants has not been fed to ruminants.~~

EU comment

According to this proposal, a country could be recognised with BSE negligible risk without enforcing the minimum Ruminant to Ruminant feed ban currently required across the board. The EU understands the logic for this major evolution, which is based on the demonstration that BSE agents are not recycled in the country. However, the EU would like to stress that:

- as expressed in point 1) of Article 11.4.1., 'oral exposure to contaminated feed is the main route of transmission of classical BSE'. Fully securing the feed system is therefore of paramount importance to prevent a future recurrence of BSE in the world;

- the variety of real-life situations are usually not 100% captured by country-level assessments and overall conclusions.

In this context, the EU considers that the current Ruminant-to-Ruminant feed ban should remain compulsory in all countries applying for the BSE negligible or controlled risk status, as a safety net.

The EU therefore proposes the addition of the following point 1a) as an additional condition to be met to be granted the negligible BSE risk status (for the preceding 8 year) or the controlled BSE risk status in accordance with Article 11.4.4. Article 1.8.5 will need to be adjusted accordingly, particularly point '2 Exposure assessment'.

'1a) Protein meal derived from ruminants has not been fed to ruminants.'

2) The *surveillance* provisions as described in Article 11.4.~~20~~18. have been implemented.

3) EITHER:

a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported or has been diagnosed as atypical BSE as defined in this chapter;

OR

b) if there has been an indigenous *case* of classical BSE:

EITHER:

i) all *cases* were born at least eight years ago;

OR

ii) where a *case* was born within the preceding eight years, subsequent investigations have confirmed that the ~~likelihood~~risk of BSE being recycled within the cattle population has continued to be negligible.

4) Any *cases* of BSE that have been detected have been completely destroyed or disposed of to ensure that they do not enter the animal *feed* chain.

The country or the *zone* will be included in the list of countries or *zones* posing a negligible risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1 to 4 above. Documented evidence should be resubmitted annually for points 1 to 4 above.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

Article 11.4.3bis.

Recovery of negligible BSE risk status

~~When~~Should an indigenous *case* of classical BSE ~~is reported~~ in an animal born within the preceding eight years occur in a country or *zone* recognised as ~~having~~posing a negligible ~~BSE~~ risk for BSE, the status~~,~~ of the ~~negligible BSE risk status~~country or *zone* is suspended ~~and the recommendations for controlled BSE risk status apply, pending~~. The status may be recovered when the outcome of subsequent investigations ~~confirming~~confirms that the ~~likelihood~~risk of BSE being recycled within the cattle population continues to be negligible. ~~The~~In the interim, the provisions for a country or *zone* ~~will regain~~with a controlled BSE risk status apply.

The negligible BSE risk status of the country or *zone* will be reinstated only after the submitted evidence has been accepted by the OIE.

Article 11.4.4.

Controlled BSE risk

The BSE risk of the cattle population of a country, *zone* or *compartment* can be considered to be controlled provided the conditions of Article 11.4.3. are met, but at least one of the conditions has not been met for at least the preceding eight years.

EU comment

Consistently with the comment provided on the title of Article 11.4.2., with reference to the wording used in the first sentence of Articles 11.4.2. and 11.4.3., the EU suggests that the first sentence is amended as follows:

'The BSE risk ~~of the cattle population~~ of a country, zone or compartment can be considered to be controlled provided the conditions of Article 11.4.3. are met, but at least one of the conditions has not been met for at least the preceding eight years.'

The country or the *zone* will be included in the list of countries or *zones* posing a controlled risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1 to 4 of Article 11.4.3. Documented evidence should be resubmitted annually for points 1 to 4 of Article 11.4.3.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

Article 11.4.5.

Undetermined BSE risk

The BSE risk of the cattle population of a country, *zone* or *compartment* is considered to be undetermined if it cannot be demonstrated that it meets the requirements for negligible or controlled BSE risk.

EU comment

Consistently with the comment provided on the title of Article 11.4.2. and on Article 11.4.4., with reference to the wording used in the first sentence of Articles 11.4.2. and 11.4.3., the EU suggests that the sentence is amended as follows:

'The BSE risk ~~of the cattle population~~ of a country, zone or compartment is considered to be undetermined if it cannot be demonstrated that it meets the requirements for negligible or controlled BSE risk.'

~~Article 11.4.6.~~

~~**Recommendations for importation of cattle from a country, zone or compartment posing a negligible BSE risk**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that cattle selected for export came from a country, *zone* or *compartment* posing a negligible BSE risk.~~

Article 11.4.7.

Recommendations for importation of cattle from a country, zone or compartment posing a negligible or controlled BSE risk

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

1) the cattle selected for export~~:~~

~~1)~~ came from a country, *zone* or *compartment* posing a negligible or controlled BSE risk and are identified through an *animal identification system* enabling each *animal* to be traced throughout its lifetime;

AND EITHER:

2) the cattle selected for export were born in the country, *zone* or *compartment* during the period when the ~~likelihood~~risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

EU comment

The EU would like to point out that the above-proposed wording of point 2) seems to imply that the cattle have to be born in the country where "the cattle selected for export came from" (see point 1); in addition, the proposed wording does not address the risk of contamination between the date of birth and the latest period of life of the cattle, should it be sold initially in a country at a time when the risk of recycling is not negligible there. The EU considers the provision should allow for the cattle to be born and raised in different countries, provided they have always remained in a country during the period when the risk of recycling was negligible in that country.

The EU therefore suggests that point 2) is amended as follows:

'2) the cattle selected for export were born and constantly raised in a~~the~~ country, zone or compartment, or in countries, zones or compartments, during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible'

OR

3)-

~~a) are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime; and~~

~~b)~~ ~~are~~ it is demonstrated ~~as having~~that the cattle selected for export have not been fed protein meal derived from ruminants.

Article 11.4.8.

Recommendations for importation of cattle from a country, zone or compartment posing an undetermined BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that ~~cattle selected for export~~:

1) the cattle selected for export are identified ~~by a permanent individual~~ through an *animal identification system* ~~from birth~~ enabling each animal to be traced throughout its lifetime;

2) ~~are~~it is demonstrated ~~as having~~ that the cattle selected for export have not been fed protein meal derived from ruminants.

~~Article 11.4.9.~~

~~**Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a negligible BSE risk**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the cattle from which the *fresh meat* and *meat products* were derived:~~

~~1) came from a country, *zone* or *compartment* posing a negligible BSE risk;~~

~~2) have been subjected to an ante-mortem inspection with favourable results.~~

Article 11.4.10.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a negligible or controlled BSE risk

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

1) the cattle from which the *fresh meat* and *meat products* were derived came from a country, *zone* or *compartment* posing a ~~controlled BSE risk~~negligible or controlled BSE risk and are identified through an *animal identification system*;

EU comment

The EU welcomes the addition of the necessary identification of the cattle from which the meat and meat products were derived. However, the EU wishes to underline that it should be clarified that the animal identification system enables each animal to be traced throughout its lifetime. This is of major importance to ensure that the provisions of this article can be effectively applied and controlled.

The EU therefore suggests that point 1) is amended as follows:

'1) the cattle from which the fresh meat and meat products were derived came from a country, zone or compartment posing a negligible or controlled BSE risk and are identified through an animal identification system enabling each animal to be traced throughout its lifetime'

2) they have been subjected to an ante-mortem inspection with favourable results;

AND EITHER:

3) they were born in the country, *zone* or *compartment* during the period when the ~~likelihood~~ risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

EU comment

The EU wishes to recall the comments submitted in December 2019 on Articles 11.4.9. and 11.4.10.

The EU is of the opinion that the proposed system, with various levels of application of the SRM provisions depending on the sub-populations in a country with negligible or controlled BSE risk, will be very difficult to apply and control, considering the complexity of the food chain processes and circuits, and of trade schemes. The EU would have therefore preferred that one clear rule applies to the whole cattle population in a given country, as is currently the case.

In addition, the EU would like to make the following points:

- by not requesting the systematic exclusion of at least some of the commodities listed in Article 11.4.14. (commodities with the greatest BSE infectivity) the proposed article does not adequately address the risk of recycling the prion from atypical BSE cases. The EU therefore proposes that the removal of a shortlist of the commodities with the greatest BSE infectivity applies in countries with a negligible or controlled BSE risk to the cattle born during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible (e.g.: skull, brain, eyes and spinal cord of cattle as currently enforced in the EU Member States with a negligible BSE risk status).

- the above-proposed wording of point 3) seems to imply that the cattle have to be born in the country where "the cattle from which the fresh meat and meat products were derived came from" (see point 1); in addition, the proposed wording does not address the risk of contamination between the date of birth and the latest period of life of the cattle, should it be sold initially in a country at a time when the risk of recycling is not negligible there. The EU considers that the wording should allow for the cattle to be born and raised in different countries, provided they have always remained in a country during the period when the risk of recycling was negligible in that country.

Considering these points, the EU would like to propose the following language, which builds on the amendment proposed for Article 11.4.14.:

> **'3) they were born and constantly raised in a~~the~~ country, zone or compartment, or in countries, zones or compartments, during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible, and the fresh meat and meat products were produced and handled in a manner which ensures that such products do not contain and are not contaminated with the commodities listed in points 2) of Article 11.4.14;'**

OR

4) the *fresh meat* and *meat products*:

   a) derived from cattle not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to *slaughter*; and

   b) were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

i) the *commodities* listed in point~~s~~ 1~~)~~ ~~a) and 1) *b)*~~ of Article 11.4.14.;

ii) mechanically separated meat from the skull ~~and~~nor from the vertebral column from cattle over 30 months of age.

Article 11.4.11.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing an undetermined BSE risk

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

1) the cattle from which the fresh meat and meat products were derived~~:~~

~~*a)*~~ are identified through an *animal identification system*;

2) it is demonstrated ~~as having~~that the cattle from which the *fresh meat* and *meat products* were derived have not been fed protein meal derived from ruminants;

~~*b*~~3) the cattle from which the *fresh meat* and *meat products* were derived:

a) were subjected to an ante-mortem inspection with favourable results;

~~c~~b) were not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to *slaughter*;

~~2~~4) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

a) the *commodities* listed in point~~s~~ 1~~)~~ ~~*a) and 1) b)*~~ of Article 11.4.14.;

b) mechanically separated meat from the skull ~~and~~nor from the vertebral column from cattle over 30 months of age.

EU comment

The EU welcomes the addition in point 1 of the necessary identification of the cattle from which the meat and meat products were derived. However, the EU wishes to underline that it should be clarified that the animal identification system enables each animal to be traced throughout its lifetime. This is of major importance to ensure that the provisions of this article can be effectively applied and controlled.

Also, with a view to improve the clarity of the text, the EU suggests to merge points 1 and 3.

The EU therefore suggests that points 1) to 4) are amended as follows:

‘1) the cattle from which the fresh meat and meat products were derived

a) are identified through an animal identification system enabling each animal to be traced throughout its lifetime;

b) were subjected to an ante-mortem inspection with favourable results;

c) were not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to slaughter;

2) it is demonstrated that the cattle from which the fresh meat and meat products were derived have not been fed protein meal derived from ruminants;

~~**3) the cattle from which the fresh meat and meat products were derived:**~~

~~**a) were subjected to an ante-mortem inspection with favourable results;**~~

~~**b) were not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to slaughter;**~~

3~~**4**~~**) the fresh meat and meat products were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:**

a) the commodities listed in points 1 of Article 11.4.14.;

b) mechanically separated meat from the skull nor from the vertebral column from cattle over 30 months of age.'

Article 11.4.12.

Recommendations for importation of cattle-derived protein meal from a country, zone or compartment posing a negligible BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the cattle from which the protein meal was derived ~~came from a country, *zone* or *compartment* posing a negligible BSE risk.~~ :

1) came from a country, *zone* or *compartment* posing a negligible BSE risk;

2) are identified through an *animal identification system* and were born in the country, *zone* or *compartment* during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

EU comment

The EU welcomes the addition of point 2), which addresses the comment made by the EU in December 2019. However, as regards the animal identification system, and in line with the comments already made on point 1) of Articles 11.4.10. and 11.4.11., the EU wishes to underline that it should be clarified that the animal identification system enables each animal to be traced throughout its lifetime, to ensure that the provision of the second part of this point can be effectively applied and controlled.

The EU therefore suggests that point 2) is amended as follows:

'2) are identified through an animal identification system enabling each animal to be traced throughout its lifetime and were born in the country, zone or compartment during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible'

Article 11.4.13.

Recommendations for importation of blood and blood products derived from cattle (except foetal blood)

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

EITHER:

1) the blood and blood products came from a country, *zone* or *compartment* posing a negligible or controlled BSE risk; and

~~OR~~

2) the ~~blood and blood products came from a country, *zone* or *compartment* posing a controlled BSE risk and the~~ cattle from which the blood and blood products were derived are identified through an *animal identification system* and were born in the country, *zone* or *compartment* during the period when the ~~likelihood~~ risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

EU comment

The EU welcomes the addition of the necessary identification of the cattle from which the blood and blood products were derived. However, in line with the comments already made on point 1) of Articles 11.4.10. and 11.4.11., and on point 2) of Article 11.4.12., the EU wishes to underline that it should be clarified that the animal identification system enables each animal to be traced throughout its lifetime, to ensure that the provision of the second part of this point can be effectively applied and controlled.

Furthermore, the EU would like to point out that the above-proposed wording of point 2) seems to imply that the cattle have to be born in the country where "the blood and blood products came from" (see point 1); in addition, the proposed wording does not address the risk of contamination between the date of birth and the latest period of life of the cattle, should it be sold initially in a country at a time when the risk of recycling is not negligible there. The EU considers the provision should allow for the cattle to be born and raised in different countries, provided they have always remained in a country during the period when the risk of recycling was negligible in that country.

The EU therefore suggests that point 2) is amended as follows:

'2) cattle from which the blood and blood products were derived are identified through an animal identification system enabling each animal to be traced throughout its lifetime and were born and constantly raised in a~~the~~ country, zone or compartment, or in countries, zones or compartments, during the period when the likelihood risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;'

OR

3) the blood and blood products were:

   a) collected from cattle not subjected to a stunning process, or to any other procedure that can contaminate the blood with nervous tissue, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to *slaughter*; and

   b) collected and processed in a manner that ensures they are not contaminated with nervous tissue.

Article 11.4.14.

Recommendations in relation to the trade of the commodities with the greatest BSE infectivity

~~1)~~ Unless covered by other articles in this chapter, the following *commodities* ~~originating from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk, and any *commodity* contaminated by them,~~ should not be traded ~~for the preparation of food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices~~:

   ~~a~~1) ~~distal~~ Distal ileum from cattle of any age; ~~*b)*~~ skull, brain, eyes, vertebral column and spinal cord from cattle that were at the time of *slaughter* over 30 months of age~~.~~; or any *commodity* contaminated by

them, for the preparation of protein products, food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices, which originate from a country, *zone* or *compartment* posing:

a) an undetermined BSE risk;

b) a controlled BSE risk or a negligible BSE risk if the *commodities* are derived from cattle born before the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

EU Comment

The EU wishes to recall the comments submitted in December 2019 on Articles 11.4.9. and 11.4.10., and the comment proposed above on point 3) of Article 11.4.10.

The EU is of the opinion that the proposed system, with various levels of application of the SRM provisions depending on the sub-populations in a country with negligible or controlled BSE risk, will be very difficult to apply and control, considering the complexity of the food chain processes and circuits, and of trade schemes. The EU would have therefore preferred that one clear rule applies to the whole cattle population in a given country, as is currently the case.

In addition, the EU is of the opinion that by not requesting the systematic exclusion of at least some of the commodities listed in point 1 the proposed article does not adequately address the risk of recycling the prion from atypical BSE cases. The EU therefore proposes that the removal of a shortlist of the commodities with the greatest BSE infectivity applies in countries with a negligible or controlled BSE risk to the cattle born during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible (e.g.: skull, brain, eyes and spinal cord of cattle as currently enforced in the EU Member States with a negligible BSE risk status).

The EU would therefore like to propose the following language for this article:

'Unless covered by other articles in this chapter, the following commodities should not be traded:

1) Distal ileum from cattle of any age; skull, brain, eyes, vertebral column and spinal cord from cattle that were at the time of slaughter over 30 months of age.; or any commodity contaminated by them, for the preparation of protein products, food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices, which originate from a country, zone or compartment posing:

a) an undetermined BSE risk;

b) a controlled BSE risk or a negligible BSE risk if the commodities are derived from cattle born before the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

2) Skull, brain, eyes and spinal cord from cattle that were at the time of slaughter over 30 months of age.; or any commodity contaminated by them, for the preparation of protein products, food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices, which originate from a country, zone or compartment posing a controlled BSE risk or a negligible BSE risk if the commodities are derived from cattle born during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

3) Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices prepared using commodities listed in points 1 and 2 above.

43) Cattle-derived protein meal, or any commodities containing such products, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk.'

2) Protein products, food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices prepared using *commodities* listed in points 1) *a)* or 1) *b)* above of this article, which originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk, should not be traded.

3) Cattle-derived protein meal, or any *commodities* containing such products, which originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk, should not be traded.

These points do not apply to cattle in a country or *zone* with a controlled BSE risk when they are born during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

Article 11.4.15.

Recommendations for importation of tallow (other than as defined in Article 11.4bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1) the tallow came from a country, *zone* or *compartment* posing a negligible BSE risk; or

2) the tallow is derived from cattle which have been subjected to an ante-mortem inspection with favourable results, and has not been prepared using the *commodities* listed in pointspoint 1) a) and 1) b) of Article 11.4.14.

Article 11.4.16.

Recommendations for importation of dicalcium phosphate (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1) the dicalcium phosphate came from a country, *zone* or *compartment* posing a negligible BSE risk; or

2) the dicalcium phosphate is a co-product of bone gelatine.

Article 11.4.16bis.

Recommendations for importation of tallow derivatives (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1) originate from a country, *zone* or *compartment* that poses a negligible BSE risk; or

2) are derived from tallow that meets the conditions referred to in Article 11.4.15.; or

3) have been produced by hydrolysis, saponification or transesterification that uses high temperature and pressure.

EU comment

In order to clarify that the expression 'that uses high temperature and pressure', in point 3, only applies to the transesterification process, the EU would like to propose the following adjustment:

'3) have been produced by hydrolysis, saponification, or by transesterification that uses high temperature and pressure.'

Article 11.4.17.

Procedures for reduction of BSE infectivity in protein meal

The following procedure should be used to reduce the infectivity of any ~~transmissible spongiform encephalopathy~~BSE agents ~~which~~that may be present during the production of protein meal containing ruminant proteins.

1) The raw material should be reduced to a maximum particle size of 50 mm before heating~~.~~;

2) The raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

Article 11.4.18.

Surveillance

EU comment

The EU generally welcomes this latest version of the draft Article 11.4.18., which reinforces the clarity of the message on the necessity to test animals at risk. However, the EU considers that the comment included below should be addressed before this article can be supported.

~~1) *Surveillance* for BSE consists of the regular reporting of animals with clinical signs suggestive of BSE to the *Veterinary Authority* for subsequent investigation and diagnosis. The credibility of the *surveillance* programme is supported by:~~

~~a) compulsory notification of BSE throughout the whole territory by all those stakeholders involved in the rearing and production of livestock including farmers, herdsmen, *veterinarians*, transporters and *slaughterhouse/abattoir* workers;~~

~~b) an ongoing awareness programme to ensure that all stakeholders are familiar with the clinical signs suggestive of BSE as well as the reporting requirements;~~

~~c) appropriate *laboratory* investigations in accordance with the *Terrestrial Manual* and follow-up field investigation as necessary of all clinical suspects.~~

~~2~~1) BSE is a progressive, fatal disease of the nervous system of cattle that usually has an insidious onset that is refractory to treatment. A range of clinical signs that vary in severity and between animals have been described for classical BSE:

a) progressive behavioural changes that are refractory to treatment such as increased excitability, depression, nervousness, excessive and asymmetrical ear and eye movements, apparent increased salivation, increased licking of the muzzle, teeth grinding, hypersensitivity to touch and/or sound (hyperaesthesia), tremors, excessive ~~vocalization~~vocalisation, panic-stricken response and excessive alertness;

b) postural and locomotory changes such as abnormal posture (dog sitting), abnormal gait (particularly pelvic limb ataxia), low carriage of the head (head shyness), difficulty avoiding obstacles, inability to stand and recumbency;

c) ~~generalized~~generalised non-specific signs such as reduced *milk* yield, loss of body condition, weight loss, bradycardia and other disturbances of cardiac rhythm.

Some of these signs are also likely to be relevant for atypical BSE, particularly those associated with difficulty in rising and recumbency. A nervous form of atypical BSE resembling classical BSE may be observed with over-reactivity to external stimuli, unexpected startle responses and ataxia. In contrast, a dull form of atypical BSE may be observed with dullness combined with a low head carriage and compulsive behaviour (licking, chewing, pacing in circles).

The clinical signs of BSE usually progress over a few weeks to several months, but ~~in~~on rare occasions cases can develop acutely and progress rapidly. In the continuum of the disease spectrum, the ~~The~~ final stages are characterised by recumbency, coma and death.

~~Cattle displaying some of the above mentioned progressive neurological signs without signs of infectious illness, and that are refractory to treatment, are candidates for examination.~~

Since these signs are not pathognomonic for either classical or atypical BSE, all Member Countries with cattle populations ~~may~~ are likely to observe individual animals displaying clinical signs suggestive of BSE. ~~The rate at which they are likely to occur~~General statements about the likely frequency of occurrence of such animals cannot be ~~reliably predicted~~made as they will vary depending on the epidemiological situation in a particular country. ~~In addition, in~~

2) Surveillance for BSE consists of the reporting of all animals that lie on the continuum of the BSE spectrum to the *Veterinary Authority* for subsequent investigation and follow-up.

In those countries where cattle are intensively reared and subjected to regular observation, it is likely that ~~such~~ animals that display clinical signs suggestive of BSE will be more readily seen. Behavioural changes, that may be very subtle in the early clinical phase, are best identified by those who handle animals on a daily basis and who can monitor them closely for a progression of the signs. In more extensive systems however, where cattle are not monitored as closely, situations may ~~inevitably~~ arise where an animal might be considered as a clinical suspect, yet if it was not observed for a period of time, it may only be initially seen as a downer (non-ambulatory) or found dead (fallen stock). ~~Under such circumstances, if there is an appropriate supporting clinical history, these animals that lie on the continuum of a progressive disease from clinical suspect to downer to fallen stock may still be suitable candidates for *surveillance*.~~

The investigation of potential *surveillance* candidates should take into account that the vast majority of BSE cases arise as single, isolated events. The concurrent occurrence of multiple animals with behavioural or neurological signs, non-ambulatory or fallen stock is most likely associated with other causes.

The following animals that lie on the continuum of the disease spectrum should be targeted for BSE *surveillance*:

a) those displaying some of the progressive clinical signs mentioned in point 1 of Article 11.4.18. suggestive of BSE that are refractory to treatment, and where other common causes of behavioural or neurological signs (e.g., infectious, metabolic, traumatic, neoplastic or toxic causes) have been ruled out;

b) those showing behavioural or neurological signs that have been subjected to an ante-mortem inspection with unfavourable results at *slaughterhouses/abattoirs*;

c) those presented as downers (non-ambulatory), with an appropriate supporting clinical history;

d) those found dead (fallen stock), with an appropriate supporting clinical history.

EU comment

The EU is of the opinion that it is much too restrictive to target downers and fallen stock only 'with an appropriate supporting clinical history' (subpoints c and d). In particular, as expressed in the first paragraph of this point 2), in 'more extensive systems… where cattle are not monitored as closely…, situations may arise where an animal… may only be initially seen as a downer or fallen stock': such animals have by definition no clinical history and would therefore never have to be targeted, according to the proposed wording of subpoints c) and d). Yet they should also be targeted for BSE surveillance.

In addition, the EU notes that no age limit is set for cattle requested to be targeted for BSE surveillance. In order to avoid spending resources on younger cattle that are of no or very little significance for BSE, the EU would like to propose including the following age limits:

- cattle over 30 months of age in categories a) and b), in accordance with the provisions of the current Article 11.4.20., point 4a) and 4b);

- cattle over 48 months of age in categories c) and d), in accordance with the current practice in the EU, and in line with Chapter 3.4.5. of the OIE Terrestrial Manual presentation of BSE in point A.1. of the OIE Manual, where it is reported that "during the main epizootic most cases were observed in dairy cattle aged 4–6 years".

The EU therefore requests that the language of subpoints c) and d) is amended along the following line:

> **'a) those over 30 months of age displaying some of the progressive clinical signs mentioned in point 1 of Article 11.4.18. suggestive of BSE that are refractory to treatment, and where other common causes of behavioural or neurological signs (e.g., infectious, metabolic, traumatic, neoplastic or toxic causes) have been ruled out;**
>
> **b) those over 30 months of age showing behavioural or neurological signs that have been subjected to an ante-mortem inspection with unfavourable results at slaughterhouses/abattoirs;**
>
> **c) those over 48 months of age presented as downers (non-ambulatory), when no specific cause, other than BSE, has been identified and explains the situation~~with an appropriate supporting clinical history~~;**
>
> **d) those over 48 months of age found dead (fallen stock), when no specific cause, other than BSE, has been identified and explains the situation~~with an appropriate supporting clinical history~~.'**

All these animals should be followed up with appropriate laboratory testing in accordance with the *Terrestrial Manual* to accurately confirm or rule out the presence of BSE agents.

3) The credibility of the *surveillance* programme is supported by:

a) ongoing awareness and training programmes to ensure that all those stakeholders involved in the rearing and production of livestock including farmers, herdsmen, *veterinarians*, transporters and *slaughterhouse/abattoir* workers are familiar with the clinical signs suggestive of BSE as well as the statutory reporting requirements;

b) the fact that BSE is a compulsorily *notifiable disease* throughout the whole territory;

c) appropriate *laboratory* testing in accordance with the *Terrestrial Manual*;

d) robust, documented, evaluation procedures and protocols for the identification and reporting of potential candidates for BSE *surveillance*, for determination of animals to be subjected to laboratory testing, for the collection and submission of samples for laboratory testing, and for follow-up epidemiological investigation for BSE positive findings.

Annex 21

DRAFT CHAPTER 1.8.

APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF RISK STATUS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

EU comment

The EU thanks the OIE for the latest version of the revised Chapter 1.8. on the questionnaire for BSE status. The EU has an overall positive view on this draft chapter, but wishes to highlight the following:

- addressing the comment made on point 4 of Article 1.8.5., as well as the last comment on subpoint 4.g) of Article 1.8.6., will be of critical importance for a possible future support of this chapter by the EU.

- the EU is of the opinion that the period to be indicated in the questionnaire, as a result of the previous point (comment made on point 4 of Article 1.8.5.), will be a central information for the future implementation of Chapter 11.4. by the OIE Members, if adopted, and definitely as important and necessary as the BSE status of the countries. As a consequence, the EU considers of critical importance that total transparency is ensured on this information. Therefore, the EU respectfully requests that, for each country applying for a BSE status, that period is submitted to approval by the OIE Members, together with the BSE status itself, and published in the Resolution adopted at the general session annually.

EU comment

The EU notes that the word 'likelihood' has been replaced by 'risk' throughout the latest version of Chapter 11.4. The same applies to the expression 'country or zone' which has been replaced by 'country, zone or compartment'.

For the sake of consistency, the wording in Chapter 1.8. should be aligned with that of Chapter 11.4., as regards the 21 occurrences of the word 'likelihood' and the 13 occurrences of the expression 'country or zone'.

Article 1.8.1.

Guidelines

In accordance with Article 11.4.2., the bovine spongiform encephalopathy (BSE) risk of the cattle (*Bos indicus* and *Bos taurus*) population of a country or *zone* is determined on the basis of a *risk assessment* that evaluates the risk of BSE agents (classical and atypical) being recycled within the cattle population by identifying all potential factors associated with the occurrence of BSE, the ongoing implementation of a *surveillance* programme, and the history of occurrence and management of BSE *cases*.

In this chapter, "BSE" refers to both classical and atypical forms, unless specified otherwise.

The information specified in Articles 1.8.2. to 1.8.6. should be provided by OIE Member Countries in support of their application for official recognition of BSE risk status in accordance with Chapter 11.4. of the *Terrestrial Code*. The structure of the dossier should follow guidelines provided in the "Standard Operating Procedure for official

recognition of disease status and for the endorsement of national official control programmes of Member Countries" (available on the OIE website).

Each element of the core document of the dossier provided to the OIE, should be clearly and concisely addressed with an explanation, where relevant, of how each one complies with the provisions of the *Terrestrial Code* for the BSE risk status for which the Member is applying. The rationale leading to the conclusions reached for each section needs to be clearly explained and as appropriate, figures, tables and maps should be provided. The core document of the dossier should include the following sections:

– The history of occurrence and management of BSE *cases* in the country or *zone* (Article 1.8.2.)

– Legislation (Article 1.8.3.)

– Veterinary system (Article 1.8.4.)

– BSE risk assessment (Article 1.8.5.)

– BSE surveillance (Article 1.8.6.).

The terminology defined in the *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in the dossier. The dossier and all of its annexes should be provided in one of the OIE official languages.

Article 1.8.2.

History of occurrence and management of BSE cases in the country or zone

Describe the history of occurrence and management of BSE *cases* by providing the following documentary evidence:

1) If a *case* of BSE has ever been diagnosed in the country or *zone*, indicate the total number of BSE *cases*, and:

   a) Provide a table of aggregated data on all *cases* of BSE encountered in the country or *zone*, by type (classical or atypical), origin (indigenous or, if imported, the country of origin), and the year of birth;

   b) For the past eight years, provide a table to indicate, for each *case*, the year of occurrence, the origin (indigenous or, if imported, the country of origin), the type (classical or atypical), and the year of birth of each indigenous *case* of classical BSE.

EU comment

The EU considers that the restriction of the proposed subpoint b) to cases of classical BSE only is not consistent with subpoint a), which implies that the information requested in subpoint b), in particular the year of birth, is known for all cases of BSE, classical and atypical.

The EU therefore suggests that the wording of subpoint b) is amended as follows:

'b) For the past eight years, provide a table to indicate, for each case <u>of BSE</u>, the year of occurrence, the origin (indigenous or, if imported, the country of origin), the type (classical or atypical), and the year of birth ~~of each indigenous case of classical BSE~~.'

2) If there have been *cases* of BSE, confirm that they were excluded from the feed chain and describe how this was achieved. In the table under Article 1.8.3. provide details of the national legislation, regulations and *Veterinary Authority* directives that describe these procedures.

Article 1.8.3.

Legislation

Provide a table listing all relevant legislation, regulations, *Veterinary Authority* directives, legal instruments, rules, orders, acts, decrees, etc., related to BSE. For each, provide the date of promulgation and implementation as well as a brief description of the relevance to mitigating against the risks associated with BSE. The table should include the legislation, regulations and directives referred to in the core document of the dossier. These instruments may be provided as annexes or as weblinks to supporting documents.

Article 1.8.4.

Veterinary system

The quality of the *Veterinary Services* of a Member is important to the establishment and maintenance of confidence in its *international veterinary certificates* by the *Veterinary Services* of other Members (Article 3.1.1.). It also supports an evaluation of the BSE risk status of the cattle population of a country or *zone*.

1) Describe how the *Veterinary Services* of the country comply with the provisions of Chapters 1.1., 3.1. and 3.2.

2) The applicant Member may provide information on any recent (not older than five years) OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway, and highlight the results relevant to BSE.

3) Describe how the *Veterinary Services* supervise, control, enforce and monitor all BSE-related activities.

4) Provide a description of the involvement and the participation of industry; producers; farmers; herdsmen; private *veterinarians*; *veterinary paraprofessionals*; transporters; workers at livestock *markets*, auctions and *slaughterhouses/abattoirs*; and other relevant non-governmental stakeholders in the control of BSE.

5) Describe the official cattle identification, registration, *traceability* and movement control system. Provide evidence of its effectiveness. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic. Indicate if there are any industry associations or organisations involved in cattle identification, registration, *traceability* and movement control systems that provide guidance, set standards or provide third party audits; include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

Article 1.8.5.

BSE risk assessment

1. Entry assessment

   As described in Article 11.4.2., an entry assessment evaluates the likelihood that the classical BSE agent has been introduced into the country or *zone* through the importation of *commodities.*

   For the purposes of undertaking an entry assessment, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.).

   The *commodities* to be considered in the entry assessment are:

   – Cattle.

   – Ruminant-derived protein meal.

   – *Feed* (not intended for pets) that contains ruminant-derived protein meal.

   – Fertilizers that contain ruminant-derived protein meal.

   – Any other *commodity* that either is or could be contaminated by *commodities* listed in Article 11.4.14. e.g., over 30 months old cattle carcass or half carcass from which the spinal cord and vertebral column

were not removed, originating from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk.

EU comment

The EU notes that the example provided in the last indent does not reflect the provision in the latest version of Article 11.4.14. The following aspects should also be considered to ensure consistency:

- countries with a negligible BSE risk;

- whether the cattle, when from a country with a negligible or a controlled risk of BSE, were born during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

The EU would therefore appreciate that the OIE propose a revised wording.

a) For each *commodity* listed above indicate if they were imported in the preceding eight years, and if so, from which countries.

For each *commodity* listed above describe the import requirements applied by the applicant country or *zone* and how they are related to the BSE risk status of the *exporting country* or *zone* and whether or not they are consistent with, or provide an equivalent level of assurance with, the recommendations laid out in Chapter 11.4. for the importation of such a *commodity*. Where the import requirements are not consistent with the recommendations in Chapter 11.4. but are considered to provide an equivalent level of assurance, provide an explanation outlining the rationale and supporting evidence. In situations where an import requirement does not provide an equivalent level of assurance to the relevant measure in Chapter 11.4., provide an explanation of how this is likely to impact the entry assessment.

Describe the importation process for these *commodities* and how are they controlled, regulated and monitored by the *Competent Authority* with references as appropriate to the relevant legislation in the table under Article 1.8.3. Provide supporting evidence of the importation process including, where relevant, import permits or their equivalent, and examples of *international veterinary certificates* issued by *exporting countries*.

Describe the intended end use of the imported *commodities*, for example: cattle may be imported for breeding or immediate *slaughter*; rendered products may be imported for incorporation into *feed* for non-ruminant species such as pigs or *poultry*. Provide information on any systems in place and their results to monitor or track imported *commodities* to ensure they are used as intended.

Describe the actions available under national legislation to prevent illegal introduction of the *commodities* considered above and provide information on any illegal introductions detected and the actions taken.

b) Conclusions for the entry assessment.

Given the sanitary measures applied (if any), what was the likelihood that, during the preceding eight years, any of the *commodities*, in the form that they were imported, harboured or were contaminated by the classical BSE agent?

Clearly and concisely describe the rationale leading to the conclusions reached.

2. Exposure assessment

As emphasised in Article 11.4.1., atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population. Although uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated *feed*, this is the main route of transmission of classical BSE. Considering that atypical BSE may potentially be capable of being recycled in a cattle population if cattle were to be exposed to contaminated *feed*, it is necessary to undertake an exposure assessment regardless of the outcome of the entry assessment.

As described in Article 11.4.2., an exposure assessment evaluates the likelihood of cattle being exposed to the BSE agents either through imported *commodities* (classical BSE) or as a result of the presence of BSE agents (classical or atypical BSE) in the indigenous cattle population of the country or *zone*.

EU comment

The EU notes that point 1)b) of Article 11.4.2. does not restrict the exposure to classical BSE only. When it mentions that 'the exposure assessment … evaluates the likelihood of cattle being exposed to BSE', BSE should be understood as defined in point 3)a) of Article 11.4.1., which includes atypical BSE.

Furthermore, point 1) of Article 11.4.1. acknowledges that 'atypical BSE is also considered capable of being recycled in a cattle population if cattle are orally exposed to contaminated feed'. Therefore, the EU sees no reason why only classical BSE should be considered when evaluating the likelihood of cattle being exposed to the BSE agents through imported commodities.

The EU suggests that the above paragraph is amended as follows:

> **'As described in Article 11.4.2., an exposure assessment evaluates the likelihood of cattle being exposed to the BSE agents either through imported commodities ~~(classical BSE)~~ or as a result of the presence of BSE agents ~~(classical or atypical BSE)~~ in the indigenous cattle population of the country or zone.'**

For the purposes of undertaking an exposure assessment for the evaluation of BSE status, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.). At its discretion, the applicant Member may provide the information requested for a different period (i.e., longer than eight years for those applying for a negligible risk status, or for the time they have the information if applying for a controlled risk status) to establish the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible (i.e., to determine the period of time to be attested in point 2 of Articles 11.4.6., 11.4.7., 11.4.9., 11.4.12. and 11.4.13.).

EU comment

The cross-references to Article 11.4. need to be adjusted as follows:

> **'For the purposes of undertaking an exposure assessment for the evaluation of BSE status, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.). At its discretion, the applicant Member may provide the information requested for a different period (i.e., longer than eight years for those applying for a negligible risk status, or for the time they have the information if applying for a controlled risk status) to establish the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible (i.e., to determine the period of time to be attested in point 2 of Articles ~~11.4.6.,~~ 11.4.7., <u>point 3 of Article 11.4.10.</u>~~11.4.9.~~<u>, point 2 of Articles 11.4.11,</u> 11.4.12. and 11.4.13.<u>, point 1.b) of Article 11.4.14.</u>).'**

As indicated in point 1b) of Article 11.4.2., the first step in the exposure assessment involves an evaluation of the impact of livestock industry practices on preventing cattle from being fed ruminant-derived protein meal and, depending on the outcome of this step, an evaluation of the impact of specific mitigation measures on preventing cattle from being fed ruminant-derived protein meal.

a) Livestock industry practices.

Because oral exposure to contaminated *feed* is the principal route of transmission of the BSE agents, the exposure assessment begins with a detailed description of the cattle population and associated industry practices with a particular emphasis on feeding practices; disposal of dead stock and waste

from slaughtered animals; rendering; and production, distribution and storage of *feed* that may lead to cattle being exposed to potentially contaminated *feed*.

The intent of this section is not to describe the implementation and enforcement of measures specifically targeting the exposure of the cattle population to BSE agents (such as a legislated *feed* ban) as they will be considered where relevant in Section *b) An evaluation of BSE specific mitigation measures*. The intention here is to evaluate the likelihood and extent of exposure of the cattle population to the BSE agents, given the ongoing livestock industry practices in a country or *zone*.

i) Demographics of the cattle population and production systems.

Describe the composition of the cattle population and how the cattle industry is structured in the country or *zone* considering the types of production systems, including all that apply, such as dairy, beef, feedlot, fattening and finishing, intensive, extensive, semi intensive, transhumant, pastoral, agropastoral, and mixed-species farming.

EU comment

The EU suggests that the proposed list of production systems in the above paragraph is restructured and somewhat reduced as there is some cross-over between descriptions (e.g. feedlot, fattening and finishing).

In addition, the EU is of the opinion that this paragraph should be more prescriptive by clearly also requesting data on the number and size of farms in each production system. These numbers are necessary to provide an accurate picture of the structure of the livestock industry in a country.

The EU therefore proposes that the language of subpoint i) is amended as follows:

'i) Demographics of the cattle population and production systems.

Describe the composition of the cattle population and how the cattle industry is structured in the country or zone considering the types of production ~~systems, including all that apply~~, such as dairy, beef rearing~~, feedlot, fattening~~ and beef finishing, and the farming systems, such as intensive, extensive, semi intensive, transhumant, pastoral~~,~~ and agropastoral~~, and mixed-species farming~~. The description should include the number and size of farms in each type of production system.'

ii) Feeding practices.

For each type of production system, describe the rearing and production practices related to feeding ruminants of various ages, including the types of *feed* and *feed ingredients* (animal or plant based). Where animal based ingredients are used, describe whether or not they are derived from rendered products of ruminant or non-ruminant origin as well as the respective proportions used.

Provide an indication of the proportion of the national *feed* production prepared commercially (including local mills) or mixed on farm using either imported or domestically produced ingredients.

Describe whether or not fertilizers containing ruminant-derived protein meal, composted materials derived from fallen stock (i.e., cattle of any age which were found dead or were killed on a farm, during transportation or at a *slaughterhouse/abattoir*), *slaughterhouse/abattoir* waste or animals condemned at *ante mortem* inspections or any other materials derived from or that incorporate ruminant protein are applied to land where cattle graze or where forage is harvested for feeding to cattle. Where such fertilizers or composted materials are used, provide information on the extent and frequency of use.

Describe, for mixed-species farms that include ruminants, the number and size of such farms and whether or not there are any practices in place to ensure that ruminants are not likely to be fed with *feed* meant for non-ruminant species or that ruminant *feed* is not likely to be cross-contaminated with *feed* intended for non-ruminants that may contain rendered products of ruminant origin.

iii) Slaughtering and waste management practices.

Describe the practices for fallen stock that occur on farm, during transport, at livestock *markets* or auctions or prior to *slaughter*, with particular reference to their transportation, disposal or destruction, including composting, burial, rendering or incineration. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Describe the places where cattle are slaughtered (for example, on farm, at a *slaughterhouse/abattoir* or *market*) together with the respective proportions and associated ages.

Describe whether or not places where animals are slaughtered are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Describe how animals condemned at *ante mortem* inspection and waste declared as unfit for human consumption from slaughtered animals are processed, disposed of or destroyed, including composting, burial, rendering, incineration or other industrial uses such as salvaging and crushing bones for use in animal *feed*. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

iv) Rendering practices.

Rendering is a process by which animal material is transformed into products such as protein meal that may be used in animal *feed*. It provides the pathway for the introduction of the BSE agents (classical or atypical) into the animal feed chain.

Describe whether or not there are any rendering facilities in the country or *zone*, if they are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Using tables as appropriate, for each of the preceding eight years, provide a breakdown of the number of rendering facilities operating, indicating for each facility:

– the source and types of raw materials handled;
– whether or not they receive and process material from a particular species or process mixed materials including those derived from ruminants;
– whether or not ruminant waste is segregated from non-ruminant waste and if so how segregation is maintained to avoid potential cross-contamination of non-ruminant rendered materials during processing, storage and transport of rendered products, for example through dedicated lines, storage bins or silos, transport vehicles or establishments;
– the parameters of the rendering process (time, temperature, pressure, etc.);
– the type and intended end use of rendered products produced. If available, provide the amount of rendered products produced annually by type and intended end use;
– if materials derived from imported cattle are managed differently, describe the process.

Indicate if there are any industry associations or organisations involved in the rendering industry that provide guidance, set standards or provide third party audits in relation to Hazard Analysis and Critical Control Points (HACCP) programs, *good manufacturing practices*, etc. Include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

v) Feed production, distribution and storage.

Where rendered products are used as ingredients in the production of animal *feed* the exposure of cattle to the BSE agents (classical and atypical) may arise as a result of the use of rendered products containing materials of ruminant origin as ingredients in cattle *feed* or as a result of cattle *feed* being cross-contaminated when such products are used in the production of *feed* for other species.

Describe whether or not facilities producing *feed* for ruminant or non-ruminant livestock as well as pets are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

For each of the preceding eight years, provide a breakdown using tables as appropriate of the number and types of facilities producing *feed*, indicating for each facility:

– excluding those listed in Article 11.4.1bis., whether or not rendered ruminant products were used as ingredients in *feed* for ruminants, non-ruminants and pets;

EU comment

With a view to improving the clarity of the language, the EU suggest restructuring the above indent as follows:

'– ~~excluding those listed in Article 11.4.1bis.,~~ whether or not rendered ruminant products<u>, excluding those listed in Article 11.4.1bis.,</u> were used as ingredients in feed for ruminants, non-ruminants and pets;'

– whether or not each facility was dedicated to manufacturing *feed* for a particular species or manufactured *feed* for multiple species including ruminants.

Where facilities manufactured *feed* for multiple species including ruminants, indicate whether or not there were any practices in place to avoid ruminant *feeds* from being contaminated with rendered ruminant products during *feed* manufacture, storage and transport.

Indicate if there are any industry associations or organisations involved in *feed* production, distribution and storage that provide guidance, set standards or provide third party audits in relation to HACCP programs, *good manufacturing practices*, etc. Include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

vi) Conclusions for livestock industry practices.

– Given the livestock industry practices described above, is the likelihood that the cattle population has been exposed to either classical or atypical BSE during the preceding eight years negligible or non-negligible?

– Clearly and concisely describe the rationale leading to the conclusion reached.

– Where the likelihood estimate is negligible, proceed to *Section 4) Risk estimatio*n.

– Where the likelihood estimate is non-negligible, proceed to *Section b) An evaluation of BSE specific mitigation measures*.

b) An evaluation of BSE specific risk mitigation measures.

EU comment

The EU commented in Article 11.4.3. about the need to maintain the ruminant-to-ruminant feed ban a condition to be granted the negligible or controlled BSE risk status.

This part of Article 1.8.5. will need to be aligned accordingly.

For those countries that have reported classical BSE *cases* in indigenous cattle, it is apparent that their historic livestock industry practices did not prevent the recycling of the BSE agent in their cattle population. These countries, together with others whose livestock industries practices would have been

conducive to recycling may have implemented specific measures, such as through a legislated *feed* ban to ensure that the likelihood of recycling would be negligible. To qualify for official recognition of a BSE risk status, these countries need to demonstrate that the measures specifically targeting BSE have been and continue to be effectively implemented and enforced.

i) The nature and scope of a feed ban.

Indicate if there is a ban on feeding ruminants with protein meal derived from ruminants.

Where a *feed* ban has been implemented, clearly and concisely describe the date it was introduced, its nature and scope and how it has evolved over time.

In addition, if the *feed* ban has been implemented through national legislation, provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

ii) Commodities with the greatest BSE infectivity.

Indicate whether or not any of those *commodities* listed in point 1 of Article 11.4.14. are removed from the carcass at the time of *slaughter* or subsequent fabrication or processing.

If so, also:

– Describe how they are disposed or destroyed through burial, composting, rendering, alkaline hydrolysis, thermal hydrolysis, gasification, incineration, etc.

– Describe any measures in place that ensure *slaughter* waste declared as unfit for human consumption that is rendered is not cross-contaminated with these *commodities*.

– Describe whether these *commodities* from fallen stock and animals condemned at *ante mortem* inspection are excluded from rendering and how this is done.

EU comment

As proposed, the above indent suggests that the commodities listed in point 1 of Article 11.4.14. are not to be rendered, while these commodities are actually rendered, at least in the EU. The EU is of the opinion that the intention is actually to check if cross-contamination might occur at the rendering process level, and therefore suggests to clarify the sentence as follows:

'– Describe whether these commodities from fallen stock and animals condemned at ante mortem inspection are excluded from rendering <u>with slaughter waste declared as unfit for human consumption</u> and how this is done.'

– Where these *commodities* are not excluded from *slaughter* waste declared as unfit for human consumption, describe the final disposal of this waste, and how it is handled and processed.

– Describe whether or not all these processes and methods are subject to approval and oversight by the *Veterinary Services* or other *Competent Authority*.

In addition, if there is specific national legislation concerning the definition, identification, removal and disposal or destruction of those *commodities* listed in point 1 of Article 11.4.14., provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

iii) Parameters of the rendering process.

Describe whether or not the parameters of the rendering process are prescribed in legislation and if they are consistent with, or provide an equivalent level of assurance to, the procedures for the reduction of BSE infectivity in ruminant-derived protein meal as described in Article 11.4.17. Provide details of the legislation, if applicable, in the table under Article 1.8.3.

iv) Cross-contamination.

Describe the measures in place to prevent cross-contamination during rendering, *feed* production, transport, storage and feeding such as dedicated facilities, lines and equipment, as well as measures to prevent misfeeding, such as the use of warning labels. Provide information as to whether any of these measures are prescribed in legislation and if facilities involved in rendering and *feed* production are required to be registered or approved under the *feed* ban by the *Veterinary Services* or other *Competent Authority*.

v) Awareness programme under the scope of the feed ban.

Provide information on the existence of any ongoing awareness programmes or other forms of guidance given to all those stakeholders involved in rendering, *feed* production, transport, storage, distribution, sale and feeding under the scope of the *feed* ban. Provide examples of communication materials including publications, brochures and pamphlets.

vi) Monitoring and enforcement of the feed ban.

Describe how the *feed* ban, if implemented, has been and continues to be monitored and enforced. Provide information on:

- official oversight from the *Veterinary Authority*, other *Competent Authority* or a third party;
- training and accreditation programmes for inspectors;
- the planned frequency of inspections, the procedures involved including manuals and inspection forms;
- sampling programmes and *laboratory* testing methods used to check the level of compliance with the *feed* ban and cross-contamination;
- options available to deal with infractions (non-compliances) such as recalls, destruction and monetary penalties.

Provide information on the ongoing results of the official inspection programme for each of the preceding eight years using tables as appropriate:

- planned *versus* actual delivery inspections at rendering facilities, *feed* mills, farms, etc., with an explanation of any significant variance and how they may have impacted the programme;
- number and type of samples taken during inspections to verify that ruminant *feed* does not contain or is not cross contaminated with rendered products containing ruminant material (excluding those listed in Article 11.4.1bis.). Provide information by year, by source (rendering facility, *feed* mill or farm), indicating the *laboratory* test(s) used and the results obtained;
- the types of infractions (non-compliance) that occurred and corrective actions undertaken;
- any infractions (non-compliances) that were likely to have led to cattle being exposed to *feed* contaminated with ruminant material (excluding those listed in Article 11.4.1.bis) and how they were resolved.

vii) Conclusions for the evaluation of BSE specific risk mitigation measures.

- In evaluating the effectiveness of a *feed* ban, if implemented, for each of the preceding eight years, consideration needs to be given to:
  - the management of *commodities* listed in point 1 of Article 11.4.14., and the associated likelihood that these materials, or other materials cross contaminated by them, may have entered the animal feed chain;
  - the rendering industry and the associated likelihood that rendered products containing ruminant material may retain BSE infectivity;
  - the *feed* industry, and the associated likelihood that *feed* for cattle may contain or has been cross-contaminated with ruminant-derived protein meal.

– Given the evaluation of BSE specific risk mitigation measures and their enforcement as described above, is the likelihood that, during the preceding eight years, the cattle population has been exposed to either classical or atypical BSE negligible or non-negligible?

Clearly and concisely describe the rationale leading to the conclusion reached.

– Where the likelihood estimate is negligible, proceed to *Section 4) Risk estimation*.

– Where the likelihood estimate is non-negligible, proceed to *Section 3) Consequence assessment*.

3. Consequence assessment

While uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated *feed*, it is reasonable to assume for the purposes of a consequence assessment, that the likelihood of cattle becoming infected would be similar to classical BSE.

As described in Article 11.4.2., a consequence assessment evaluates the likelihood of cattle becoming infected following exposure to the BSE agents (classical or atypical) together with the likely extent and duration of any subsequent recycling and amplification.

For the purposes of undertaking a consequence assessment for the evaluation of BSE risk status, the period of interest is the preceding eight years.

Considering that, for all practical purposes, oral exposure to contaminated *feed* is the principal, if not the only route of transmission of the BSE agents, to initiate a cycle of BSE infectivity within a cattle population the following series of events would need to unfold:

– *commodities* listed in point 1 of Article 11.4.14. from an infected animal are included in raw materials that are rendered into ruminant-derived protein meal;

– the rendering process does not destroy infectivity of the BSE agent(s);

– the ruminant-derived protein meal is incorporated as an ingredient in cattle *feed*, or cattle *feed* is cross-contaminated during *feed* production, distribution and storage, or cattle are incorrectly fed with *feed* intended for non-ruminant species that includes the ruminant-derived protein meal as an ingredient;

– one or more animals that ingest contaminated *feed* become infected;

– the infected animal survives long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically;

– *commodities* listed in point 1 of Article 11.4.14. are then included in raw materials that are rendered into ruminant-derived protein meal, completing one cycle.

Recycling arises when this cycle is repeated one or more times. Any level of recycling within a given period is sufficient to conclude that the consequences of exposure to contaminated *feed* for that period within the cattle population are non-negligible.

a) Factors to consider when evaluating the likely extent of recycling of the BSE agents within a cattle population:

i) Age at exposure.

Animals less than 12 months of age are considered to be much more susceptible to *infection* than older animals, which are likely to be increasingly refractory to *infection* as they mature.

ii) Production type.

– Calves reared as replacement animals for the breeding *herd*.

Cattle exposed to BSE agents at less than 12 months of age and destined to enter the breeding *herd* are much more likely to become infected and survive long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically. If these

materials were rendered and subsequently contaminated cattle *feed*, it is highly likely that some level of recycling would occur.

– Feedlot cattle.

Even if cattle reared in a feedlot that were destined to be slaughtered within the next two to six months were to become infected after consuming contaminated *feed*, the likelihood that they would have reached the later stages of a protracted incubation period (when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically) would essentially be negligible.

Considering that mature cattle are likely to be much more refractory to *infection* than animals within their first year of life, even if they were to consume contaminated *feed*, it is highly unlikely that those *commodities* listed in point 1 of Article 11.4.14. would pose a threat if they were rendered and subsequently contaminated cattle *feed*.

iii) The impact of livestock industry practices or the implementation of measures under a *feed* ban.

When evaluating the potential for the recycling of the BSE agents in the cattle population where an infraction (non-compliance) has occurred that may have led to *feed* being cross-contaminated, it is important to consider the impact of both the livestock industry practices and the ongoing measures under a *feed* ban. Even if an infraction that arose several years ago led to susceptible young animals becoming infected, in evaluating the likelihood of recycling in future years, consideration would need to be given to the effectiveness of the *feed* ban in subsequent years or whether or not any changes to livestock industry practices may have influenced the exposure risk.

EU comment

With a view to improving the clarity of the language, the EU suggest amending the above subpoint iii) as follows:

'iii) The impact of livestock industry practices or the implementation of measures under a feed ban.

When evaluating the potential for the recycling of the BSE agents in the cattle population where an infraction (non-compliance) <u>to a feed ban</u> has occurred that may have led to feed being ~~cross-~~contaminated, it is important to consider the impact of both the livestock industry practices and the ongoing measures under <u>that</u>~~a~~ feed ban. Even if an infraction that arose several years ago led to susceptible young animals becoming infected, in evaluating the likelihood of recycling in future years, consideration would need to be given to the effectiveness of the feed ban in subsequent years or whether or not any changes to livestock industry practices may have influenced the exposure risk.'

b) Conclusions for the consequence assessment.

Where the outcome of the evaluation of livestock industry practices or the evaluation of BSE specific mitigation measures, that include the nature and scope of the *feed* ban and its enforcement, has concluded that there was a non-negligible likelihood that the cattle population has been exposed to the BSE agents, what is the likelihood that they have been recycled within the cattle population during the preceding eight years?

Clearly describe the rationale leading to the conclusions reached.

4. <u>Risk estimation</u>

As described in Article 11.4.2., risk estimation combines the results and the conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk that BSE agents have been recycled in the cattle population through the feeding of ruminant-derived protein meal.

a) Provide a summary of the entry and exposure assessments and the conclusions reached.

b) If applicable, provide a summary of the consequence assessment, and the conclusions reached.

c) When the condition of point 1 of Article 11.4.3. has not been met, that is, it cannot be demonstrated that for at least eight years the risk that the BSE agents have been recycled in the cattle population has been negligible, provide an explanation for the period of time within the preceding eight years for which it can be considered that the risk has been negligible. Clearly describe the rationale leading to the conclusions reached.

EU comment

In line with the comment provided on subpoint 1.d) of Article 11.4.2., the EU considers that the outcome of the risk estimation should also indicate the 'period when the risk of BSE agents being recycled in the cattle population has been demonstrated to be negligible', as this will be a critical information for the implementation of the provisions of Articles 11.4.7., 11.4.10., 11.4.12., 11.4.13. and 11.4.14. This requirement should definitely be added in plain language in the present subpoint 4.c), so that the information is systematically provided, including when the period has been more than the preceding eight years.

The EU therefore strongly insists that subpoint 4.c) is redrafted as follows:

'c) <u>Indicate the period of time for which it can be considered that the risk of BSE agents being recycled in the cattle population has been negligible. Provide explanations and clearly</u> ~~When the condition of point 1 of Article 11.4.3. has not been met, that is, it cannot be demonstrated that for at least eight years the risk that the BSE agents have been recycled in the cattle population has been negligible, provide an explanation for the period of time within the preceding eight years for which it can be considered that the risk has been negligible. Clearly~~ describe the rationale leading to the conclusions reached.'

EU comment

It is not fully clear for the EU how the proposed system will actually apply in the case of an applicant country wishing to claim that the 'period when the risk of BSE agents being recycled in the cattle population has been demonstrated to be negligible' is more than eight years, e.g. the preceding fifteen years: will that country be expected to consider the preceding fifteen years when performing the risk assessment (entry assessment, exposure assessment, etc.) in order to justify the outcome of the risk estimation that the period is indeed fifteen years?

In addition, could the OIE confirm that, when applying for the reconfirmation of the status in the following years, the country will only have to justify that the risk has remained negligible during the previous year and will not be expected to provide the relevant justifications for all of the preceding 16 years, then 17, etc.?

The EU would therefore appreciate receiving some clarification from the OIE on how the system will work in practice to ensure that the claimed period is properly justified, while simultaneously avoiding imposing a disproportionate administrative burden on the applicant countries.

Article 1.8.6.

BSE surveillance

Article 11.4.18. describes the criteria that underpin a credible *surveillance* programme together with an overview of the range and progression of clinical signs that cattle affected by BSE are likely to exhibit.

Requirements under point 2 of Article 11.4.18. are focused on subsets of the cattle population where disease is more likely to be detected, if it is actually present.

EU comment

The EU would like to highlight that, as expressed in point 1) of Article 11.4.1., 'Atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population.' The EU therefore considers that it is not appropriate to question the presence of BSE (i.e. classical <u>and</u> atypical BSE, in line with point 3.a) of Article 11.4.1.), and suggests to amend the above paragraph as follows:

> **'Requirements under point 2 of Article 11.4.18. are focused on subsets of the cattle population where disease is more likely to be detected~~, if it is actually present~~.'**

The Member applying for recognition of a negligible or a controlled BSE risk status should submit documentary evidence that the provisions of point 3 of Article 11.4.18. have been effectively implemented.

For the purposes of *surveillance*, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.).

Animals that lie on the continuum of the disease spectrum (i.e., from clinically ill to non-ambulatory to fallen stock) should be targeted for BSE surveillance and include those animals described in points 2a) to 2d) of Article 11.4.18.

1. <u>Awareness and training programmes (point 3a) of Article 11.4.18.)</u>

   Ongoing awareness and training programmes are essential to ensure that all stakeholders are familiar with clinical signs suggestive of BSE (those described in point 1 of Article 11.4.8.) as well as their statutory reporting requirements.

   a) Describe the stakeholder groups targeted for BSE awareness and training programmes. Describe the methods used to identify stakeholder groups within the jurisdiction and methods used to identify how, for example, the size and characteristics of the stakeholder group changes over time.

   b) Describe the type(s) of awareness and training programmes implemented for specific stakeholder groups. Describe how these programmes are adapted to meet the specific obligations and activities of each stakeholder group by those involved in caring for livestock, as well as the protocols for sample collection and submission by *veterinarians* and animal health technicians).

   c) Provide information on the number of awareness and training activities, the stakeholder groups targeted, the number of individuals reached per activity (if available), and the geographic coverage for these activities.

   d) Provide a description including examples of materials used in the awareness programme including training manuals, supporting documents such as publications in local newspapers and farming magazines, pamphlets and videos (weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist).

   e) Provide details on how the effectiveness of the awareness and training programmes is evaluated.

   f) Provide details of any contingency or preparedness plan for BSE.

2. <u>Compulsory notification (point 3b) of Article 11.4.18.)</u>

   To ensure the reporting and further investigations of any animals that lie on the continuum of the BSE spectrum, appropriate legislation, policies and incentives to support compulsory notification, investigation and verification should be in place.

a) Indicate the date of implementation of any supporting legislation and associated policies making notification of BSE compulsory. Indicate if a definition for a "BSE suspect" exists. If appropriate, outline relevant legislation in the table under Article 1.8.3.

b) Describe the supportive measures in place for notification of animals that lie on the continuum of the BSE spectrum, such as incentives, compensations or penalties.

c) Describe the guidance given to all stakeholders involved in the rearing and production of livestock including farmers, herdsmen, *veterinarians*, transporters, workers at livestock *markets*, auctions and *slaughterhouses/abattoirs* in terms of the criteria for reporting animals that lie on the continuum of the BSE spectrum. What mechanisms are in place to ensure that these guidelines reach those stakeholders?

d) Describe the reporting framework for animals that lie on the continuum of the BSE spectrum for evaluation. Has this framework evolved over time and, if so, how?

3. Laboratory testing (point 3c) of Article 11.4.18.)

Provide documentary evidence that the relevant provisions of Chapter 3.4.5. of the *Terrestrial Manual* are applied, including the following:

a) If BSE samples are submitted to a *laboratory* in the country or *zone* for testing provide an overview of how many are involved in testing BSE samples, how they are approved or certified, their number, location and diagnostic procedures and the time frame for reporting results.

b) If the BSE samples are not submitted to a *laboratory* in the country or *zone* for testing or suspicious or positive samples are referred to a *laboratory* outside the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

c) Describe the diagnostic protocol and tests used for processing samples for classical and atypical BSE and how they may have evolved over time, indicating: what is the primary test used?; what would be the series of secondary tests performed, if any, depending on the results of the primary test (i.e., negative, positive and inconclusive)?; and what test would be undertaken if discordant results between primary and secondary tests arise (e.g., primary positive result followed by a secondary negative result)?

4. Evaluation procedures and protocols to identify and report potential candidates for BSE surveillance, to determine animals to be subjected to laboratory testing, to collect and submit samples for laboratory testing, and to follow up with epidemiological investigation BSE positive findings (point 3d) of Article 11.4.18.)

Because the incidence of BSE is likely to be very low in Member Countries it is important that *surveillance* efforts focus on subsets of the cattle population where disease is more likely to be detected, if it is actually present. Hence, those animals described in points 2a) to 2d) of Article 11.4.18. must be targeted for BSE *surveillance*.

EU comment

The EU would like to highlight that, as expressed in point 1) of Article 11.4.1., 'Atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population.' The EU therefore considers that it is not appropriate to question the presence of BSE (i.e. classical and atypical BSE, in line with point 3.a) of Article 11.4.1.), and suggests to amend the above paragraph as follows:

'Because the incidence of BSE is likely to be very low in Member Countries it is important that surveillance efforts focus on subsets of the cattle population where disease is more likely to be detected~~, if it is actually present~~. Hence, those animals described in points 2a) to 2d) of Article 11.4.18. must be targeted for BSE surveillance.'

Considering that BSE is a progressive disease and that animals to be included in the *surveillance* programme may arise at the farm, the *slaughterhouse/abattoir*, or during transportation, procedures and protocols should be in place covering all points in the livestock production chain for: (1) the identification and reporting of animals potentially lying on the continuum of the BSE spectrum (e.g., by the farmer, *animal handler*, *veterinarian*, etc.), (2) the criteria to determine which of these reported animals need to be tested for BSE (e.g., the criteria used by the *veterinarian* that allows the discrimination of reported animals subject to laboratory testing), (3) the collection and submission of samples for testing in a laboratory, and (4) a follow-up epidemiological investigation for BSE positive findings.

EU comment

The EU is of the opinion that no epidemiological investigation is necessary in case of atypical BSE positive findings, and such investigation should be required only in case of classical BSE.

The EU therefore suggests to amend the above paragraph as follows:

'Considering that BSE is a progressive disease and that animals to be included in the surveillance programme may arise at the farm, the slaughterhouse/abattoir, or during transportation, procedures and protocols should be in place covering all points in the livestock production chain for: (1) the identification and reporting of animals potentially lying on the continuum of the BSE spectrum (e.g., by the farmer, animal handler, veterinarian, etc.), (2) the criteria to determine which of these reported animals need to be tested for BSE (e.g., the criteria used by the veterinarian that allows the discrimination of reported animals subject to laboratory testing), (3) the collection and submission of samples for testing in a laboratory, and (4) a follow-up epidemiological investigation for classical BSE positive findings.'

It is important that appropriate procedures and protocols are in place to ensure that BSE can be definitively ruled out on the list of differential diagnoses.

a) List the common cattle disorders with clinical signs compatible with BSE in the country or zone. If available, provide the incidence/prevalence of these disorders, ideally by production system (e.g., dairy, beef) and by age group.

b) Describe the procedures and protocols in place for reporting animals potentially lying on the continuum of the BSE spectrum (those described in points 2a) to 2d) of Article 11.4.18.) to the *Competent Authority*. For example, these procedures and protocols may include the steps that a farmer may follow once an animal with clinical signs suggestive of BSE is identified. These procedures and protocols should cover the clinical continuum of the disease spectrum ranging from clinical suspects to non-ambulatory to fallen stock.

c) Describe the procedures and protocols in place for the investigation of reported animals potentially lying on the continuum of the BSE spectrum (those described in points 2a) to 2d) of Article 11.4.18.) that allow the discrimination of reported animals to be subjected to laboratory testing. For example, these procedures and protocols may include the range of clinical signs to be considered, and how the age, the clinical history of the animal and epidemiological data of the *herd* are taken into account. An evaluation procedure may, for example, be in the form of a protocol, a checklist or a decision tree, and should cover the clinical continuum of the disease spectrum ranging from clinical suspects to non-ambulatory to fallen stock.

EU comment

In order to improve the clarity of the text, and ensure that the procedures will describe both inclusion and exclusion criteria, the EU suggests amending the wording as follows:

'c) Describe the procedures and protocols in place for the investigation of reported animals potentially lying on the continuum of the BSE spectrum (those described

in points 2a) to 2d) of Article 11.4.18.) that allow the discrimination of reported animals to be subjected to laboratory testing and animals excluded from laboratory testing. For example, these procedures and protocols may include the range of clinical signs to be considered, and how the age, the clinical history of the animal and epidemiological data of the herd are taken into account. An evaluation procedure may, for example, be in the form of a protocol, a checklist or a decision tree, and should cover the clinical continuum of the disease spectrum ranging from clinical suspects to non-ambulatory to fallen stock.'

d) Describe the methods applied to assess the age of animals investigated, such as individual identification or dentition.

e) Describe the procedures and protocols for the transport of live or dead animals for sampling, and transfer of samples to laboratories for testing, including details of the cattle identification system, the maintenance of the chain of custody of the carcass and the samples, and the reconciliation of samples with the animals they were collected from.

f) Provide the procedures and protocols for a follow-up epidemiological investigation of BSE positive results.

EU comment

In line with the comment provided on the second paragraph of this point 4, the EU suggests to amend the above subpoint 4.f) as follows:

'f) Provide the procedures and protocols for a follow-up epidemiological investigation of classical BSE positive results.'

g) Provide a summary table for each year (Table 1) of the number of animals reported and the number of animals subjected to BSE testing for each clinical presentation (those in points 2a) to 2d) of Article 11.4.18.).

EU comment

With a view to improving the clarity of the language, the EU suggests to amend the above subpoint 4.g) as follows:

'g) Provide a summary table for each of the preceding eight years (Table 1) of the number of animals reported and the number of animals subjected to BSE testing for each clinical presentation (those in points 2a) to 2d) of Article 11.4.18.).'

Table 1.		
Year: _____		
Table 1 - Summary of all animals that were reported and evaluated for testing by the Veterinary Authority		
Clinical presentation (see point 2 of Article 11.4.18.)	Number of reported animals	Number of animals subjected to BSE testing
(A) Cattle displaying progressive behavioural or neurological signs suggestive of BSE that are refractory to treatment		
(B) Cattle showing behavioural or neurological signs that did not pass the ante-mortem inspection at slaughterhouses/abattoirs		

(C) Cattle presented as downers (non-ambulatory) with an appropriate supporting clinical history		
(D) Cattle found dead (fallen stock) with an appropriate supporting clinical history		

EU comment

In line with the comment made on subpoints a), b), c) and d) of point 2) of Article 11.4.18.:

1/ The EU is of the opinion that it is much too restrictive to target downers and fallen stock only 'with an appropriate supporting clinical history' (lines C and D of table 1). In particular, as expressed in the first paragraph of this point 2) of Article 11.4.18., in 'more extensive systems… where cattle are not monitored as closely…, situations may arise where an animal… may only be initially seen as a downer or fallen stock': such animals have by definition no clinical history and would therefore never have to be targeted, according to the proposed wording of subpoints c) and d). Yet they should also be targeted for BSE surveillance when no specific cause, other than BSE, has been identified and explains the situation.

2/ In addition, the EU notes that no age limit is set for cattle requested to be targeted for BSE surveillance. In order to avoid spending resources on younger cattle that are of no or very little significance for BSE, the EU would also like to propose including the following age limits:

- cattle over 30 months of age in categories a) and b), in accordance with the provisions of the current Article 11.4.20., point 4a) and 4b);

- cattle over 48 months of age in categories c) and d), in accordance with the current practice in the EU, and in line with Chapter 3.4.5. of the OIE Terrestrial Manual presentation of BSE in point A.1. of the OIE Manual, where it is reported that "during the main epizootic most cases were observed in dairy cattle aged 4–6 years".

The EU therefore requests that the language of lines A, B, C and D of Table 1 is amended along the following line:

> **'(A) Cattle <u>over 30 months of age</u> displaying progressive behavioural or neurological signs suggestive of BSE that are refractory to treatment**
>
> **(B) Cattle <u>over 30 months of age</u> showing behavioural or neurological signs that did not pass the ante-mortem inspection at slaughterhouses/abattoirs**
>
> **(C) Cattle <u>over 48 months of age</u> presented as downers (non-ambulatory)<u>, when no specific cause, other than BSE, has been identified and explains the situation</u>~~with an appropriate supporting clinical history~~;**
>
> **(D) Cattle <u>over 48 months of age</u> found dead (fallen stock)<u>, when no specific cause, other than BSE, has been identified and explains the situation</u>~~with an appropriate supporting clinical history~~.'**

5. <u>Animals subjected to laboratory testing</u>

   a) Provide in Table 2 details of all animals that were subjected to laboratory testing (see point 2 of Article 11.4.18.).

EU comment

With a view to improving the clarity of the language, the EU suggests to amend the above subpoint 5.a) as follows:

'a) Provide in Table 2, for each of the preceding eight years, details of all animals counted in Table 1 that were subjected to laboratory testing (see point 2 of Article 11.4.18.).'

Table 2. Details of the animals that were subjected to laboratory testing.

Year notified	Laboratory identification number or individual identification number	Age (in months) at first detection	Type of production system (dairy, beef, mixed, etc.)	Description of observed clinical signs	Clinical presentation (A, B, C or D)	Final diagnosis (if BSE, specify the strain)	For a BSE case, indicate the origin (indigenous or imported; if imported, indicate the country of birth)

EU comment

The EU is concerned that filling out this table will be a disproportionate administrative burden in the EU Member States, where more than 1 million cattle are tested each year in the framework of the EU BSE monitoring.

The EU would appreciate that the OIE proposes alternative options more easily applicable in situations like that of the EU.

Article 1.8.7.

Recovery of BSE risk status

Following the occurrence of an indigenous *case* of classical BSE in an animal born within the preceding eight years in a negligible BSE risk status of a country or *zone*, the outcome of the investigation together with any additional measures implemented that confirm or ensure that the risk of BSE being recycled within the cattle population continues to be negligible should be provided with reference to the provisions in Article 1.8.5. as appropriate. Information in relation to other sections need to only be supplied if relevant.

EU comment

With a view to improving the clarity of the language, the EU suggests to amend Article 1.8.7. as follows (in line with the language of Article 11.4.3.):

'Recovery of BSE risk status

Following the occurrence of an indigenous case of classical BSE in an animal born within the preceding eight years in a country or zone recognised as posing a negligible risk for BSE~~negligible BSE risk status of a country or zone~~, the outcome of the investigation together with any additional measures implemented that

confirm or ensure that the risk of BSE being recycled within the cattle population continues to be negligible should be provided with reference to the provisions in Article 1.8.5. as appropriate. Information in relation to other sections need to only be supplied if relevant.'

Annex 22

CHAPTER 11.10.

INFECTION WITH *THEILERIA ANNULATA, T. ORIENTALIS* AND *T. PARVA*

EU comment

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

Article 11.10.1.

General provisions

*Animal*s susceptible to *infection* with *Theileria* are bovines (*Bos indicus*, *B. taurus* and *B. grunniens*), water buffaloes *(Bubalus bubalis)*, African buffaloes *(Syncerus caffer)*, sheep *(Ovis aries)*, goats *(Capra hircus),* camels (*Camel dromedarius* and *C. bactrianus)* and some *wild* ruminants.

Infection with *Theileria* can give rise to disease of variable severity and to *Theileria* transmission. *Theileria* may persist in ruminants for their lifetime. Such *animals* are considered carriers.

For the purposes of the *Terrestrial Code*, *infection* with *Theileria annulata*, *T. orientalis* and *T. parva* ~~are~~ is defined as a tickborne *infection* of bovines and water buffaloes with *T. annulata, T. orientalis* Ikeda, *T. orientalis* Chitose and *T. parva*.

For the purposes of this chapter, *Theileria* means *T. annulata, T. orientalis* Ikeda, *T. orientalis* Chitose and *T. parva.*

The following defines the occurrence of *infection* with *Theileria*:

1) *Theileria* has been identified in a sample from a bovine or water buffalo; or

2) antigen or nucleic acid specific to *Theileria* has been identified in a sample from a bovine or water buffalo showing clinical signs consistent with *infection* with *Theileria*, or epidemiologically linked to a suspected or confirmed *case*, or giving cause for suspicion of previous association with *Theileria*; or

3) antibodies specific to *Theileria* have been detected in a sample from a bovine or water buffalo that either shows clinical signs consistent with *infection* with *Theileria*, or is epidemiologically linked to a suspected or confirmed *case* or giving cause for suspicion of previous association with *Theileria*.

For the purposes of the *Terrestrial Code*, the *incubation period* for *infection* with *Theileria* shall be 35 days.

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

Article 11.10.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Theileria*-related conditions regardless of the *infection* with *Theileria* status of the *animal population* of the *exporting country*:

1) *meat* and *meat products*;

2) *casings*;

3) *milk* and *milk products*;

4) gelatine and collagen;

5) tallow;

6) semen and embryos;

7) hooves and horns;

8) bones.

Article 11.10.3.

Country or zone free from infection with *Theileria*

1) A country or a *zone* may be considered free from *infection* with *Theileria* when the disease is notifiable in the entire country, importation of bovines and water buffaloes and their *commodities* is carried out in accordance with this chapter, and:

   a) the country or *zone* is historically free as described in Article 1.4.6.; or

   b) a *surveillance* programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with *Theileria* in the country or *zone* for at least two years; or

   c) an ongoing *surveillance* programme in accordance with Chapter 1.5. has found no competent tick *vectors* for at least two years in the country or *zone*.

2) A country or *zone* free from *infection* with *Theileria* in which ongoing *vector surveillance*, performed in accordance with Chapter 1.5., has found no competent tick *vectors* will not lose its free status through the introduction of vaccinated, test-positive or infected bovines or water buffaloes from infected countries or *zones*.

3) A country or *zone* free from *infection* with *Theileria* will not lose its status as a result of introduction of seropositive or vaccinated bovines, water buffaloes or their *commodities*, provided they were introduced in accordance with this chapter.

Article 11.10.4.

Recommendations for importation from countries or zones free from infection with *Theileria*

For bovines and water buffaloes

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

1) showed no clinical sign of *infection* with *Theileria* on the day of shipment;

2) come from a country or *zone* free from *infection* with *Theileria*.

Article 11.10.5.

Recommendations for importation from countries or zones not free from infection with *Theileria*

For bovines and water buffaloes

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

1) showed no clinical sign of *infection* with *Theileria* and no *infestation* with tick *vectors* on the day of shipment;

2) were kept isolated for at least 35 days prior to shipment, in an e*stablishment* where no *case* of *infection* with *Theileria* has occurred during the preceding two years;

3) were treated with a registered acaricide the efficacy of which has been confirmed in relation to the area of origin of the *animals*, at the entrance of the isolation *establishment* and then at regular intervals, according to manufacturer's instructions, allowing continuous protection against ticks until their shipment ~~48 hours prior to entry to the *establishment*, no more than two days after entering the *establishment* and three days prior to shipment~~;

4) were subjected to serological and agent detection tests with negative results on samples taken on entry to the *establishment* and five days before shipment.

Article 11.10.6.

Recommendations for importation of hides and skins from countries or zones not free from infection with *Theileria*

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

1) dry-salted or wet-salted for a period of at least 14 days prior to dispatch; or

2) treated for a period of at least seven days in salt (NaCl) with the addition of 2% sodium carbonate (Na_2CO_3); or

3) dried for a period of at least 42 days at a temperature of at least 20°C; or

4) frozen to at least -20°C for at least 48 hours.

Article 11.10.7.

Recommendations for importation of trophies derived from susceptible ~~wild~~ ruminants from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products have been processed to ensure the destruction of tick *vectors*.

Annex 23

CHAPTER 11.11.

TRICHOMONOSIS

EU comment

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

Whereas the term "agent identification" is still used in the current corresponding OIE Manual chapter (Chapter 3.4.15., most recently adopted in 2018), the EU notes that in the most recent draft Manual chapters circulated for member country comment in October 2020, that term is systematically being replaced with "detection of the agent". We thus suggest confirming with the OIE Biological Standards Commission which term to use in the present draft Code chapter.

Article 11.11.1.

General provisions

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

Article 11.11.2.

Recommendations for the importation of cattle for breeding

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

1) the animals showed no clinical sign of trichomonosis on the day of shipment;

2) the animals were kept in a *herd* in which no *case* of trichomonosis has been reported; and/or

3) ~~for~~ females which have been mated~~, direct microscopic examination and culture of vaginal mucus were negative~~ were subjected to an agent identification test with negative results.

Article 11.11.3.

Recommendations for the importation of bulls for breeding (natural service or artificial insemination)

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

1) the animals showed no clinical sign of trichomonosis on the day of shipment;

2) the animals were kept in a *herd* in which no *case* of trichomonosis has been reported; and/or

3) the animals have never been used for natural service; or

4) the animals have only mated virgin heifers; or

5) the animals were subjected to ~~a direct microscopic and cultural examination of preputial specimens~~ an agent identification test with negative results.

Article 11.11.4.

Recommendations for the importation of bovine semen

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

1) the donor animals have never been used for natural service; or

2) the donor animals have only mated virgin heifers; or

3) the donor animals were kept in an *establishment* or *artificial insemination centre* where no *case* of trichomonosis has been reported;

4) the donor animals were subjected to ~~a direct microscopic and cultural examination of preputial specimens~~ an agent identification test with negative results;

5) the semen was collected, processed and stored in accordance with Chapter 4.6. and 4.7.

Annex 24

CHAPTER 12.2.

INFECTION WITH TAYLORELLA EQUIGENITALIS (CONTAGIOUS EQUINE METRITIS)

EU comment

The EU in general supports the proposed changes to this chapter. Comments are inserted in the text below.

Article 12.2.1.

General provisions

This chapter addresses the occurrence of clinical or asymptomatic *infection* of a mare caused by *Taylorella equigenitalis* as well as the presence of *T. equigenitalis* on the genital mucous membrane surface in the male horse.

For the purposes of the *Terrestrial Code,* the following defines *infection* with *T. equigenitalis:*

1) *T. equigenitalis* has been isolated and identified from a genital swab sample from a horse;

2) antigen or genetic material specific to *T. equigenitalis* has been identified in a sample from a mare showing clinical or pathological signs consistent with *infection* with *T. equigenitalis* or epidemiologically linked to a confirmed or suspected *case* of *infection* with *T. equigenitalis*;

3) genetic material specific to *T. equigenitalis* has been identified in a sample from a male horse.

For the purposes of the *Terrestrial Code*:

– due to long-term persistence of *T. equigenitalis* in horses, the *infective period* shall be lifelong;

– the *incubation period* in mares shall be 14 days.

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

EU comment

The EU notes that there are no standards for vaccines described in the Terrestrial Manual for contagious equine metritis, as no vaccines are available.

For the purposes of this chapter, a temporary importation refers to the introduction of a horse into a country or *zone*, for competition or cultural events excluding breeding, for a defined period of time, not exceeding 90 days, during which the *risk* of transmission of the *infection* is mitigated through specific measures under the supervision of the *Veterinary Authority.* Temporary imported horses are re-exported at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or *zone,* should be defined in advance.

When authorising import or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 12.2.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *T. equigenitalis* status of the *exporting country*, *zone* or *establishment*.

Article 12.2.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *T. equigenitalis*-related conditions regardless of the *T. equigenitalis infection* status of the *exporting country*, *zone*, or *establishment*:

1) geldings;
2) *milk* and *milk products*;
3) *meat* and *meat products*;
4) hides and skins;
5) hooves;
6) gelatine and collagen.

Article 12.2.3.

Establishment free from *infection* with *T. equigenitalis*

1. Prerequisite

Infection with *T. equigenitalis* has been a *notifiable disease* in the entire country for at least the past two years.

2. Qualification

To qualify as free from *infection* with *T. equigenitalis*, an *establishment* should satisfy the following conditions:

a) it is under the control of the *Veterinary Authority;*

b) no *case* has occurred for at least two years;

c) all horses from the *establishment* have been subjected to *T. equigenitalis* tests, with negative results. These tests should have been carried out on three occasions, within a 12-day period with an interval of no less than three days apart between each test. Horses must have not been treated with antibiotics for at least 21 days before the sampling;

d) stored semen was subjected to a test to detect *T. equigenitalis* with negative results, carried out on an aliquot of the stored semen.

3. Maintenance of freedom

a) requirements in points 1 and 2a) and 2b) of Article 12.2.3 are met;

b) appropriate *surveillance*, capable of detecting *infection* with *T. equigenitalis* even in the absence of clinical signs, is in place; this may be achieved through a *surveillance* programme in accordance with Chapter 1.4. and this chapter;

c) the introduction of horses and their germplasm into the *establishment* is carried out in accordance with the import conditions for these *commodities* listed in this chapter.

4. Recovery of freedom

When a *case* is detected in a previously free *establishment*, the free status of the *establishment* should be suspended until the following conditions are met in the affected *establishment*:

a) the *disinfection* of the *establishment* has been applied;

b) 21 days after the last removal or the last treatment of an infected horse, all horses have been subjected to a *T. equigenitalis* test, with negative results, on three occasions, within a 12-day period with an interval of no less than three days apart between each test;

c) stored semen was subjected to a test to detect *T. equigenitalis* with negative results, carried out on an aliquot of the stored semen;

d) the introduction of horses and their germplasm into the *establishment* is carried out in accordance with the import conditions for these *commodities* listed in this chapter.

Article 12.2.4.

Recommendations for importation of stallions or mares

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

1) mares showed no clinical sign of *infection* with *T. equigenitalis* on the day of shipment;

AND

2) horses have been kept in an *establishment*:

a) free from *infection* with *T. equigenitalis* since birth or for at least two years prior to shipment;

OR

b)

i) in which no *case* has been reported during the 60 days prior to shipment**;**

AND

ii) were subjected to *T. equigenitalis* tests, with negative results, on three occasions, within a 12-day period with an interval of no less than three days apart between each test, being the last test carried out within the 30 days prior to shipment. Horses must not have been treated with antibiotics for at least 21 days prior to sampling.

Article 12.2.5.

Recommendations for temporary importation of horses

When importing on a temporary basis horses that do not comply with recommendations in Article 12.2.4. for purposes different than breeding and rearing, *Veterinary Authorities* should:

1) require:

a) the animals be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status *subpopulation* as defined in Chapter 4.17.;

b) the presentation of *an international veterinary certificate* attesting that the mares showed no clinical sign of *infection* with *T. equigenitalis* on the day of shipment;

c) the duration of the temporary importation period and the destination after this period, and the conditions required to leave the country or *zone* be defined;

2) ensure that during their stay in the country or *zone*, the animals:

a) are not used for breeding (including artificial insemination, semen collection, used as teaser stallions) and do not have any sexual contact with other horses;

EU comment

The EU suggests deleting the word "stallion" after the word "teaser" in point a) above, as not only stallions may be used as teasers (e.g. teaser mares to test stallions).

b) do not undergo any genital examinations;

EU comment

The EU suggests deleting point b) above. Indeed, it is not clear why a genital examination, possibly by a vet, should not be allowed, when daily toilet by a groom is allowed.

c) are kept and transported individually in stalls and *vehicles/vessels* which are subsequently cleaned and disinfected before re-use.

Article 12.2.6.

Recommendations for importation of semen of horses

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

1) semen was collected in an *approved* centre and collection, processing and storing was done in accordance with Chapter 4.6; and

EITHER

2) the donor stallion was kept in an *establishment* free from *infection* with *T. equigenitalis*;

OR

3)

a) the donor stallion was kept in an *establishment* in which no *case* has been reported during the 60 days prior to semen collection; and

b) the donor stallion was subjected to *T. equigenitalis* identification tests, with negative results, on three occasions, within a 12-day period with an interval of no less than three days apart between each test, being the last test carried out within the 30 days prior to shipment. The donor stallion must not have been treated with antibiotics for at least 21 days prior to sampling;

OR

4) aliquots of fresh semen were subjected to culture and a test for detection of genetic material for *T. equigenitalis* with negative results, carried out immediately prior to processing and on an aliquot of semen collected within 15 to 30 days after the first collection of the semen to be exported;

OR

5) aliquots of frozen semen corresponding to the earliest and the most recent collection were subjected to culture and a test for detection of genetic material for *T. equigenitalis* with negative results.

Article 12.2.7.

Recommendations for importation of oocytes or embryos of horses

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

1) the oocytes and embryos were collected, processed and stored in *approved* centres following the general provisions in accordance with Chapters 4.9. and 4.10.;

2) the donor mare showed no clinical signs of *infection* with *T. equigenitalis* on the day of collection;

AND

for the importation of embryos:

3) the semen used for embryo production complied with Chapters 4.6. and 4.7.

Article 12.2.8.

Surveillance

1. General principles of surveillance

Surveillance for *infection* with *T. equigenitalis* is relevant for *establishments* seeking to achieve and demonstrate freedom from *infection*, as well as part of an *official control programme* in countries where the disease is endemic.

The *surveillance* strategy chosen should be adequate to detect the *infection* with *T. equigenitalis* even in the absence of clinical signs.

The *Veterinary Services* should implement programmes to raise awareness among farmers and workers who have day-to-day contact with horses, as well as *veterinarians*, *veterinary paraprofessionals* and diagnosticians, who should report promptly any suspicion of *infection* with *T. equigenitalis* to the *Veterinary Authority.*

Under the responsibility of the *Veterinary Authority*, Member Countries should have in place:

a) a formal and ongoing system for detecting and investigating *cases*;

b) a procedure for the rapid collection and transport of samples from suspected *cases* to a *laboratory* for diagnosis;

c) a system for recording, managing and analysing diagnostic and *surveillance* data.

2. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs by close physical examination of horses and based on reproduction performance. However, clinical *surveillance* should be complemented by bacteriological and molecular tests, as asymptomatic carriers play an important role in the maintenance and transmission of the *infection*.

3. Agent surveillance

An active programme of *surveillance* of horses to detect *case*s should be implemented to establish the status of a country, *zone* or *establishment*. Culture for *T. equigenitalis* and molecular testing are the most effective methods of detection of the *case*.

Stored semen should be included in *surveillance* programmes. It represents a valuable source of material and may be very helpful in contributing to retrospective studies, including providing support for claims of freedom from *infection* and may allow certain studies to be conducted more quickly and at lower cost than other approaches. Samples can be gathered through representative sampling or following a *risk*-based approach.

4. Serological surveillance

Serological *surveillance* is not the preferred strategy for detecting *T. equigenitalis.* If used, serology should be used in conjunction with culture in assessing the status of a mare that may have been infected with *T. equigenitalis*. The usefulness of serological tests is further described in the *Terrestrial Manual*.

EU comment

Preferably, serological surveillance should not be offered as a surveillance option, at least not on its own. Thus, if it is to be included, we would suggest replacing the words "should be used" in the second sentence of point 4 above with "should only be used" or "must be used ".

Furthermore, we suggest replacing "culture" with "culture or molecular testing" (or simply with "an agent identification test").

Annex 25

CHAPTER 12.7.

~~EQUINE PIROPLASMOSIS~~ *INFECTION* WITH *THEILERIA EQUI* AND *BABESIA CABALLI* (EQUINE PIROPLASMOSIS)

EU comment

The EU in general supports the proposed changes to this chapter. One comment is inserted in the text below.

Article 12.7.1.

General provisions

The use of the term equine piroplasmosis indicates clinical diseases caused by the transmission of *Theileria equi (T. equi)* or *Babesia caballi (B. caballi)* through competent ticks or iatrogenic practices. This chapter deals not only with the occurrence of clinical signs caused by *infection* with *T. equi* or *B. caballi*, but also with the presence of *infection* with *T. equi* or *B. caballi* in the absence of clinical signs.

Susceptible animals for *infection* with *T. equi* or *B. caballi* are primarily domestic and *wild* equids. Although old-world camelids are susceptible to *infection* and potential reservoirs, they are not found to play a significant role in the epidemiology of the disease.

Equids infected with *T. equi* or *B. caballi* may remain carriers of these blood parasites for long periods, sometimes lifelong and act as sources of *infection* for competent tick *vectors* of the genera *Dermacentor, Rhipicephalus, Hyalomma* and *Amblyomma*.

For the purposes of the *Terrestrial Code*, the following defines *infection* with *T. equi* or *B. caballi*:

1) identification of the parasite by microscopic examination of a sample from an equid showing clinical or pathological signs consistent with *infection* with *T. equi* or *B. caballi* or epidemiologically linked to a confirmed or suspected *case* of *infection* with *T. equi* or *B. caballi*; or

2) antigen or genetic material specific for *T. equi* or *B. caballi* has been identified in a sample from an equid showing clinical or pathological signs consistent with *infection* with *T. equi* or *B. caballi* or epidemiologically linked to a confirmed or suspected *case* of *infection* with *T. equi* or *B. caballi*; or

3) antibodies specific to *T. equi* or *B. caballi* have been identified in a sample from an equid showing clinical or pathological signs consistent with *infection* with *T. equi* or *B. caballi* or epidemiologically linked to a confirmed or suspected *case* of *infection* with *T. equi* or *B. caballi.*

For the purposes of the *Terrestrial Code*, the *incubation period* of *infection* with *T. equi* or *B. caballi* in equids shall be 30 days and the *infective period* shall be lifelong.

For the purposes of this chapter, a temporary importation refers to the introduction of equids into a country or *zone*, for a defined period of time, not exceeding 90 days, during which the *risk* of transmission of the *infection* is mitigated through specific measures under the supervision of the *Veterinary Authority.* Temporarily imported horses are re-exported or slaughtered at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or *zone,* should be defined in advance.

When authorising import or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 12.7.2. *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the status of *infection* with *T. equi* and *B. caballi* of the *exporting country* or *zone.*

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

EU comment

The EU notes that there are no standards for vaccines described in the Terrestrial Manual for equine piroplasmosis, as no vaccines are available.

Article 12.7.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any conditions related with *infection* with *T. equi* or *B. caballi*, regardless of the *infection* status of the *exporting country* or *zone*:

1) *milk* and *milk products*;

2) *meat* and *meat products*;

3) hides and skins;

4) hooves;

5) gelatine and collagen;

6) semen collected;

7) sterile filtered horse serum;

8) embryos collected, processed and stored in accordance with Chapters 4.9. and 4.10.

Article 12.7.3.

Country or zone free from infection with *T. equi* and *B. caballi*

1) Historical freedom as described in Chapter 1.4. does not apply to *infection* with *T. equi* and *B. caballi.*

2) A country or a *zone* may be considered free from *infection* with *T. equi* and *B. caballi* when:

   a) *infection* with *T. equi* and infection with *B. caballi* have been notifiable diseases in the entire country for at least the past 10 years and, in the country or *zone:*

      EITHER:

      i) there has been no *case* of *infection* with *T. equi* and no *case* of *infection* with *B. caballi* during the past six years; and

      ii) a *surveillance* programme performed in accordance with Article 12.7.9. has demonstrated no evidence of *infection* with *T. equi* and no evidence of *infection* with *B. caballi* in the past six years;

      OR

      iii) an ongoing *surveillance* programme performed in accordance with Article 12.7.9. has found no competent tick *vectors* for at least six years;

   b) imports of equids into the country or *zone* are carried out in accordance with this chapter. A country or *zone* free from *infection* with *T. equi* and *B. caballi* in which ongoing *vector surveillance*, performed in accordance with Article 12.7.9., has found no competent tick *vector* will not lose its free status through the introduction of seropositive or infective equids;

   c) a country or *zone* free from *infection* with *T. equi* and *B. caballi* adjacent to an infected country or *zone* should include a high-risk area in which continuous serological, agent and *vector surveillance* is conducted in accordance with Article 12.7.9.

Annex 25 (contd)

Article 12.7.4.

Recovery of a free status

When *infection* with *T. equi* or *B. caballi* is detected in a previously free country or *zone*, Article 12.7.3. applies.

Article 12.7.~~2~~5.

Recommendations for the importation of ~~equines~~ equids

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

1) the animals showed no clinical signs ~~equine piroplasmosis~~ of *infection* with *T. equi* or *B. caballi* on the day of shipment, and

2) EITHER:

   a) the animals were kept in a country or *zone* free from *infection* with *T. equi* and *B. caballi* since birth;

   OR

~~2)~~ ~~were subjected to diagnostic tests for equine piroplasmosis (Theileriaequi and Babesia caballi) with negative results during the 30 days prior to shipment;~~

   b) i) were subjected to a serological or agent identification test with molecular techniques for the detection of *T. equi* and *B. caballi* with negative results carried out on a blood sample taken within the 14 days prior to shipment; and

~~3) were maintained free from ticks, by preventive treatment when necessary, during the 30 days prior to shipment.~~

   ii) were maintained free from competent ticks in accordance with Article 12.7.7. during the 30 days prior to sampling and after sampling until shipment and throughout the transport to the destination country or *zone*.

Article 12.7.~~3~~6.

Recommendations for the temporary importation of equids ~~of competition horses on a temporary basis~~

~~Veterinary Authorities of importing countries should consider the possibility of importing competition horses on a temporary basis and which are positive to the testing procedure referred to in point 2) of Article 12.7.2. under the following safeguards:~~

If the importation of equids on a temporary basis does not comply with the recommendations in Article 12.7.5., *Veterinary Authorities* of *importing countries* should:

~~1.~~

1) require that:

   a) ~~the horses are~~ the animals be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status *subpopulation* as defined in Chapter 4.17.;

   ~~2.~~b) ~~the Veterinary Authorities of importing countries require~~ the presentation of *an international veterinary certificate* attesting that the animals:

      ~~a.~~i) showed no clinical sign of ~~equine piroplasmosis~~ *infection* with *T. equi* or *B. caballi* on the day of shipment;

Annex 25 (contd)

~~b) were treated against ticks within the seven days prior to shipment;~~

ii) were maintained free from ticks in accordance with Article 12.7.7. during the 30 days prior to shipment and during transport;

c) the duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or *zone,* be defined;

~~3) the horses are kept in an area where necessary precautions are taken to control ticks and that is under the direct supervision of the Veterinary Authority;~~

~~4) the horses are regularly examined for the presence of ticks under the direct supervision of the Veterinary Authority.~~

2) ensure that during their stay in the country or *zone*:

a) the animals are protected from ticks in accordance with Article 12.7.7.;

b) equids are examined daily for the presence of ticks of the genera *Dermacentor*, *Rhipicephalus*, *Hyalomma* and *Amblyomma* with particular attention to the ears, false nostrils, inter-mandibular space, mane, lower body areas, including the axillae, and inguinal region, and the perineum and tail, with negative results;

c) the animals are not subjected to any practice that may represent a risk of iatrogenic transmission of *infection* with *T. equi* or *B. caballi*.

Article 12.7.7.

Protecting equids from ticks

Under the direct supervision of the *Veterinary Authority*:

1) equids are kept in tick-protected facilities and transported in protected vehicles according to Article 12.7.8.;

2) equids have been preventively treated according to the manufacturer's recommendations with an acaricide effective against the competent ticks.

Article 12.7.8.

Protecting facilities and transports from ticks

The *establishment* or facility should be approved by the *Veterinary Authority* and the means of protection should at least comprise the following:

1) measures to limit or eliminate habitats for competent tick *vectors* should be implemented for an appropriate time and over an appropriate distance in the vicinity of the area where equids are kept;

2) the facility and immediate surroundings of the stables and exercise or competition areas should be treated with an effective acaricide before the arrival of equids;

3) when transporting animals through infected countries or *zones*:

a) the vehicle should be treated with an effective acaricide before transporting the animals;

b) preventive treatment with an acaricide with an extended residual effect that lasts at least for the duration of any stopover during the trip should be conducted.

Annex 25 (contd)

Article 12.7.9.

Surveillance strategies

1. General principles of surveillance

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with *T. equi* and the presence of *infection* with *B. caballi*, even in the absence of clinical signs, given the prevailing epidemiological situation in accordance with Chapter 1.4. and Chapter 1.5. and under the responsibility of the *Veterinary Authority*.

An active programme of *surveillance* of equids to detect evidence of *infection* with *T. equi* and evidence of *infection* with *B. caballi* by serological or agent identification molecular testing is required to establish the status of a country or *zone* considering that asymptomatic carriers play an important role in the maintenance and transmission of the *infection*.

The *Veterinary Services* should implement programmes to raise awareness among *veterinarians*, horse owners, riders and workers who have day-to-day contact with equids, as well as *veterinary paraprofessionals* and diagnosticians, who should report promptly any suspicion of *infection* with *T. equi* and any suspicion of *infection* with *B. caballi* to the *Veterinary Authority*.

Under the responsibility of the *Veterinary Authority*, Member Countries should have in place:

– a formal and ongoing system for detecting and investigating cases;

– a procedure for the rapid collection and transport of samples from suspected cases of *infection* with *T. equi* or *B. caballi* to a laboratory for diagnosis;

– a system for recording, managing and analysing diagnostic and surveillance data.

2. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs by close physical examination of equids.

3. Serological and agent surveillance

An active programme of *surveillance* of equids to detect evidence of *infection* with *T. equi* and evidence of *infection* with *B. caballi* by serological or agent identification test with molecular techniques is required to establish the status of a country or *zone* considering that asymptomatic carriers play an important role in the maintenance and transmission of the *infection*.

The study population used for a serological survey should be representative of the population at risk in the country or *zone*.

4. Surveillance in high-risk areas

Disease-specific enhanced *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with an *infected* country or *zone*, based upon geography, climate, history of *infection* and other relevant factors. The *surveillance* should be carried out particularly over the border with that country or *zone* unless there are relevant ecological or geographical features likely to limit the spatial distribution and thereby prevent the *infestation* of equids from competent ticks and interrupt the transmission of *infection* with *T. equi* or *B. caballi*.

5. Vector surveillance

Infection with *T. equi* or *B. caballi* is transmitted between equine hosts by species of Ixodid ticks in the genera *Dermacentor*, *Rhipicephalus*, *Hyalomma*, and *Amblyomma*.

Annex 25 (contd)

Vector surveillance is aimed at demonstrating the absence of tick *vectors* or defining high, medium and low-risk areas and local details of seasonality by determining the various species present in an area, their respective seasonal occurrence, and abundance. *Vector surveillance* has particular relevance to potential areas of spread. Long term *surveillance* can also be used to assess *vector* abatement measures or to confirm the continued absence of *vectors*.

Vector surveillance sampling should be scientifically based. The choice of the number and types of traps to be used in *vector surveillance* and the frequency of their use should consider the size and ecological characteristics of the area to be surveyed as well as the biology and behavioural characteristics of the local *vector* species of Ixodid ticks.

The use of a *vector surveillance* system to detect the presence of circulating *T. equi* or *B. caballi* is not recommended as a routine procedure. Animal-based *surveillance* strategies are preferred to detect *T. equi* or *B. caballi* transmission than entomological *surveillance*.

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