Report of the Meeting of WOAH Terrestrial Animal Health Standards Commission

Annex 1

Original: English (EN)

7 to 17 February 2023
Paris

EU position

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

A number of general comments on the part A of the February 2023 meeting report of the Code Commission as well as the intended positions of the EU on the draft Terrestrial Code chapters proposed for adoption at the 90th WOAH General Session are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report (appended as Annexes 4 to 22 to this document).

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

Introduction and Member contribution

This report presents the work of the WOAH Terrestrial Animal Health Standards Commission (hereinafter 'the Code Commission'), which met from 7 to 17 February 2023, in Paris, France.

The Code Commission thanked the following Members for providing comments: Argentina, Australia, Brazil, Canada, China (People's Republic of), Chinese Taipei, Indonesia, Japan, New Caledonia, New Zealand, Norway, Republic of Korea, Singapore, South Africa, Switzerland, Thailand, the United Kingdom (UK), the United States of America (USA), Members of the WOAH Americas Region, the Member States of the European Union (EU). The Commission also thanked the following organisations for providing comments: the International Coalition for Animal Welfare (ICFAW), the International Meat Secretariat (IMS), as well as various experts of the WOAH scientific network.

The Code Commission reviewed all comments that were submitted prior to the deadline and were supported by a rationale. The Commission focused its more detailed explanations on issues that were deemed significant. Where amendments were of an editorial nature, no explanatory text has been provided. The Commission wished to note that not all texts proposed by Members to improve clarity were accepted; in these cases, it considered the text clear as currently written. The Commission made amendments to draft texts, where relevant, in the usual manner by 'double underline' and 'strikethrough'. In relevant Annexes, amendments proposed at this meeting are highlighted in yellow to distinguish them from those made previously.

Status of annexes

Texts in **Part A** (Annexes 4 to 22) will be proposed for adoption at the 90th General Session in May 2023. Texts in **Part B** (Annexes 3 and 23 to 34) are presented for comments.

How to submit comments

World Organisation for Animal Health
Founded as OIE

Standards Department
[TCC.Secretariat@woah.org]

12, rue de Prony
75017 Paris, France

T. +33 (0)1 44 15 18 88
F. +33 (0)1 42 67 09 87
woah@woah.org
www.woah.org

The Code Commission strongly encourages Members and International Organisations that have a Cooperative Agreement with WOAH to participate in the development of WOAH International Standards by submitting comments on this report and on relevant annexes of this report. All comments should be submitted to WOAH through the WOAH Delegates or from organisations with which the WOAH has a Cooperative Agreement.

The Commission also draws the attention of Members to those instances where the Scientific Commission for Animal Diseases (the Scientific Commission), the Biological Standards Commission, a Working Group or an *ad hoc* Group have addressed specific comments or questions and proposed answers or amendments. In such cases the rationale is described in the reports of the relevant entity and Members are encouraged to review these reports together with the report of the Code Commission. These reports are no longer annexed to the Commission's report. Instead, they are available on the dedicated webpages on the WOAH website, e.g., *ad hoc* Group reports:

https://www.woah.org/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/

Comments should be submitted as Word files rather than pdf files. Comments should be presented within the relevant annex, and include any amendments to the proposed text, supported by a rationale, any relevant data or scientific references. Proposed deletions should be indicated in '~~strikethrough~~' and proposed additions with 'double underlined'. Members should not use the automatic 'track-changes' function provided by MS Word, as such changes may be lost in the process of collating submissions into working documents.

Deadline for comments

Comments on texts circulated for comment (Part B) must be emailed to the Secretariat by 5 July 2023 to be considered at the September 2023 meeting of the Code Commission.

Where to send comments

All comments should be sent to the Standards Department at: TCC.Secretariat@woah.org

Date of the next meeting

The Code Commission noted the dates for its next meeting: 5 to 14 September 2023.

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1. Welcome

1.1. Deputy Director General-International Standards and Science

Dr Montserrat Arroyo, WOAH Deputy Director General, International Standards and Science (DDG ISS), welcomed members of the Code Commission and thanked them for their ongoing contributions to the work of WOAH. Dr Arroyo commended the Commission for its ambitious agenda and extended her appreciation to the members' employing institutions and national governments.

Dr Arroyo informed the Commission that the Selection process for experts seeking nomination for election to WOAH Specialist Commissions will start with the Call for experts in July 2023 and that the elections will take place during the 91st General Session in May 2024. More information will be provided to the Delegates in due course.

Dr Arroyo informed the Commission that pre-General Session Commission webinars will be held, as has been done in recent years, where texts that will be proposed for adoption will be presented for Members information. The Code Commission President, Dr Bonbon, will deliver a presentation on the 19 April 2023 on the new and revised chapters of the *Terrestrial Code* that will be proposed for adoption. The webinar will have simultaneous interpretation into French and Spanish and will be recorded and uploaded to the WOAH website.

Dr Arroyo informed the Commission that the new WOAH acronym will be applied to WOAH Codes and Manuals in the 2023 versions.

Dr Arroyo acknowledged the agreement of the Presidents of the Code Commission, the Biological Standards Commission and the Scientific Commission on the process for standard setting and interaction between the Commissions, which will be incorporated into ongoing work to document the WOAH Standards-setting process in more detail. Dr Arroyo informed the Commission of the new 'Terrestrial Standards Coordination' (TSC), a mechanism established within the WOAH Secretariat and chaired by the DDG ISS aiming at achieving a more efficient and integrated management of the process to develop new or revised standards for terrestrial animals. The TSC integrates the planning of activities of relevant WOAH departments providing technical support, coordination, and input to WOAH Standard-setting work, as well as the coordination of work plans across the Specialist Commissions involved in the development of WOAH standards for terrestrial animals.

The DDG-ISS informed the Code Commission that WOAH was undertaking work to develop a new online navigation tool for the Codes and Manuals, and that a consultation of suppliers had been launched to implement a new tool that would provide a more interactive online navigation and an easier search of the content, improve the visualisation of standards across different languages, and allow external users to easily download, print and share content.

The members of the Code Commission thanked Dr Arroyo for the excellent support provided by the WOAH Secretariat, and praised the different initiatives being undertaken to improve its work. The Commission also highlighted the importance of the timely publication and distribution of the Specialist Commissions reports to allow Members sufficient time for consideration and commenting on the Commissions' proposals, as well as of ensuring the timely publication and the quality of the translation of proposed standards to avoid possible differences or misinterpretation in the different languages, and to allow for non-English speakers, notably in Africa and the Americas, to examine the drafts and provide comments. Dr Arroyo explained that the Secretariat works hard to minimise the time to publication, while noting that as English is the drafting language there will always be a delay in the publication of the French and Spanish versions of the report.

The Commission welcomed the initiative to develop a new online navigation tool for the Codes and Manuals and recognised the need to improve how WOAH Standards are made available to Members and highlighted that WOAH Codes and Manuals are a core output of the organisation and a key element connecting the organisation with its Membership. The Commission noted that facilitating access should ultimately improve the use of WOAH International Standards by WOAH Members as the reference for the

development of national regulations, the agreement on trade measures and implementation of their programmes.

1.2. Director General

Dr Monique Eloit, the WOAH Director General, met the Code Commission on 14 February and thanked its members for their support and commitment to achieving WOAH objectives.

Dr Eloit informed the Commission about new developments in the programme of the 90th General Session, and highlighted the initiative of including a new 'Animal Health Forum' which will be focused this year on Avian influenza, aimed at promoting Members' discussion on the challenges faced in controlling this global animal health issue. The Code Commission supported this initiative and noted the importance of also promoting the understanding and implementation of the recent development of WOAH Standards for this disease, noting that a revised Chapter 10.4. Infection with high pathogenicity avian influenza viruses of the *Terrestrial Code* and a revised Chapter 3.3.4. Avian influenza (including infection with high pathogenicity avian influenza viruses) of the *Terrestrial Manual* were adopted in 2021.

Dr Eloit updated the Commission on the progress of the review of the WOAH Science System and the evaluation of the benchmarking against other international organisations. Dr Eloit assured the Code Commission, as other Specialist Commissions, that she would keep them informed as the process progresses. The Commission acknowledged this initiative and recognized the importance of reviewing how WOAH accesses and uses science and highlighted that it is necessary to also discuss the different outputs of the Organisation, such as International Standards, Guidelines or other publications, their expected audience and use, and their value for Members.

Dr Eloit highlighted the recently published WOAH Observatory annual report and indicated that it will help Members understand how the Observatory programme provides insight into the implementation of WOAH standards. The report contains recommendations for both WOAH and its Members to support in the improvement for the implementation of the standards. The Commission recognised the significant amount of information contained in the report and expressed interest in getting feedback from Members and to consider how they could make use of this to better ensure their work is aligned with Members' needs.

The Code Commission thanked Dr Eloit for these updates.

1.3. Updates from WOAH Headquarters

1.3.1. WOAH Specialist Commission reports

The Secretariats of the WOAH Specialist Commissions are always looking to improve the efficiency of the production and publication of their respective Specialist Commission reports whilst ensuring alignment, as relevant. The DDG ISS considered the proposals made by the Secretariat and agreed with the following changes to the publication of the Commission reports starting in February 2023:

1. All Specialist Commission reports will be published as a single report per Commission. (Note: The Scientific Commission has always been produced as a single report);
2. Unofficial reports in English will no longer be published;
3. Specialist Commission reports will be published on the Delegates website (in Word format for the Aquatic Animals Commission and the Code Commission, and in PDF format for the Biological Standards Commission and the Scientific Commission) and on the public website (all in PDF format) per language (i.e. English, French and Spanish) once final. A gap between the publication of the English version and the French and Spanish versions is unavoidable because the WOAH standards and reports are first drafted in English. However, the Secretariat endeavours to keep this period to a minimum.
4. The four Specialist Commission reports of February will be published in English at least two weeks prior to the pre-GS webinars.

1.3.2. Pre-General Session

1. Pre-General Session information webinars will be held every year for the Aquatic Animals Commission, Biological Standards Commission and the Code Commission (with support from the Scientific Commission), in one time-zone only and recorded and uploaded onto the General Session website. These webinars will be presented by the President of the respective Commission and will focus on presenting information about new or revised standards that will be proposed for adoption at the General Session.

   NOTE: 2023 dates are: Biological Standards Commission - 18 April 2023; Code Commission - 19 April 2023; Aquatic Animals Commission - 20 April 2023. All webinars will be held between 12:00-2:00 pm CEST.

2. WOAH will no longer provide a mechanism for Members to submit pre-General Session positions, as was the case in 2021 and 2022 when General Sessions were held in a virtual or hybrid format. However, if Members wish to unofficially send pre-General Session positions to assist the Presidents of the Specialist Commissions prepare their General Session reports, this can be done through email to the relevant Secretariat.

1.3.3. Use of the acronym 'WOAH' in the *Terrestrial Code*

Background

At the 89th General Session in May 2022, the World Assembly of Delegates adopted Resolution No. 10, recognising that the acronym OIE will be replaced by WOAH (and OMSA for French and Spanish) as part of a rebranding of the Organisation.

At the September 2022 meetings, the Specialist Commissions were informed by the WOAH DDG ISS that the new acronym would be introduced into WOAH Standards to replace OIE. The Commissions were informed that the relevant Secretariat would present an analysis and proposal to each Commission at its February 2023 meetings.

In addition, prior to the February 2023 meeting, the Code Commission received comments from several Members requesting to use the acronym 'WOAH' instead of 'OIE'.

Discussion

The Code Commission considered an analysis prepared by the Secretariat on the use of the acronym 'OIE' in the current edition of the *Terrestrial Code* and discussed a proposed approach to replace OIE by WOAH. The Commission was informed that the Secretariats for the Specialist Commissions had worked collectively to ensure this amendment would be conducted in a consistent manner across all WOAH Standards (i.e., the *Terrestrial Code,* the *Terrestrial Manual*, the *Aquatic Code*, and the *Aquatic Manual*).

The Commission agreed that the 'WOAH list' and '*listed diseases*' (as the term defined in the Glossary) be used instead of 'OIE list' and 'OIE *listed diseases*', respectively throughout the *Terrestrial Code*. It also agreed that the title of Chapter 1.2. be amended to 'Criteria for the inclusion of diseases, infections and infestations in the WOAH list', as well as the title Chapter 1.3. to 'Diseases, infections and infestations listed by WOAH'.

The Commission noted that the term 'World Assembly of Delegates' and 'World Assembly of OIE Delegates' are both used in the *Terrestrial Code*. For these, the Commission agreed that only the 'World Assembly of Delegates' be used for consistency.

The Commission noted that the term 'OIE Organic Statutes' is referred to in the User's guide and Chapter 1.1. of the *Terrestrial Code.* The Commission agreed to replace it with 'Organic Statutes of the Office International des Epizooties' which is the formal title of the legal document.

The Code Commission agreed that in the rest of the cases, it will be appropriate to simply replace 'the OIE' with 'WOAH' (or 'the WOAH' following WOAH's internal re-branding guidelines), except for instances where the acronym 'OIE' was used as part of the title of an external document published in the past (such as the OIE/FAO Guide to Good Farming Practices for Animal Production Food Safety) or to a specific past *ad hoc* Group, for which the Commission agreed to maintain the original reference.

The Commission agreed that these amendments are editorial in nature and do not impact the interpretation of the *Terrestrial Code*. The Commission agreed to the proposal from the DDG-ISS that these amendments be applied in the 2023 edition of the *Terrestrial Code*.

The Commission wished to note that these changes, as relevant, have been made in all Annexes circulated in this report as silent changes, i.e. without strikethrough / double underline as they are considered editorial.

2. Adoption of the agenda

The proposed agenda was discussed and adopted, taking into consideration the priorities of the work programme and time availability. The agenda and the list of participants are presented in Annexes 1 and 2 respectively.

3. Cooperation with other Specialist Commissions

3.1. Scientific Commission for Animal Diseases

The Secretariat updated the Code Commission on relevant activities of the Scientific Commission and the Commission provided responses, as relevant, as noted below.

The Code Commission wished to thank the Scientific Commission for its collaborative work in providing opinions to support the consideration of relevant Member comments received. The Code Commission reminded Members that its consideration of the Scientific Commission's contributions is noted under the relevant agenda items of this report and encouraged Members to read this report together with the reports of the Scientific Commission.

Assessments of pathogenic agents against the Chapter 1.2. Criteria for the inclusion of diseases, infections and infestations in WOAH list, of the *Terrestrial Code*

The Code Commission considered the conclusions of the Scientific Commission provided in its September 2022 report on the assessment of *Theileria mutans* and strangles (infection with *Streptococcus equi* subsp. *equi*) and agreed that they did not meet the criteria. The Commission requested that future reports on these assessments also include the origin of the requests, as well as the rationale for undertaking the assessment, to provide a complete overview of the implementation of the Standard operating procedure for listing decisions for pathogenic agents of terrestrial animals, which should include steps for the assessment of epidemiologically significant species.

Assessments to determine whether diseases should be considered as 'emerging diseases'

The Code Commission noted the conclusion of the Scientific Commission provided in its September 2022 report on the assessments to determine whether some diseases should be considered as emerging, as well as of the annual reassessment of emerging diseases, based on the Standard operating procedure for determining whether a disease should be considered as emerging.

Consideration of the listing criteria in Chapter 1.2.

The Code Commission considered the conclusion of the Scientific Commission provided in its September 2022 report regarding the difficulties encountered in interpreting and applying the listing criteria by experts conducting assessments. The Code Commission agreed with the proposed approach to address these difficulties by means other than amending Chapter 1.2., such as by revising the guidance for experts

undertaking the assessments. The Code Commission highlighted, nonetheless, the importance of remaining within the text of the current criteria and not going into interpretations that could go beyond the intention of the standard.

In response to the Scientific Commission's opinion on the specific criteria, the Code Commission considered the following:

Criterion 1 ('international spread of the pathogenic agent (via live animals or their products, vectors, or fomites) has been proven':

The Commission noted the opinion of the Scientific Commission but highlighted that the current wording requires that the spread should have been proven, and hence this could not be just considered as a potential. In this regard, the Commission agreed with the proposal of the Scientific Commission that a preliminary assessment of this criterion be conducted before undertaking the whole assessment, and considered that this, including the availability of relevant information, should be part of the initial consideration by the DDG ISS, in consultation with the Specialist Commissions, on whether a request should proceed (SOP Step 2-2).

Criterion 2 ('at least one country has demonstrated freedom or impending freedom from the disease'): The Code Commission agreed with the opinion of the Scientific Commission that it would be relevant, for the assessment of the criterion, to know whether some Members regard the pathogenic agent as important, as demonstrated by actions managed or supervised by the Veterinary Authority to prevent either the entry or the spread of the disease. The Commission recommended not to refer to 'official control programmes' as the Glossary definition for the term may not be appropriate in this context.

Criterion 3 ('reliable means of detection and diagnosis exist, a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections or infestations'):

The Code Commission agreed that the diagnostic tests should be practical and suitable to be used in the epidemiological context. Nonetheless, the Commission did not agree that it was necessary for the test to be adequate for risk management purposes such as to support official control programmes or for the prevention of the spread though international trade. The Commission explained that the means of diagnosis should be sufficient to support notification to WOAH, with the purpose to provide information for actions to be taken, and not necessarily to guide the actions to be taken.

For criteria 4(a), (b) and (c), the Code Commission agreed with the opinion of the Scientific Commission.

The Code Commission's opinion, together with amendments proposed to the 'Guidance for the application of the criteria for listing terrestrial animal diseases' were forwarded to the Scientific Commission for its consideration.

Categorisation used in Chapter 1.3. of the *Terrestrial Code*

The Code Commission considered the discussion of the Scientific Commission at its September 2022 meeting about the animal categorisation used in Chapter 1.3. Diseases, infections and infestations listed by WOAH. The Code Commission noted that this discussion omitted previous decisions and comments the Code Commission had made at its February 2022 (item on bovine viral diarrhoea) and September 2022 meetings (item on the use of the term 'cattle' in Article 1.3.2.), as well as other previous revisions of Chapter 1.3. (e.g. relocation of Japanese encephalitis from equine disease category to multiple-species category in 2005), which already addressed some of the points mentioned.

In conclusion, the Code Commission summarised that:

- the scope of animal species between each article of Chapter 1.3. and the titles of Sections in Volume II of the *Terrestrial Code* should be aligned;
- taxonomical classification should be considered to refer to animal categorisation both in each article of Chapter 1.3. and title of Volume II of the *Terrestrial Code*;

- placement of a disease under a given category in Chapter 1.3. (i.e., article) and the corresponding Section of Volume II, should be based on the content of the relevant disease-specific chapter, notably the case definition, which should be science based and indicate the precise species (the epidemiologically significant ones) that should be targeted for the purpose of notification to WOAH; and

- changes in the animal species included in the case definition of a chapter must be supported by an assessment based on Chapter 1.2. and could result in a change of the categorisation of the disease within Chapter 1.3. as a consequence.

The Code Commission also noted that the Scientific Commission observation that the consistency between the species categories in Chapter 1.3. and the section names in Volume II should be improved and agreed to make the necessary amendments to Chapter 1.3., titles of Sections of the *Terrestrial Code* and relevant parts of User's guide for consistency. (See item 6.3 of this report).

The Code Commission's decisions were forwarded to the Scientific Commission.

Following the rationale outlined above, the Code Commission requested that the Secretariat review the current chapters to see if there is any relevant issues that should be addressed.

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

On the margin of this meeting, the Bureaus (i.e. the President and the two Vice-Presidents) of the Code Commission and the Scientific Commission held a meeting chaired by WOAH DDG ISS. The purpose of the meeting was to provide joint updates on relevant standing items, to agree on how to address any points that may impact the potential adoption of important chapters, and to agree on the plans to undertake work of common interest. The overall objective is to provide agreement on concrete outcomes that would allow the Secretariat to undertake their role in a coordinated manner, while ensuring alignment with the vision of these two Specialist Commissions.

At the meeting, the bureaus were updated on ongoing works based on the SOP for listing decisions for pathogenic agents and the SOP for determining whether a disease should be considered as emerging, and also on the progress of the work to develop case definitions.

The Bureaus discussed the following Code Chapters to be proposed for adoption in May 2023:

- Infection with foot and mouth disease virus (Chapter 8.8.) (see item 6.4 of this report);
- Infection with rabies virus (Article 8.14.6bis. of Chapter 8.14.) (see item 6.5 of this report);
- Bovine spongiform encephalopathy (Chapter 11.4.), Application for official recognition by WOAH of risk status for bovine spongiform encephalopathy (Chapter 1.8.) (see item 6.8 of this report);

The Bureaus also discussed plans for the following works which require the Commissions' coordination.

- New chapter on biosecurity (Chapter 4.X.) (see item 5.2.5 of this report)
- Revision of chapters on equine encephalitis (Chapters 8.10., 12.4. and 12.11.)
- Revision of chapter on dourine (Chapter 12.3.) and new chapter on Surra (Chapter 8.Z.)
- New chapter on Crimean Congo haemorrhagic fever (Chapter X.X.)

3.2. Biological Standards Commission

The Code Commission was updated on relevant ongoing activities of the Biological Standards Commission, including the list of chapters in the *Terrestrial Manual* that will be updated during the 2023/2024 review cycle.

Given that the revision of some of these chapters could have impacts on the corresponding chapters in the *Terrestrial Code*, the Code Commission agreed to continue to work closely with the Biological Standards Commission to ensure that relevant amendments in the corresponding chapters of the *Terrestrial Code* and the *Terrestrial Manual* are well coordinated.

At its September 2022 meeting, the Code Commission discussed the terminology used in the *Terrestrial Code* that refers to diagnostic methods and procedures, as part of the provisions to define the occurrence of a disease (i.e. Article X.X.1.). The Code Commission requested the advice of the Biological Standards Commission on some points in order to define a consistent approach that could be applied across all disease-specific chapters used in the *Terrestrial Code*.

At its February 2023 meeting, the Code Commission considered the advice received from the Biological Standards Commission, and agreed that:

- in the first point of a case definition, in disease-specific chapters, where it refers to the confirmation of the presence of the pathogenic agent, the word 'isolated' should be used for a virus, bacteria or other microorganism for which culture is relevant, whereas the word 'observed' should be used for protozoa, chlamydia or other microorganisms, as relevant, when referring to the direct visualisation (i.e. without isolation) of the agent, acknowledging that for some specific diseases, other wording may be appropriate;
- in the first point of a case definition, in disease-specific chapters, the wording 'isolated and identified as such' should be used for clarity;
- in points that refer to clinical signs, only the wording '(clinical signs) consistent with (disease name)' should be used, i.e. the wording '(clinical signs) suggestive of (disease name)' should not be used as it is too vague for case definitions;
- in points in disease-specific chapters referring to nucleic acid-based testing, only the term 'nucleic acid' should be used, i.e. the term 'genetic material' is not appropriate (as it is often used to mean germinal products), nor the term 'deoxyribonucleic acid / ribonucleic acid' (as it is unnecessarily detailed for the *Terrestrial Code*); and
- in points in disease-specific chapters that refers to nucleic acid-based testing or antigen or antibody detection methods, only the wording 'nucleic acid / antigen / antibodies specific to (pathogen name) has/have been **detected'** should be used, i.e. the wording 'antigen / nucleic acid / antibodies specific to (pathogen name) has/have been identified' should not be used.

The Code Commission agreed to progressively address these points when a disease-specific chapter is being revised.

The Code Commission wished to thank the Biological Standards Commission for providing inputs to support the decisions of the Code Commission on relevant comments. The Code Commission reminded Members that its consideration of the Biological Standards Commission's responses to specific chapters are noted under the relevant agenda item of this report and encouraged Members to read its report together with the Biological Standards Commission's report, when relevant.

Potential impact on the *Terrestrial Code* from *Terrestrial Manual* updates to be proposed for adoption in the next General Session

At their September 2022 meetings, the Code Commission and the Biological Standards Commission agreed on a new process by which the Biological Standards Commission will advise the Code Commission as to whether the proposed revisions to *Terrestrial Manual* chapters could trigger a need to update the corresponding Code chapters, based on the opinion of experts who had revised the Manual texts. At its February 2023 meeting, the Code Commission considered the recommendations from the Biological Standards Commission on the possible impact of updates in the following *Manual* chapters to be proposed for adoption in 2023:

- Chapter 3.1.1. Anthrax
- Chapter 3.1.18. Rabies (infection with rabies virus and other lyssaviruses)
- Chapter 3.1.19. Rift Valley fever (infection with Rift Valley fever virus)
- Chapter 3.1.22. Trichinellosis (infection with *Trichinella spp*.)
- Chapter 3.2.2. American foulbrood of honey bees (infection of honey bees with *Paenibacillus larvae*)
- Chapter 3.2.3. European foulbrood of honey bees (infection of honey bees with *Melissococcus plutonius*)

- Chapter 3.4.12. Lumpy skin disease

The Code Commission agreed to discuss a recommendation on Chapter 8.15. Infection with Rift Valley fever virus, which is currently under revision at this meeting (see item 6.6 of this report). The Code Commission also agreed to include in its work programme (as priority 3) on the partial revision of Chapter 8.17. Infection with *Trichinella* spp., to align the number of taxon of the pathogenic agent with the corresponding *Manual* chapter, pending its adoption.

The Code Commission reminded Members that the *Terrestrial Manual* chapters were regularly updated to reflect scientific and technical developments and emphasised the importance of this new collaborative mechanism which provides an opportunity for early identification of needs to update the *Terrestrial Code* chapters and ensure consistency between the two sets of standards.

3.3. Aquatic Animals Health Standards Commission

The Secretariat updated the Code Commission on progress made by the Aquatic Animals Commission on the items that had been identified as of common interest at a meeting of the Bureaus of the Code Commission and the Aquatic Animals Commission held in September 2022.

The Code Commission was informed that the Aquatic Commission had reviewed the usage of the terms 'Competent Authority', 'Veterinary Authority', 'Veterinary Services' and 'Aquatic Animal Health Services' throughout the *Aquatic Code* (see items 6.1 and 7.11 of this report). The Commission was also informed that the Aquatic Commission had invited Members to provide their experiences using and applying compartmentalisation and that the Commission would use this information to inform its revision of Chapter 4.3. Application of compartmentalisation.

The Code Commission agreed to keep the Aquatic Animals Commission informed of its ongoing work on the revision Chapters 5.4. to 5.7. and Chapter 6.10., given the importance of ensuring alignment, as relevant, in the corresponding chapters in the *Aquatic Code*.

4. WOAH Terrestrial Standards Coordination

The Commission was informed of a new mechanism established within the WOAH Secretariat and chaired by the DDG ISS aiming to achieve more efficient and integrated management of the process to develop new or revised standards for terrestrial animals, by integrating the planning of activities of WOAH teams providing technical support, coordination, and input to WOAH Standard-setting work, as well as the coordination of work plans across the Specialist Commissions involved in the development of WOAH standards for terrestrial animals. The Commission was informed that this mechanism was supported by a process agreed upon by the Commissions' Presidents on the steps and specific Commissions intervention and interaction in standards setting.

The Commission agreed with the proposed approach and noted that it was in line with the developments introduced in their work programme management over the past years for the development and review of the *Terrestrial Code*, notably regarding the improved transparency on the prioritisation process and promoting awareness and involvement of Members in those discussions, as well as with the progress in coordination of activities between Specialist Commissions through the regular meeting of their Bureaus and the closer interactions between the Secretariats.

The Code Commission praised the initiative and highlighted that this mechanism will be critical to allow the Commission achieving better management of its work programme. The Commission acknowledged that its work is driven by Members' needs expressed through comments on their reports, but also from different sources such as other Specialist Commissions, WOAH Working Groups, the WOAH Director General, WOAH programmes and activities, recommendations from WOAH Regional Commission Conferences or WOAH global or regional thematic conferences, reminded that the progress of some preparatory work without early involvement of the Commission or adequate consideration of the potential impact in its work plan has been challenging to manage in some occasions, and hoped that this mechanism will help prevent such problems. The Commission also noted that, as acknowledged in its prioritisation discussions, the progress of work depends on the availability of resources and recognised

that this mechanism will support the DDG ISS in her role of coordinating Secretariat teams and Specialist Commissions work programmes.

The Commission also highlighted the new process implemented at this meeting for the Biological Standards Commission to provide early advice to the Code Commission on the potential need to update the *Terrestrial Code* as a consequence of updates being proposed for adoption in the *Terrestrial Manual* and noted that it was an exemplary contribution to this coordination, to ensure consistency between these two complementary sets of Standards and continuity between the work programmes of the two Commissions.

5. Work Programme and priorities

The Code Commission discussed ongoing priority topics on its work programme, pending issues with recently adopted chapters and considered comments and new requests received. Specific discussions are captured in the relevant item of this section of the report.

5.1. Comments received on the Code Commission Work Programme

Comments were received from Australia, Canada, Indonesia, New Caledonia, Norway, New Zealand, Switzerland, the USA, Members of the WOAH Americas Region and the EU.

Comments to propose new work are addressed in item 5.4 of this report.

In response to a comment emphasising its interest in the chapters relating to stamping-out and disposal of carcases, the Code Commission reminded Members that a work to revise Chapter 4.13. Disposal of dead animals, was included in its work programme as priority 2.

The Code Commission agreed with a comment emphasising that, with regard to the work to revise Chapters 5.4. to 5.7., an aligned approach should be taken between the Commission and the Aquatic Animals Commission, and explained that this work would be dealt with in liaison with the Aquatic Animals Commission.

In response to comments to prioritise the work to review Chapter 14.8. Scrapie, the Code Commission agreed to change the priority level to ‘priority 2’. Noting that the Members requested that, as part of the update, live animal testing and testing for genetic resistance to scrapie be included as valid methods for ensuring the safe trade of sheep and goats, the Commission requested the Secretariat to see if the corresponding Manual Chapter 3.8.11. Scrapie, provides sufficient information for such testing.

The Commission reminded Members that the work programme outlines the current and planned work to be undertaken to develop *Terrestrial Code* standards. The Commission acknowledged the increased interest shown by Members for the discussion of the work programme, and strongly encouraged Members to continue to provide feedback as to whether they agree with the topics being proposed, as well as their level of prioritisation.

5.2. Ongoing priority topics (other than texts circulated for comments)

The Code Commission discussed the progress of a number of ongoing priority topics for which no new or revised text is circulated in this report.

5.2.1. Wildlife health

Background

At its September 2021 meeting, the Code Commission discussed a proposal from the WOAH Working Group on Wildlife (WGW) to develop a new chapter in the *Terrestrial Code* on surveillance of diseases of wildlife. The Commission discussed this proposal and provided feedback and requested the Working Group to consider its comments before progressing with this work. In

February 2022, the Code Commission was informed that the WGW had progressed other work related to this request. The Commission agreed to continue discussing the possible inclusion of new items related to wildlife health management in its work programme at its next meeting.

In September 2022, considering the progress being made under the WOAH Wildlife Health Framework the Commission agreed to include a new item on its work programme to consider how the *Terrestrial Code* addresses wildlife health, and agreed to continue discussions with the WGW on relevant work.

Discussion

The Code Commission met with the Chair of the WOAH Wildlife Working Group, Dr William Karesh, who provided an update on the outcomes of the Working Group's meeting in December 2022, notably on the possible new developments for WOAH to provide guidance and recommendations to its Members regarding wildlife health. Dr Karesh highlighted the vision of the Group that it was important to consider wildlife health with a broad perspective, including diseases but also considering the environment, biodiversity and wildlife welfare. Dr Karesh highlighted the recommendations provided by the different analyses prepared by consultants that were used to inform the discussions of the Group presented in its December 2022 report, and noted that they provided valuable inputs for WOAH's work.

The Code Commission noted that wildlife has been progressively taken into consideration in the *Terrestrial Code* and acknowledged that it was challenging to address new issues through International Standards, as these require a sound knowledge base and consensus among Members, which normally takes time to develop. The Commission agreed that WOAH has the mandate to cover most of the needs identified and noted that this could be done through different mechanisms which could support the initial exploration, raise awareness, and build the necessary support for the future development of standards. The Commission acknowledged the recommendations provided by the experts to the WGW and noted that they provided useful guidance on topics to address. The Commission highlighted the importance of ensuring the potential needs of the *Terrestrial Manual* are also addressed, as adequate international standards on diagnosis are critical elements to provide recommendations for risk management for diverse host species or new pathogenic agents, and are often a limiting factor. It also pointed out that since wildlife health is not always within the remit of Veterinary Authorities of WOAH Members, the standard setting process for potential new standards on wildlife health might be more complex.

The Commission and the Chair of the Working Group agreed to foster a closer collaboration to promote early identification of potential new work in standards development for the *Terrestrial Code* and to include possible contributions from the WGW to relevant items in the Code Commission's work programme.

5.2.2. Inclusion of the 'Five Domains' concept in Section 7

Background

In February 2022, the Code Commission considered a comment to add the 'five domains' concept in Chapter 7.7. Dog population management. The Commission recognised the importance of the 'five domains' concept and asked that more information be provided.

At its September 2022 meeting, the Commission reviewed a document drafted by the Secretariat and the WOAH Animal Welfare Collaborating Centres (AWCC). The Commission noted that the 'five domains' as an animal welfare concept is recognised internationally, and it may be relevant to include it in Chapter 7.1. Introduction to the recommendations for animal welfare. However, as this is still a relatively new concept, the Commission agreed that more information was needed to explain the concept to Members and to clarify how it is linked to the 'five freedoms' concept and to the assessment of the welfare of animals. The Commission requested that the Secretariat continue to work in collaboration with WOAH Animal Welfare Collaborating Centres (AWCCs) to develop an

explanatory note and draft text for possible inclusion in Chapter 7.1. as well as an assessment of the impact of its inclusion in other chapters in the *Terrestrial Code*.

Discussion

The Commission considered a paper prepared by the Animal Welfare Collaborating Centres that explained the 'five domains' concept and compared it to the 'five freedoms' concept currently used in the Code. The paper also proposed a possible application of the 'five domains' concept in WOAH Standards. The Commission thanked the Collaborating Centres for their support. The Commission gave its feedback on the paper for the Secretariat's further consideration.

The Commission agreed that this additional information made it worth to partly revise Chapter 7.1. The Commission requested that the Secretariat continue to work with the AWCCs to prepare a proposal for the revision of Chapter 7.1. and report back to the Commission at its September 2023 meeting. The Commission also agreed to add the revision of Chapter 7.1. onto its work programme.

5.2.3. Animal health status and pathogenic agents held in laboratories.

Background

At its September 2022 meeting, the Code Commission considered a request from a Member to improve clarity as to whether Members can hold pathogenic agents in laboratories without affecting their animal health status.

The Code Commission noted that in addition to Chapter 5.8., references relevant to recommendations for laboratories were also included in Chapter 3.2., Chapter 3.4. (Article 3.4.7.), and Chapters 1.7. to 1.12. in the *Terrestrial Code* and in Chapters 1.1.3. and 1.1.4. of the *Terrestrial Manual*.

The Code Commission agreed that this specific request should be addressed in the context of official status recognition by WOAH by amending Chapter 1.6. The Commission agreed to include this item as priority 3 of its work programme and proposed to share this proposal with the Scientific Commission for its consideration.

Discussion

The Code Commission reviewed the draft revised chapter proposed by the Secretariat that aimed to improve clarity regarding a Member's animal health status if it holds pathogenic agents in laboratories.

The Code Commission agreed to develop a new Article 1.6.4. to clarify that the presence of a pathogenic agent in an approved laboratory with an appropriate level of containment and biosecurity in accordance with the *Terrestrial Manual* will not impact the animal health status of a country or zone. The Commission agreed to cover in the same article other similar provisions currently included in other horizontal chapters.

The Code Commission requested the Secretariat to forward the draft new Article 1.6.4. to the Scientific Commission for its consideration.

5.2.4. Revision of Chapter 4.4. Zoning and compartmentalisation

Background

At its September 2021 meeting, the Code Commission discussed specific issues raised in the context of the 88th General Session on several texts that were adopted at that General Session. Among these topics, the Commission agreed with a comment to consider amending Article 4.4.7. to clarify that a time limit should be defined for a containment zone. The Code Commission referred

to a similar proposal by the Scientific Commission that had been discussed at the Code Commission's February 2021 meeting. The Code Commission discussed possible ways to address this request and shared a proposed amended text with the Scientific Commission for its consideration.

Discussion

The Code Commission noted the opinion of the Scientific Commission at its September 2022 meeting regarding how the proposed amendment should be applied to diseases for which WOAH grants an official animal health status.

The Code Commission agreed that the Secretariat prepare a revised draft text, taking into consideration these recommendations, to be presented for the consideration of both Commissions at their September 2023 meetings.

5.2.5. New chapter on biosecurity (Chapter 4.X.)

Background

In September 2017, the Code Commission discussed the importance of biosecurity for disease prevention and control and agreed to develop a new chapter on biosecurity for the *Terrestrial Code* and added this to its work programme.

In February 2022, the Commission reiterated the importance of having a chapter on biosecurity in the *Terrestrial Code* and requested the Secretariat to develop a discussion paper on objectives, scopes and concepts to be covered in a new draft chapter.

In September 2022, the Code Commission and the Scientific Commission considered the discussion paper and advised on the scope of the new chapter and requested that an *ad hoc* Group be convened to commence this work and to present its report to the Scientific Commission and the Code Commission at their February 2023 meetings.

The meeting of the *ad hoc* Group was held in November 2022.

Discussion

The Code Commission considered the report of the *ad hoc* Group. The Commission thanked the *ad hoc* Group members for their work in developing a chapter structure and elaborating on the potential content to cover. The Commission agreed with the proposed structure of the new Chapter 4.X., and with the overall proposed content and provided guidance for the Group's further consideration. The Commission requested that the Group be reconvened to continue its work on the text of each article taking into consideration the Commission's guidance.

The Code Commission encouraged Members to read the report of the *ad hoc* Group on Biosecurity that is available on the WOAH website.

5.2.6. Revision of Chapters 5.4. to 5.7.

Background

At its September 2017 meeting, the Code Commission agreed to include a review of Section 5. Trade measures, import/export procedures and veterinary certification, in its work programme given that some of the chapters in this section required updating to better support Members in managing the risks of introduction of diseases through the importation of commodities.

At its September 2021 meeting, the Code Commission reviewed the current chapters of Section 5 and agreed that the revision of Chapters 5.4. to 5.7. should be given priority. The Commission also

discussed the scope of the revisions and requested that the Secretariat further develop the scope of this work.

At its February 2022 meeting, the Code Commission requested that an *ad hoc* Group be convened to progress this work and discussed a number of points that it considered important to include in the Terms of Reference of the *ad hoc* Group.

At its September 2022 meeting, the Code Commission considered comments received and reviewed the draft Terms of Reference for the *ad hoc* Group. The Commission requested that all relevant proposals and comments be provided to the *ad hoc* Group for its consideration.

The meeting of the *ad hoc* Group was convened in November 2022.

Discussion

The Code Commission reviewed the *ad hoc* Group's report and commended the members for their comprehensive work.

The Code Commission supported the *ad hoc* Group's proposal to replace the current Chapters 5.4., 5.5., 5.6. and 5.7. with the development of three new chapters that provide recommendations on measures and procedures that are applicable in the 'exportation (from the origin to the exit of the exporting country)', 'transit' and 'importation (from arrival until clearance)', respectively, as well as a fourth chapter to address key facilities required (e.g. border control/inspection posts, quarantine facilities).

The Commission also discussed the proposed structure for each chapter and the proposed revision of some Glossary definitions and provided some feedback on these proposals. The Commission requested that a second meeting of the *ad hoc* Group be convened to progress the development of the four chapters. The Commission requested that the report of the meeting be presented for its consideration at its September 2023 meeting.

The Code Commission encouraged Members to read the report of the *ad hoc* Group on the revision of Chapters 5.4. to 5.7. of the *Terrestrial Code* that is available on the WOAH website.

5.2.7. Revision of Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine

Comments were received from Brazil, Canada, China (People's Republic of), Chinese Taipei, Japan, New Caledonia, Singapore, Switzerland, the UK, the USA and the EU.

Background

At its February 2019 meeting, the Code Commission agreed to include in its work programme a review of Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine, in response to comments received and considering the adoption in 2018 of some revised definitions in Chapter 6.9. Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals. The Commission had requested the advice of the WOAH Working Group on Antimicrobial Resistance (AMR Working Group) on the revision of Chapter 6.10. The AMR Working Group considered this request at its 2019 meeting and recommended that a review of Chapter 6.10. be undertaken but not until the revision of the Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005) of the Codex Alimentarius Task Force on Antimicrobial Resistance had been completed, to avoid inconsistencies.

At its February 2022 meeting, the Code Commission was informed that the revised Codex Code of Practice had been adopted at the Codex Alimentarius Commission in November 2021, and that the AMR Working Group, at its October 2021 meeting, had agreed to work on the development of a revised Chapter 6.10.

At its September 2022 meeting, the Code Commission discussed the revised chapter drafted by the Working Group, made some additional amendments to improve clarity and ensure alignment with other chapters of the *Terrestrial Code* and agreed to circulate it for comments.

Discussion

The Code Commission appreciated the large number of comments received.

The Code Commission considered all comments and identified those that required advice from the AMR Working Group. The Commission requested the Working Group to consider the identified comments, and report back to the Commission at its September 2023 meeting.

In response to comments specifically referring to the establishment of clinical breakpoints, the Code Commission considered that clinical breakpoints should be established in accordance with the *Terrestrial Manual* Chapter 2.1.1. Laboratory methodologies for bacterial antimicrobial susceptibility testing. The Commission, therefore, requested that the Biological Standards Commission be asked to consider whether Chapter 2.1.1. provides sufficient and up-to-date information on the establishment of clinical breakpoints or whether it needs to be revised, and to advise the Code Commission as to how the establishment of clinical breakpoints should be covered in the revised Chapter 6.10.

5.2.8. New chapter on Animal welfare and laying hen production systems (Chapter 7.Z.)

Background

A new Chapter 7.Z. Animal welfare and laying hen production systems was presented for adoption at the 88th General Session in May 2021, but was not adopted by the Assembly as the support did not reach the two-thirds majority required by the WOAH General Rules.

During the last quarter of 2021, several Members and partner organisations submitted comments to WOAH noting the importance of having a WOAH standard for animal welfare and laying hen production systems. Given the divergent opinions of the Members, WOAH undertook to seek feedback from Delegates of the various WOAH Regions and relevant international organisations with a cooperative agreement to try to determine if there was any likelihood of reaching consensus on the proposed text. The responses received indicated that there were still diametrically divergent views and no clear pathway or approach on how to reach consensus.

Discussion

The Code Commission noted the update provided by the Secretariat and discussed possible alternatives and whether it would be feasible to once again review the proposed chapter.

The Commission recalled that the proposed chapter had been circulated five times for Member comments, and that it had been drafted and reviewed considering the available scientific evidence and the diversity of production systems around the world and the different perspectives expressed by Members. The Commission noted that there had been a tremendous amount of work invested in this process and that the Commission agreed that the proposed text was well balanced and considered different views and contexts for implementation.

The Commission reviewed once again the key points where Members held divergent views and concluded that there were no simple amendments that could be made to the text that would be acceptable to all Members.

The Commission reminded Members that the final objective of the WOAH standard setting process is the development of recommendations that are agreed by its Membership to achieve the goal of improving animal health and welfare worldwide, and to which Members could commit on a progressive implementation, and not to impose any regulatory framework. Nevertheless, the

Commission clarified that the explicit inclusion of text within the chapter indicating that some provisions could be implemented in a progressive way was not appropriate, and it would not be in line with the approach of WOAH Standards texts. The Commission noted that such an explanation was of general nature and could rather be included in the User's Guide. The Commission agreed that there was no agreement among Members about how to progress this work and that there were other priorities and ongoing work, hence it agreed to remove this item from its work programme. Nonetheless, the Commission agreed to consider this topic again for inclusion in its work programme if Members showed that it would be feasible to develop a draft chapter that could reach consensus. The Commission invited Members to provide their proposals as to how to progress in that direction.

5.2.9. Revision of Chapter 7.2. Transport of animals by land and Chapter 7.3. Transport of animals by sea

Background

In April 2019, the first WOAH Animal Welfare Global Forum was held with the theme of 'Animal Transport: A Shared Responsibility'. This forum highlighted the necessity of revising the current chapters on the welfare of animals during transport by land, sea and air (Chapters 7.2, 7.3 and 7.4 of the *Terrestrial Code),* given that there have been significant developments in the animal welfare science, notably in the use of animal-based measures, since these chapters were last adopted.

In February 2021, the Code Commission considered the recommendation and agreed to include a review of these chapters in its work programme. At its September 2020 meeting, the Commission agreed to commence this work and requested that an *ad hoc* Group be convened.

Discussion

The Commission considered the draft Terms of Reference for a new *ad hoc* Group on the revision of Chapter 7.2. Transport of animals by land and Chapter 7.3. Transport of animals by sea. The Commission recognised the importance of this work and requested that an *ad hoc* Group be convened and report back to the Commission at its February 2024 meeting.

5.2.10. Revision of Chapter 10.5. Avian mycoplasmosis

Background

At its September 2022 meeting, the Code Commission considered a comment made at the 2022 General Session that Chapter 10.5. only addressed *M. gallisepticum* and not *M. synoviae*, while both pathogens were listed separately in Chapter 1.3., and the corresponding *Terrestrial Manual* chapter addressed both pathogens. The Commission agreed on the need to clarify the way these pathogenic agents are used in the Code and that there should be a coherent approach between the Code and the Manual. The Commission agreed to include this item in its work programme. The Commission requested the Secretariat to seek expert advice on the inclusion of the two pathogens, *M. gallisepticum* and *M. synoviae* in one single Code chapter, including essential provisions such as a case definition, and to undertake this work in coordination with the Scientific Commission.

Discussion

The Secretariat informed the Code Commission that the Secretariat had requested the Scientific Commission for its advice as to whether to address *M. gallisepticum* and *M. synoviae* in a same chapter of the *Terrestrial Code* and its perspective of providing recommendations for disease prevention and control.

The Commission requested that the Secretariat provide an update at its next meeting, in September 2023.

5.2.11. Terminology: Use of terms ‘‘animal-based measures’, ‘animal-based measurables’, ‘resource-based measures’, ‘management-based measures’ and ‘outcome’

Background

In September 2020, the Code Commission asked the Secretariat to review terms in the animal welfare chapters in Section 7, used to assess the impact on the welfare of animals, either directly observed in animals or indirectly through the management and resources provided to them. The terms reviewed included ‘animal-based measures’, ‘animal-based measurables’, ‘resource-based measures’, ‘management-based measures’ and ‘outcome’.

In September 2022, the Commission considered a discussion paper prepared by the Secretariat and agreed that the term ‘measures’ should be used instead of ‘measurables’ as well as to replace outcome-based (measurables) with animal-based (measures). This agreed terminology should be harmonised throughout the animal welfare chapters. The Commission requested that the Secretariat assess the work needed to do this harmonisation work across Section 7.

The Commission also requested that the Secretariat propose explanatory text to include in Chapter 7.1. Introduction to the recommendations for animal welfare, to help Members understand the different terms in the right context: ‘animal-based measures’, ‘resources-based measures’, ‘management-based measures’, and ‘outcome or welfare outcome’.

Discussion

The Commission reviewed the working document prepared by the Secretariat and agreed that, given the Commission’s intention to revise Chapter 7.1. Introduction to the recommendations for animal welfare, the proposed modifications to harmonise the terminology will be considered during that revision process.

5.3. Items under consideration for inclusion in the work programme

The Code Commission discussed the following topic for which a proposal or request for inclusion in the Commission’s work programme had been previously considered but a decision was not yet made due to different considerations.

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

Background

The revised Chapter 11.10. Infection with *Theileria annulata*, *T.orientalis* and *T.parva* was adopted during the 89th General Session in May 2022.

At its September 2022 meeting, the Code Commission considered comments raised at the time of adoption and agreed not to undertake new work on the chapter at this stage and requested the Secretariat to seek further advice from experts, the Biological Standards Commission and the Scientific Commission, if needed, to review and consider the references provided by the Members along with their comments, before further considering this item for inclusion in their work programme.

Discussion

The Secretariat informed the Commission that it had requested the Scientific Commission to provide its advice as to whether there is a need to reconsider the listing of *T. orientalis*, and whether the African buffaloes play an epidemiologically significant role.

The Commission requested that the Secretariat provide an update at its next meeting, in September 2023.

5.4. New proposals and requests for inclusion in the work programme

The Code Commission considered the following proposals or requests for new developments or revisions of standards in the *Terrestrial Code*.

5.4.1. New chapter on turkey rhinotracheitis

The Secretariat informed the Code Commission that the Scientific Commission, at its September 2022 meeting, had endorsed a draft case definition for turkey rhinotracheitis that had been developed by subject-matter experts.

The Code Commission considered the draft case definition and requested that the Scientific Commission clarify some points, notably on epidemiologically significant host species. The Code Commission agreed that once these points have been clarified it will develop a new single-article chapter for turkey rhinotracheitis to address general provisions including the case definition. The Code Commission agreed not to add the development of a more comprehensive chapter to its work plan at this moment.

5.4.2. Chapter 14.9. Sheep pox and goat pox

In response to a comment to review Chapter 14.9. Sheep pox and goat pox, the Code Commission agreed to add the work as priority 3 to its work programme, given that the chapter had not been revised since its first adoption in 1986 and did not include the case definition and recommendations for the importation of some commodities.

5.4.3. Chapter 5.8. International transfer and Laboratory containment of animal pathogenic agents

In response to a comment to revise Chapter 5.8. International transfer and laboratory containment of animal pathogenic agents, the Code Commission agreed with a need to revise the chapter, noting that some articles of the chapter might not be in line with the *Terrestrial Manual*. The Commission requested that advice be sought from the Biological Standards Commission before adding the work to its work programme.

5.4.4. Chapter 7.7. Dog population management

The Code Commission did not agree with a comment to add recommendations on the use of chemical methods for euthanasia in Chapter 7.7. Dog population management, as it considered that those details should be provided elsewhere.

5.4.5. Chapter 15.1. Infection with African swine fever virus

In response to a comment requesting that WOAH prioritise adding ‘extruded dry pet food’ as a safe commodity to Chapter 15.1. Infection with African swine fever virus, the Code Commission agreed to add the work as priority 2 to its work programme. The Commission requested that Secretariat review the scientific references on this disease that had been provided by the Global Alliance of Pet Food Associations (see the relevant part of the February 2022 Code Commission report) and report back at its September 2023 meeting. The Commission also noted that its decision to progressively consider the inclusion of this commodity as well as ‘heat-treated meat products in a hermetically sealed container with an F0 value of 3 or above’ in the relevant disease-specific chapters had not been captured in the Commissions work programme and agreed to include the topic as a general work item.

5.5. Prioritisation of items on the work programme

Based on several considerations and the progress of the different topics since its last meeting, as well as the specific discussions during this meeting, the Code Commission discussed the prioritisation of ongoing and future work, and agreed to add or remove the items as presented below:

Added items:

- Consider 'extruded dry pet food' and 'heat-treated meat products in a hermetically sealed container with an F0 value of 3 or above' for listing as 'Safe commodities' in disease-specific chapters (when revised)

- Consider 'extruded dry pet food' for listing as 'Safe commodities' in Chapter 15.1. Infection with African swine fever virus

- Revision of disease names and animal categories (in Chapter 1.3. Diseases, infections and infestations listed by WOAH)

- Chapter 14.9. Sheep pox and goat pox

Removed items:

- Glossary definition for 'poultry'

- Chapter 7.Z. New chapter on animal welfare and laying hen production systems

The Code Commission updated its work programme accordingly.

The Commission reminded Members that the order of prioritisation used in the work programme reflects the level of priority agreed upon by the Commission, through the rigorous assessment of each item, in terms of its necessity and urgency, taking into consideration WOAH Members and Headquarters requests.

The Code Commission highlighted that the inclusion of an item in the work programme means there is a collective agreement of the Commission on the need to undertake certain work but this does not mean that the work would be immediately initiated. The decision as to when to commence each work item depends on the overall consideration of priorities, the progress of ongoing work and the resources and data available. The prioritisation order aims at providing a guide to plan and organise the work of the Commission and the Secretariat, as well as to improve Members' awareness of the progress of the different topics. The Commission highlighted that the prioritisation order used in its work programme is not necessarily parallel to the progress of each work, which depends on the complexity of the specific tasks to be undertaken.

The Commission reminded Members that, although it reviews its work programme at each meeting and re-considers the prioritisation of items according to changes in necessity and urgency (e.g., in response to Member requests, changes in the epidemiological situation of diseases etc.), it would not significantly modify the prioritisation order frequently, for reasons of efficiency and predictability.

The Code Commission reminded Members that the schedule of planned *ad hoc* Group meetings is presented on the WOAH website and that WOAH Delegates can nominate experts for specific *ad hoc* Groups, in particular for those that are in the planning phase and not yet formally established, by using the dedicated link.

The updated work programme is presented in Annex 3, for comments.

6. Texts proposed for adoption in May 2023 (Annexes Part A)

The Code Commission discussed the following new or revised texts which will be proposed for adoption at the 90th General Session in May 2023.

6.1. User's Guide

Comments were received from Norway, Switzerland and the EU.

Background

At its September 2022 meeting, following the recent adoption of a revised definition for the terms 'Veterinary Authority', 'Competent Authority' and 'Veterinary services', the Code Commission agreed to amend point C(6) of the Users' Guide and circulate the amended text for comment.

Discussion

In considering the conclusions of the Aquatic Animals Commission on the use of the terms 'Aquatic Animal Health Services', 'Competent Authority' and Veterinary Authority' in the *Aquatic Code*, the Code Commission noted the need to align point B(5) of the User's Guide and agreed to add 'and the Veterinary Authority' after 'Veterinary Services', in the second sentence.

The revised point C(6) and point B(5) of the User's guide are presented as part of Annex 4 and will be proposed for adoption at the 90th General Session in May 2023.

6.2. Glossary

a) 'poultry'

Comments were received from Australia, Canada, Japan, New Caledonia, South Africa, Switzerland, the USA and the EU.

Background

In February 2022, the Code Commission agreed to consider a comment to clarify the Glossary definition for poultry, and whether 'populations of pet birds kept and bred for selling to hobby holdings, backyard holdings or pet bird owners' were considered as 'poultry' in the current definition, depending on the epidemiological situation of each event.

The Code Commission noted then that the definition for poultry clearly states that pet birds are excluded, if they have no direct or indirect contact with poultry or poultry facilities, but agreed to amend the definition to clarify that populations of pet birds for breeding or selling are excluded from the definition of poultry.

The proposed revised definition was circulated for comments twice, the last time in the Commission's September 2022 report.

Discussion

The Commission noted several comments pertaining to other aspects of the definition, which were not currently under discussion. The Code Commission reminded Members that the definition of 'poultry' was last adopted in 2021 together with the extensive work on the revision of Chapter 10.4. Infection with high pathogenicity avian influenza viruses, that was adopted after the consideration of several rounds of Members comments received throughout the revision process.

The Commission agreed that the current definition for poultry was clear and fit for purposes of the *Terrestrial Code*. Noting that the scope of this work was not to fully revise a recently adopted text, but to improve the clarify of a specific point, the Commission agreed not to address the comments which were outside of the scope of this revision.

The Commission also acknowledged a comment regarding inconsistencies between the French and English versions of the definition but noted that no concrete proposal for harmonisation had been

submitted. The Commission invited the Members to submit proposals for improved translations to WOAH Headquarters for its consideration.

In view of the comments received since its first circulation in February 2022, the Code Commission considered that while this partial revision had only been intended to introduce a minor amendment for further clarity, it appeared that it had raised confusion amongst some Members. Given that the definition had only been recently adopted and that any further revisions may reopen points already extensively discussed, the Commission agreed not to propose amendments to the definition at this stage and to withdraw this item from its work programme.

b) 'distress', 'pain' and 'suffering'

As part of the discussion on the revision of Chapter 7.5. Slaughter of animals and related definitions (See item 7.3 of this report), the Commission agreed that the definitions 'distress' and 'pain' in Article 7.8.1. of Chapter 7.8. Use of animals in research and education, were fit for purpose and, as they appear in more than one chapter, they should be moved from Chapter 7.8. to the Glossary. On the other hand, the Commission agreed to delete the definition of 'suffering' from the Chapter 7.8., noting the convention to only include terms definitions in the Code, where common dictionary definitions are not deemed to be adequate for the use in the Code.(see Item 7.3. of this report). Noting that these were editorial changes, the Commission agreed to propose these changes for adoption at the 90th General Session in May 2023.

The definitions of 'distress' and 'pain' to be moved from Article 7.8.1. to the Code Glossary and the amended Article 7.8.1. are presented as part of Annex 5 and as Annex 6, respectively, and will be proposed for adoption at the 90th General Session in May 2023.

EU position

The EU in general supports transferring definitions used in several Code chapters to the Glossary. However, it cannot support the deletion of the specific definition of "suffering" from the Code. One important comment to that effect is inserted in the texts of Annexes 5 and 6 that should be considered by the Code Commission before adoption.

6.3. Diseases, infections and infestations listed by WOAH (Chapter 1.3.)

Comments on Article 1.3.3. were received from Switzerland and the EU.

Background

At its September 2019 meeting, the Code Commission was informed that *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* 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 February 2019 report of the Scientific Commission).

At its February 2022 meeting, the Code Commission agreed that given a new Chapter 3.8.13. Theileriosis in sheep and goats (infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi*), for the *Terrestrial Manual* was to be proposed for adoption in May 2022, it would propose to add infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* to Article 1.3.3. of the *Terrestrial Code* and circulated the revised article for comments.

At the same meeting, the Code Commission proposed developing new chapters on infection with MERS-CoV and Infection with *Leishmania* spp. and agreed to propose additional amendments to Article 1.3.9. to align the names of the diseases with the ones used in the proposed new chapters after they had undergone rounds of comments.

Discussion

The Code Commission noted that only comments in support of the proposed changes were received.

In Article 1.3.9., the Code Commission agreed to delete 'of dromedary camels' from 'infection of dromedary camels with Middle East respiratory syndrome coronavirus' given that the susceptible hosts are humans as well as dromedary camels (refer to February 2022 report for details). The Commission proposed to add a new Section 16. Camelidae to Volume II of the *Terrestrial Code*, in which the new chapter for infection with Middle East respiratory syndrome coronavirus be placed, for alignment with the *Terrestrial Manual*.

Also in Article 1.3.9., the Code Commission agreed to replace 'Leishmaniosis' with 'Infection with *Leishmania* spp' (refer to the Code Commission's February 2022 report for details). In addition, the Commission proposed moving Infection with *Leishmania* spp. (Leishmaniosis)' to Article 1.3.1. multiple species diseases, given that multiple species are referred to in the definition of the disease in the proposed new chapter (see item 6.14 of this report). This also aligns with the corresponding *Terrestrial Manual* chapter which is placed in Section 3.1. diseases of multiple species.

Noting that the Scientific Commission recommended that consistency between the species categories in Chapter 1.3. and the section names in Volume II of the *Terrestrial Code* be improved (see item 3.1 of this report), the Code Commission made relevant amendments to Chapter 1.3., titles of Sections 9 and 11 and relevant parts of User's guide.

The revised Chapter 1.3., the revised User's guide and the revised titles of Sections 9, 11 and 16 are presented as Annex 7, part of Annex 4 and Annex 21, respectively, and will be proposed for adoption at the 90th General Session in May 2023.

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

Comments were received from Argentina, Australia, Canada, China (People's Rep. of), Japan, New Zealand, Republic of Korea, Singapore, Switzerland, Thailand, the UK, the USA, Members from the WOAH America's Region, the EU and the IMS.

Background

Chapter 8.8. Infection with foot and mouth disease virus, has undergone a comprehensive revision. The revised text was first circulated for comments in September 2015, and has been circulated four times since then. The *ad hoc* Group on foot and mouth disease provided inputs in two meetings (June 2016, and June 2020) to contribute to the revised draft chapter. The revised chapter has been reviewed by the Scientific Commission and the Code Commission throughout this process, and inputs have also been sought from the Biological Standards Commission.

In September 2022, the Code Commission considered the most recent comments received and circulated a revised chapter for comment.

Discussion

General Comments

The Code Commission acknowledged a proposal from some Members requesting that a new approach with a less significant impact on trade be developed for Chapter 8.8. Infection with foot and mouth disease, as it was done with the chapter on Bovine Spongiform Encephalopathy. The Members requested that such an approach review the status categories currently in force (free with vaccination, free without vaccination or infected) and their linkage with vaccinated animals in terms of their potential role in virus transmission, considering the development and evolution of current tools such as the quality of vaccines and available DIVA tests, and alternatives to stamping out or the exclusive use of vaccination as a containment method. In response, the Commission highlighted that the current revision of the chapter includes extensive amendments and provides up-to-date risk mitigation measures and has required more than 6 years of work. Consequently, the Commission agreed not to consider initiating any new work on this chapter for the time being. Nonetheless, the Commission noted that the use of vaccination in the context of global foot and mouth disease control was considered within the Global FMD Control Strategy

and requested the Secretariat to forward this issue for WOAH to discuss with its partners at the relevant fora, and that eventual further evolution of the Global strategy could be a driver for the future works on Chapter 8.8. Infection of foot and mouth disease virus.

The Commission acknowledged comments expressing concerns about the proposed amendments that would give the possibility for countries or zones free from FMD where vaccination is not practised to introduce vaccinated animals without having their animal health status affected. The Members considered that these changes would impose an additional burden on importing countries that are free without vaccination. The Commission reminded Members that the proposed new provisions are based on the safety of such vaccinated animals if imported in compliance with the recommendations of the chapter. The Commission answered the specific concerns in each of the relevant articles.

In response to a comment requesting that Chapter 1.11. Application for official recognition by the WOAH of free status for foot and mouth disease, be amended to reflect changes in Chapter 8.8., the Code Commission, in agreement with the Scientific Commission, considered that no changes should be required in the questionnaire at this stage.

Article 8.8.1.

In point 2, in response to comments on the list of susceptible animals, the Code Commission explained that the proposed amendments were based on the recommendation of the joint TAHSC-SCAD Taskforce, which had been endorsed by both the Scientific Commission (at its February 2021 meeting) and the Code Commission (at its September 2021 meeting). Nevertheless, the Code Commission, in agreement with the opinion of the Scientific Commission at its February 2023 meeting, agreed to include ‘and antilopinae’.

In point 2bis, in response to comments on the proposal to replace 'cattle’ with ‘bovine’, the Code Commission reiterated its position to use the term ‘bovine’ and explained that this term is only used in specific parts of the article, which is only intended to refer to the species *Bos taurus* or *Bos indicus*, and consequently, the definition for the purpose of this chapter is limited to those species as they are most frequently intended for trade and thus have more epidemiological relevance. The Commission noted that this definition is not intended to refer to the susceptible species which are defined in point 2 of Article 8.8.1. Other species are covered by the terms ‘susceptible animals’ or ‘ruminants’ according to the context of the text.

In point 3(a), the Code Commission did not agree with a comment to delete ‘and identified as such’ noting that this was aligned with the previous opinions of the Biological Standards Commission and the Scientific Commission. The Commission reminded Members that this text was added following the request from experts to ensure that adequate confirmation of the identity of the virus was always required and that it was also being harmonised in other disease-specific chapters.

The Code Commission agreed with a comment to replace ‘suspected or confirmed’ with ‘confirmed or suspected’ in point 3(b) and to replace ‘identified’ with ‘detected’ in point 3(c) to align with disease-specific chapters currently under review.

In point 3(c), the Code Commission agreed with a comment to add ‘proteins’ in front of the abbreviation (SP) as this acronym was used for the first time in the chapter.

In point 5, in response to a comment referring to the use of the ‘incubation period’, the Code Commission reiterated that its position was noted in its September 2022 report. The Code Commission requested the Biological Standards Commission to consider the need to provide more information on the concept of ‘latent period’ in the ongoing revision of Chapter 3.1.8. Infection with the foot and mouth diseases virus, of the *Terrestrial Manual*. Nevertheless, the Commission considered that the current use of the ‘incubation period’, in accordance with its Glossary definition, provided the safest time (longer than the latent period) reference for risk management purposes.

In point 6, the Code Commission did not agree with a comment to add ‘potentially possible’ after ‘rare’, as it considered the text was clear as written.

Article 8.8.1bis.

In the first paragraph, the Code Commission amended the text for harmonisation and consistency with other chapters.

The Code Commission did not agree with a comment to remove 'protein meal' and 'extruded dry pet food' from the list of 'safe commodities' and explained that 'extruded dry pet food' meets the criteria in Chapter 2.2. Safe commodities, of the *Terrestrial Code* and therefore can be considered to be safe as regards FMD. The Commission reminded Members that its rationale was provided in its February 2022 report.

In response to a comment requesting more information on the assessment for the inclusion of 'limed hides, pickled pelts and semi-processed leather' in the list of 'safe commodities', the Commission explained that these commodities undergo standardized processing (chemical and mechanical processes used in the tanning industry) which is sufficient to inactivate FMDV, and hence those commodities meet the criteria in Chapter 2.2. Safe commodities, of the *Terrestrial Code*. The Commission reminded Members that the provisions in current Article 8.8.27. already state that these commodities were safe, and no sanitary measures should be required for their trade, and consequently this is not a change from the current chapter.

The Code Commission acknowledged a comment to consider 'irradiation' as a treatment option for non-food commodities and agreed that it could be considered if relevant information regarding inactivation was provided.

In response to a comment regarding the international trade of 'gamma irradiated fetal bovine serum', the Code Commission reiterated that it had been informed that the industry had encountered difficulties in the international trade of 'fetal bovine serum' due to different sanitary measures requested by countries, which included limitations or heterogenous requirements to trade from infected countries, and that 'gamma irradiation' was not a specific step of the standardized manufacturing process for the commodity, but rather a measure being specifically applied to address potential risks of transmission of FMDV and other pathogens. Based on this information, the Commission agreed on the potential value of providing an international standard on recommendations for the safe trade of 'fetal bovine serum', and to consider including gamma irradiation as an effective risk mitigation measure. Nonetheless, the Commission considered that the current draft was too close to adoption to add this change, and requested the Secretariat to review the information provided by the industry and assess if sufficient evidence is available and propose a new draft article for consideration, in consultation with experts, for consideration at its next meeting.

Article 8.8.2.

In paragraph 5, the Code Commission did not agree with comments to delete 'relevant' as this text was harmonised with other chapters for which WOAH grants official recognition of status, which were recently circulated and adopted.

In paragraph 6, in response to a request asking for the rationale for removing 'have a record of regular and prompt animal disease reporting', the Commission explained that this point is already addressed in Article 1.6.1. of Chapter 1.6. Procedures for official recognition of animal health status, endorsement of an official control programme, and publication of a self-declaration of animal health status, by WOAH. The Commission reminded Members that this was also aligned with text harmonised in similar chapters.

In paragraph 6 points 2 and 3, the Code Commission did not agree to delete 'current knowledge of, and' and 'habitat' as it considered these relevant for this article. The Commission explained that these provisions were not prescriptive and provided sufficient flexibility for Members to implement measures adapted to specific contexts and noted that this text was also aligned with harmonised text in similar chapters.

In response to a comment requesting more information on the format and level of details that the Veterinary Authority should provide to WOAH for the demonstration of freedom, the Code Commission

noted that Members can find this in the specific guidance on the WOAH Official Status recognition procedures, which is available on WOAH webpage on official status.

In point 5, the Code Commission acknowledged comments expressing concerns on the proposed amendments that would give the possibility for FMD-free countries or zones where vaccination is not practised to introduce vaccinated animals without affecting their animal health status. Noting that this introduction only refers to animals coming from countries, zones or compartments free from FMD and compliant with the provisions in articles 8.8.11. and 8.8.11bis., referring to the demonstration of the absence of FMDV infection in the animals to be introduced, the Commission, in agreement with the opinion of the Scientific Commission, considered that the disease incursion risk from such introduced animals would be negligible. The consequence of such introduction on the surveillance programmes of the importing countries or zones is another issue that is up to those countries to take into consideration when they choose to import. The Commission amended the text for clarity.

In point 6, third paragraph, the Code Commission agreed with the comments to delete 'relevant' for clarity.

The Code Commission did not agree with a comment to add further details on the measures to be implemented in the case of an incursion of an African buffalo from a neighbouring infected country or zone and reminded Members that the term 'incursion' does not imply the occurrence of infection.

In addition, in response to a comment, the Code Commission noted that in case of an incursion of an African buffalo from a neighbouring infected country or zone, enhanced passive surveillance in the free country or zone would be in place and reinforced, and if the case definition is not met, the incursion should not be notified.

Article 8.8.3bis.

The Commission agreed with a comment to include a provision highlighting the possibility for FMD vaccination programmes to include an exit strategy in line with Chapter 4.18. and proposed some amendments to the text.

In paragraph 1, the Code Commission agreed with a comment to replace 'with vaccination' with 'from FMD where vaccination is practised' for consistency with the name of the official status granted by WOAH and to align with other articles of the chapter.

In paragraphs 1 and 2, the Code Commission agreed with a comment to replace 'withdrawn' with 'suspended', to align with the current WOAH Official recognition procedures.

Article 8.8.5bis.

In paragraph 2 point 4, in agreement with the opinion of the Scientific Commission, the Code Commission agreed with a comment that for the implementation of a 'protection zone,' it may not be necessary to apply 'intensified biosecurity' in the entire country, considering that such a prescriptive measure was not needed, especially in large countries, and amended the text to clarify that this applies only to the 'protection zone'.

In the second last paragraph, the Code Commission agreed with a comment to amend the text for clarity about the alternative to the recovery of free status in the event of an outbreak within a previously free protection zone.

Article 8.8.6.

In points 1 and 2, in agreement with the opinion of the Scientific Commission, the Code Commission agreed with comments to amend the text considering that by the time of confirmation of the case, the Veterinary Authorities would not be able to define the extent of the containment zone.

Article 8.8.8.

The Code Commission agreed with a comment to add ‘within a country’ to the title to clarify that ‘Direct transfer’ refers to movements between zones within a country. The same amendment was made in Article 8.8.9bis. for consistency.

Article 8.8.10.

The Code Commission did not agree with the comment to delete point 4, because vaccinated animals could be present in countries, zones or compartments free from FMD where vaccination is not practised due to different reasons already covered in this chapter, such as when vaccination would have been applied and stopped before being recognized as free from FMD, when a country or zone free from FMD would have transitioned vaccination status, or when free status recovery would have been recovered after implementation of a ‘vaccination-to-live’ policy would have been implemented in response to an outbreak.

Article 8.8.11.

In response to a comment seeking clarification on the meaning of the word ‘domestic’ in this article, the Code Commission reminded Members that in the context of the *Terrestrial Code*, it refers to those animals which are not ‘wild’, ‘captive wild’ or ‘feral animals’ as per the definitions in the Glossary. With regard to the species to be considered under this article, the Commission noted that it would include all relevant species of the families and subfamilies listed in Article 8.8.1.

In paragraph 2, the Code Commission did not agree with a comment to delete ‘if not vaccinated’ in point 3 and the whole text in point 4, and reiterated the rationale explained above under ‘general comments’ about the introduction of vaccinated animals from free countries or zones where vaccination is practised.

In response to a comment seeking clarification, the Code Commission explained that, while it acknowledged the consideration of the Biological Standards Commission that diagnostic techniques applied to a sample from a single animal at a single point in time in the absence of any other additional risk mitigation measures may have limitations to completely certify the absence of infection with FMD, in the context of this article, not only other risk mitigation measures are recommended in the certificate in addition to testing, but also it refers to animals originating from FMD free countries or zones, i.e. which are part of a population where the absence of infection and transmission has been duly demonstrated as per the relevant provisions in the chapter, which provides a sufficient level of safety for international trade.

Article 8.8.11bis.

The Code Commission did not agree with a comment to delete the entire article, as it considered it to be relevant, and reiterated the rationale explained above under ‘general comments’ about the introduction of vaccinated animals from free countries where vaccination is practised.

Article 8.8.12.

In the title, the Code Commission did not agree with a comment to refer to the ‘WOAH endorsed official control programme'. The Code Commission reminded Members to refer to the glossary definition for this term and explained that the endorsement of official control programmes by WOAH is not intended only for trade purposes. This response applies to similar comments in other parts of the chapter.

In paragraph 5 point b), the Commission did not agree with a comment to add ‘past 6 months and in’ after ‘during’ as it considered that the isolation for 30 days (covering at least two incubation periods), was sufficient, and noted that this was done in conjunction with other risk mitigation measures such as testing with negative results collected at least 28 days before isolation, which also represented two incubation periods.

The Code Commission did not agree with a comment to amend the text to consider surveillance principles rather than individual testing for a large group of animals ‘in areas functioning as a quarantine station’, as the provisions of Article 8.8.12. refer to the importation of animals from an infected zone.

Article 8.8.18.

The Code Commission agreed with a comment noting that embryos of other species may pose FMD transmission risk and invited Members to submit proposals and supporting evidence for its future consideration.

Article 8.8.21.

In response to a comment on the scope of the terms 'ruminants and pigs' in the title, the Code Commission noted that the term was already used in the current chapter, and that the terms cover both domestic and wild animals. The Commission made editorial amendments in points 1, 2 and 3 for clarity.

Article 8.8.22.

The Code Commission acknowledged the comments on the risk mitigation measures and reminded Members that the Code does not provide specific details on practical implementation, which is the responsibility of Members.

Articles 8.8.22bis.

In response to the comments suggesting merging Articles 8.8.22bis. and 8.8.22ter. because some provisions were similar, the Code Commission noted that it was agreed to develop separate articles for pigs and small ruminants, as different mitigation measures are recommended.

Article 8.8.22ter.

In the title of the article, the Code Commission replaced 'domestic small ruminants' with 'sheep and goats' for consistency with other chapters.

In point 4, the Code Commission did not agree with a comment to delete 'either' and 'or', as it considered that, in addition to points 1 to 3, measures in point 4 were equivalent to those in point 5, and were sufficient to make the commodity safe for trading.

In point 5 (a), the Code Commission acknowledged a comment to include a reference to vaccination of small ruminants in addition to bovines and water buffaloes, and invited Members to submit proposals and supporting evidence for its future consideration.

Article 8.8.24.

The Code Commission agreed with a comment to amend the title to delete the reference to the end use of the commodity.

Article 8.8.25.

The Code Commission agreed with a comment to delete 'where an official programme exists' in the title, as it was not relevant.

Article 8.8.27.

In point 2, the Code Commission agreed with a comment to replace 'or' with 'and', for clarity about the need to address both steps 'collection' and 'processing'.

Articles 8.8.29.

In the title, the Code Commission agreed with comments to replace 'wildlife' with 'animals (other than those listed in Article 8.8.1bis.)' for consistency with other articles. This amendment was also applied to the title of article 8.8.30.

Article 8.8.31.

In response to a comment suggesting that the measures provided in this chapter would also apply to pet food, the Code Commission noted that these measures were not targeting any specific end-use of the meat and meat products, but rather to ensure the inactivation of the virus, irrespective of the end use, so that the commodity is rendered safe.

Article 8.8.35.

In the title of the article, the Code Commission agreed with a comment to add 'and milk products', as the measures would also be applicable to products derived from milk.

In response to comments questioning the efficacy of the measures provided in point 1), the Code Commission reiterated its position that the heat treatment should not be considered alone, but together with a previous reduction of the pH of the milk to less than 7, and that it considered this equivalent to the provisions in current Article 8.8.36. The Commission agreed to introduce a new point 3) to include consideration of other equivalent treatments that have been demonstrated to inactivate, as done in other chapters of the Code.

Article 8.8.40.

In response to comments referring to the development of guidelines for FMD surveillance, the Code Commission reminded Members that such documents are intended to support Members in the implementation of adopted Standards and are not part of the WOAH Standard setting process. The Commission also noted, in agreement with the Scientific Commission, that the surveillance provisions of the proposed chapter are sufficient for both unvaccinated and vaccinated populations.

In point 2, the fourth paragraph, the Code Commission acknowledged comments expressing concerns about the additional surveillance requirements for FMD free countries or zones where vaccination is not practised in case of importation of vaccinated animals and noted that its rationale is explained above in Article 8.8.2.

Article 8.8.41.

Based on the inputs of the Scientific Commission the Commission amended the text of the third paragraph in point 1), to address the difficulty of sampling wildlife for surveillance purposes.

The revised Chapter 8.8. Infection with foot and mouth disease virus, is presented as Annex 8 and will be proposed for adoption at the 90th General Session in May 2023.

EU position

The EU thanks the Code Commission and provides important comments inserted in the text of Annex 8.

6.5. Infection with rabies virus (Articles 8.14.6bis. and 8.14.7. and 8.14.11bis. of Chapter 8.14)

Comments were received from Argentina, Australia, Canada, Singapore, Switzerland, the UK and the EU

Background

Following the adoption of revised Chapter 8.14. Infection with rabies virus, in 2019, the Code Commission, at its September 2019 meeting, acknowledged that there was still some work pending on the chapter.

At its September 2020 meeting, the Code Commission considered the advice of the *ad hoc* Group (October 2019) on Rabies and the Scientific Commission and agreed to add a new Article 8.14.6bis. on

recommendations for the importation of dogs from countries or zones infected with rabies virus and amend the title of Article 8.14.7. and circulate the amended articles for comments.

At its February 2021 meeting, the Code Commission considered comments received on the revised articles and decided, in agreement with the Scientific Commission, not to propose any further amendments to Articles 8.14.8. to 8.14.10. until new scientific evidence becomes available.

At its September 2021 meeting, the Scientific Commission endorsed the advice received from the WOAH Rabies Reference Laboratory network (RABLAB) which was also considered by the Code Commission at its February 2022 meeting.

In September 2022, the Code Commission considered the advice of the Scientific Commission and the experts of the RABLAB, addressed comments received and circulated the revised articles for comments.

Discussion

Article 8.14.6bis.

The Commission acknowledged comments that did not support the proposed reduction in the waiting period from 3 months to 30 days for the importation of vaccinated dogs from infected countries or zones, based on risk assessments developed by specific countries. The Commission agreed with the opinion of the Scientific Commission on the reference provided, and reiterated its previous position that while these risk assessments may support a Member's decision to protect its specific situation by the application of more stringent sanitary measures than those recommended in the Code, if they are scientifically sound and conducted in accordance with Chapter 2.1. Import risk analysis, they were not necessarily suitable for the global context. The Commission reiterated that the proposed draft article was based on scientifically robust evidence.

Article 8.14.11bis.

In point 2 (a), the Commission agreed with a comment to replace 'immediately' with 'quickly' for consistency with the wording of the rest of the points and because it reflects better the way the number of cases would decline in a country after vaccination is conducted.

In point 2 (b) the Commission agreed with a comment to replace 'regular' with 'frequent' for clarity and because regularity is already mentioned in the text of this point.

In point 3 (a) the Commission did not agree with a comment to replace 'animal identification system' with 'database', as it considered that 'database' always implied a centralized computerized system and that, to monitor the vaccination coverage, registration should cover not only the record of the vaccination, but also the link with other key data such as the location of the dogs, the identification of the persons responsible for the dog, among others, and that this was in line with the Glossary definition for 'animal identification system'.

In point 3 (b), the Commission agreed with a comment to add 'date of vaccination and product', because this information would be useful to monitor the programme and to take actions if needed.

In point 3 (c), the Commission acknowledged a comment to take into consideration both parenteral and oral rabies vaccination campaigns. The Commission discussed the role oral vaccination plays in the context of rabies control and agreed to consider this in the future.

The new Article 8.14.6bis., the revised Article 8.14.7., and the new Article 8.14.11bis. are presented as Annex 9, and will be proposed for adoption at the 90th General Session in May 2023.

EU position

The EU thanks the Code Commission for the latest version of the revised Chapter 8.14. on Infection with rabies virus and agrees with the changes made on the article introduced in the draft to address dog-mediated rabies vaccination programmes.

However, as explained in its previous comments and in line with the risk assessment carried out by the European Food Safety Authority in this regard, the EU continues to oppose the changes proposed by WOAH in Article 8.14.6bis and therefore does not support the adoption of this chapter as presented.

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

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

Background

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

An *ad hoc* Group meeting was convened in June 2021 to develop guidance for RVF surveillance during epidemic and inter-epidemic periods, as well as the consideration of other issues such as the development of provisions for the recovery of freedom in a country or zone previously free from RVF. The report of the meeting was endorsed by the Scientific Commission at its September 2021 meeting.

At its February 2022 meeting, the Code Commission discussed the comments previously received, together with the report of the *ad hoc* Group, made additional amendments, and circulated the revised chapter for comments.

At its September 2022 meeting, the Code Commission discussed the comments received, made additional amendments, and circulated the revised chapter for comments.

Discussion

General

The Code Commission noted an update from the Biological Standards Commission that the corresponding *Terrestrial Manual C*hapter 3.1.19. Rift Valley fever (infection with Rift Valley fever virus), has been amended to include diagnostic tests suitable for trade in live animals, by revising the column on 'individual animal freedom from infection prior to movement' in Table 1 of the *Terrestrial Manual* chapter, and will be proposed for adoption at the 90th General Session in May 2023 (See item 3.2 of this report). The Code Commission agreed that, once the revised Manual chapter has been adopted, it would be worth revising relevant trade provisions. The Code Commission agreed to consider this at its next September 2023 meeting, pending the adoption of the corresponding *Terrestrial Manual* chapter.

Article 8.15.1.

In points 4(b) and 4(c), the Code Commission did not agree with a comment to replace 'a human infected with RVFV' with 'an indigenous infection of a human with RVFV'. The Commission reiterated that humans are dead-end hosts for RVFV, and if an epidemiological investigation concluded that a suspected infection in an animal has no epidemiological link to an infection in humans, which includes one that has been acquired in a different geographical area, the condition regarding an epidemiological link would not be met.

Article 8.15.2.

In the first paragraph, the Code Commission amended the text for harmonisation and consistency with other chapters.

The Code Commission did not agree with a comment to delete point 3, based on the same rationale provided in the discussion on Chapter 8.8. Infection with foot and mouth disease virus (See item 6.4 of this report).

Article 8.15.5.

The Code Commission did not agree with a comment to add 'in epidemic areas' after 'en route', as it considered that there may be vectors in areas other than epidemic areas and therefore there is no need to limit the geographical area for this point.

Article 8.15.8.

In point 2, the Code Commission did not agree with a comment to add 'and a qRT-PCR test for RVFV viral genome, with negative result' at the end of point (b), as it considered that a seropositive animal is not infectious. The Commission reminded Members that the June 2021 *ad hoc* Group on Rift Valley fever had concluded that there was insufficient scientific evidence to indicate that semen remains infective following the recovery of infected animals. On the other hand, the Commission noted that the risks derived from *in vivo* derived embryos and *in vitro* produced embryos had not been sufficiently discussed and considered that this was the case for not only Rift Valley fever but also other listed diseases. The Commission agreed that this issue should be addressed horizontally across the disease-specific chapters at a future meeting.

Article 8.15.11.

In response to a comment querying what belongs to 'high vector' and 'low vector' and 'why low vector is important to the transmission of the disease', the Code Commission explained that this point concerned the degree of activity of vector, not a type of vector. The Commission also reminded Members that the June 2021 *ad hoc* Group on Rift Valley fever had concluded that it was not feasible to propose a recommendation for the establishment of a baseline for low RVFV activity, as there were too many epidemiological variations and different ecological situations among countries.

In the sixth paragraph, in response to a comment to highlight the importance of public awareness messages to prevent infection in humans handling animals, the Code Commission proposed amendments to the last paragraph to refer to 'the use of public health messages to prevent human exposure'.

The revised Chapter 8.15. Infection with Rift Valley fever virus, is presented as Annex 10 and will be proposed for adoption at the 90th General Session in May 2023.

EU position

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

6.7. Infection with Newcastle disease virus (Article 10.9.1. of Chapter 10.9.)

Comments were received from Switzerland and the EU.

Background

At its February 2022 meeting, in response to a comment, the Code Commission proposed to remove the definition of poultry from Chapter 10.9. Infection with Newcastle disease virus, given that the revised Glossary definition for poultry was adopted in 2021 there was no need to include a definition in a disease-specific chapter.

While acknowledging that Chapter 10.9. may benefit from other updates, the Commission informed Members that the current revision would be limited to addressing this change for consistency with other

chapters, and that a review of other aspects of the chapter would be considered for prioritisation in the future.

The proposed deletion of the definition from Article 10.9.1. has been circulated for comments twice, the last time in the Commission's September 2022 report.

Discussion

The Code Commission considered the comments received expressing support to the proposed text.

The revised Article 10.9.1. of Chapter 10.9. Infection with Newcastle disease virus, is presented as Annex 11 and will be proposed for adoption at the 90th General Session in May 2023.

EU position

The EU supports the adoption of this revised chapter.

6.8. Bovine spongiform encephalopathy (Chapter 11.4.; Chapter 1.8.; Glossary definitions for 'protein meal' and 'meat-and-bone meal')

Background

In February 2018, the Code Commission and the Scientific Commission agreed to an in-depth review of Chapter 11.4. Bovine spongiform encephalopathy (BSE). WOAH convened four *ad hoc* meetings between July 2018 and March 2019 to draft a revised Chapter 11.4.

At its September 2019 meeting, the Code Commission reviewed the *ad hoc* Group's reports together with the opinion of the Scientific Commission and circulated the revised draft Chapter 11.4. for comments.

At its February 2020 meeting, the Code Commission considered comments received and requested that the joint *ad hoc* Group on BSE risk assessment and surveillance be reconvened to address comments of a technical nature as well as to review Chapter 1.8. Application for official recognition by WOAH of risk status for bovine spongiform encephalopathy, to ensure alignment with the proposed changes in Chapter 11.4.

At its September 2020 meeting, the Code Commission reviewed the joint *ad hoc* Group report and the revised draft Chapters 11.4. and 1.8. and made some additional amendments and circulated the revised chapters for comments in its September 2020 report.

The Code Commission considered comments received at its February 2021, September 2021 and February 2022 meetings, respectively, and amended the chapters, as appropriate, and circulated the revised chapters in each of these meeting reports. Revised draft Chapters 1.8. and 11.4. were proposed for adoption at the 89th General Session in May 2022.

At the 89th General Session, the President of the Code Commission reported that several Members had submitted positions on the revised chapter prior to the General Session, and that while some supported the adoption of the text as proposed, others expressed concerns or did not support its adoption. He also acknowledged that significant amendments had been made to the text at the last two Commission meetings and Members might not have had enough time to adequately review the amended text. Therefore, he proposed to the Assembly the withdrawal of the proposed revised Chapters 11.4. and Chapter 1.8. from adoption, so the Commission could undertake further work and recirculate the chapters for comment.

At its September 2022 meeting, the Code Commission considered comments received during the 89th General Session and prior to the September 2022 meeting, made amendments, and circulated the revised chapters for comments.

Discussion

a) Chapter 11.4. Bovine spongiform encephalopathy

Comments were received from Australia, Brazil, Canada, China (People's Republic of), Japan, New Caledonia, New Zealand, Republic of Korea, Switzerland, the UK and the EU.

General comments

The Code Commission acknowledged the submission of a number of comments proposing how to address atypical BSE in this chapter.

The Code Commission did not agree with a comment not supporting the Code Commission's and the Scientific Commission's conclusion that atypical BSE does not meet the listing criteria, noting that its rationale, together with that of the Scientific Commission, had been stated in its September 2022 report.

The Code Commission explained that once the revised chapters (1.8. and 11.4.) have been adopted, none of the Members will need to notify to WOAH as per Article 1.1.3. the occurrences of atypical BSE, and noted that the scope of BSE risk assessment described in point 1 of Article 11.4.2. and point 1 of Article 11.4.3. would be limited to classical BSE. In response to a comment, the Code Commission, in agreement with the Scientific Commission, noted that information on any animal affected by atypical BSE would be collected as part of the annual reconfirmation in substantiating the effectiveness of the surveillance system. During annual reconfirmations (and when submitting a dossier for the official recognition of a BSE risk status), Members will also need to document that there are measures in place to prevent recycling of the BSE agents, and provide evidence of the effectiveness of those measures, including the destruction or disposal of BSE cases and animal affected by atypical BSE.

The Code Commission clarified that, when applying for an official recognition of BSE risk status, Members will need to submit data on the BSE risk assessment as well as data on the ongoing implementation of a surveillance programme for BSE (described in point 2 of Article 11.4.2. and point 2 of Article 11.4.3.), and on the history of occurrence and management of cases of BSE and bovines affected by atypical BSE (described in point 3 of Article 11.4.2. and points 3 and 4 of Article 11.4.3.). The Code Commission emphasised that the provisions on atypical BSE are essential because the potential for recycling of atypical BSE cannot be ruled out and thus should be avoided. The Commission encouraged Members to refer to the details explained by the Scientific Commission in its September 2022 meeting report.

Based on this position, the Code Commission made some additional amendments to the chapter (as well as Chapter 1.8.) for clarity.

The Commission explained that it was not necessary to change the title of the chapter to 'classical bovine spongiform encephalopathy' as some provisions described in the chapter are not limited to classical BSE.

The Code Commission also acknowledged comments requesting WOAH to publish the BSE surveillance guidelines as soon as possible, and encouraged Members to refer to the February 2023 Scientific Commission report.

In response to a Member's request for sufficient transition period to be allowed after the adoption of the revised chapters to ensure that Members can prepare for and effectively implement the revised surveillance provisions mainly in terms of budgetary planning, the Code Commission as well as the Scientific Commission were of the view that the proposed revisions should reduce the cost of surveillance and Members already having an official status based on the current BSE standards should already meet the requirements of the revised standards. The Code Commission also reminded Members that it had been explained in the September 2022 Scientific Commission report that the procedures for official recognition and annual reconfirmation of BSE risk status will be delayed for one year after the adoption of the BSE chapters.

Similarly, in response to a comment querying when the revised annual reconfirmation form for maintenance of BSE risk status will be re-circulated to Members, the Code Commission encouraged Members to refer to the September 2022 Scientific Commission report where the latest version was

shared. The final version, to be used for the annual reconfirmation in 2024, will be finalised after the adoption of the revised chapters and shared with Members in the September 2023 meeting report of the Scientific Commission.

In response to a comment stating that WOAH should work in line with the provisions of its Basic Texts stating that 'in making decisions to adopt, amend or delete standards, the Assembly shall make every effort to reach agreement by consensus', the Commission would like to remind Members that the revised chapter has been circulated for comments six times, with a huge implication of experts from ad hoc groups and specialist commissions, and that at the General Session in May 2022 the proposal of the chapters for adoption was postponed until May 2023 in order to get the best possible version to reach agreement by consensus. It also highlighted that it was now up to the Assembly indeed to make the effort to reach this consensus.

Article 11.4.1.

In point 1, in response to comments to clarify the last sentence, the Code Commission agreed to replace 'but' with 'although' to reflect that both parts of the sentence are equally important for the rest of this chapter.

In point 3, the Code Commission agreed to delete 'the immunohistochemical (IHC) or immunochemical' given that this level of detail can be found in the *Terrestrial Manual* and is not necessary in the *Terrestrial Code*. In addition, the Commission agreed to replace 'C-type' BSE with 'classical' BSE, to improve the readability.

Article 11.4.2.

In point 1(b)(i), in the second bullet point, in response to a comment on Article 1.8.5., the Code Commission, in agreement with the Scientific Commission, agreed to add 'including the use of fertilisers containing ruminant proteins on land for grazing or harvesting forage' at the end of the point, for clarity. (See Article 1.8.5. below for more details)

In point 1(d), the Code Commission agreed to delete 'to determine the date from which the risk of BSE agents being recycled within the bovine population has been negligible' and add this text at the end of the article, including a reference to points 1 to 3. The Commission explained that the intention of this modification was to clarify that the 'date from which the risk of BSE agents being recycled within the bovine population has been negligible' is determined when Members determine the BSE risk of the country, zone or compartment following all the criteria described in points 1 to 3 of the article (i.e. not only point 1 on BSE risk assessment).

In line with this position, the Commission clarified that 'classical' should not be added in the phrase 'date from which the risk of BSE agents being recycled within the bovine population has been negligible'.

Article 11.4.3.

In points 3(b)(i) and (ii), the Code Commission did not agree with a comment to add 'classical' before 'BSE' based on the same rationale described above in point 1(d) of Article 11.4.2.

In point 4, in response to a comment on the risk that may be represented by cohort animals, the Code Commission reiterated that the *ad hoc* Group on BSE risk assessment that met in July 2018 had concluded that any risks associated with cohort animals would be effectively eliminated as long as measures including a feed ban and the removal and destruction of commodities listed in Article 11.4.14. had been continuously and effectively implemented, and an effective surveillance system for the detection and investigation of cases is in place.

In point 4, the Code Commission did not agree with a comment to replace 'animal feed chain' with 'ruminant feed chain' as it considered that 'completely destroyed or disposed of' noted in this point would

ensure that they do not enter any feed chain. Nevertheless, the Commission agreed to delete 'animal' as it considered it to be redundant given that 'feed' is a defined term in the Glossary of the *Terrestrial Code*.

Article 11.4.4.

The Code Commission did not agree with a comment that controlled risk countries should be required to annually declare the date from which all conditions have been continuously in place. The Commission explained that (as described above in General comments), if Members having a controlled BSE risk status cannot demonstrate, in the annual reconfirmation campaign, that they continue to comply with points 1 to 4 of Article 11.4.3., they will lose their BSE risk status. In addition, the Commission reminded Members that, as described in the September 2021 Scientific Commission report, the date from which recycling of BSE agents could be considered negligible for Members having a negligible BSE risk status would be at least 8 years prior to the year of official recognition by WOAH, and for those having a controlled BSE risk status it would be at least from the year of official recognition by WOAH.

Article 11.4.5bis.

The Code Commission, in agreement with the Scientific Commission, agreed to add a paragraph to clarify that the BSE risk status of a country or zone is not affected by imported cases of BSE or cases of BSE born before the date from which the risk of BSE agents being recycled within the bovine population has been negligible, or by any bovine affected by atypical BSE, as long as they are managed in accordance with Articles 11.4.3. or 11.4.4.

The Code Commission did not agree with a comment to add 'classical' before 'BSE' based on the similar rationale described above (point 1(d) of Article 11.4.2.). The Commission also emphasised that, as described in September 2022 Scientific Commission report, the control measures in place for mitigating the risk of classical BSE would also be relevant to prevent any potential recycling and amplification of atypical BSE in a bovine population.

The Code Commission, in agreement with the Scientific Commission, did not agree with a comment to add a sentence 'However, when the Member Country fails to identify the source of infection, it could remove the environmental risk, including the replacement of feed chain' at the end of the article. The Commission emphasised that, as described above, if Members having official BSE risk status cannot demonstrate that they continue to comply with points 1 to 4 of Article 11.4.3., they will lose the official BSE risk status, and reiterated that such measures to remove the environmental risk may not be justified, noting that a recently published modelling study on cases born after reinforced feed bans (BARB), which was referred to in February 2022 Code Commission report, showed an exponential decline in the number of the BARB cases. The Commission also reiterated that occurrence of a limited number of indigenous cases of BSE in animals born after the date from which the risk of BSE agents being recycled within the bovine population has been negligible did not necessarily reflect a failure of effective control measures as repeatedly explained in previous relevant Commission and *ad hoc* Group reports.

Article 11.4.7.

The Code Commission did not agree with a comment stating that point 1 is not necessary for a negligible BSE risk country, as it considered that the animal identification system was essential to demonstrate that the animal was born after the 'date'. The Commission also did not agree with a comment that proposed that negligible and controlled risk requirements be described separately in this article, as in the end there was no difference between the recommendations for the two risk statuses.

The Code Commission agreed with a comment to replace 'not' with 'never' for clarity. The Commission noted that this amendment will also be made in Articles 11.4.8. and 11.4.11.

Article 11.4.10.

The Code Commission did not agree with a comment to add 'enabling it to be traced throughout its lifetime'. The Commission explained that, unlike Article 11.4.8. on recommendations for live bovines, the

provision ‘throughout its lifetime’ is not relevant for animal products. The Commission noted that this response also applies to similar comments submitted for Articles 11.4.11., 11.4.12. and 11.4.13.

The Code Commission noted some comments that did not support the deletion of a part of point 3(b) and all of point 4 which had been proposed at its September 2022 meeting. The Commission agreed that the risk derived from a bovine population born before the date (from which the risk of BSE agents being recycled within the bovine population has been demonstrated to be negligible) in controlled BSE risk countries or zones was higher than in negligible BSE risk countries or zones, and thus agreed to make amendments to reinstate the reference to the different subpopulations for Members with the controlled BSE risk status. On the other hand, the Commission emphasised that the similar provision for Members with a negligible BSE risk status were not justified given the global context and epidemiology with respect to diminishing overall BSE and vCJD risks. The Commission noted that similar amendments also apply to Article 11.4.13. on recommendations for blood and blood products.

Article 11.4.11.

The Code Commission agreed with a comment to delete ‘or compartment’ from the heading of the article to align with amendments made in Articles 11.4.5. and 11.4.8.

Article 11.4.14.

In point 1, in response to a comment that it was necessary to keep the list of SRMs as they are in the BSE chapter, the Commission reminded Members that the *ad hoc* Group on BSE (August 2016) as well as the *ad hoc* Group on BSE risk assessment and surveillance (March 2019) had recommended that the restriction applicable to tonsils be removed based on scientific evidence (EFSA Journal 2011 ;9(1):1947).

The Code Commission did not agree with a comment requesting the addition of an article to provide a wider range of options for safe trade in fertilisers, and noted that the *Terrestrial Code* does not generally address the end use of traded commodities. As a consequence of this discussion, the Commission agreed to delete the reference to end use of the commodities from the headings of Articles 11.4.15., 11.4.15bis. and 11.4.16.

Article 11.4.17.

The Code Commission did not agree with a comment that did not support the addition of point 2 which had been proposed at its September 2022 meeting. The Commission reiterated that this provision ensures flexibility for equivalent measures and is used in other disease-specific chapters, such as Article 10.4.19. of Chapter 10.4., Article 15.1.22. of Chapter 15.1. and Article 15.2.26. of Chapter 15.2.

Article 11.4.18.

In point 2, the Code Commission, in agreement with the Scientific Commission, did not agree with a comment to set an age limit of 30 months for the BSE passive surveillance. Both Commissions explained that the rationale not to set an age limit for testing had been provided in the October 2018 report of the *ad hoc* Group on BSE surveillance.

In the same point, the Code Commission did not agree with a comment stating that it will result in a significant number of bovines that should be considered for sampling. The Commission reiterated that all animals that lie on the clinical spectrum of BSE should be targeted by the BSE surveillance and, out of those animals, only animals listed in points 2(a) to 2(d) should be reported and followed up with appropriate laboratory testing. The Commission clarified that the scope of the word ‘BSE surveillance’ is not limited to ‘sampling for laboratory testing’ nor ‘laboratory testing’ itself, but rather covers processes such as bovine keepers’ contact with veterinarians to inform the presence of bovines that lie on the clinical spectrum of BSE, which occurs before reporting animals listed in points 2(a) to 2(d).

In point 2, in the fourth paragraph, the Code Commission did not agree with a comment to clarify the texts, as it considered them sufficiently clear and in line with the position described above.

In points 2(a) to 2(d), in response to comments to clarify, the Code Commission, in agreement with the Scientific Commission, agreed to make necessary amendments as it considered that the term 'ruling out' implies the need to test for multiple causes of behavioural or neurological signs. The Commission explained that only animals whose clinical presentation cannot be attributed to these causes 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, including discrimination between atypical and classical BSE strains.

In point 3(d), in the first bullet point, in response to a comment, the Code Commission made some amendments to the point and created a new bullet point to clarify it based on the position described above.

b) Chapter 1.8. Application for official recognition by WOAH of risk status for bovine spongiform encephalopathy

Comments were received from Canada, New Zealand, New Caledonia, Switzerland, the UK, the USA and the EU.

General comments

In response to comments received, and amendments made in Chapter 11.4., the Code Commission made relevant amendments to Chapter 1.8.

In response to a comment asking if the risk assessment could be reviewed prior to the submission of the entire dossier for application for a BSE risk status, the Code Commission encouraged Members to refer to the February 2023 Scientific Commission report. The Code Commission agreed with the Scientific Commission that the risk assessment is only one of the criteria for official recognition of BSE risk status as specified in Article 11.4.3.

Article 1.8.1.

The Code Commission moved the first indented point 'history of occurrence and management of BSE in the country or zone' to the end to align with the order used in Chapter 11.4., i.e. BSE risk assessment (described in point 1 of Article 11.4.3.), BSE surveillance (described in point 2 of Article 11.4.3.) and the history of occurrence and management of BSE in the country or zone (described in points 3 and 4 of Article 11.4.3.). Further, following these amendments, the Commission proposed moving the Article 1.8.2. to after Article 1.8.6. (i.e. developing Article 1.8.6bis.) and, in the headings of Articles 1.8.5., 1.8.6. and 1.8.6bis., adding references to the relevant points of articles in Chapter 11.4. The Commission explained that these amendments would clarify that these three articles are conditions required to obtain the BSE risk status described in Articles 11.4.3. and 11.4.4.

Article 1.8.5.

In the third paragraph of point 2(a)(ii), the Code Commission explained that the point clearly provided a description of the feeding practices and specifically asked for i) whether or not fertilisers containing ruminant proteins are applied to land where bovines graze or where forage is harvested for feeding bovines, and ii) to provide information on the extent and frequency of their use; nevertheless, it did not specify the need to describe any risk mitigation measures in place. The Commission further explained that while the parameters for rendering specified in revised Article 11.4.17. reduce the infectivity of the BSE agent in bovine protein meal, these do not completely eliminate infectivity and therefore the risk via accidental ingestion (or exposure) when grazing or harvesting fodder remains. In this regard, the Code Commission in agreement with the Scientific Commission, agreed to make amendments for clarity. (See Article 11.4.2. above)

In the first and fourth paragraphs of point 2(a)(ii) and in point 2(b)(i), the Code Commission did not agree with a comment to replace 'ruminants' with 'bovines'. The Commission reminded Members that, as described in points 1(a) and 1(b) of Article 11.4.3., ruminant-to-ruminant feed ban is one of the conditions to obtain official BSE risk status.

In point 2(a)(iii), the Code Commission noted a comment to replace 'waste' with 'by-products' or with 'bovine material', and explained that this comment will be addressed as part of the ongoing work on the use of the term 'animal by-products' in the *Terrestrial Code* (See item 7.1 of this report). The Commission noted that this response also applies to a similar comment submitted for point 2(a)(iv).

In point 4(c), to align with the amendments described in point 1(d) of Article 11.4.2. above, the Code Commission agreed to delete the point and to add the corresponding sentence in Article 1.8.1.

Article 1.8.6.

In point 2(b), the Code Commission noted a comment querying whether the proposed text described a targeted enhanced passive surveillance system or active targeted surveillance system. The Commission reiterated that all animals on the clinical spectrum of BSE should be targeted by BSE surveillance and, out of those animals, only animals listed in points 2(a) to 2(d) should be reported and followed up with appropriate laboratory testing (see Article 11.4.18. above). In the same point, the Commission did not agree with a comment to replace 'supportive measures … BSE and for' with 'awareness system that supports', as point 1 had provisions on awareness programmes.

In point 2(d), the Code Commission agreed with a comment to replace 'framework' with 'reporting system' as it was consistent with the previous sentence.

In point 3(c), the Code Commission agreed with a comment that it was necessary to adequately monitor and discriminate classical and atypical BSE, and thus made an amendment. In the same point, in response to a comment to reinstate 'classical and atypical', the Commission explained that the proposed amendment would address this comment.

In point 4(b), the Code Commission did not agree with a comment to add 'showing the signs' after 'animals' as points 2(a) to 2(d) of Article 11.4.18. lists animals that should be reported, not clinical signs.

In Table 2, in response to a comment, the Code Commission made amendments to the table for clarity. In response to a comment stating that this table will be part of the annual reconfirmation form, the Code Commission reminded Members that the latest draft revised form was provided in the meeting report of the June 2022 *ad hoc* Group, and that it will be further revised once the BSE chapters have been adopted (see general comments in Chapter 11.4.).

Article 1.8.6bis. (moved from Article 1.8.2.)

In point 1, the Code Commission did not agree with a comment to add 'of each indigenous case' at the end of the point. The Commission explained that the purpose of this point was to provide general information on cases of classical BSE that applicants have detected, either indigenous or imported (which is used to assess the applicant's compliance with point 3 of Article 11.4.3.), whereas point (b) is to assess the applicant's compliance with point 3(b) of Article 11.4.3.

The Code Commission clarified that Members with an official recognition of BSE risk status are required to demonstrate that cases of BSE or bovines affected by atypical BSE were completely destroyed or disposed of, to ensure they are excluded from the feed chain, considering that the risk of recycling of atypical BSE agent cannot be ruled out.

c) Glossary definitions for protein meal and meat-and-bone meal

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

With regard to the proposed definition for 'protein meal', the Code Commission agreed with a comment to replace 'molecular weight' with 'molecular mass' as Dalton is a measure of mass.

The Code Commission noted that the other comments supported the proposed changes.

The revised Chapter 11.4. Bovine spongiform encephalopathy, and the revised Chapter 1.8. Application for official recognition by WOAH of risk status for bovine spongiform encephalopathy, and the Glossary definition for 'protein meal' and deletion of definition for 'meat-and-bone meal' are presented as Annex 12, Annex 13 and as part of Annex 5, respectively, and will be proposed for adoption at the 90th General Session in May 2023.

EU position

The EU thanks the Code Commission for the latest version of the revised Chapters 11.4. and 1.8. and appreciates the amendments introduced to address some of the EU comments submitted previously. Comments are inserted in the text of Annexes 12 and 13.

6.9. Contagious equine metritis (Chapter 12.2.)

Comments were received from Canada, China (People's Rep. of), New Caledonia, New Zealand, Switzerland, the UK, the USA and the EU.

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 and to undertake a comprehensive revision. The Commission requested that experts be convened to undertake this work.

An electronic expert consultation was conducted in 2019 and its report, including a draft revised chapter, was endorsed by the Scientific Commission at its February 2020 meeting. At its September 2020 meeting, the Code Commission considered the draft revised chapter, made additional amendments, and circulated the revised chapter for comments.

At its February 2021 meeting, the Code Commission reviewed the comments received and agreed to defer its discussion until its September 2021 meeting, due to time constraints. The Secretariat sought the advice of the Scientific Commission and the Biological Standards Commission on selected comments. At its February 2022 meeting, the Code Commission considered the comments received, the advice provided by the Scientific Commission, the Biological Standards Commission, and subject-matter experts, and circulated the revised chapter.

The revised text has been circulated four times, the last time in the Commission's September 2022 report.

Discussion

Article 12.2.1.

In the first paragraph, point 1, regarding the use of the terms 'subclinical' and asymptomatic' the Code Commission noted that there was a mistake in the September 2022 meeting report, and clarified that 'subclinical' refers to a state where a disease is not detectable by clinical observations, while 'asymptomatic' refers to an infection not causing any sign of illness or disease, and confirmed that 'asymptomatic' was the appropriate term to be used in this point.

Also in point 1, the Code Commission did not agree to delete 'and identified as such' as this reflected the opinion of the Biological Standards Commission.

In point 2 and 3, the Code Commission amended the text for harmonisation and consistency with other chapters.

In the first indent of the first paragraph, the Code Commission agreed with a comment to acknowledge the possibility to treat the animals effectively, as considered in point 4(b) of Article 12.2.3.

Article 12.2.2.

In the first paragraph, the Code Commission amended the text for harmonisation and consistency with other chapters.

The Code Commission did not agree with a comment to exclude ‘geldings’ from the list of safe commodities, and reiterated the rationale captured in the Code Commission’s September 2022 meeting report. It highlighted that there was no evidence of the disease ever being transmitted by ‘geldings’.

Article 12.2.3.

In point 2(c), in response to comments, the Code Commission amended the text for clarity regarding sample collection and timing after antibiotic treatment. The Commission made the same amendment in all relevant places of the chapter.

In point 2(d), The Code Commission, in response to a comment, clarified that ‘stored semen’, for the purposes of this chapter, should be considered as stored frozen semen, and not fresh semen awaiting being used.

In point 2(d), the Code Commission replaced the term ‘genetic material’ with nucleic acid, for consistency with the use of this term in the chapter.

In point 3(c) the Commission replaced ‘germplasm’ with ‘germinal products’ as this is a more commonly used term and adds clarity. This amendment was applied throughout the chapter.

In point 4(a), the Code Commission did not agree with a comment questioning the need to include this recommendation, as it considered it important to emphasise the need to disinfect every establishment.

In point 4(b), the Code Commission agreed with a comment to align the wording with other parts of the chapter. The Commission also agreed to harmonise the text regarding sample collection.

In point 4(c) the Code Commission agreed with a comment to amend the text to clarify the destruction of semen samples.

Article 12.2.4.

The code commission modified the point 2(b)(ii) for clarity and to align it with other articles, regarding the period of time for different treatments not to be applied prior to the first sample collection.

Article 12.2.5.

In the title, the Code Commission agreed to replace ‘horses’ with ‘stallions and mares’, to be precise as to the type of horses considered.

In point 1 (c), the Code Commission did not agree with a comment to remove the point and explained that even if it is already covered by the definition of ‘temporary importation’ in Article 12.2.1., it is necessary to mention it as part of the specific points Veterinary Authorities should require.

Article 12.2.6.

In the title, the Code Commission agreed to replace ‘horses’ with ‘stallions, to be precise as to the type of horses considered.

Article 12.2.7.

In point 1, the Code Commission agreed to add a cross-reference to Chapter 4.8 and Article 12.2.6.

Article 12.2.8.

In point 2 the Code Commission agreed to replace 'bacteriological' with 'culture for *T. equigenitalis*' for clarity.

The revised Chapter 12.2. Contagious equine metritis, is presented as Annex 14, and will be proposed for adoption at the 90th General Session in May 2023.

EU position

The EU thanks the Code Commission and in general supports the adoption of this revised chapter. A comment is inserted in the text of Annex 14.

6.10. Infection with equine influenza virus (Chapter 12.6.)

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

Background

At its February 2019 meeting, the Code Commission proposed amendments to Article 12.6.6. of Chapter 12.6. Infection with equine influenza virus, based on a WOAH Reference Laboratory work on equine influenza vaccination protocols prior to shipment of horses. The Commission circulated the revised article for comments.

At its February 2021 meeting, the Code Commission reviewed the comments received and agreed with a proposal to revise `the case definition that the Scientific Commission had endorsed at its February 2021 meeting.

At its February 2022 meeting, the Code Commission considered the comments received and agreed to review the entire chapter and proposed further amendments to other articles to incorporate the changes proposed by the Scientific Commission regarding the case definition and include recommendations for the temporary importation of horses in line with the new approach taken for the proposed revised Chapter 12.2. Contagious equine metritis, and Chapter 12.7. Equine piroplasmosis.

The revised Chapter 12.6. has been circulated three times for comments, the last time in the Commission's September 2022 report.

Discussion

The Code Commission considered the comments received.

Article 12.6.1.

In the first paragraph, the Code Commission did not agree with a comment to delete H7N7 subtype as it still met the listing criteria described in Chapter 1.2. even if no case has been reported recently. The Commission reminded Members that infection with rinderpest virus remains listed even after its eradication.

In point 3, the Commission agreed to delete the term 'virus' after EIV as it is already covered by the initialism.

In the seventh paragraph, in response to the Biological Standards Commission's opinion on the length of the infective period, the Commission did not agree with the proposal to keep the suggested 21 days. The Biological Standards Commission explained that the infective period of 10 days was based on the virus isolation in embryonated eggs, which is not a sensitive method, thus recommended keeping the 21 days as precautionary measures. The Commission agreed with the need for a precautionary approach given the impact of the introduction of the disease, especially in naïve countries but agreed that 21 days was

unnecessarily long. Therefore, the Commission proposed a period of 14 days to take into account the latent period of up to 4 days and the fact that infected horses have been found to shed the virus for up to 10 days via nasal discharge. This change has been applied throughout the chapter for consistency.

Article 12.6.2.

In the first paragraph, the Code Commission amended the text for harmonisation and consistency with other chapters.

In point 2, the Commission considered a comment regarding the need for recommendations for the importation of in vitro embryos and agreed that the point is relevant and suggested that this be looked into once more consolidated data are available (see item 9.2 of this report).

Article 12.6.4.

The Commission did not agree with a comment stating that adapting the surveillance as mentioned in the last sentence of the first paragraph seemed to be in contradiction with the Commission report. The Commission reminded Members that equine influenza (EI) was defined as an infection of domestic and captive wild equids, being the categories of equids that cause the greatest global concern in terms of trade. However, Members who want to seek freedom from EI also need to demonstrate freedom in wild equids.

Article 12.6.4bis.

In the first paragraph, the Commission did not agree with a comment to change '12 months' with '24 months' to harmonise with the first paragraph of Article 12.6.4. as they are not referring to the same concept; the latter being about regaining freedom after an outbreak, which takes less time if well managed. The Commission agreed to add a sentence to clarify that to recover freedom actions must be taken in accordance with Chapter 4.19. and Article 12.6.4.

The revised Chapter 12.6. Infection with equine influenza virus, is presented as Annex 15 and will be proposed for adoption at the 90th General Session in May 2023.

EU position

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

6.11. Equine piroplasmosis (Chapter 12.7.)

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

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 and it agreed that given this chapter had not been reviewed for some time, a comprehensive revision should be undertaken. The Commission requested that experts be convened to undertake this work.

An electronic expert consultation was conducted in 2019 and its report, including the draft revised chapter, was endorsed by the Scientific Commission at its February 2020 meeting. At its September 2020 meeting, the Code Commission considered the draft revised chapter, made additional amendments, and circulated it for comments.

At its February 2021 meeting, the Code Commission requested the advice of the Scientific Commission and the Biological Standards Commission on selected comments. The Scientific Commission asked for additional expert advice and an expert group on equine piroplasmosis was consulted electronically and its report was discussed at the Scientific Commission September 2021 meeting.

The Code Commission, at its February 2022 meeting discussed the comments previously received, together with the advice from the Scientific Commission and the Biological Standards Commission and circulated the revised chapter for comments.

At its September 2022 meeting, the Code Commission considered comments received, made additional amendments, and circulated the revised draft chapter for comments.

Discussion

The Code Commission considered the comments received.

Article 12.7.1.

In the first paragraph, the Commission did not agree to replace asymptomatic with subclinical and reiterated that 'subclinical' refers to a state where a disease is not detectable by clinical observations, while 'asymptomatic' refers to an infection not causing any sign of illness or disease, and that 'asymptomatic' was the appropriate term in the context of this chapter.

In the third paragraph, the Commission did not agree to add the genera of ticks *Ixodes* and *Haemaphysallis* to the list of competent vectors as there is no evidence that they are competent vectors under natural conditions and it is not an exhaustive list.

In the third paragraph, the Commission noted a comment highlighting the fact that the genus *Amblyomma* was not mentioned in the corresponding *Terrestrial Manual* chapter. The Commission confirmed that the Biological Standards Commission agreed that it should be added for consistency.

In point 1, the Commission did not agree with a comment to add 'regardless of whether or not it is showing clinical signs of diseases' as it is implicit.

In points 2 and 3, the Commission agreed with a comment to replace 'identified' with 'detected' for consistency with other chapters in the Code and with the corresponding *Terrestrial Manual* chapter.

Article 12.7.2.

In the first paragraph, the Code Commission amended the text for harmonisation and consistency with other chapters.

In point 8, the Commission agreed with a comment to add a reference to Chapter 4.8. as it is relevant.

Article 12.7.3.

In point 1, the Commission, in agreement with the Scientific Commission, did not agree with a comment suggesting deleting point 1 on historical freedom because the provisions under point 2 of Article 1.4.6. are not applicable to *T. equi* or *B. caballi* as the majority of infections are asymptomatic.

In point 2(a)(ii), the Commission agreed with a comment to clarify the duration of active surveillance needed, changing 'in the past six years' to 'for the past six years' to make it clear that surveillance should be continuous over the six years prior to the day that free status is confirmed.

In point 2(b), the Commission agreed with a comment to replace 'equids' with 'horses' as the provisions apply to horses only and not to other equids.

Article 12.7.4.

The Commission noted a comment regarding the lack of conditions for recovery, and explained that considering the difficulties to prove the absence of infection of EP due to its specific characteristics, it was not convenient to establish reduced conditions for recovery of freedom other than the ones of Art.12.7.3.

Article 12.7.5.

In point 2 (b)(i), the Commission did not agree to modify the text as it is aligned with the *Terrestrial Manual*.

Article 12.7.6.

In point 1(c), the Commission did not agree with a comment to add 'in advance' at the end of the sentence as it is implicit.

Article 12.7.8.

The Commission agreed with a comment to clarify that we are protecting the equids and not the establishments. It also agreed to merge Article 12.7.7. with Article 12.7.8. and renumbered the points accordingly.

Article 12.7.9.

In the third paragraph of point 1, the Commission agreed with a comment to add 'breeders' and also added 'keepers' and deleted 'workers' for consistency with other chapters.

In the fourth paragraph of point 1, the Commission agreed with a comment to simplify and harmonise the text referring to the early warning system in accordance with Article 1.4.5. by deleting the first two indents and merging the third indent with the paragraph.

In point 2, the Commission did not agree with a comment to specify the clinical signs of Equine piroplasmosis as done in Chapter 12.8. as this was not relevant in the context of this disease.

In point 5, the Commission did not agree with a comment to clarify that active surveillance for vectors is not compulsory for freedom as it is clearly mentioned under point 1, first paragraph.

In point 5, third paragraph, the Commission agreed with a comment to replace 'Ixodidae' with 'competent' for consistency with the first paragraph.

The revised Chapter 12.7. Equine piroplasmosis, is presented as Annex 16 and will be proposed for adoption at the 90th General Session in May 2023.

EU position

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

6.12. Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* (New Chapter 14.X.)

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

Background

A new Chapter 14.X. Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* was first circulated for comment in the Code Commission's September 2017 report, 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 comments which questioned the listing of some *Theileria* spp., the Commission agreed to seek expert advice regarding listing and to put on hold the review of comments received.

At its September 2019 meeting, the Code Commission was informed that *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* had been assessed by experts against the criteria for listing in accordance with Chapter 1.2. and they were found to meet the criteria for listing (refer to Annex 19 of the February 2019 report of the Scientific Commission).

At its September 2020 meeting, the Code Commission agreed not to progress this work until the Biological Standards Commission finalised work on a new chapter for the *Terrestrial Manual* given the importance of having a recommendation for diagnostic tests for these pathogenic agents.

At its February 2022 meeting, noting that a new chapter for the *Terrestrial Manual* was to be proposed for adoption in May 2022, the Code Commission discussed the comments previously received on the proposed new Chapter 14.X. for the *Terrestrial Code*, and circulated the proposed chapter and a revised Article 1.3.3. for comments.

At its September 2022 meeting, the Code Commission discussed the comments received, made additional amendments, and circulated the revised chapter for comments.

Discussion

General Comments

In response to a comment requesting to harmonise across all disease-specific chapters the use of 'not free from infection', 'infected with' and 'considered infected with', the Code Commission explained that these terms can have specific meanings for different diseases (e.g. 'not free from infection' may include 'infected with' and 'unknown'), and thus applying the same wording across all chapters may cause confusion.

Article 14.X.1.

In the first paragraph, the Code Commission reminded that in accordance with agreed convention for the Code terminology, the term 'bovines', if not defined otherwise in the relevant chapters, means by default all members of the tribe Bovini (see item 5.15 of the September 2022 Code Commission report and Item 6.16 of this report); it amended the paragraph to reflect this approach.

In point 1, the Code Commission did not agree with a comment to replace 'observed' with 'detected, isolated'. In point 2, the Commission agreed with a comment to replace 'identified' with 'detected'. The Commission explained its rationale for the use of these terms in item 3.2 of this report.

In points 2 and 3, the Code Commission did not agree with a comment to add 'the animal (is)' before 'epidemiologically linked' and 'giving cause', as it considered that the text was clear as currently written.

Article 14.X.2.

In the first paragraph, the Code Commission amended the text for harmonisation and consistency with other chapters.

Article 14.X.3.

For point 1(c), the Code Commission did not agree with a comment to delete this point as the scientific evidence, that it had previously requested, to support this proposed modification was not provided by the Member. The Commission reiterated that if a country demonstrates the absence of competent vectors that are essential for the transmission of the disease, the country should be considered free from the infection without having to demonstrate the absence of cases.

In point 2, the Code Commission did not agree with a comment to add 'and epidemiological investigation demonstrates no transmission of infection', as it considered that the point was covered by the condition 'provided they were introduced in accordance with this chapter', and implementing the recommendation provided in Article 14.X.5. would ensure safe trade of sheep and goats.

The new Chapter 14.X. Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi*, is presented as Annex 17 and will be proposed for adoption at the 90th General Session in May 2023.

EU position

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

6.13. Middle East Respiratory Syndrome Coronavirus (MERS-CoV) (New Chapter 16.1.)

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

Background

At its September 2019 meeting, the Code Commission agreed to add the development of a new chapter for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) to its work programme, pending the adoption of the inclusion of 'infection of dromedary camels with Middle East respiratory syndrome coronavirus' as a WOAH listed disease in Chapter 1.3., and a new chapter on this disease in the *Terrestrial Manual.*

Following the adoption of the abovementioned texts in May 2021, at its February 2022 meeting, the Code Commission agreed to draft a new chapter for infection with MERS-CoV, noting that at this time it would only consist of a single article for the general provisions, including the definition of its occurrence. A new Chapter X.X. Infection with MERS-CoV was circulated for comment in the Code Commission's February 2022 report.

At its September 2022 meeting, the Code Commission discussed the comments received and amended the text to align with the corresponding *Terrestrial Manual* chapter as well as other chapters in the *Terrestrial Code* and circulated the chapter for a second time.

Discussion

Taking into consideration the proposal to add a new Section 16. Camelidae to the *Terrestrial Code* (see item 6.3 of this report), where this Chapter will be placed, the Commission amended the number of the chapter to 'Chapter 16.1.'.

In the third paragraph of Article 16.1.1., the Code Commission acknowledged a concern regarding the disease impact on humans, and recalled that it had replaced 'human infection have a significant public health impact' with 'it causes severe disease in humans' at its previous meeting, the Commission noted that although morbidity is low in humans it can cause severe disease in humans. The Commission agreed to amend the text to clarify this point.

In point 1, the Code Commission did not agree to delete 'and identified as such' as this reflected the opinion of the Biological Standards Commission.

In point 2, the Code Commission agreed with a comment to add 'or to a human infected with MERS-CoV'.

The new Chapter 16.1. Infection with Middle East respiratory syndrome coronavirus, is presented as Annex 18 and will be proposed for adoption at the 90th General Session in May 2023.

EU position

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

6.14. Infection with *Leishmania* spp. (leishmaniosis) (New Chapter 8.Y.)

Comments were received from Canada, China, Switzerland, the UK and the EU.

Background

At its September 2020 meeting, the Code Commission agreed to add the development of a new chapter for Leishmaniosis to its work programme.

At its February 2022 meeting, the Code Commission agreed to develop a new Chapter X.Y. Infection with *Leishmania spp.* (Leishmaniosis), based on the case definition developed by subject matter experts, and endorsed by the Scientific Commission in February 2021. A new Chapter X.Y. consisting of a single article for the general provisions including the definition of its occurrence was developed by the Commission and circulated for comment in its February 2022 report.

At its September 2022 meeting, the Code Commission discussed the comments received and amended the text to align with the *Terrestrial Manual* and other chapters in the *Terrestrial Code,* and circulated the new Chapter X.Y. Infection with *Leishmania spp.* (Leishmaniosis), for a second time.

Discussion

Taking into consideration the proposal to amend Chapter 1.3. to move 'Infection with *Leishmania* spp' to Article 1.3.1. multiple species diseases (see item 6.3 of this report), the Commission acknowledged that this would mean placing this Chapter in Section 8 of the *Terrestrial Code,* and amended the chapter number to 'Chapter 8.Y.'.

In the first paragraph, in response to comments on the taxonomy of animal species, the Code Commission noted that for the purposes of the *Terrestrial Code*, only dogs and cats should be considered as susceptible species due to their epidemiologically significant role. The Commission added '(hereafter 'susceptible animal')' after 'dogs and cats' and, in points 1 to 3, replaced 'a dog or a cat' with 'a susceptible animal' for consistency with other relevant chapters.

The Code Commission acknowledged comments asking why the definition of the disease is being included in the new chapter even though it is only used once. The Commission explained that it was a convention to provide a definition when the common name of the disease was frequently used, and that in this case it was needed for consistency with the *Terrestrial Manual* Chapter 3.1.11. The Commission also noted that this would be useful if more articles were to be developed at a later time.

In point 3, in response to a comment questioning why vaccination was referred to in the text, the Code Commission explained that it had been included because, even in the absence of an International Standard, vaccination was applied in some countries and this should be taken into consideration when interpreting the laboratory results.

The new Chapter 8.Y. Infection with *Leishmania* spp.(Leishmaniosis), is presented as Annex 19 and will be proposed for adoption at the 90th General Session in May 2023.

EU position

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

6.15. Terminology: Use of terms 'fetal', 'foetal', 'fetus' and 'foetus'

Comments were received from Switzerland and the EU.

Background

At its September 2021 meeting, the Code Commission agreed to replace 'foetal'/'foetus' with 'fetal' /'fetus' as this reflected the current usage in scientific literature. It requested that the Secretariat review the use of these terms in the *Terrestrial Code* to determine where it would need to be amended.

At its September 2022 meeting, the Commission considered an analysis prepared by the Secretariat and agreed to replace 'foetal'/'foetus' with 'fetal' /'fetus', respectively, in Article 4.10.3. of Chapter 4.10. Collection and processing of micromanipulated oocytes for embryos from livestock and horses in the English version of the *Terrestrial Code* and circulated this amendment for comment.

Discussion

The Code Commission noted that all comments received were in support of the proposed change.

The revised Article 4.10.3. of Chapter 4.10. Collection and processing of micromanipulated oocytes for embryos from livestock and horses, is presented as Annex 20 and will be proposed for adoption at the 90th General Session in May 2023.

EU position

The EU supports the adoption of this revised article.

6.16. Terminology: Use of terms 'bovid', 'bovidae', 'bovine' and 'cattle'

Comments were received from Canada, Switzerland, the UK, the USA and the EU.

Background

At its September 2022 meeting, the Code Commission considered an analysis prepared by the Secretariat presenting different meanings of these terms (i.e. dictionary definitions & scientific taxonomy classification) and the contexts in which they were used in the *Terrestrial Code*, and concluded that the term 'cattle' (used in the English version of the Code) was not precise in zoological terms and was not possible to be correctly translated into the other WOAH official languages. The Commission thus agreed to stop using the term 'cattle' and to use the following taxonomical classification:

- In English: 'Ruminant(s)', In Spanish: 'Rumiante(s)', In French: 'Ruminant(s)'): meaning all members of the sub-order *Ruminantia*;
- In English: 'Bovid(s)', in Spanish 'Bóvido(s)', in French 'Bovidé(s)': meaning all members of the family Bovidae, including the sub-families *Bovinae*, Caprinae and *Antilopinae;*
- In English: 'Bovine(s)', in Spanish 'Bovino(s)', in French 'Bovin(s)'): meaning all members of the tribe *Bovini*, including the genus *Bos, Bubalus, Bison, and Syncerus;* and, if relevant for a given chapter, a dedicated definition for 'bovine' (possibly by simple enumeration of the concerned species in parenthesis after the term) should be provided to specify the genus or species concerned.

The Code Commission agreed to make the necessary amendments to the texts being currently reviewed in line with this approach in the three languages, and observed that, in the English version, Article 1.3.2., lists 'cattle' diseases and infections, whereas the title of Section 11 of the *Terrestrial Code* is 'Bovidae', and agreed that these should be urgently aligned and amended accordingly, highlighting that this would be in line with the title of Section 3.4. of the *Terrestrial Manual* is 'Bovinae'. The Commission agreed to circulate the proposed amendments to User's guide, Article 1.3.2. and the title of Section 11.

Discussion

In response to a comment requesting a more in-depth explanation of the use of family *Bovidae* and the relevant subfamilies for clarity, the Code Commission agreed to consider adding in User's guide more detailed explanation on some terms such as Bovidae and Leporidae (See item 7.9 of this report) used in the *Terrestrial Code* at its next September meeting.

The revised texts in the User's guide, Article 1.3.2. and the title of Section 11, are presented as parts of Annex 4, Annex 7 and Annex 21, respectively, and will be proposed for adoption at the 90th General Session in May 2023.

EU position

The EU thanks the Code Commission and supports the adoption of the revised User's guide, the revised Chapter 1.3. and the revised texts presented in Annex 21.

6.17. Terminology: Use of terms ‘enzootic’, ‘endemic’, ‘epizootic’ and ‘epidemic’

Comments were received from Switzerland, the UK and the EU.

Background

At its February 2021 meeting, the Code Commission acknowledged that the use of the terms ‘epizootic’, ‘epidemic’ and other related terms was heterogenic across the *Terrestrial Code*, and agreed on the need to address this in detail and added this topic to its work programme.

In June 2021, the *ad hoc* Group on Rift Valley fever suggested considering replacing ‘epizootic’ with ‘epidemic’ throughout Chapter 8.15. Infection with Rift Valley fever, noting that the terminology ‘epizootic’ and ‘inter-epizootic’ had been replaced in the wider scientific community by ‘epidemic’ and ‘inter-epidemic’. At its February 2022 meeting, the Commission agreed to replace ‘epizootic’ with ‘epidemic’ throughout the chapter and requested the Secretariat to review the use of these terms in other parts of the *Terrestrial Code*.

At its September 2022 meeting, the Commission considered the analysis prepared by the Secretariat and agreed to make amendments to Chapters 4.19. (Article 4.19.1.) and 9.3. (Article 9.3.1.) to replace ‘epizootic/enzootic’ with ‘epidemic/endemic’.

Discussion

The Code Commission noted that only comments in support of the proposed change were received.

The revised Article 4.19.1. and Article 9.3.1. are presented as Annex 22 and will be proposed for adoption at the 90th General Session in May 2023.

EU position

The EU supports the adoption of these revised articles.

7. Texts circulated for comments (Annexes Part B)

The Code Commission discussed the following new or revised texts and circulated the texts for comments.

7.1. New Glossary definitions for ‘animal products’, ‘product of animal origin’ and ‘animal by-product’

Background

At its September 2019 meeting, the Code Commission discussed the use of the terms ‘commodities’, ‘animal products’, ‘products of animal origin’ and ‘animal by-products’ in the *Terrestrial Code* based on a discussion paper prepared by a Commission member. The Commission acknowledged the importance of clarifying the use of these terms and whether to develop definitions for some terms. It agreed to continue this work out of session and to discuss further.

At its February 2020 meeting, the Code Commission discussed the use of the terms and the need to clarify the use of these terms and whether to develop definitions for some additional terms and agreed to discuss this at a future meeting.

Discussion

The Code Commission considered an analysis prepared by the Secretariat presenting the usage of the terms ‘commodity’, ‘products of animal origin’, ‘animal products’ and ‘(animal) by-products’ in the *Terrestrial Code*, as well as the usage of similar terms in the *Aquatic Code*.

Noting that 'commodity' was clearly defined in the *Aquatic Code*, the Code Commission agreed that the 'commodity' defined in the Glossary of the *Terrestrial Code* has to be improved as the terms 'products of animal origin' and 'biological products' were not defined. The Commission also agreed that the difference between 'animal products' and 'products of animal origin' was not clear.

To address these issues, the Code Commission agreed to develop a new Glossary definition for 'animal product' and to revise the Glossary definition for 'commodity' as a consequence of the development of this new definition. The Commission explained that it would address any necessary amendment to the usage of these and other relevant terms throughout the *Terrestrial Code* at a later stage.

In addition, the Code Commission considered that the term 'animal genetic material' used in the definition for 'commodity' was vague and confusing as the term was often used to refer to nucleic acid, not animal semen, etc., in the *Terrestrial Code*, and thus proposed a new Glossary definition for 'germinal products'.

With regard to the term 'biological products' used in the definition for 'commodity', the Code Commission agreed that there was a need to develop a new Glossary definition for this term, and requested that this be discussed with the Biological Standards Commission at the next meeting of the Bureaus in September 2023.

With regard to the term '(animal) by-product', the Commission agreed not to create a Glossary definition at this point, as it would be covered by 'animal product' and it considered that the term '(animal) by-product' should be interpreted case by case.

The revised Glossary definition for 'commodity' and the new Glossary definitions for 'animal product' and 'germinal products' are presented as Annex 23, for comments.

7.2. General hygiene in semen collection and processing centres (Chapter 4.6.)

Comments were received from Australia, New Zealand, Switzerland, the USA, the EU

Background

At its September 2019 meeting, the Code Commission 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*. This work had been requested to resolve inconsistencies among the chapters and to ensure that the 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 was also requested to consider the inclusion of provisions to address equine semen in relevant chapters.

The *ad hoc* Group met virtually during 2020 and 2021 and produced a revised draft Chapter 4.6., which was considered by the Code Commission at its September 2021 meeting and revised by an expert with the support of a Commission member, in June 2022.

At its September 2022 meeting, the Code Commission considered the report of the *ad hoc* Group together with the draft Chapter 4.6., amended the draft chapter, as relevant, and circulated it for comment.

Discussion

The Code Commission considered the comments received and the advice of relevant experts about the applicability of the proposed text for equids and swine.

General comments

The Code Commission agreed to amend the title of this chapter to better reflect the content of the revised chapter.

Article 4.6.1.

The Code Commission agreed with a comment to present some paragraphs in this article as numbered points, with specific sub points, for clarity.

In the new point (b), the Code Commission agreed with a comment to delete ‘operation of’ in front of ‘semen collection centres’, and to delete ‘measures’ after biosecurity as it considered this was redundant considering the glossary definition for ‘biosecurity’.

In the third paragraph, the Code Commission agreed with a comment to replace ‘in’ with ‘through’, as it considered it more appropriate wording.

The fourth paragraph was amended to avoid repetitions and provide more clarity.

The Code Commission did not agree with a comment to delete the fifth paragraph and explained that this chapter not only addresses hygiene but also other aspects of semen collection and processing and that it was relevant to mention animal welfare of which animal health is a critical component. However, it agreed that it was not within the scope of this chapter to address specific animal welfare measures, but rather referred to relevant provisions in Section 7 of the *Terrestrial Code*. The Commission amended the text for clarity.

In the sixth paragraph, the Code Commission agreed with a comment to delete ‘other’ in front of ‘relevant’, as it considered it more appropriate wording.

In the new point 2(c), the Code Commission agreed with a comment to replace ‘laboratories’ with ‘processing unit’ to be better aligned with current common practices and to provide more flexibility about the possible configuration of the facilities, including mobile ones, as well as to avoid confusion with diagnostic laboratories.

In points 3(b) and (c), the Code Commission agreed with a comment to add ‘animal’ in front of ‘accommodation facility’ to make it clear that this refers to the animal accommodation facility described in point 1 of this article. In addition, in response to a comment that the definition of pre-entry isolation facility could not be applicable for all species, the Commission noted that this diversity was already taken into consideration in Article 4.6.3.

In point 4(d) of paragraph 2, the Code Commission agreed with a comment to replace ‘germplasm storage tank’ with ‘cryogenic tank’, to use a more generic term and account for potential differences between those used for storage and transport. The Commission agreed with a comment to replace the term ‘canister’ with ‘tank’ given that a canister is within the tank, and cannot be individually sealed.

Article 4.6.2.

In the second paragraph, the Code Commission agreed with a comment to amend the text for clarity.

In the third paragraph, the Code Commission agreed with comments to amend the text for clarity and to indicate that accurate records should be maintained and easily accessible.

In the fifth paragraph, the Code Commission agreed with a comment to delete ‘with the national regulation’, as it was considered unnecessary.

In the seventh paragraph, the Code Commission agreed with a comment to delete ‘for each facility’ as it considered it unnecessary.

In point 1, the Code Commission agreed with a comment to remove the reference for ‘high standards of' as it was unclear.

In point 2, the Commission agreed with the recommendation from an expert that, in the case of horses, some companion animals (e.g. goats, etc.) often reside with them to enhance social behaviour or for other reasons, and amended the text to allow for such considerations.

In point 3, the Code Commission did not agree with a comment to delete 'at least four weeks prior to entry into the pre-entry isolation facility' as it considered the information of natural mating to be necessary before entering the facility; nonetheless the Commission amended the text for clarity. In addition, the Commission replaced 'four weeks' with '30 days' for alignment with other chapters in the Code.

In point 4, the Code Commission agreed to replace 'wildlife' with 'wild and feral animals' and move the content of point 7 referring to rodents and arthropods, to this point.

In point 5, the Code Commission agreed to rearrange the text by listing the specific points to be considered in the biosecurity plan.

The Code Commission agreed that accurate records should be accessible and added a new point.

Article 4.6.3.

In the first paragraph, the Code Commission agreed with a comment on editorial amendments but did not agree to delete the second sentence of paragraph 2 as it considered the text was clear as written, and that the animal accommodation facilities should be species-specific, when relevant.

In the third paragraph, the Code Commission did not agree with a comment to add 'and approved by the Veterinary Authority' at the end of the paragraph, as it considered obvious that the biosecurity plan would have been approved by the Veterinary Authority when it approved the semen collection centre. In the same paragraph, the Commission agreed with the recommendation of an expert and added 'such as for the collection of equine semen' after 'the pre-entry isolation facility is not required', as it considered it relevant to specify this example.

In the fourth paragraph, the Code Commission agreed with a comment to delete the last sentence of the paragraph noting that this is addressed in Article 4.6.1. by making reference to Chapter 7.1.

In the last paragraph, the Code Commission agreed with a comment to delete 'and be in compliance with all relevant health and environmental legislation', as this was beyond the remit of the *Terrestrial Code*.

Article 4.6.4.

In the third paragraph, the Code Commission agreed to add a new sentence, 'Any exception should be justified and adequately managed by the biosecurity plan.' to address the potential risks of collection in the resident facilities.

In the fourth paragraph, the Code Commission agreed with a comment to amend the text to refer to point 5 of Article 4.6.2., which already addressed some of the content.

In the same paragraph, following the advice from an expert, the Code Commission agreed to add that waiting periods before re-entering the centre can be required.

In the fourteenth paragraph, the Code Commission noted a comment on the term 'new artificial vagina' and noted that this would include not only brand-new ones but also freshly cleaned ones.

In the fifteenth paragraph, the Code Commission agreed with comments to add 'labelled' in front of 'sterile receptacle', as labelling is important.

In paragraph 16, the Code Commission agreed to replace 'laboratory' with 'semen processing facility', in line with the amendments in Article 4.6.1.

Article 4.6.5.

In the ninth paragraph, in response to comments the Commission amended the text for clarity.

In point 3, the Code Commission agreed with a comment to add 'for preparing the semen diluent' and also to delete '121°C for 30 minutes or equivalent' as it was not the intention of the chapter to provide specific parameters, and the text was clear on the requirement for the water to be 'sterile'.

In point 4, the Commission agreed with a comment to limit the text to the use of egg yolk as extender only, and also agreed with a comment to include milk in addition to 'powdered skim milk', and added 'UHT milk' after 'commercial'.

Article 4.6.6.

In the fourth paragraph, the Code Commission agreed with a comment to add 'and the storage room should be locked when not in use', at the end of the sentence.

The revised Chapter 4.6. General hygiene in semen collection and processing centres, is presented as Annex 24, for comments.

7.3. Slaughter of animals (Chapter 7.5.) and associated Glossary definitions

Comments on Chapter 7.5. Slaughter of animals, were received from Australia, Canada, China (People's Republic of), Japan, New Zealand, Norway, Singapore, Switzerland, Thailand, the UK, the USA, the EU and ICFAW.

Comments on Glossary definitions were received from Australia, Norway, the USA, the UK and the EU.

Background

In February 2018, the Code Commission agreed to revise Chapter 7.5. Slaughter of animals, together with Chapter 7.6. Killing of animals for disease control purposes, and requested that an *ad hoc* Group be convened to undertake this work as well as the revision of some Glossary definitions.

In September 2019, the Code Commission considered the proposal made by the *ad hoc* Group convened to revise Chapters 7.5. Slaughter of animals, and 7.6. Killing of animals for disease control purposes, to revise the definitions for 'euthanasia', 'slaughter', 'stunning', 'death', 'distress', 'pain' and 'suffering'. The revised Chapter 7.5. and associated Glossary definitions have been circulated three times, and the Code Commission has received the support of the *ad hoc* Group to address the comments received.

The revised Chapter 7.5. was last circulated in the Code Commission's February 2022 report. In September 2022 the Commission considered the comments and requested the *ad hoc* Group to provide recommendations on the comments received.

Discussion

a) Animal welfare during slaughter (Chapter 7.5.)

The Code Commission considered the report of the *ad hoc* Group and thanked its members for their comprehensive work to review all comments previously received. The Commission considered the report of the *ad hoc* Group and reviewed the amendments it proposed to the revised chapter. The Commission reminded Members that the rationale for amendments made by the *ad hoc* Group to the draft Chapter 7.5. circulated for comment in February 2022 are provided in the *ad hoc* Group report which is available on the WOAH website. The Commission made some further amendments, mostly of editorial nature, and of substance which are noted below.

Article 7.5.13.

In point 2), the Commission replaced ‘measurables’ with ‘measures’ to be consistent with the changes made throughout Chapter 7.1. and deleted the term ‘include’ as it is implicit. These changes were applied throughout the chapter.

In point 3), the Commission replaced the term ‘measures’ with ‘equipment’ to be more precise and to be consistent with how the term ‘measures’ is used in other contexts. In the last paragraph, the Commission rephrased the last sentence to present the content in a recommendation format.

The Commission deleted point 4) as it is not necessary to have such a point when there are no identified species-specific recommendations. This change was applied throughout the chapter.

Article 7.5.15.

In point 3), 5th paragraph, the Commission replaced ‘must’ with ‘should’ to be consistent with the writing style of the recommendations in the *Terrestrial Code*. This was applied throughout the chapter.

In point 3), 9th paragraph, the Commission added the terms ‘design’ and ‘methods’ and moved ‘intentionally’ to the end of the sentence to improve the readability of the recommendation.

In point 3), the last paragraph, the Commission added the term ‘normally’ to ‘animal that cannot move due to injuries’ to avoid confusion with the preceding text that refers to animals that may have ‘excessive and unpredictable movements’.

Article 7.5.17.

In point 1), the last paragraph, the Commission replaced ‘semi-wild’ with ‘feral’ to be consistent with the *Terrestrial Code* terminology.

Article 7.5.18.

In point 4), first indent, the Commission replaced ‘cattle’ with ‘bovine’ to be consistent with the terminology used in the *Terrestrial Code*. These changes were applied throughout the chapter.

In point 4), the last paragraph, the Commission deleted the term ‘electrical’ as the previous sentence made it clear to what frequencies are being referred to.

Article 7.5.22.

In the first paragraph, the Commission added ‘should be described in the emergency plan and’ to clarify that the emergency plan should consider these principles when developed.

Article 7.5.23.

In point 1), the first sentence, the Commission simplified the wording to reflect the changes made in the title regarding the list of practices that should not be used under any circumstances. This change in the format was applied throughout the chapter.

Article 7.5.25.

In point 1), the second paragraph, the Commission replaced the text ‘exposed to the elements’ proposed by the *ad hoc* Group with ‘exposed to adverse weather or climate conditions’ to improve clarity of the sentence.

Article 7.5.27.

In point 3), the third paragraph, the Commission rephrased the first sentence to follow the usual style for a recommendation, and to indicate that the recommendation of mistreatment applies to all animals arriving in containers and not only to birds.

Article 7.5.33.

In point 3), the Commission moved the third and fourth indents to point 4) as these are 'species-specific' recommendations.

b) Definitions for 'death', 'euthanasia', 'slaughter', 'stunning', 'distress', 'pain', and 'suffering'

Discussion

The Code Commission considered the report of the *ad hoc* Group and the proposed amendments to the definitions related to Chapter 7.5. Animal welfare during slaughter. i.e., 'death', 'euthanasia', 'slaughter', 'stunning', 'distress', 'pain', and 'suffering'.

'death' and 'suffering'

The Code Commission agreed to delete the definition of 'death' from the Glossary and not to include the definition of 'suffering', but rather delete it from the Chapter 7.8., noting the convention to only include terms definitions in the Code, where common dictionary definitions are not deemed to be adequate for the use in the Code.

'distress' and 'pain'

The Commission agreed that the definitions 'distress' and 'pain', were still fit for purpose and as they appear in more than one chapter, they should be moved from Chapter 7.8. to the Glossary. The Commission agreed to propose this change for adoption at the 90th General Session in May 2023 (See item 6.2 of this report).

'euthanasia'

The Commission agreed that the current glossary definition continues to be relevant for Section 7 of the Code, and agreed to replace 'act of inducing death' by 'killing of animal', as this phrase more clearly describes the result of the euthanasia procedure, with an already defined term.

'slaughter'

The Commission agreed with some editorial amendments proposed by the *ad hoc* Group.

'stunning'

The Commission agreed to move 'for the purpose of killing' to the first part of the definition for improved readability.

The revised Chapter 7.5. Slaughter of animals, and the revised Glossary definitions of 'death', euthanasia', slaughter' and 'stunning' are presented as Annex 25 and Annex 26, respectively, for comments.

7.4. Infection with *Coxiella burnetii* (Q fever) (New Chapter 8.X.)

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

Background

At its September 2022 meeting, the Code Commission considered a proposal to develop a new chapter for Infection with *Coxiella burneti* (Q fever) in the *Terrestrial Code*, given that a case definition had been developed by experts and endorsed by the Scientific Commission at its February 2022. The Code Commission drafted a new Chapter 8.X. Infection with *Coxiella burneti* (Q fever), consisting of a single article for the general provisions, including the definition of its occurrence, which was circulated in its September 2022 meeting report for the first time.

Discussion

In response to the comments on the taxonomy of animal species, the Code Commission agreed to add new text to explain that many of the animals that are known to be susceptible do not play a significant epidemiological role, taking into account the rationale included in the Scientific Commission's February 2022 report and the corresponding Chapter 3.1.17. of the *Terrestrial Manual*. The Commission reiterated that for the purposes of the *Terrestrial Code*, susceptible species are defined as domestic and captive wild ruminants, the main reservoirs, and dogs and cats, due to their potential role in risk to public health based on the opinions of experts.

The Code Commission acknowledged that it could be difficult to detect antibodies in a sample of susceptible animals that are epidemiologically linked to a suspected case. However, it agreed to keep the suspected case in the current text as this was the opinion of the experts and the Scientific Commission.

The Code Commission agreed with comments to include a reference to clinical signs as an indicator of a case.

The new Chapter 8.X. Infection with *Coxiella Burnetii* (Q fever), is presented as Annex 27, for comments.

7.5. New chapter on infection with *Trypanosoma evansi* (New Chapter 8.Z.)

Background

The Code Commission and the Scientific Commission agreed that three separate chapters on animal trypanosomes with different coverage of trypanosome species and host animals should be developed.

Since 2015, a draft new Chapter 8.Z. Infection with *Trypanosoma evansi* (Surra), and a revised Chapter 12.3. Dourine, have been proposed and extensively discussed but due to the need to clarify the scope of these chapters in terms of host species and pathogenic agents, in February 2018, both Commissions agreed to put Chapters 8.Z. and 12.3. on hold and to progress work on Chapter 8.18. Infection with *Trypanosoma brucei, T. congolense, T. simiae* and *T. vivax*, which was adopted in May 2021. Both Commissions had also agreed that, notwithstanding the diagnostic issues, the scope of the new Chapter 8.Z. should address surra of multiple species including horses and that the scope of Chapter 12.3. should remain as dourine of equids, and that the work would continue after the adoption of the new Chapter 8.18.

At its February 2021 meeting, the Code Commission was informed that experts had been consulted to develop case definitions for surra and dourine that were considered by the Scientific Commission at its February 2021 meeting and that an *ad hoc* Group would be convened to draft a new Chapter 8.Z. Infection with *T. evansi* (Surra), and revise Chapter 12.3. Dourine. The Code Commission requested that the *ad hoc* Group also consider relevant Member comments that were received in 2018.

In June 2021, a meeting of the *ad hoc* Group was convened to draft Chapter 8.Z. Infection with *Trypanosoma evansi* (Surra). The Scientific Commission, at its September 2021 meeting, reviewed the report of the meeting and made some modifications to the proposed draft text.

In September 2022, the Code Commission reviewed the draft new Chapter 8Z. and the *ad hoc* Group report, together with the opinion of the Scientific Commission. The Code Commission identified a number of critical points that were not clearly explained in the supporting reports, and agreed not to circulate the proposed text for comments and requested that the draft text be further reviewed by addressing the points

of concern. The Commission agreed to review this revised draft together with additional information from the experts, at its next meeting.

Discussion

The Code Commission considered information provided by the Secretariat to address the points that it had requested clarification.

The Code Commission made further amendments for harmonisation, clarity, and consistency with other chapters.

In point 2 of Article 8.Z.1., the Code Commission agreed with the text proposed by the *ad hoc* Group but noted that the phrase 'relevant epidemiological context (including clinical signs, endemicity, origin of the host, absence of other *Trypanosoma* spp., absence of tsetse transmission) to support surra', was not sufficiently clear and it, therefore, requested the Secretariat to seek expert's advice to improve its clarity.

The Code Commission agreed with the Scientific Commission's opinion to not include recommendations for the importation of dogs and cats from countries or zones infected with *T. evansi*, which had been proposed by the *ad hoc* Group.

The Code Commission was of the view that, noting that susceptible animals defined in Article 8.Z.1. include a broad range of animals such as rodentia, some articles on recommendations for the importation of commodities derived from the susceptible animals (other than dogs and cats) might not be fully utilised by Members. Nevertheless, the Commission agreed to circulate the text as proposed and requested Members' opinions on this point.

The new Chapter 8.Z. Infection with *Trypanosoma evansi*, is presented as Annex 28, for comments.

7.6. Infection with *Mycoplasma mycoides* subsp. *mycoides SC* (Contagious bovine pleuropneumonia) (Chapter 11.5.)

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

Background

The last amendment of Chapter 11.5. was adopted in 2014, to include the WOAH-endorsed official control programme for contagious bovine pleuropneumonia (CBPP). The *ad hoc* Group on CBPP proposed additional revisions to the chapter at its meeting in October 2015. The Scientific Commission, at its February 2016 meeting, reviewed and endorsed most of the proposed amendments.

At its September 2018 meeting, the Code Commission agreed to review Chapter 11.5. Infection with *Mycoplasma mycoides* subsp. *Mycoides SC* (Contagious bovine pleuropneumonia) to harmonise the provisions for official recognition and maintenance of free status, and endorsement and maintenance of official control programmes with other disease-specific chapters with official recognition of status.

At its September 2022 meeting, the Code Commission reviewed all proposals, introduced additional amendments for clarity and consistency with other chapters, and circulated the revised chapter for comments.

Discussion

Title

The Code Commission deleted 'SC' from the title for consistency with amendments made to the chapter at its September 2022 meeting. The Commission also made an amendment to delete 'SC' from the disease name listed in Article 1.3.2.

Article 11.5.1.

In point 1, the Code Commission agreed with a comment to delete ‘domestic’ given that the term ‘bovines’ was described in parenthesis by the relevant host species. Additionally, the Commission made further amendments for harmonisation, clarity, and consistency with other chapters, including the replacement of ‘susceptible animals’ by ‘bovines’ throughout the chapter.

In point 4, the Code Commission did not agree with a comment to delete ‘the occurrence of’, as this was consistent with the wording in other disease-specific chapters.

In point 4(c), in response to a comment to replace ‘and epidemiological links to a confirmed case’ with ‘or epidemiologically linked to a confirmed or suspected case’ and a comment querying why clinical signs and suspected cases are not referred to in this point, the Code Commission reminded Members that this point was consistent with point 2 of current Article 11.5.1. The Commission considered that, although clinical surveillance is referred to in Articles 11.5.13. and 11.5.14., clinical signs would not be useful when determining the occurrence of the disease.

Article 11.5.2.

In the first paragraph, the Code Commission amended the text for harmonisation and consistency with other chapters.

Article 11.5.3.

In the first paragraph, the Code Commission did not agree with a comment to delete ‘relevant’ as there are three options described in point 2 of Article 1.4.6.

In point 6, in response to a comment querying why the time limit for not having introduced vaccinated animals is ‘since the cessation of vaccination’, the Code Commission proposed deleting the phrase as it agreed that it was not appropriate to have a different time frame from the ‘past 24 months’ described in the first paragraph.

Article 11.5.5bis.

In the first paragraph, the Code Commission agreed with a comment to replace ‘can’ with ‘may’ for clarity and consistency with Article 4.4.7. and with other disease-specific chapters.

In point 1, in response to a comment to clarify this point, the Code Commission made a number of amendments to points 1 and 2. The Commission also proposed the same amendments to other disease-specific chapters that have similar points that are under review.

In the third paragraph, the Code Commission agreed with a comment to add a sentence ‘The free status of the areas outside the containment zone is suspended while the containment zone is being established.’ for consistency with other disease-specific chapters.

Article 11.5.8.

In point 3, the Code Commission proposed to replace ‘slaughterhouse/abattoir’ with ‘place of shipment’ as it was not feasible that an international veterinary certificate issued by an exporting country attests that the animals are transported complying with the conditions of the slaughterhouse/abattoir in the importing country.

Article 11.5.12.

In point 1(c), the Code Commission agreed to replace ‘domestic bovids and water buffaloes’ with ‘bovines’ to align with Article 11.5.1.

The revised Chapter 11.5. Infection with *mycoplasma mycoides* subsp. *Mycoides SC* (Contagious Bovine Pleuropneumonia), is presented as Annex 29 for comments.

7.7. Infection with bovine pestiviruses (bovine viral diarrhoea) (New Chapter 11.X.)

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

Background

At its February 2022 meeting, the Code Commission was informed that in September 2021 the Scientific Commission had endorsed a draft case definition developed by subject-matter experts for bovine viral diarrhoea (BVD). The Code Commission reviewed the experts' reports and the Scientific Commission's opinion and considered that the rationale provided for the draft case definition was not sufficient to support commencing work on a new disease-specific chapter for this listed disease. The Commission also pointed out that the draft case definition described bovine viral diarrhoea (BVD) as an infection of suids, ruminants and camelids, while the disease was listed as a cattle disease in Article 1.3.2.,and requested that an assessment against the criteria in Chapter 1.2. be undertaken before including these proceeding with this item.

At its February 2022 meeting, the Scientific Commission considered the opinion of the Code Commission and subsequently reviewed the text and endorsed a new case definition for bovine viral diarrhoea.

In September 2022, the Code Commission noted that the Scientific Commission had agreed to remove swine and camelids and limited the susceptible animals to *Bos taurus*, *Bos indicus*, and *Bubalus bubalis*, and agreed to draft a new Chapter 11.X. Infection with bovine pestiviruses (bovine viral diarrhoea), consisting of one single article for the general provisions, including the definition of its occurrence.

The Code Commission also agreed to amend the name of the listed disease in Article 1.3.2. to 'Infection with bovine pestiviruses (Bovine viral diarrhoea)' but to circulate this amendment closer to adoption, after considering the comments on the proposed new disease-specific chapter. The proposed new Chapter 11.X. Infection with bovine pestivirus (Bovine viral diarrhoea), was circulated for comments.

Discussion

Article 11.X.1.

In response to comments on the taxonomy of the virus, the Code Commission explained that the taxonomy used is based on the International Committee on Taxonomy of Viruses (ICTV) and encouraged Members to refer to the details that were provided in Annex 11 of the Scientific Commission's September 2021 report.

The Code Commission acknowledged comments highlighting the relevance of persistently infected animals in the context of prevention and control of this disease but noted that this was beyond the context of the proposed text, which aimed at providing a case definition for the purposes of notification to WOAH. The Commission noted that risk management measures would eventually be developed in other articles, such as for the definition of animal health status or to provide recommendations for safe trade, but noted that this was not currently in their work programme and invited Members to submit justified proposals if interested in proposing such work.

In response to comments on the taxonomy of bovines, the Code Commission reiterated its position to keep the text as proposed and referred Members to the opinion of experts that only *Bos taurus*, *Bos indicus* and *Bubalus bubalis* play a significant epidemiological role in BVD.

In point 1, the Code Commission did not agree to delete 'and identified as such' as this reflected the opinion of the Biological Standards Commission.

The Code Commission did not agree with a comment to combine points 1 and 2, as they considered these to be clear as separate points.

The Code Commission did not agree with comments to add 'detection of antibodies to bovine pestivirus' as a third option to confirm a case, and encouraged Members to refer to the September 2021 report of the Scientific Commission and the corresponding Chapter 3.4.7. Bovine viral diarrhoea, of the *Terrestrial Manual*.

The new Chapter 11.X. Infection with bovine pestivirues (Bovine viral diarrhoea), is presented as Annex 30, for comments.

7.8. Infection with African horse sickness virus (Chapter 12.1.)

Comments were received from Australia, Chinese Taipei, New Caledonia, NZ, Singapore, Switzerland, the USA and the EU.

Background

The Code Commission had agreed to review Chapter 12.1. African horse sickness, to harmonise the provisions for official recognition and maintenance of free status, and endorsement and maintenance of official control programmes with other disease-specific chapters with official recognition of status at its February 2021 meeting, the Scientific Commission reviewed and endorsed the amendments proposed by the *ad hoc* Group on African horse sickness. At its September 2021 meeting, the Scientific Commission finalised its discussion on a point on protection zone and agreed to refer to 'area' instead of 'zone' for clarity in Article 12.1.2.

In September 2022, the Code Commission reviewed the amendments proposed by the *ad hoc* Group and the Scientific Commission, reviewed the draft chapter and circulated the revised Chapter 12.1. Infection with African horse sickness virus, for comments.

Discussion

General

The Code Commission acknowledged a comment expressing difficulties to consider the full consequences of the changes in this chapter, without being able to access the 2016 *ad hoc* report providing the rationale for the proposed changes. The Commission reminded that the rationale for the amendments to the chapter was described in Annex 5 of the Scientific Commission's February 2021 report, and in the September 2021 report of the Scientific Commission, which are available on the WOAH website. Nevertheless, the Commission requested the Secretariat to address this issue and ensure that all relevant documents supporting the revision of this chapter be made available.

Article 12.1.1.

The Code Commission did not agree with a comment to add the sentence 'This chapter deals not only with the occurrence of clinical signs caused by infection with AHSV but also with the presence of infection with AHSV in the absence of clinical signs', as it considered it obsolete, as it was implicit in the case definition that occurrence of infection could be defined without clinical signs.

The Code Commission agreed with a comment to review the use of the term 'AHSV Group' across the chapter. The Commission agreed to refer only to 'AHSV', as this was how the pathogenic agent was defined in the first paragraph of this article and noted that further details regarding the pathogenic agent would belong in the *Terrestrial Manual*.

In point 2) the Code Commission did not agree with a comment to include reference to antigen detection because although Chapter 3.6.1. of the *Terrestrial Manual* refers to such techniques in the 'Summary'

section, it provides no description of any specific technique, and in the absence of an international standard, they cannot be considered definitive for the confirmation of the occurrence of a case.

The Code Commission amended the points 1, 2 and 3 for clarity and consistency with other chapters currently being circulated.

In the sixth paragraph, in response to several comments on the species for which the defined infective period applies, the Code Commission agreed to delete 'for horses' after '40 days', as the disease is defined as an infection of equids, and hence it applies to all equids and not only horses.

Article 12.1.2.

The Code Commission agreed with a comment to add an article listing 'safe commodities' for this disease and requested the Secretariat to seek expert advice to provide a draft list with supporting evidence for the consideration of the Commission.

In point 1(a), the Code Commission did not agree with a comment to delete 'knowledge of' after 'current', as it considered this was a general recommendation, not prescriptive and especially important for a vector-borne disease. In point 1(b), for the same reasons, the Commission did not agree to delete 'habitat' after 'distribution'.

In point 1), in response to comments, the Code Commission proposed amendments to points (c) and (d) for clarity. The Commission requested the Secretariat to seek the opinion of the Scientific Commission on the proposed amendments at the same time they were circulated to Members.

In point 1(c)(ii) that was deleted and moved under point 1(d), the Code Commission did not agree with a comment to replace '*Culicoides'* with 'known vectors', as all vectors referred to in the *Terrestrial Manual* are *Culicoides* species. The Commission noted that the same response applied to comments received on Articles 12.1.6., 12.1.7., 12.1.10., and invited Members to submit comments to the Biological Standards Commission if they considered that standards in the *Terrestrial Manual* should be reviewed.

In the last paragraph, the Code Commission agreed with a comment and deleted 'relevant' before provisions for clarity with regard to the provisions of point 4 of Article 1.4.6. which should be taken into consideration.

In response to a comment querying about the lack of references to the absence of vaccination for annual reconfirmation of free status, the Commission noted that such reference was not necessary. It was understood that all conditions for freedom should be maintained, and the absence of vaccination was already referred to in point 2 of this article.

Article 12.1.3.

The Code Commission did not agree with a comment to add 'WOAH' after 'requirements', as it considered it unnecessary as it was understood in the context of the chapter.

Article 12.1.4.

In the first paragraph, the Code Commission did not agree with a comment to replace 'zone' with 'area' after 'protection', as it considered that this replacement was not correct in the context of this article, which refers to a 'protection zone' as defined in Chapter 4.4.

In the same paragraph, the Code Commission agreed to replace 'can' with 'may', for clarity and consistency with Article 4.4.7.

In the second paragraph, in response to a comment, the Code Commission agreed to delete 'in support of the application', to allow for more flexibility regarding the timing of submission of the information. The commission agreed to introduce this amendment to similar chapters being currently circulated.

In point 1, the Code Commission amended the text in agreement with comments and for alignment with changes introduced in similar chapters being currently circulated.

In point 1(d), the Code Commission agreed to add ‘epidemiological’ before ‘investigations’, for clarity.

In point 2, the Code Commission did not agree with a comment to replace ‘targeted surveillance’ with ‘risk-based surveillance’, as the current terminology was in line with Chapter 1.4.

In point 3, the Code Commission did not agree with a comment to replace ‘zone’ with ‘area’ after ‘protection’, as it considered that this replacement was not correct in the context of this article that refers to a ‘protection zone’ as defined in Chapter 4.4.

In the fourth paragraph from the end, the Code Commission amended the text in agreement with comments and for alignment with changes introduced in similar chapters being currently circulated.

Article 12.1.5.

In the second paragraph, the Code Commission did not agree with a comment to add a mandatory minimum period for which the conditions should be met in order for the free status to be regained as it considered this was conditioned by the compliance with provisions in Article 12.1.2.

Article 12.1.6.

In the title of the article, the Code Commission agreed with a comment to incorporate the words ‘of equids’ for clarity and consistency with other chapters currently being circulated.

Article 12.1.8.

In point 3(b), the Code Commission noted a comment to update the term ‘artificial insemination centre’ as per the proposed amendments in the context of the revision of Chapter 4.6. (See item 7.2 of this report) but agreed to introduce such changes only after the proposed modifications to the Glossary are adopted.

Article 12.1.10.

In point 2, the first paragraph, the Code Commission agreed with a comment to amend the text for clarity.

In point 2(a), the Code Commission replaced ‘road’ with ‘land’ for consistency with other chapters in the *Terrestrial Code*.

Article 12.1.11.

In the second paragraph, the Code Commission did not agree with a comment suggesting adding additional vector species because the *Terrestrial Code* chapters should be based on the information provided in the Manual in this regard. The Commission noted that this applied also to comments received in point 5 of Article 12.1.13. and invited Members to submit comments to the Biological Standards Commission if they considered that standards in the *Terrestrial Manual* should be reviewed. The Commission agreed to amend the text for clarity and to remove unnecessary geographical references which could also be inaccurate.

Article 12.1.12.

In point 3, the Code Commission agreed with a comment to replace the word ‘bordering’ with ‘adjacent to’, for clarity and consistency with other relevant articles in the Code, and to replace ‘based upon’ with ‘taking into account’, for clarity.

Article 12.1.13.

In point 2, the Code Commission agreed with a comment to add 'Surveillance plans should include consideration of species that display clinical signs less commonly, such as donkeys or zebra', to ensure surveillance is appropriate and representative when these species are present.

The revised Chapter 12.1. Infection with African horse sickness virus, is presented as Annex 31, for comments.

7.9. Revision of Articles 13.2.1. and 13.2.2. of Chapter 13.2. Rabbit haemorrhagic disease

Background

At its September 2022 meeting, the Scientific Commission recommended that Chapter 13.2. Rabbit haemorrhagic disease, be revised as the current chapter did not contain a case definition nor provisions for recovery of free status.

At its February 2022 meeting, the Code Commission noted a comment from a Member about the need to clarify the impact of the detection of sero-positive animals after importation on a country's free status and agreed to add the revision of Chapter 13.2. to its work programme and requested the Scientific Commission to progress work on the development of a case definition in line with the *Terrestrial Manual*.

At its September 2022 meeting, the Scientific Commission endorsed a case definition drafted by an expert group and forwarded it to the Code Commission for consideration for inclusion in Chapter 13.2. Additionally, the Scientific Commission recommended that the provisions of Article 13.2.2. be amended to reflect the expanded host range.

Discussion

The Code Commission discussed the case definition that had been endorsed by the Scientific Commission and agreed to add this case definition, with some amendments, to Article 13.2.1. The Commission agreed to change the title of the chapter to 'infection with pathogenic rabbit lagoviruses (rabbit haemorrhagic disease)', in line with its approach throughout the disease-specific chapters of the Code.

The Commission also amended Article 13.2.2. to reflect the expanded host range of the case definition, i.e. replacement of rabbit with 'leporids' and to harmonise terminology used in other disease-specific chapters.

The Code Commission agreed that it could consider revising the whole chapter, including consideration as to whether trade recommendations for rabbits are also relevant for other Leporidae animals, if needed. The Commission requested Members to provide feedback on the need to undertake a more comprehensive review.

The Code Commission agreed that the name of the listed disease in Article 1.3.7. should be amended to 'Infection with pathogenic rabbit lagoviruses (rabbit haemorrhagic disease)'. However, the Commission agreed not to propose the amendment to Article 1.3.7. until it has received comments from Members on the proposed changes to Articles 13.2.1. and 13.2.2.

The revised Articles 13.2.1. and 13.2.2. of Chapter 13.2. Rabbit haemorrhagic disease, are presented in Annex 32, for comments.

7.10. Infection with Camelpox virus (New Chapter 16.Z.)

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

Background

At its September 2020 meeting, the Code Commission agreed with a request to include the development of a new *Terrestrial Code* chapter on Camelpox in its work programme and requested the Secretariat to seek expert advice. The Code Commission also agreed with the Scientific Commission on the importance of developing a case definition for this disease to support Members notification. A Chapter 3.5.1. Camelpox, of the *Terrestrial Manual* was adopted in May 2021.

In September 2022, the Code Commission considered the case definition that was endorsed by Scientific Commission in February 2022, the experts' recommendations, opinions from Biological Standards Commission and the recently adopted Chapter 3.5.1. in the *Terrestrial Manual*. The Commission drafted a new Chapter X.Z. Infection with Camelpox virus, consisting of a single article for the general provisions, including the definition of its occurrence. The Code Commission also agreed to amend the name of the listed disease in Article 1.3.2. to 'Infection with Camelpox virus' but to circulate this amendment closer to adoption, after considering the comments on the proposed new disease-specific chapter. The proposed new Chapter X.Z. Infection with Camelpox virus, was circulated for comments.

Discussion

Taking into consideration the proposal to add a new Section 16. Camelidae to the *Terrestrial Code* (see item 6.3 of this report), where this chapter will be placed, the Commission amended the number of the chapter to 'Chapter 16.Z.'.

General Comment

The Code Commission agreed to follow the recommendations of the International Committee on Taxonomy of Viruses (ICTV) regarding the nomenclature.

Article 16.Z.1.

The Code Commission did not agree with comments to include New World camelids (i.e. llamas and alpacas) as a host for the disease and reiterated that this was aligned with the expert opinion that for the purposes of the *Terrestrial Code*, the animals that play a significant epidemiological role are the dromedary and Bactrian camels.

In point 1, the Code Commission did not agree to delete 'and identified as such' as the current wording reflected the opinion of the Biological Standards Commission. The Code Commission did not agree with comments to delete point 4 of the second paragraph in Article 16.Z.1. among the options to confirm a case, and encouraged Members to refer to the Scientific Commission's February 2022 report and the corresponding Chapter 3.5.1. Camelpox, of the *Terrestrial Manual*.

The new Chapter 16.Z. Infection with Camelpox virus, is presented as Annex 33**,** for comments.

7.11. Terminology: Use of terms 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'

Background

At the 89th General Session, in May 2022, revised Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' in the *Terrestrial Code* were adopted. The revision of these definitions was done in coordination with the Aquatic Animals Commission. Revised Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Aquatic Animal Health Services' for the *Aquatic Code* were also adopted in May 2022. Both Commissions agreed to revise the use of these definitions in the *Terrestrial Code* and *Aquatic Code*, respectively, to ensure consistent use when relevant.

In September 2022, the Code Commission considered the use of the terms 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' in the *Terrestrial Code* (2022 edition), based on the rationale for the use of these terms provided by the Code Commission in its September 2021 report, and agreed on several amendments that would need to be addressed. Before proposing these amendments

for comments, the Commission wished to discuss its conclusions with the Aquatic Animals Commission to ensure alignment with proposed changes for the use of corresponding terms in the Aquatic Code. The two Commissions agreed to circulate proposed amendments in their respective February 2023 report to allow Members to consider them at the same time. The Commission also agreed to propose amendments to the use of these terms in the User's Guide.

Discussion

The Commission reviewed the proposed amendments to harmonise the use of the revised definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' in the *Terrestrial Code* discussed at their September 2022 meeting and also considered the conclusions of the Aquatic Animals Commission February 2023 meeting regarding the use of the terms 'Competent Authority', 'Veterinary Authority' and 'Aquatic Animal Health Services' in the *Aquatic Code*, as well as the amendments it considered necessary in the *Aquatic Code*.

The Code Commission agreed to proposed amendments to the following sections of the *Terrestrial Code*:

Glossary definitions for 'Animal for slaughter' and 'Slaughterhouse/abattoir', point 6(c)(i) of Article 1.7.1., point 6(c)(i) of Article 1.7.2.; point 6(d)(i) of Article 1.9.1.; point 6(c)(i) of Article 1.10.1.; point 6(c)(i) of Article 1.10.2., point 3(e)(iii) of Article 1.10.3., point 6(d)(i) of Article 1.11.1., point 6(d)(i) of Article 1.11.2., point 6(d)(i) of Article 1.11.3., point 6(d)(i) of Article 1.11.4., point3(e)(iv) of Article 1.11.5., point 6(c)(i) of Article 1.12.1., point 6(c)(i) of Article 1.12.2., point 3(e)(iii) of Article 1.12.3., point 8 of Article 3.2.3., Article 4.1.1., point 4 of Article 4.13.2., Article 4.19.1., point 3 of Article 5.1.4., point 3 of Article 5.6.4., Article 6.3.3., Article 6.3.6., point 1 of Article 7.4.4., Article 7.7.6., point 2(a) of Article 8.3.15., point 2(a) of Article 8.18.8., point 2(a) of Article 10.4.27., Article 10.4.29., point 2(a) of Article 15.1.29., point 2(a) of Article 15.2.29., and point 2(a) of Article 15.3.14.

The Commission noted that related amendments are being circulated concurrently by the Aquatic Animals Commission for the *Aquatic Code* and encouraged Members to consider these in parallel.

The Commission reminded Members that the proposed changes are only to ensure consistency of the use of these definitions and are not intended to open the discussion on other aspects or parts of the texts.

The revised texts are presented in Annex 34, for comments.

8. Updates on WOAH initiatives relevant to the Code Commission

8.1. WOAH Observatory

The Observatory provided an update on the state of play of the programme and made a summary of the main elements of the first Annual Report, which was published in January 2023.

There was a description of how to find the report on the website and a tool to navigate through it to find different documents, namely the dashboards and executive summaries corresponding to each section of the report. Specific examples on AMR as well as zoning and compartmentalisation were provided. The Observatory discussed one particular recommendation of direct interest for the Commission that had been made in the report regarding the need to improve the quality of the Members' reporting on control measures.

The Observatory also presented the plans to deliver thematic studies and explained that the first ones will be on zoning and compartmentalisation, and animal welfare during transport. The Commission expressed interest in the topics and in contributing to its preparation, as relevant.

8.2. Global Burden of Animal Diseases (GBADs)

The Code Commission was updated on the progress of the programme since the September 2022 Commission meeting. The Secretariat reported that several key milestones have been met in developing,

refining, and testing GBADs methodologies and informatics. The focus has been on deriving burden estimates in Ethiopia, implementing the Ethiopia stakeholder workshop, and obtaining initial user feedback for the various dashboards developed thus far. In the coming months, the work plan will focus on: (i) completing the scientific validation process of the GBADs approach, (ii) demonstrating the utility of GBADs in Ethiopia, and (iii) updating the knowledge engine prototype build to align with overall progress to move GBADs out of the proof-of-concept phase. These activities will ensure that the GBADs approach is flexible enough to account for differences in data availability, diseases of concern and regional characteristics while still providing comparable estimates for decision-makers.

The Commission provided feedback on the information presented and expressed appreciation for the programme outcomes and highlighted the value these would have to support advocating for activities in WOAH mandate.

8.3. WOAH Global Animal Welfare Strategy

Background

As part of the ongoing implementation of the WOAH Global Animal Welfare Strategy (GAWS), a two-year work plan (2022-2023) has been developed. This work plan includes nine activities that address the four pillars of the Strategy: 'Development of animal welfare standards', 'Capacity building activities', 'Implementation of animal welfare standards and policies' and 'Communication with governments and the public'.

Discussion

The Commission noted the Secretariat's update on the status of the implementation of the Strategy's work plan. The Secretariat provided an update on a number of relevant activities including: the publication of the public call for the development of e-learning modules Chapter 7.14. Killing of reptiles for their skin, meat and other products; activities associated with the Regional Animal Welfare Strategies and Platforms; outcomes of the Fourth WOAH Global Animal Welfare Forum: 'Animal Welfare Economics', held on the 12-13 October 2022 including that Forum participants agreed that it was necessary to consider the economic aspect of animal welfare from a holistic perspective. In addition, challenges such as unreliable data, low implementation of standards, and difficulty in identifying the overall costs and benefits associated with implementing animal welfare policies or measures were highlighted. This event was supported by the GBADs project team.

8.4. WOAH Scientific and Technical review Vol. 41(1) 2022 'Safety, regulatory and environmental issues related to international trade of insects'

Update

The Code Commission was informed that the recently published WOAH Scientific and Technical review Vol. 41(1)2022 'Safety, regulatory and environmental issues related to international trade of insects' included articles that addressed the state of play of live insect trade, experiences with shipping insects and the risks and gaps associated with this trade.

The Code Commission noted the challenges raised by some of the authors which included the absence of an overarching framework for the international trade in insects, diverse requirements between different international, regional and national technical or regulatory bodies, and the use of sanitary certificates for the trade of insects. Although insects (except bees) are not covered in the definition of 'animal' in the *Terrestrial Code*, the Code Commission was of the view that general principles pertaining to import risk analysis would apply to the assessment of the risks posed by the movement of insects. In addition, Veterinary Authorities could also refer to veterinary certificates being used for bees as basis for the development of certificates for insects.

The Code Commission agreed that in the context of the *Terrestrial Code*, the potential risks to animal health from the trade of insects should be assessed, especially those insects that are identified as competent vectors in disease-specific chapters of the *Terrestrial Code*.

The Code Commission acknowledged that insects are used as food and feed and, noted that Chapter 6.4. The control of hazards of animal health and public health importance in animal feed, of the *Terrestrial Code*, which aims at ensuring the control of animal and public health hazards through adherence to recommended practices during the production (growing, procurement, handling, storage, processing and distribution) and use of both commercial and on-farm produced animal feed and feed ingredients for terrestrial animals, could be relevant to manage risks associated with insects.

The Commission acknowledged the possibility of insects being better recognised as a production species and highlighted the need for a clear scope and objectives of this work within WOAH, notably in terms of species to address and relevant animal health issues.

The Commission noted the plan of WOAH Headquarters to engage relevant organisations such as the International Plant Protection Convention and Codex to discuss consistency in international standards on insect trade, and indicated it would continue to follow this work, as relevant.

8.5. *Terrestrial Code* data standardisation

8.5.1. Framework for *Terrestrial Code* standards

Background

At the February 2021 Code Commission meeting, WOAH Secretariat proposed developing framework for disease-specific chapters of the *Terrestrial Code* that would define key headings of a disease-specific chapter, describe the information to be considered for inclusion in each heading and capture standard language and wordings which have been agreed among relevant Scientific Commissions in recent years.

The objective to develop the framework is to have a common understanding on the disease-specific chapters among WOAH Secretariat which is involved in the work of the *Terrestrial Code*, and eventually to serve as a reference for those undertaking work on revising or developing a disease-specific chapter. The Secretariat believes that this work would contribute to developing consistent and sustainable disease-specific chapters of the *Terrestrial Code*.

The Secretariat drafted the framework for the disease-specific chapter, and the Code Commission members provided their inputs electronically before its February 2022 meeting. The draft template was also presented to the Scientific Commission for its inputs in September 2022.

Discussion

The Code Commission considered the inputs from the Scientific Commission and provided the Secretariat with its additional feedback. The Commission appointed a member from the Commission to work with the Secretariat to finalise the draft based on the feedback, and requested to report back at its September 2023 meeting.

8.5.2. Commodities

Background

At its September 2021 meeting, the Commission agreed to apply the SOP when assessing commodities for inclusion in the list of safe commodities in disease-specific chapters of the *Terrestrial Code*.

At its February 2022 meeting, the Commission agreed that the SOP should also cover the standardisation of names of commodities used throughout the *Terrestrial Code*.

Discussion

The Secretariat presented an update on the progress of the work to implement the WOAH Internal processes to manage commodities' names and their listing as 'safe commodities' in *Terrestrial Code* chapters. The Commission was informed that the Secretariat had compiled and categorised all references to commodities used in the *Terrestrial Code* and presented an approach to harmonise their use, including the development of a registry of commodities used in the *Terrestrial Code*.

The Commission expressed its appreciation to the Secretariat for this work and nominated Commission members to work with the Secretariat to progress work on the internal registry of commodities including a consolidated approach to the management of commodity names in the *Terrestrial Code* and to provide an update at its next meeting.

9. Update on the other standard-setting bodies and international organisations

The Code Commission was updated on the work of other standard-setting bodies and international organisations relevant to its work.

9.1. Update on IATA collaboration

Background

WOAH has had a Collaboration Agreement with the International Air Transport Association (IATA) since 2008, and since 2006, WOAH has been a member of the IATA Live Animal and Perishable Board (LAPB) and has been actively engaged.

There is an important complementarity between the IATA Live Animal Regulations (LAR) Chapter 10 and the *Terrestrial Code* Chapter 7.4. Transport of animals by air, with both including cross-references to each other.

Discussion

The Commission noted the update from the Secretariat that during the 55th meeting of the LAPB board, the IATA LAPB offered support for the revision of Chapter 7.4. given their work in developing regulations for air transport of live animals. The Commission was informed that the IATA LAPB had created a Task Force to collaborate on the revision process once this started.

9.2. Update on collaboration with the International Embryo Technology Society (IETS)

Background

The International Embryo Technology Society (IETS) is a long-standing partner in the development of WOAH standards. The IETS Manual is a key reference for national regulations on this topic and is also referenced in the relevant chapters of the Code.

The President of the Code Commission participated in the last meeting of the Health and Safety Advisory Committee of IETS (IETS HASAC) in January 2023 and updated the Commission on the discussions held at that forum and further areas for collaboration.

Discussion

The Code Commission President, Dr Etienne Bonbon, reported that the IETS HASAC discussed the important developments in the technologies and use of *in-vitro* produced embryos, as well as its relevance in the context of international trade. The IETS HASAC also expressed interest in contributing to the update

of the international standards and in the development of recommendations on disease risk mitigation measures for *in-vitro*-produced embryos. However, it also recognised that there was still not sufficient standardisation of the practices nor consolidated data on *in-vitro* produced embryos while there is a lot of empirical information, which needs to be collated in a systematic way to allow for interpretation and use.

The Commission agreed it was important to follow the progress of *in-vitro*-produced embryo technologies and to consider developing new standards or revising existing standards when sufficiently standardised references were available. The Commission requested the Secretariat to also refer this knowledge 'gap' to the WOAH Research Coordination Group.

Dr Bonbon also reported that the updated 5th edition of the IETS Manual had recently been published and includes several changes. The Commission agreed on the need to consider potential amendments to current *Terrestrial Code* chapters as a consequence of the changes in the IETS Manual and requested the Secretariat to liaise with IETS and report back at its next meeting.

The Commission acknowledged the good collaboration with IETS and the importance of maintaining a close interaction and ensuring timely exchanges to identify the development and application of embryo and related technologies that should be addressed in the Code.

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…/Annexes

Annex 1. Adopted Agenda

MEETING OF THE WOAH TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 7 to 17 February 2023

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1. **Welcome**
   - **1.1. Deputy Director General**
   - **1.2. Director General**
2. **Adoption of agenda**
3. **Cooperation with other Specialist Commissions**
   - **3.1.** Scientific Commission for Animal Diseases
     - **3.1.1.** Listing assessment SOP:
       - **3.1.1.1.** Listing assessments forwarded to TAHSC (SOP Step 3 conclusions): *Theileria mutans*, Strangles
     - **3.1.2.** Emerging diseases SOP:
       - **3.1.2.1.** Annual reassessment of emerging diseases (SOP Step 5.1): Infection with SARS-CoV-2
       - **3.1.2.2.** New assessments: Monkeypox, Avian influenza (H3N8)
       - **3.1.2.3.** Consideration of stable events that previously were submitted to WAHIS as emerging disease events
     - **3.1.3.** Consideration of the listing criteria in Chapter 1.2.
     - **3.1.4.** Categorisation used in Chapter 1.3.
   - **3.2.** Biological Standards Commission
     - **3.2.1.** Biological Standards Commission's recommendations to the *Terrestrial Code*
     - **3.2.2.** Consideration of terms used in provisions to define the occurrence of a disease (Article X.X.1. of disease-specific chapters)
   - **3.3.** Aquatic Animals Commission
   - **3.4.** Terrestrial Standards Coordination
4. **Code Commission's work programme not including texts proposed for comments or adoption**
   - **4.1. Ongoing work items (not in order of priority)**
     - **4.1.1.** Wildlife health
     - **4.1.2.** Inclusion of the 'Five Domains' concept in Section 7
     - **4.1.3.** New Glossary definitions for 'animal products', 'product of animal origin' and 'animal by-product'
     - **4.1.4.** Revision of Chapter 1.6. Procedures for official recognition of animal health status, endorsement of an official control programme, and publication of a self-declaration of animal health status, by WOAH
     - **4.1.5.** Revision of Chapter 4.4. Zoning and compartmentalisation
     - **4.1.6.** New chapter on biosecurity (Chapter 4.X.)
     - **4.1.7.** Revision of Chapters 5.4. to 5.7.
     - **4.1.8.** New chapter on Animal welfare and laying hen production systems (Chapter 7.Z.)
     - **4.1.9.** Revision of Chapter 7.2. Transport of animals by land and Chapter 7.3. Transport of animals by sea

4.1.10. New chapter on infection with Trypanosoma evansi (Chapter 8.X.)

4.1.11. Revision of Chapter 10.5. Avian mycoplasmosis

4.1.12. Revision of Chapter 13.2. Rabbit haemorrhagic disease

4.1.13. Terminology: Use of terms 'animal-based measures' and 'measurables'

4.1.14. Terminology: Use of terms 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'

4.2. Items under consideration for inclusion in work programme

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

4.3. New proposals and requests for inclusion in work programme

4.3.1. Revision of chapters on diseases for which WOAH grants official recognition of animal health status

4.3.2. New chapter on turkey rhinotracheitis

4.4. Prioritisation of items in work programme

5. **Texts proposed for adoption in May 2023**

5.1. User's Guide

5.2. Glossary definition for 'Poultry'

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

5.4. Infection with rabies virus (Articles 8.14.6bis., 8.14.7. and 8.14.11bis. of Chapter 8.14.)

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

5.6. Infection with Newcastle disease virus (Article 10.9.1. of Chapter 10.9.)

5.7. Bovine spongiform encephalopathy (Chapter 11.4.), Application for official recognition by WOAH of risk status for bovine spongiform encephalopathy (Chapter 1.8.) and Glossary definitions ('protein meal' and 'meat-and-bone meal')

5.8. Contagious equine metritis (Chapter 12.2.)

5.9. Infection with equine influenza virus (Chapter 12.6.)

5.10. Equine piroplasmosis (Chapter 12.7.)

5.11. Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* (New Chapter 14.X.)

5.12. Infection with Middle East respiratory syndrome coronavirus (New Chapter X.X.)

5.13. Infection with *Leishmania* spp. (New Chapter X.Y.)

5.14. Revision of Chapter 1.3.: Article 1.3.3. (Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi*) and Article 1.3.9. (Infection of dromedary camels with Middle East respiratory syndrome coronavirus and Leishmaniosis)

5.15. Terminology: Use of terms 'fetal', 'foetal', 'fetus' and 'foetus'

5.16. Terminology: Use of terms 'bovid', 'bovidae', 'bovine' and 'cattle'

5.17. Terminology: Use of terms 'enzootic', 'endemic', 'epizootic' and 'epidemic'

6. **Texts circulated for comments**

6.1. In September 2022 Report

6.1.1. Collection and processing of semen of animals (Chapter 4.6.)

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

6.1.3. Infection with *Coxiella burnetii* (Q fever) (New Chapter 8.X.)

6.1.4. Infection with *Mycoplasma mycoides* subsp. *mycoides SC* (Contagious bovine pleuropneumonia) (Chapter 11.5.)

6.1.5. Infection with bovine pestiviruses (Bovine viral diarrhoea) (New Chapter 11.X.)

6.1.6. Infection with African horse sickness virus (Chapter 12.1.)

6.1.7. Infection with camelpox virus (New Chapter X.Z.)

6.2. Previously circulated

6.2.1. Revision of Chapter 7.5. Slaughter of animals and Glossary definitions for ‘death’, ‘distress’, ‘euthanasia’, ‘pain’, ‘slaughter’, ‘stunning’ and ‘suffering’

7. **WOAH and HQ’s initiatives relevant to TAHSC (Updates)**

7.1. WOAH Observatory

7.2. GBADs

7.3. WOAH Global Animal welfare strategy

7.4. WOAH Scientific and technical review Vol. 41(1) 2022 ‘Safety, regulatory and environmental issues related to international trade of insects’

7.5. *Terrestrial Code* data standardisation

7.5.1. Framework for *Terrestrial Code* standards

7.5.2. Commodities

7.5.3. Code navigation tool

7.6. WOAH Rebranding

8. **Updates on works of other standard-setting bodies and international organisations**

8.1. Updated on IATA collaboration

8.2. Update on collaboration with IETS (International Embryo Technology Society)

9. **Meeting review**

10. **Date of next meeting**

Annex 2. List of Participants

MEETING OF THE WOAH TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 7 to 17 February 2023

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MEMBERS OF THE COMMISSION

Dr Etienne Bonbon
(President)
Seconded National Expert
European Commission,
Brussels,
BELGIUM

Dr Salah Hammami
(Vice-President)
Epidemiologist and virologist,
National School of Veterinary Medicine,
Sidi Thabet,
TUNISIA

Dr Gaston Maria Funes
(Vice-President)
Counsellor for Agricultural Affairs,
Embassy of Argentina to the EU,
Brussels,
BELGIUM

Dr Bernardo Todeschini
(member)
Agricultural Attaché,
Ministry of Agriculture, Livestock and Food Supply,
Brussels,
BELGIUM

Dr Kiyokazu Murai
(member)
Animal Health Division,
Ministry of Agriculture, Forestry and Fisheries,
Tokyo,
JAPAN

Dr Lucio Ignacio Carbajo Goñi
(member)
Agricultural Attaché,
Ministry of Agriculture, Food and Environment,
Béjar (Salamanca)
SPAIN

WOAH HEADQUARTERS

Dr Gillian Mylrea
Head
Standards Department

Dr Francisco D'Alessio
Deputy Head
Standards Department

Dr Yukitake Okamura
Chargé de mission
Standards Department

Dr Leopoldo Stuardo
Chargé de Mission
Standards Department

Ms Elizabeth Marier
Chargée de mission
Standards Department

Dr Serin Shin
Chargée de mission
Standards Department

Annex 4

USER'S GUIDE

EU position

The EU supports the adoption of this revised User's guide.

[...]

B. *Terrestrial Code* content

[...]

5. The standards in the chapters of Section 3 are designed for the establishment, maintenance and evaluation of Veterinary Services, including veterinary legislation and communication. These standards are intended to assist the Veterinary Services and Veterinary Authority of Member Countries to meet their objectives of improving terrestrial animal health and welfare and veterinary public health, as well as to establish and maintain confidence in their international veterinary certificates.

[...]

10. The standards in each of the chapters of Sections 8 to ~~15~~ 16 are designed to prevent the pathogenic agents of OIE listed diseases, infections or infestations from being introduced into an importing country. The standards take into account the nature of the traded commodity, the animal health status of the exporting country, zone or compartment, and the risk reduction measures applicable to each commodity.

These standards assume that the agent is either not present in the importing country or is the subject of a control or eradication programme. Sections 8 to ~~15~~ 16 each relate to the host species of the pathogenic agent: multiple species or ~~single~~ species of ~~Apidae~~ Apinae, Aves, ~~Bovidae~~ Bovinae, Equidae, Leporidae, Caprinae, ~~and~~ Suidae and Camelidae. Some chapters include specific measures to prevent and control the infections of global concern. Although WOAH aims to include a chapter for each listed disease, not all listed diseases have been covered yet by a specific chapter. This is work in progress, depending on available scientific knowledge and the priorities set by the World Assembly.

[...]

C. Specific issues

[...]

5. Trade requirements

[...]

WOAH aims to include an article listing the commodities that are considered safe for trade without the need for risk mitigation measures specifically directed against a particular listed disease, infection or infestation, regardless of the status of the country or zone of origin for the agent in question, at the beginning of each listed disease-specific chapter in Sections 8 to ~~15~~ 16. This is work in progress and some chapters do not yet contain articles listing safe commodities. When a list of safe commodities is present in a chapter, importing countries should not apply trade restrictions to such commodities with respect to the agent in question. Chapter 2.2. describes the criteria used to assess the safety of commodities.

6. International veterinary certificates

An international veterinary certificate is an official document that the Veterinary Authority of an exporting country issues in accordance with Chapters 5.1. and 5.2. It lists animal health requirements and, where appropriate, public health requirements for the exported commodity. The quality of the exporting country's Veterinary Services is essential in providing assurances to trading partners regarding the safety of exported animals and products. This includes the ~~Veterinary Services'~~ Veterinary Authority's ethical approach to the provision of veterinary certificates and their history in meeting their notification obligations.

[...]

Annex 5

G L O S S A R Y

EU position

The EU in general supports transferring definitions used in several Code chapters to the Glossary. However, it cannot support the deletion of the specific definition of "suffering" from the Code. One important comment to that effect is inserted in the text below for consideration by the Code Commission before adoption.

[…]

DISTRESS

means the state of an animal, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

[…]

~~*MEAT-AND-BONE MEAL*~~

~~means the solid protein products obtained when animal tissues are rendered, and includes any intermediate protein product other than peptides of a molecular weight less than 10,000 daltons and amino-acids.~~

[…]

PAIN

means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

[…]

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~~ mass less than 10,000 daltons and amino-acids.

[…]

EU comment

Together with the definitions of "distress" and "pain", the EU proposes to also move the definition of "suffering" from Chapter 7.8. to the Glossary without any amendments:

“<u>Suffering means an unpleasant, undesired state of being that is the outcome of the impact on an animal of a variety of noxious stimuli and/or the absence of important positive stimuli. It is the opposite of good welfare</u>.”

Justification:

The term “suffering” is widely used in many of the chapters under Section 7 and a specific definition for that term has been agreed and adopted in Chapter 7.8. That definition is fit for purpose for use throughout the Terrestrial Animal Health Code and should therefore also be moved to the Glossary. Indeed, the definition of “suffering” is equally important and relevant in the context of animal welfare as the definitions of “distress” and “pain”.

In particular, the definition of “suffering” should not be deleted from the Code as it cannot be replaced by a generic dictionary definition. Indeed, the definition of “suffering” in Chapter 7.8. contains several animal welfare specific elements and concepts not contained in dictionary definitions that would otherwise be lost. This would be a considerable step back that the EU cannot support.

CHAPTER 7.8.

USE OF ANIMALS IN RESEARCH AND EDUCATION

EU position

The EU cannot support the changes to this chapter as proposed. One important comment is inserted in the text below that should be considered by the Code Commission before adoption.

[…]

Article 7.8.1.

Definitions

For the purposes of this chapter the following definitions apply:

Biocontainment means the system and procedures designed to prevent the accidental release of biological material including allergens.

Bioexclusion means the prevention of the unintentional transfer of adventitious organisms with subsequent infection of animals, resulting in adverse effects on their health or suitability for research.

Biosecurity means a continuous process of risk assessment and risk management designed to minimise or eliminate microbiological infection with adventitious organisms that can cause clinical disease in the infected animals or humans, or make animals unsuitable for biomedical research.

Cloned animal means a genetic copy of another living or dead animal produced by somatic cell nuclear transfer or other reproductive technology.

~~**Distress** means the state of an animal, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.~~

Endangered species means a population of organisms which is at risk of becoming extinct because it is either few in numbers, or threatened by changing environmental or predation parameters.

Environmental enrichment means increasing the complexity (e.g. with toys, cage furniture, foraging opportunities, social housing, etc.) in a captive animal's environment to foster the expression of non-injurious species-typical behaviours and reduce the expression of maladaptive behaviours, as provide cognitive stimulation.

Ethical review means consideration of the validity and justification for using animals including: an assessment and weighing of the potential harms for animals and likely benefits of the use and how these balance (see harm-benefit analysis below); and consideration of experimental design; implementation of the Three Rs; animal husbandry and care and other related issues such as personnel training. Ethical judgements are influenced by prevailing societal attitudes.

Harm-benefit analysis means the process of weighing the likely adverse effects (harms) to the animals against the benefits likely to accrue as a result of the proposed project.

Humane endpoint means the point in time at which an experimental animal's pain and/or distress is avoided, terminated, minimised or reduced, by taking actions such as giving treatment to relieve pain and/or distress, terminating a painful procedure, removing the animal from the study, or humanely killing the animal.

Laboratory animal means an animal that is intended for use in research. In most cases, such animals are purpose-bred to have a

defined physiological, metabolic, genetic or pathogen free status.

Operant conditioning means the association that an animal makes between a particular response (such as pressing a bar) and a particular reinforcement that may be positive (for example, a food reward) or negative (e.g. a mild electric shock). As a result of this association, the occurrence of a specific behaviour of the animal can be modified (e.g. increased or decreased in frequency or intensity).

~~**Pain** means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.~~

Project proposal (sometimes called protocol) means a written description of a study or experiment, programme of work, or other activities that includes the goals of the work, characterises the use of the animals, and includes ethical considerations.

~~**Suffering** means an unpleasant, undesired state of being that is the outcome of the impact on an animal of a variety of noxious stimuli and/or the absence of important positive stimuli. It is the opposite of good welfare.~~

EU comment

The EU is in favour of deleting the definition of "suffering" from this chapter only if it is moved to the Glossary like the definitions of "distress" and "pain".

Justification

The term "suffering" is widely used in many of the chapters under Section 7 and a specific definition for that term has been agreed and adopted in Chapter 7.8. That definition is fit for purpose for use throughout the Terrestrial Animal Health Code and should therefore also be moved to the Glossary. Indeed, the definition of "suffering" is equally important and relevant in the context of animal welfare as the definitions of "distress" and "pain".

In particular, the definition of "suffering" should not be deleted from the Code as it cannot be replaced by a generic dictionary definition. Indeed, the definition of "suffering" in Chapter 7.8. contains several animal welfare specific elements and concepts not contained in dictionary definitions that would otherwise be lost. This would be a considerable step back that the EU cannot support.

[…]

Annex 7

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY WOAH

EU position

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

Preamble

The diseases, *infections* and *infestations* in this chapter have been assessed in accordance with Chapter 1.2. and constitute the WOAH list of terrestrial animal diseases.

In case of modifications of this list adopted by the World Assembly of Delegates, the new list comes into force on 1 January of the following year.

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 *Trypanosoma brucei*, *Trypanosoma congolense*, *Trypanosoma simiae* and *Trypanosoma vivax*

– 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 *Leishmania* spp. (Leishmaniosis)

– 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~~ bovine 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 *Mycoplasmamycoides* subsp. *Mycoides* ~~SC~~ (Contagious bovine pleuropneumonia)

– Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

– Infection with *Theileria annulata*, *Theileria orientalis* and *Theileria parva*

– Trichomonosis.

Article 1.3.3.

The following are included within the category of sheep and goat diseases and *infections*:

– Caprine arthritis/encephalitis

– Contagious agalactia

– Contagious caprine pleuropneumonia

– Infection with *Chlamydia abortus* (Enzootic abortion of ewes, ovine chlamydiosis)

– Infection with peste des petits ruminants virus

– Infection with *Theileria lestoquardi, Theileria luwenshuni* and *Theileria uilenbergi*

– Maedi–visna

– Nairobi sheep disease

– Ovine epididymitis *(Brucella ovis)*

– Salmonellosis (*S.* abortusovis)

– Scrapie

– Sheep pox and goat pox.

Article 1.3.4.

The following are included within the category of equine diseases and *infections*:

– Contagious equine metritis

– Dourine

– Equine encephalomyelitis (Western)

– Equine infectious anaemia

– Equine piroplasmosis

– Infection with *Burkholderia mallei* (Glanders)

– Infection with African horse sickness virus

– Infection with equid herpesvirus-1 (Equine rhinopneumonitis)

– Infection with equine arteritis virus

– Infection with equine influenza virus

– Venezuelan equine encephalomyelitis.

Article 1.3.5.

The following are included within the category of swine diseases and *infections*:

– Infection with African swine fever virus

– Infection with classical swine fever virus

– Infection with porcine reproductive and respiratory syndrome virus

– Infection with *Taenia solium* (Porcine cysticercosis)

– Nipah virus encephalitis

– Transmissible gastroenteritis.

Article 1.3.6.

The following are included within the category of avian diseases and *infections*:

– Avian chlamydiosis

– Avian infectious bronchitis

– Avian infectious laryngotracheitis

– Duck virus hepatitis

– Fowl typhoid

– Infection with high pathogenicity avian influenza viruses

– Infection of birds other than *poultry*, including *wild* birds, with influenza A viruses of high pathogenicity

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

– Infection with *Mycoplasma gallisepticum* (Avian mycoplasmosis)

– Infection with *Mycoplasma synoviae* (Avian mycoplasmosis)

– Infection with Newcastle disease virus

– Infectious bursal disease (Gumboro disease)

– Pullorum disease

– Turkey rhinotracheitis.

Article 1.3.7.

The following are included within the category of ~~lagomorph~~ leporids diseases and *infections*:

– Myxomatosis

– Rabbit haemorrhagic disease.

Article 1.3.8.

The following are included within the category of bee diseases, *infections* and *infestations*:

– Infection of honey bees with *Melissococcus plutonius* (European foulbrood)

– Infection of honey bees with *Paenibacillus larvae* (American foulbrood)

– Infestation of honey bees with *Acarapis woodi*

– Infestation of honey bees with *Tropilaelaps* spp.

– Infestation of honey bees with *Varroa* spp. (Varroosis)

– Infestation with *Aethina tumida* (Small hive beetle).

Article 1.3.9.

The following are included within the category of ~~other~~ camelids diseases and *infections*:

– Camelpox

– Infection ~~of dromedary camels~~ with Middle East respiratory syndrome coronavirus

– ~~Leishmaniosis.~~

_____

CHAPTER 8.8.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

EU position

The EU thanks the Code Commission and provides important comments inserted in the text below.

The EU would like thank the Code Commission for addressing the issue of Chapter 1.11. at its February 2023 meeting. However it wishes to reiterate that it would be *necessary* to adopt in parallel an updated Chapter 1.11. "*Application for official recognition by the WOAH of free status for foot and mouth disease*". Indeed, various changes proposed in Chapter 8.8. will have major consequences in Chapter 1.11. For example, such changes would need to address the fact that point c) of Article 1.11.1 requires significant details on the vaccinated population while there is currently no reference to imported vaccinated animals. Bearing in mind the SCAD assessment (from its report from the February 2022 meeting): "*The Commission recognised that the importation of vaccinated animals into an FMD free country or zone without vaccination will have an impact on the design of surveillance and will require identification of vaccinated animals*", the update of Chapter 1.11. appears even more essential.

Another example where there is a need to update Chapter 1.11., is related to the newly proposed point 3) of Article 8.8.2. where more information on the format and level of details that the Veterinary Authority shall provide in the documented evidence included in the annual reconfirmation to demonstrate that the Veterinary Authority has current knowledge of the distribution and habitat of wild and feral susceptible animals in the country or zone. The EU thanks the Code Commission for adressing this specific point in its February 2023 report, but notes that guidance on what information needs to be submited in the annual reconfirmation procedure should be included in the WOAH internationl standards (i.e. Chapter 1.11.), which have been agreed with WOAH Member Countries, rather than being delegated to a WOAH webpage or other guidance documents which do not undergo srutiny by WOAH Member Countries.

In addition, the recommendations of the SCAD (in its report from the February 2022 meeting) states that "*To further assist Members on this issue, the Commission recommended the OIE to develop FMD surveillance guidelines*". To our knowledge this recommendation still needs to be addressed as these guidelines have not been developed yet.

For these reasons, the proposed changes to the FMD chapter appear not to be ready for adoption at this stage. The EU thus suggests postponing adoption to the next General Session in May 2024, allowing for more time for the above elements to be addressed.

However, in order to allow the work to continue, some important comments are provided 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~~ies~~ *Suidae* and ~~the subfamilies *bovinae, caprinae* and *cervidae*~~*Cervidae*, the subfamilies *bovinae*~~, and~~ *caprinae* and *antilopinae* of the family *Bovidae*, ~~order *Artiodactyla*,~~ and *Camelus bactrianus* with FMDV (hereafter 'susceptible animals').

2bis) For the purposes of this chapter, ~~'cattle'~~ a 'bovine' means an animal~~s~~ of the species *Bos taurus* or *Bos indicus.*

EU comment

The EU does not support the proposed definition of the term "bovine" for the purposes of this chapter. Indeed, it is not clear why it does not include all species of the genus *Bos*, and also the genus *Bubalus*, *Bison* and *Syncerus* (as indicated under Item 6.4. of the Code Commission report). This is not appropriate given that some items are not solely restricted to *Bos taurus* or *Bos indicus*. Indeed, there are examples of in vivo derived embryos that are not solely related to *Bos taurus* or *Bos indicus* e.g.:

[*Embryo transfer in water buffalo (Bubalus bubalis).M Drost , J M Wright Jr, W S Cripe, A R Richter. PMID: 16725875 DOI: 10.1016/0093-691x(83)90082-1*]; [*Intergeneric embryo transfer between water buffalo and domestic cattle. M Dros, JM Wright, RP Elsden. https://doi.org/10.1016/0093-691X(86)90180-9*]; [*Training manual for embryo transfer in water-buffaloes by Maarten Drost. https://www.fao.org/3/T0120E/T0120E00.htm*]; [*In Vitro Production of Bison Embryos. Jennifer P Barfield. PMID: 31230280 DOI: 10.1007/978-1-4939-9566-0_12*].

To be noted that these are not solely limited to cultural and conservation interests, but also to commercial interests.

Furthermore, in some articles of this chapter, further species are added in addition to bovines as defined in point 2bis (e.g. in Article 8.8.22.), while this is not the case in others where it would also be warranted.

The EU thus reiterates its request for a broader definition of 'bovine' in point 2 bis above.

3) The following defines the occurrence of *infection* with FMDV:

a) FMDV has been isolated and identified as such from a sample from an animal listed in point 2; or

b) ~~viral~~ antigen or ~~viral ribonucleic~~ nucleic acid specific to FMDV has been ~~identified~~ detected in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a ~~suspected or~~ confirmed or suspected ~~*outbreak*~~ *case* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or

c) antibodies to structural proteins (SP) or non-structural proteins (NSP) of FMDV, that are not a consequence of *vaccination*, have been ~~identified~~ detected in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a ~~suspected or~~ confirmed or suspected ~~*outbreak*~~ *case* 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 or any cause for suspicion of previous association or contact with FMDV. Transmission of FMDV shall be notified to WOAH as occurrence of infection.

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~~ for which transmission of FMDV has been proven from persistently infected individuals is the African buffalo *(Syncerus caffer)*. However, transmission from ~~this species~~ African buffalo 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 the importation or transit of the following *commodities, Veterinary Authorities* should not require any type of FMD-related conditions, regardless of the ~~FMD~~ *animal health status* of the *exporting country* or *zone*:

1) UHT *milk* and derivatives thereof;

2) heat-treated *meat products* in hermetically sealed container with a F_0 value of 3 or above;

3) ~~*meat* and bone meal and blood~~ *protein meal*;

4) gelatine;

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

6) limed hides, pickled pelts, and semi-processed leather;

7) extruded dry pet food.

Other *commodities* of susceptible ~~species~~animals 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 4.34. 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*.~~

A country or *zone* may be considered free from FMD where *vaccination* is not practised when the relevant provisions in point 2 of Article 1.4.6. have been complied with, and when within the proposed free country or *zone* for at least the past 12 months:

~~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*:~~

1) ~~a)~~ there has been no *case* of *infection* with FMDV;

2) the *Veterinary Authority* has current knowledge of, and authority over, all *herds* of domestic and *captive wild* susceptible animals in the country or *zone*;

3) the *Veterinary Authority* has current knowledge of the distribution~~,~~ and habitat ~~and indication of disease occurrence through passive *surveillance*~~ of *wild* and *feral* susceptible animals in the country or *zone*;

4) appropriate *surveillance* has been implemented in accordance with:

a) Article 1.4.6. where historical freedom can be demonstrated; or

b) ~~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. where historical freedom cannot be demonstrated which includes the ~~has been implemented to~~ detection of clinical signs of FMD and demonstrate ~~no evidence of~~:

i) no *infection* with FMDV in unvaccinated animals;

ii) no ~~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~~;

EU comment

This comment is related to both Articles 8.8.2 and 8.8.40. The EU thanks the Code Commission for addressing this issue in their February 2023 meeting. However, some important points still need to be clarified.

The EU needs to reiterate that it does not support allowing the importation of vaccinated animals into a country or zone officially free from FMD where vaccination is not practised. This is due to the increased risk this practice entails.

The increased risk is recognised by:

1) the fact that additional risk mitigating measures would be needed (i.e. differentiated surveillance schemes); this recognises, *de facto*, that this practice increases the risk compared to the current procedure;

2) the fact that Article 8.8.11. requires the *testing* of the animals to be imported from the zone/country officially free with vaccination;

3) the SCAD also recognises the increased risk when, in its report from the February 2022 meeting, it "*recognised that the importation of vaccinated animals into an FMD free country or zone without vaccination will have an impact on the design of surveillance and will require identification of vaccinated animals*".

In addition, the fact that there would be a need to differentiate between non vaccinated populations and imported vaccinated animals, this would mean that the country, which already has an officially recognised free status without vaccination, would need to apply a similar surveillance scheme as a country that is transitioning from a free status with vaccination to a free status without vaccination.

Therefore, if additional measures are required, the risk cannot be considered negligeable.

In addition, a separate point also addressed in the Code Commission report relates to the additional costs related to increased complexity of surveillance to be supported by the importing country.

The EU would like to point out that the statements in the Code Commission report might not be systematically correct: "*that is up to those countries to take into consideration when they choose to import*", as this will depend on the reasons for such denial. If the WOAH standard does not recognise the increased risk pointed out above (on importation of vaccinated animals into a country or zone free from FMD where vaccination is not practiced) then Member Countries would need to provide an import risk analysis demonstrating why they deviate from the WOAH standards (in line with WTO SPS principles).

The EU therefore reiterates its comment and asks that WOAH standards do not allow the importation of vaccinated animals into a country or zone free from FMD where vaccination is not practised.

5) ~~d)~~ measures to prevent the introduction of the *infection* have been in place: in particular, the importations or movements of *commodities* into the country or *zone* have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code.* Introduction of vaccinated animals have only been carried out either:

a) from countries or *zones* free from FMD where *vaccination* is practised in accordance with Articles 8.8.11. or 8.8.11bis., or ~~: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;~~

~~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 aAnimals introduced~~

b) for ~~direct~~ *slaughter* in accordance with Articles 8.8.8.; and 8.8.9.bis ~~and 8.8.11bis. were should be subjected to ante- and post-mortem inspections in accordance with Chapter 6.32. with favourable results; . FfF~~or ruminants, the head, including the pharynx, tongue and associated lymph nodes, was either destroyed or treated in accordance with Article 8.8.31.;

6) *vaccination* against FMD is prohibited and the prohibition has been effectively implemented and supervised.

The country ~~Member Country or the proposed free~~ or *zone* will be included in the list of ~~FMD free~~ countries or *zones* free from FMD, where *vaccination* is not practised in accordance with Chapter 1.6.~~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 annual reconfirmation of compliance with all points above and ~~relevant~~ provisions under point 4 of Article 1.4.6. Documented evidence should be resubmitted ~~that the information in points 2, 3 and 4 above be re-submitted~~ annually for all points above. ~~And~~ Any changes in the epidemiological situation or other significant events ~~including those relevant to points 3b) and 4~~ should be ~~reported~~ notified to WOAH 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 are 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 *populations* 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 *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.~~

~~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 A~~a ~~*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.~~

A country or *zone* free from FMD where *vaccination* is not practised may maintain its free status despite an incursion of African buffalo from a neighbouring infected country or *zone* provided that it is demonstrated that the ~~relevant conditions are~~ provisions in this article continue to be met and documented evidence has been submitted to and accepted by WOAH.

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*.~~

A country or *zone* may be considered free from FMD where *vaccination* is practised when the relevant provisions in point 2 of Article 1.4.6. have been complied with, and when within the proposed free country or *zone* ~~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;~~ for at least the past 12 months:

~~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~~;

   b) there has been no *infection* of FMDV in the unvaccinated subpopulations ~~*case* with clinical sign of FMD during the past 12 months~~;

   c) the *Veterinary Authority* has current knowledge of, and authority over, all *herds* of domestic and *captive wild* susceptible animals in the country or *zone*;

   d) the *Veterinary Authority* has current knowledge of the distribution~~,~~ and habitat ~~and indication of disease occurrence through passive *surveillance*~~ of *wild* and *feral* susceptible animals in the country or *zone*;

e) compulsory systematic *vaccination* in the target *population* has been carried out to achieve adequate *vaccination* coverage and population immunity; based on the epidemiology of FMD in the country or *zone*, it may be decided to vaccinate only a defined subpopulation comprised of certain species or other subsets of the total susceptible population.

f) *vaccination* has been carried out following appropriate vaccine strain selection;

g) measures to prevent the introduction of *infection* have been in place; in particular, the importations or movements of *commodities* into the country or *zone* have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*;

2~~3~~) for the past 24 months ~~supply documented evidence that~~:

~~a)~~ appropriate *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 points 1 a) and 1 b) above. ~~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 country ~~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 in accordance with Chapter 1.6.~~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 annual reconfirmation of compliance with all points above and relevant provisions under point 4 of Article 1.4.6. Documented evidence should be resubmitted ~~that the information in points 2, 3 and 4 above be re-submitted~~ annually for all points above. ~~And~~ Any changes in the epidemiological situation or other significant events ~~including those relevant to points 3b) and 4~~ should be ~~reported~~ notified to WOAH in accordance with ~~the requirements in~~ Chapter 1.1.

Article 8.8.3bis.

Transition of vaccination status in a country or zone free from FMD

As recommended in Article 4.18.10., *vaccination* programmes may include an exit strategy.

If a Member Country that meets the requirements of a ~~FMD free~~ country or *zone* free from FMD where *vaccination* is practised and is recognised by WOAH as such, wishes to change its status to ~~FMD free~~ country or *zone* free from FMD where *vaccination* is not practised, it should notify WOAH 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 WOAH. If the ~~dossier~~ application for the new status is not provided within 24 months of the cessation or the compliance is not approved by WOAH, then the status of the country or *zone* as being free ~~with *vaccination*~~ from FMD where *vaccination* is practised will be suspended. If the country or *zone* 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~~ suspended.

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 WOAH as such, wishes to change its status to country or *zone* free from FMD where *vaccination* is practised, it should provide WOAH 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 WOAH. As soon as it is recognised free from FMD where ~~with~~ *vaccination* is practiced, 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~~ suspended.

~~If a country needs to define a *protection zone* in accordance with Article 4.34.6. 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 a~~n effective~~ *biosecurity plan* ~~management system~~.

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;~~

   a~~b~~) no ~~evidence of~~ *infection* with FMDV has ~~been found detected~~ occurred during the past 12 months;

   ~~c~~b) *vaccination* against FMD is prohibited;

   ~~d~~c) no animal vaccinated against FMD within the past 12 months is in the *compartment*;

   ~~e~~d) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;

   ~~f~~e) documented evidence shows that *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation;

   ~~g~~f) an *animal identification* and *traceability* system in accordance with Chapters 4.2~~1~~. and 4.3~~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 *infection* ~~*case*~~ or transmission of FMDV 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*.

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;~~

a~~b~~) no ~~evidence of *infection* with~~ *infection* or transmission of FMDV has ~~been found~~ occurred during the past 12 months;

b~~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;

c~~d~~) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;

d~~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;

e~~f~~) an *animal identification* and *traceability* system in accordance with Chapters 4.~~1~~2. and 4.~~2~~3. 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 2 b~~c~~), 2 d~~e~~) and 2 e~~f~~).

The *compartment* should be approved by the *Veterinary Authority*. The approval should only be granted when no *infection* ~~*case*~~ or transmission of FMDV 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~~A ~~FMD infected~~ country or *zone* shall be considered as infected with FMDV ~~is one that does not fulfil~~ when the requirements for acceptance ~~to qualify~~ as a country or *zone* free from FMD either ~~FMD free~~ where *vaccination* is not practised or ~~FMD free~~ where *vaccination* is practised are not fulfilled.

Article 8.8.5bis.

Establishment of a protection zone within a country or zone free from FMD

Susceptible animals in ~~the~~ a country or *zone* free from FMD should be protected by the application of *biosecurity* 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*.

A *protection zone* may be established, in response to an increased risk of FMD, in accordance with Article 4.4.6. The *Veterinary Authority* should submit as soon as possible to WOAH, ~~in addition to the requirements of Article 4.4.6.~~ in support of the application, documented evidence that, in addition to the requirements of Article 4.4.6.:

1) the susceptible animal populations within the *protection zone* are clearly identified as belonging to the *protection zone;*

2) strict movement control of susceptible animals and their products is in place in line with the relevant provisions of this chapter;

3) enhanced *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in place in the *protection zone* and in the rest of the country or *zone*;

4) intensified *biosecurity* in the ~~rest of the country~~ *protection zone* is in place;

5) awareness campaigns aimed at the general public, breeders, traders, *veterinarians* and other relevant stakeholders are implemented;

6) a *biosecurity plan* including the implementation of emergency *vaccination* is in place, in particular when the *protection zone* is established in a country or *zone* free from FMD where *vaccination* is not practised.

The *protection zone* is considered as effectively established when the conditions described in this article and in Article 4.4.6. have been applied and documented evidence is submitted to and has been accepted by WOAH.

If *vaccination* is implemented in the *protection zone* established within a country or *zone* free from FMD where *vaccination* is not practised, the free status of the *protection zone* is suspended ~~while~~and the free status of the rest of the country or *zone* is not affected. The status of the *protection zone* can be recovered following point 1 of Article 8.8.7. Alternatively, ~~S~~should the Member Country wish to maintain *vaccination* in the *protection zone,* Article 8.8.3bis applies.

In the event of an *outbreak* within a previously free *protection zone*, the free status of the *protection zone* is suspended and the status of the *protection zone* can be recovered following Article 8.8.7., while the free status of the rest of the country or *zone* is not affected. ~~For the establishment of~~ Alternatively, i~~I~~f the *Veterinary Authority* establishes a *containment zone* after an *outbreak* in the *protection zone*, an application in accordance with Articles 4.4.7. and 8.8.6 should be submitted as soon as possible. In particular, when applying for a *containment zone*, it should be stated whether the boundaries would be the same as the boundaries of the *protection zone* or within the boundaries of the *protection zone*.

A *protection zone*, in which the free status has remained unchanged, should be limited to less than 24 months from the date of its approval by WOAH. The Member Country should either apply for the removal of the *protection zone* or official recognition of the *protection zone* as a separate zone within 24 months from the date of its approval by WOAH.

Article 8.8.6.

Establishment of a containment zone within a ~~FMD free~~ country or zone previously free from FMD

In the event of ~~limited~~ *outbreaks* within a ~~FMD free~~ country or *zone* previously free from FMD where *vaccination* is either practised or not, including within a *protection zone*~~, with or without *vaccination*~~, a ~~single~~*containment zone*, which includes all epidemiologically

linked *outbreaks*, may be established, in accordance with Article 4.4.7., ~~for the purpose of minimising~~ to minimise the impact on the ~~entire rest of the~~ 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 WOAH, 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 animals and other *commodities* ~~mentioned in this chapter~~ are in place in the country or *zone*;

2) on confirmation, ~~an additional~~ the standstill and movement controls described in point 1 have been reinforced ~~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;~~

3~~4~~) epidemiological 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*;~~

4~~8~~) *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*;

5~~9~~) 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 areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of ~~the these~~ 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 WOAH as complying with points 1 to 5~~9~~ 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 4 a) of Article 4.4.7., the approval of the *containment zone* is withdrawn and the ~~FMD~~ free 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 4 ~~a~~b) of Article 4.4.7., the approval of the *containment zone* is withdrawn and the free 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~~18 ~~-~~ 24 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~~ *infection* with FMDV ~~*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~~ NSP 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~~ Chapter 1.11~~6.6.~~, has been accepted by WOAH.

The time periods in points 1 a) to 1 c) 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~~ *infection* with FMDV 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~~ NSP 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~~ Chapter 1.11~~6.6.~~ has been accepted by WOAH.

Where a *stamping-out policy* is not practised, the above waiting period~~s~~ does not apply, and Article 8.8.3. applies.

3) When ~~a *case* of~~ *infection* with FMDV or transmission of 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~~ NSP 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 Article~~s~~ 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~~ NSP 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~~ Chapter 1.11., has been accepted by WOAH.

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* and status has been regained following the provisions in this article.

For Member Countries not applying for recovery within 24 months after suspension of status, the provisions of Article 8.8.2., Article 8.8.3. ~~or,~~ Article 8.8.4. or Article 8.8.4.bis apply.

Article 8.8.8.

Direct transfer within a country of FMD susceptible animals from an infected zone, including 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 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~~ the *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 within a country 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~~ a ~~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 of susceptible animals 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;

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 of domestic ruminants and pigs from ~~FMD free~~ countries, ~~or~~ zones or compartments free from FMD where vaccination is practised

EU comment

This comment applies to this article and other articles where the term "domestic ruminants and pigs" is used.

The above term should be clarified. What is the exact meaning of "domestic ruminants and pigs"? Considering the glossary, "domestic" could mean any animal which is not wild nor

feral nor captive wild. This would open the question on the issue of traded animals that might have a phenotype not significantly affected by human selection (i.e. captive wild) that would be excluded from this category. Is the intention of the concerned articles to exclude measures fur captive wild animals?

Probably a revision of the wording would help increasing the clarify of the text.

~~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*~~;~~.

~~6) if transiting a free *zone* where *vaccination* is not practised, were not in contact with any FMD susceptible animal during transportation to the *place of shipment*.~~

Article 8.8.11bis.

Recommendations for the importation of vaccinated animals destined for slaughter 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 of domestic ruminants and pigs 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 ~~2~~3 a) and ~~2~~3 b) above;

5~~4a)~~ the animals were isolated for the 30 days prior to shipment:

a) in ~~an establishment or~~ a *quarantine station* ~~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~~ or

b) ~~if the animals were isolated~~ in an establishment that is not a *quarantine station*, ~~that~~ FMD did not occur within a 10-kilometre radius of the *establishment* during that period, 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 ~~, 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 of fresh and frozen semen of domestic ruminants and pigs 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*;

2) the semen was collected, processed and stored in accordance with Chapters 4.~~5~~6. and 4.~~6~~7.

Article 8.8.15.

Recommendations for importation of frozen semen of domestic ruminants and pigs 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* or compartment 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) have not been vaccinated and were subjected, not less than 21 days and not more than 60 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~~6. and 4.~~6~~7.;

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 clinical sign of FMD.

Article 8.8.16.

Recommendations for importation of frozen semen of domestic ruminants and pigs 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) have not been vaccinated and were subjected, not less than 21 days and not more than 60 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~~6. and 4.~~6~~7.;

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 of *in vitro* produced bovine embryos 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* or *compartment* 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., and 4.10. as relevant.

Article 8.8.19.

Recommendations for importation for *in vitro* produced bovine embryos 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* or *compartment* 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 and not more than 60 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., and 4.10. as relevant.

Article 8.8.20.

Recommendations for importation of fresh meat or meat products of susceptible animals 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.;

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 of fresh meat and meat products of ruminants and pigs 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) ruminants or pigs that 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.;

2) ruminants or pigs that 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 from which the head, including the pharynx, tongue and associated lymph nodes, has been excluded from the shipment.

Article 8.8.22.

Recommendations for importation of fresh meat of bovines and water buffaloes *(Bubalus bubalis)* (excluding feet, head and viscera) 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 cattlecattle~~ bovines 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 cattlecattle~~ bovines 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~~3., 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 of fresh meat of domestic pigs 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~~3., 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 8.8.22ter.

Recommendations for importation of fresh meat of domestic sheep and goats ~~small ruminants~~ (excluding feet, head and viscera) from FMD infected countries or zones where an official control programme exists

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

1) animals that were transported, in a *vehicle* which was cleaned and disinfected before the domestic sheep and goats 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*;

2) animals that 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;

3) animals that were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., with favourable results; and

EITHER,

4) animals that comply with Article 8.8.12.; and 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;

OR

5) animals that:

   a) have remained, for at least three months prior to *slaughter*, in a *zone* of the *exporting country* where bovines and water buffaloes are regularly vaccinated against FMD and where an *official control programme* is in operation;

   b) were kept for the past 30 days in:

      – a *quarantine station*; or

– an *establishment*, within a ten-kilometre radius of which FMD has not occurred during that period, and no susceptible animals were introduced into the *establishment* during that period;

c) had their carcasses deboned:

i) from which the major lymphatic nodes have been removed;

ii) 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 8.8.23.

Recommendations for importation of meat products of susceptible animals 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 of ~~milk and milk~~ products of animal origin (other than those covered by other articles ~~listed in Article 8.8.1bis.) intended for human consumption and for products of animal origin (from susceptible animals) intended for use in animal feeding or for agricultural or industrial use~~ 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 of milk and milk products (other than those listed in Article 8.8.1bis.) 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 at the time of *milk* collection 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 of wool, hair, bristles, raw hides and skins from domestic susceptible animals 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~~ and 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 of straw and forage 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 of skins and trophies derived from susceptible ~~wildlife~~ animals (other than those listed in Article 8.8.1bis.) 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 of skins and trophies derived from susceptible ~~wildlife~~ animals (other than those listed in Article 8.8.1bis.) 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:

EU comment

It would be helpful to clarify which "meat and meat products" is being referred to above. Does this refer to commodities of *susceptible species* as referred to in point 2 of Article 8.8.1.? Without clarification this could be misread as applying to any "meat and meat products", from any species.

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 milk products ~~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

EU comment

This comment is related to the heat treatment HTST (High-temperature short-time) for

pasteurisation if the milk pH is lower than 7, for a minimum of 72°C for a minimum of 15 seconds, which does not appear to be a sufficient risk mitigating measure. Hence this risk mitigating measure should be removed from the list.

Rationale can be found in Appendix B of the EFSA Assessment of the control measures of the Category A diseases of the Animal Health Law: prohibitions in restricted zones and risk-mitigating treatments for products of animal origin and other materials. [EFSA Journal 2022;20(8):7443. DOI: https://doi.org/10.2903/j.efsa.2022.7443]. Specifically in point B.3. on "Treatments assessed as not effective to mitigate the risk of spreading the Category A diseases". As indicated in the EFSA assessment, several studies mention that one HTST treatment is not sufficient to completely inactivate FMDV (Blackwell and Hyde, 1976; Dhennin and Labie, 1976, Salwa and Gaber, 2007, Tomasula *et al*., 2007). Whether the condition of pH lower than 7 will be sufficient to inactivate FMDV is doubtful, as Sonder *et al*. (1990) showed that neither acidification nor hydrogen peroxide treatment were reliable for the inactivation of FMDV in skimmed milk.

~~3~~2) if the *milk* has a pH of 7.0 or greater, the HTST process applied twice; or

3) any equivalent treatment that has been demonstrated to inactivate FMDV.~~-~~

~~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~~ animals ~~susceptible to the disease~~

For the inactivation of FMDV present in skins and trophies from susceptible ~~*wildlife*~~ *animals* ~~*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.

WOAH 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.~~

A Member ~~Countries~~ Country may, on a voluntary basis, apply for endorsement of ~~their~~ its *official control programme* for FMD in accordance with Chapter 1.6., when ~~they have~~ it has implemented measures in accordance with this article.

For a Member Country's *official control programme* for FMD to be endorsed by WOAH, the Member Country should provide a description of an *official control programme* for the control and eventual eradication of FMD in the country or *zone*. This document should address and provide documented evidence on the following:

1) epidemiology:

   a) the detailed epidemiological situation of FMD in the country, highlighting the current knowledge and gaps;

   b) the main production systems and movement patterns of susceptible animals and their products within and into the country and, where applicable, the specific *zone*;

2) surveillance and diagnostic capabilities:

   a) FMD *surveillance* in place, in accordance with Chapter 1.4. and Articles 8.8.40. to 8.8.42.;

   b) diagnostic capability and procedures, including regular submission of samples to a *laboratory* that performs diagnostic testing and further characterisation of strains;

   c) serosurveillance conducted in susceptible species, including *wildlife,* to serve as sentinels for FMDV circulation in the country;

3) *vaccination*:

   a) *vaccination* is compulsory in the target *population* and is practised in accordance with Chapter 4.18.;

   b) detailed information on *vaccination* campaigns, in particular:

      i) the strategy that is adopted for the *vaccination* campaign;

      ii) target *populations* for *vaccination*;

      iii) target geographical area for *vaccination*;

      iv) monitoring of *vaccination* coverage, including serological monitoring of population immunity;

      v) the strategy to identify vaccinated animals;

      vi) technical specification of the vaccines used including matching with the circulating FMDV strains and description of the vaccine licensing procedures in place;

      vii) if relevant, proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;

viii) the proposed strategy and work plan including the timeline for transition to the cessation of *vaccination*;

4) the measures implemented to prevent the introduction of the pathogenic agent and to ensure the rapid detection of all FMD *outbreak*s;

5) an emergency preparedness plan and an emergency response plan to be implemented in case of FMD *outbreaks*;

6) work plan and timelines of the *official control programme*;

7) performance indicators for assessing the effectiveness of the control measures to be implemented;

8) monitoring, evaluation and review of the *official control programme* to demonstrate the effectiveness of the strategies.

~~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 *populations* 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.~~

The country will be included in the list of countries having a WOAH endorsed *official control programme* for FMD in accordance with Chapter 1.6.

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 WOAH 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 WOAH 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 in unvaccinated animals. Previously or newly introduced vaccinated animals should be considered in the strategy and design of the *surveillance* programme.

EU comment

Reference is made to the EU comment included in Article 8.8.2.

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 ~~non-structural proteins~~ NSP, 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. WOAH endorsed official control programme

Surveillance strategies employed in support of a WOAH 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 WOAH 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 cattlecattle~~ bovines 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. Selection of diagnostic tests and interpretation of results should take into account ~~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 positive~~s~~ results 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 i~~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 support the interpretation of ~~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 free from FMD where ~~without~~ vaccination is not practised or early recovery of ~~free~~ status free from FMD where ~~with~~ vaccination is practised 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 practised, 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 1 c) of Article 8.8.7. or under point 3 a) 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 the *Veterinary Authority* ~~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~~ NSP 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~~ NSP 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 or husbandry systems that do not allow sufficient observation, serological surveys with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level).

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 or husbandry systems that do not allow sufficient observation, serological surveys with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level);

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 that provides high ~~potency of at least 6PD50 or equivalent~~ probability of protection which may be achieved by a vaccine with high potency of at least 6PD50 or equivalent and evidence of a good match between the vaccine strain and the field virus; or

– 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 free from FMD where ~~with~~ vaccination is practised 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 practised in the area outside of the area(s) where emergency *vaccination* has been applied, earlier than six months as specified under point 3 a) 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~~ the *Veterinary Authority* 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 or husbandry systems that do not allow sufficient observation 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;

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. However, recognising the difficulty in sampling *wildlife*, *surveillance* of domestic species in close contact with susceptible *wildlife* can provide supportive evidence of the *animal health status* of these *wildlife* populations. Hunting, capture and non-invasive sampling and observation methods can also be used to obtain information and diagnostic samples from *wildlife* species.

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 a WOAH 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~~ NSP tests or ~~structural protein~~ SP 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~~ SP and the ~~nonstructural proteins~~ NSP of the virus. Vaccinated *animals* produce antibodies mainly or entirely to the ~~structural proteins~~ SP of the virus depending upon vaccine purity. ~~The structural protein SP 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~~ SP 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 *populations*, ~~structural~~

~~protein~~ SP tests may be used to monitor the serological response to the *vaccination*. The SP tests are serotype specific. ~~and f~~For optimal sensitivity ~~one should select~~ an antigen or virus closely related to the field strain expected should be selected.

~~Nonstructural protein~~ NSP 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~~ NSP, 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~~ NSP 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 cattlecattle~~ bovines 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 factors or 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 elapsed, 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

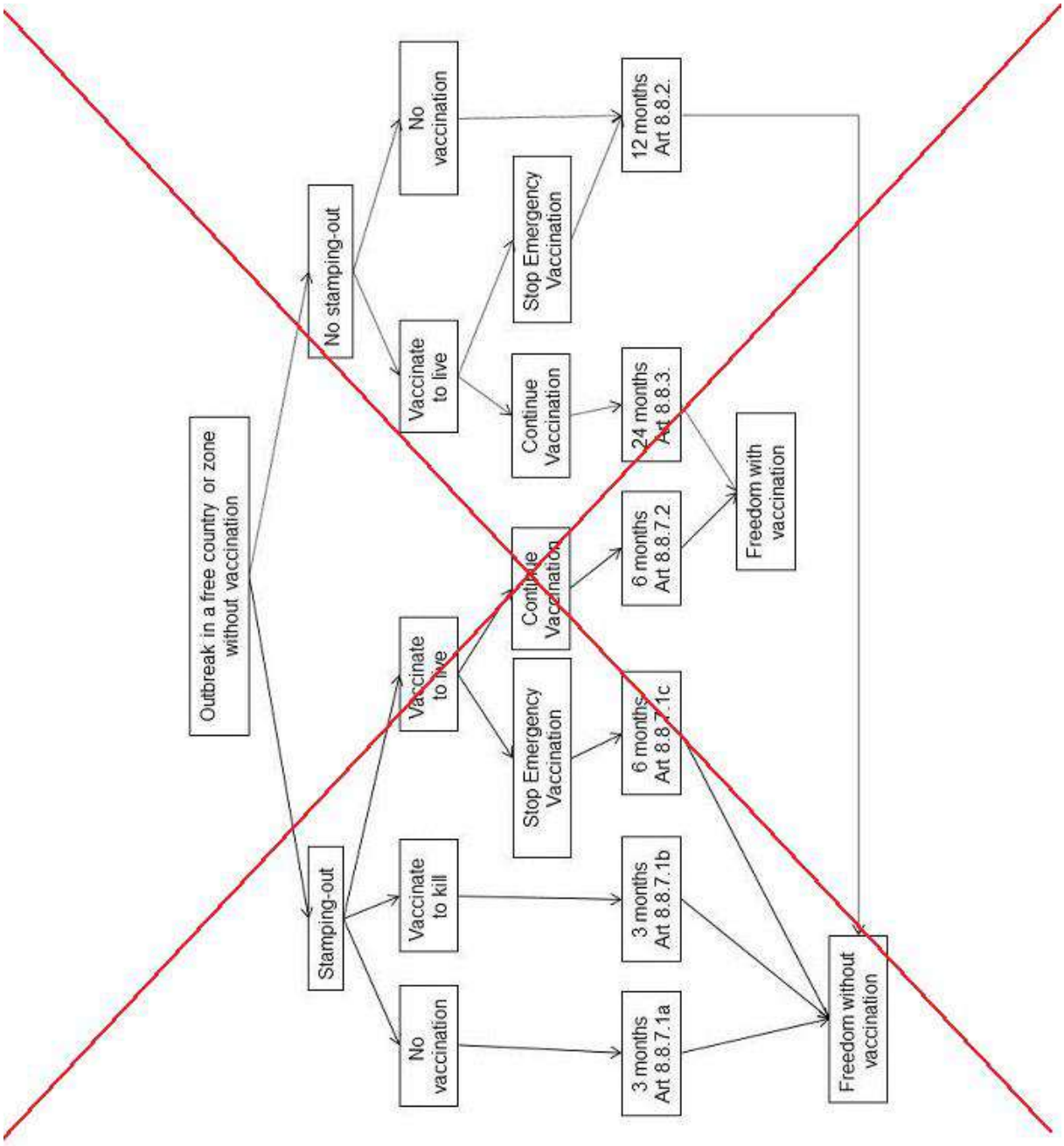
If transmission is demonstrated, an *outbreak* is declared.

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~~ NSP 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.

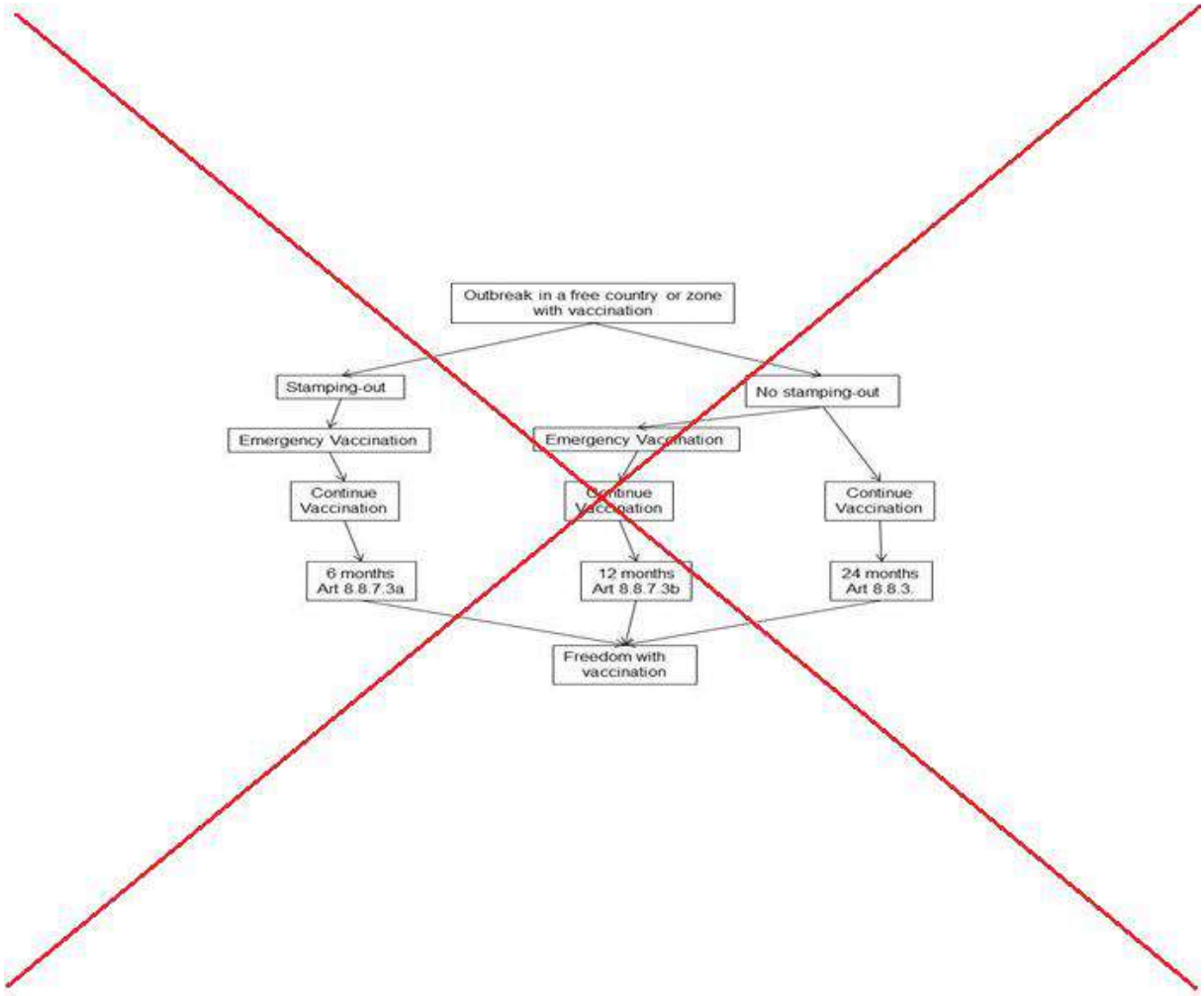
~~Abbreviations and acronyms:~~	
~~ELISA~~	~~Enzyme-linked immunosorbent assay~~
~~VNT~~	~~Virus neutralisation test~~
~~NSP~~	~~Nonstructural protein(s) of foot and mouth disease virus (FMDV)~~
~~3ABC~~	~~NSP antibody test~~
~~SP~~	~~Structural protein of foot and mouth disease virus~~

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



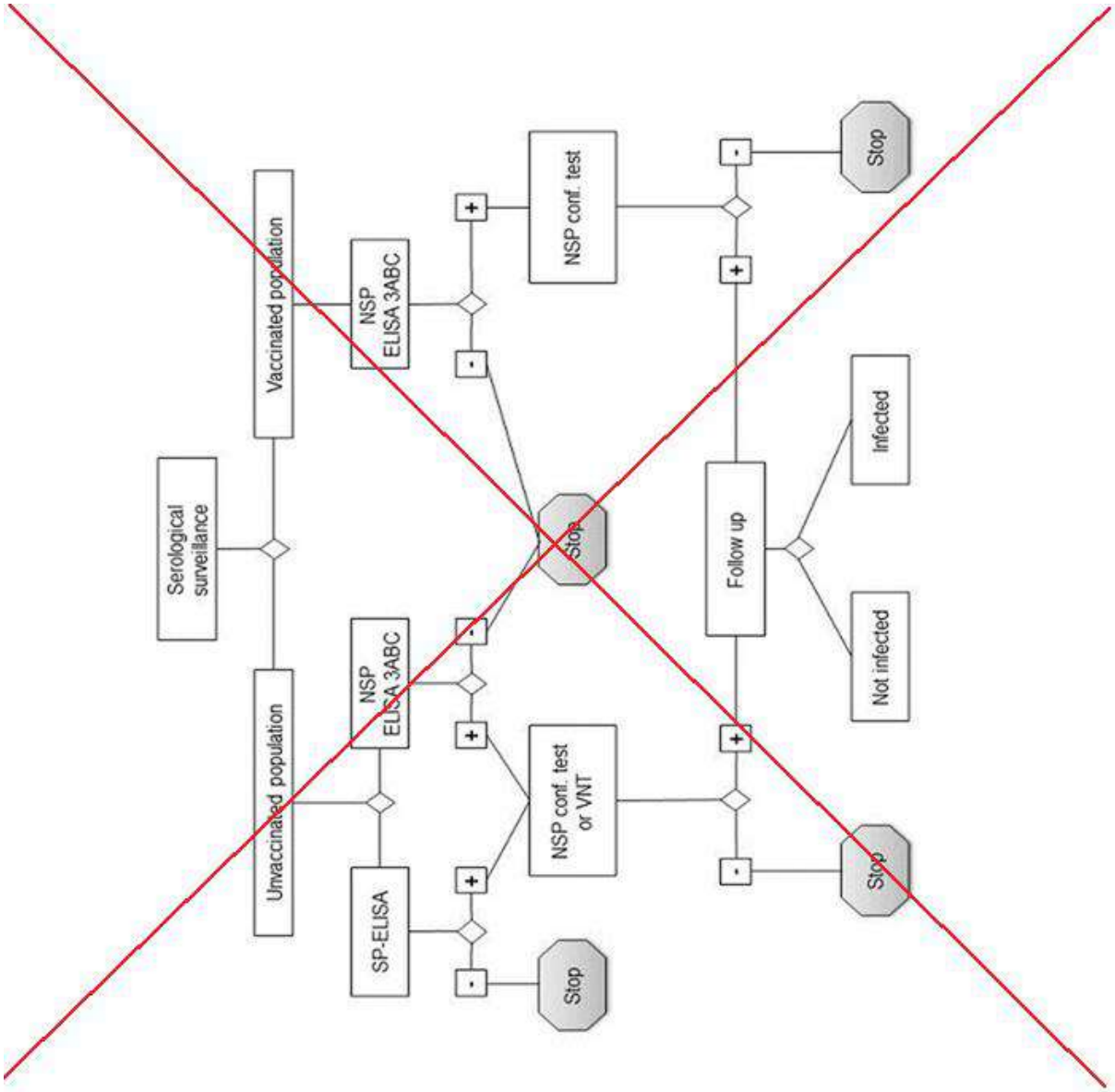
Waiting periods are minima depending upon outcome of *surveillance* specified in respective articles. If there are multiple waiting periods because of different control measures, the longest applies.

~~**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.~~

~~Fig. 3.~~ ~~Schematic representation of laboratory tests for determining evidence of infection with FMDV by means of serological surveys~~



Annex 9

CHAPTER 8.14.

INFECTION WITH RABIES VIRUS

EU position

The EU thanks the Code Commission for the latest version of the revised Chapter 8.14. on Infection with rabies virus and agrees with the changes made on the article introduced in the draft to address dog-mediated rabies vaccination programmes.

However, as explained in its previous comments and in line with the risk assessment carried out by the European Food Safety Authority in this regard, the EU continues to oppose the changes proposed by WOAH in Article 8.14.6bis and therefore does not support the adoption of this chapter as presented.

[…]

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 signs of rabies the day prior to or on the day of shipment;

2) were permanently identified and their identification ~~number~~code 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 signs of rabies the day prior to or on the day of shipment;

2) were permanently identified and their identification ~~number~~code 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.

Article 8.14.11bis.

Recommendations for dog-mediated rabies vaccination programmes

When developing and implementing *vaccination* programmes for dog-mediated rabies, in addition to provisions in Chapter 4.18., Member Countries should:

1. Prepare for the *vaccination* programme:

   a) consult with all relevant stakeholders, including target communities to define the most appropriate time to increase community participation and reduce the time required to complete *vaccination*;

   b) ensure safety of vaccination teams including training in humane dog capture and handling, and a strategy to manage exposure to suspect rabid animals.

2. Choose a vaccine and the *vaccination* strategy:

   a) Priority should be given to vaccinating *free-roaming dogs*, including puppies, to ~~immediately~~ quickly interrupt the rabies virus transmission cycle.

   b) *Vaccination* campaigns should be conducted recurrently (usually annually). More ~~regular~~ frequent *vaccination* campaigns may be considered in especially high-risk areas, or to quickly interrupt the cycle of virus transmission.

   c) The *vaccination* strategy should take into account simultaneous dog population management programmes as described in Chapter 7.7.

3. Monitor the *vaccination* programme:

   a) To monitor the *vaccination* coverage, vaccinated dogs should be identified and registered in ~~a database~~ an *animal identification system*.

   b) *Vaccination* certificates which state identification of the dog, date of *vaccination* and product should be provided to dog owners as proof of *vaccination*.

   c) *Vaccination* coverage should be monitored at the smallest administrative level possible.

Annex 10

CHAPTER 8.15.

INFECTION WITH RIFT VALLEY FEVER VIRUS

EU position

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

Article 8.15.1.

General provisions

1) The aim of this chapter is to mitigate the animal and public health risks posed by Rift Valley fever (RVF) and to prevent its international spread.

2) For the purposes of this chapter:

a) 'epizooticepidemic area' means a part of a country or *zone* in which an epizooticepidemic of RVF is occurrings, and which does not correspond to the definition of *zone*;

b) 'epizooticepidemic of RVF' means a sudden and unexpected change in the distribution or increase in *incidence* of, or morbidity or mortality of RVF;

c) 'inter-epizooticepidemic period' means a period with low levels of *vector* activity and low rates of RVF virus (RVFV) transmission between two epidemics;

d) 'susceptible animals' means ruminants and dromedary camels.

32) Humans and many animal species are susceptible to *infection* can be affected by RVF. For the purposes of the *Terrestrial Code*, RVF is defined as an *infection* of ruminants 'susceptible animals' with Rift Valley fever virus Rift Valley fever virus ((RVFV)).

43) The following defines the occurrence of *infection* with RVFV:

a) RVFV, excluding vaccine strains, has been isolated and identified as such from a sample from a ruminant susceptible animal; or

b) antigen or ribonucleic acid specific to RVFV, excluding vaccine strains, has been identified detected in a sample from a ruminant susceptible animal showing clinical signs or pathological lesions consistent with RVF, or epidemiologically linked with epidemiological links either to a confirmed or suspected *case* of RVF, including in or to a human infected with RVFV, or giving cause for suspicion of association or contact with RVFV; or

c) antibodies specific to RVFV antigens which that are not the consequence of *vaccination*, have been identified detected in a sample from a ruminant susceptible animal showing clinical signs or pathological lesions consistent with RVF, or with either epidemiological links either to a confirmed or suspected *case* of RVF, including in or to a human infected with RVFV, or giving cause for suspicion of association or contact with RVFV.

54) For the purposes of the *Terrestrial Code*, the *infective period* for RVF shall be 14 days and the *incubation period* shall be 7 days.

6) For the purposes of the *Terrestrial Code*, the *incubation period* for RVF shall be 7 days.

765) In areas where RVFV is present, epizooticepidemics of RVF may occur following favourable climatic, and other environmental conditions and availability of susceptible host animal and competent *vector* populations. EpizooticEpidemics are separated by

inter-~~epizootic~~epidemic periods. The transition from an inter-~~epizootic~~epidemic period to an ~~epizootic~~epidemic complies with point 1~~)~~(~~d~~e) of Article 1.1.3. in terms of *notification*.

~~6) For the purposes of this chapter:~~

~~a) 'area' means a part of a country that experiences epizootics and inter-epizootic periods, but which does not correspond to the definition of *zone*;~~

~~b) 'epizootic of RVF' means the occurrence of *outbreaks* at an incidence substantially exceeding that during an inter-epizootic period or the occurrence of indigenous human cases;~~

~~c) 'inter-epizootic period' means the period of variable duration, often long, with intermittent low level of *vector* activity and low rate of virus transmission, which is often not detected;~~

~~d) ruminants include dromedary camels.~~

~~7) The historical distribution of RVF has been parts of the African continent, Madagascar, some other Indian Ocean Islands and the south-western Arabian Peninsula. However, *vectors*, environmental and climatic factors, land-use dynamics, and animal movements may modify the temporal and spatial distribution of the *infection*.~~

7~~8~~) When authorising importation or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.15.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the RVF status of the ~~ruminant~~ susceptible animal population of the *exporting country*.

8~~9~~) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.15.2.

Safe commodities

When authorising the importation or transit of the following *commodities* ~~and any products made from them~~, *Veterinary Authorities* should not require any RVF-related conditions, regardless of the ~~RVF~~ *animal health status* of ~~the ruminant susceptible animal population of~~ the *exporting country* or *zone*:

1) hides and skins;

2) wool and fibre~~.~~;

3) extruded dry pet food;

4) heat-treated *meat products* in a hermetically sealed container with an F0 value of 3 or above.

Article 8.15.3.

Country or zone free from RVF

A country or a *zone* may be considered free from RVF when *infection* with RVFV is notifiable in the entire country and either:

1) it meets the requirements for historical freedom in ~~point 1 *a)* of~~ Article 1.4.6.; or

2) it meets the following conditions:

a) an on-going ~~pathogen~~-specific *surveillance* programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with RVFV in ~~ruminants~~ susceptible animals in the country or *zone* for a minimum of ten years; and

b) during that period no indigenous ~~human cases~~ infections in humans ~~have occurred has~~ have been reported by the public health authorities in the country or *zone*.

A country or *zone* free from RVF will not lose its free status through the importation of ~~ruminants~~ susceptible animals that are seropositive, so long as they are either permanently identified as such or destined for immediate *slaughter*.

Article 8.15.4.

Country or zone infected with RVFV ~~during the inter-epizootic period~~

A country or *zone* infected with RVFV~~, during the inter-epizootic period,~~ is one that does not ~~comply with~~ meet the requirements of Article 8.15.3. ~~in which virus activity is present at a low level but the factors predisposing to an epizootic are absent.~~

~~Article 8.15.5.~~

~~Country or zone infected with RVFV during an epizootic~~

~~A country or *zone* infected with RVFV, during an epizootic, is one in which *outbreaks* of RVF are occurring at an incidence substantially exceeding that of the inter-epizootic period; or one in which indigenous human cases of RVF are occurring even in the absence of detection of animal *cases*.~~

Article 8.15.~~6~~5.

Strategies to protect from vector attacks during transport

Strategies to protect susceptible animals from *vector* attacks during transport should take into account the local ecology and potential insecticide resistance of the *vectors*. ~~and potential r~~*~~Risk management~~* Protection measures include:

1) treating animals and *vehicles/vessels* with insect repellents and insecticides prior to and during transportation;

2) *loading*, transporting and *unloading* animals at times of low *vector* activity;

3) ensuring *vehicles/vessels* do not stop en route ~~during dawn or dusk, or overnight,~~ unless the animals are ~~held behind insect-proof netting~~ protected from *vector* attacks;

4) using historical and current information to identify lower risk ports and transport routes.

Article 8.15.~~7~~6.

Recommendations for importation of susceptible animals from countries or zones free from RVF

~~For ruminants~~ ~~susceptible animals~~

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

1) were kept in a country or *zone* free from RVF since birth or for at least 14 days prior to shipment;

AND

2) either:

   a) were vaccinated at least 14 days prior to leaving the free country or *zone*; or

   b) did not transit through an ~~epizootic~~epidemic area ~~experiencing an epizootic during transportation to the *place of shipment*;~~. ~~or~~

   ~~c)~~ ~~were protected from *vector* attacks when transiting through an~~ epizootic area ~~experiencing an epizootic~~.

Article 8.15.~~8~~7.

Recommendations for importation of susceptible animals from countries or zones infected with RVFV ~~during the inter-epizootic period~~

~~For ruminants susceptible animals~~

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

1) showed no clinical signs of RVF on the day of shipment;

2) met one of the following conditions:

   a) were vaccinated against RVF at least 14 days prior to shipment ~~with a modified live virus vaccine~~; or

   b) were held for at least 14 days prior to shipment in a *vector*-protected *quarantine station*, which is located in an area of demonstrated low *vector* activity. During this period the animals showed no clinical sign of RVF;

AND

3) ~~either:~~

   ~~a)~~ did not originate in or transit through an ~~area experiencing an epizooticepidemic area during transportation to the *place of shipment*; or~~

   ~~b) were protected from *vector* attacks when transiting through an area experiencing an epizootic area~~.

~~Article 8.15.98.~~

~~Recommendations for importation of susceptible animals from countries or zones infected with RVFV during an epizootic~~

~~For ruminants susceptible animals~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the susceptible animals: 1~~

~~1) showed no clinical signs of RVF on the day of shipment;~~

~~2) did not originate from an in the epizootic area of the epizootic;~~

~~3) were vaccinated against RVF at least 14 days prior to shipment;~~

~~4) were held for at least 14 days prior to shipment in a *vector*-protected *quarantine station*, which is located in an area of demonstrated low *vector* activity outside the of an epizootic area of the epizootic. During this period the animals showed no clinical signs of RVF;~~

~~AND~~

~~5) either:~~

   ~~a) did not transit through an epizootic area experiencing an epizootic during transportation to the *place of shipment*; or~~

   ~~b) were protected from *vector* attacks when transiting through an epizootic area experiencing an epizootic.~~

Article 8.15.~~10~~98.

Recommendations for importation of semen and *in vivo* derived embryos of susceptible animals from countries or zones ~~not free from~~ infected with RVFV

~~For semen and *in vivo* derived embryos of ruminants susceptible animals~~

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

1) showed no clinical signs of RVF within the period from 14 days prior to and 14 days following collection of the semen or embryos;

AND

2) either:

   a) were vaccinated against RVF at least 14 days prior to collection; or

   b) were subjected to a serological test ~~demonstrated to be seropositive~~ on the day of collection, with positive result; or

   c) were subjected to a serological test on two occasions with negative results on the day of collection and at least 14 days after collection ~~testing of paired samples has demonstrated that seroconversion did not occur within 14 days of between semen or embryo collection and 14 days after~~.

Article 8.15.~~11~~109.

Recommendations for importation of fresh meat and meat products ~~and meat products~~ from ~~ruminants~~ susceptible animals from countries or zones ~~not free from~~ infected with RVFV

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

1) the entire consignment of *meat* or *meat products* comes from:

   ~~1~~a) ~~ruminants which~~ susceptible animals that showed no clinical signs of RVF within 24 hours before *slaughter*;

   ~~2~~b) ~~ruminants which~~ susceptible animals that were slaughtered in an approved *slaughterhouse/abattoir* and were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3. with favourable results;

   ~~3~~c) carcasses ~~which~~ that were submitted to maturation at a temperature above 2°C for a minimum period of 24 hours following *slaughter*;

2) the necessary precautions were taken to avoid contact of the ~~products~~ *meat* or *meat products* with any potential source of RVFV.

~~Article 8.15.10bis.~~

~~Recommendations for importation of meat products from susceptible animals from countries or zones infected with RVFV~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat products* comes from *meat* that complies with Article 8.15.10.~~

Article 8.15.~~12~~11~~1~~10.

Recommendations for importation of milk and milk products ~~of~~ from susceptible animals from countries or zones ~~not free from~~ infected with RVFV

~~For milk and milk products~~

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

1) was subjected to pasteurisation; or

2) was subjected to a combination of ~~control measures~~ treatments with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Article 8.15.~~131211~~.

Surveillance

Surveillance for RVF should be carried out in accordance with Chapter 1.4.

Surveillance for arthropod *vectors* should be carried out in accordance with Chapter 1.5., especially to determine areas of low *vector* activity.

Detection of RVFV in *vectors* has low sensitivity and therefore is not a recommended *surveillance* method.

An epidemic should be suspected in countries or *zones* infected with RVFV, or countries or *zones* adjacent to a country or *zone* in which epidemics have been ~~reported~~ notified, when ecological conditions favour the breeding of large numbers of mosquitoes and other *vectors* with concurrent or consequent occurrence of an increased number of abortions, and mortality particularly in new-born susceptible animals showing clinical signs or pathological lesions consistent with RVF, or reports of indigenous infection in humans.

Ecological conditions can be assessed through the sharing and analysis of meteorological data, and data on precipitation and water levels ~~data~~, as well as the monitoring of *vector* activity. Clinical *surveillance* targeted at abortions and the use of sentinel *herds* can support detection of epidemics. Serological *surveillance* can also be used to assess the increase ~~of~~ in the number of seroconversions.

~~1)~~ During an ~~epizootic~~epidemic, *surveillance* should be conducted to define the extent of the ~~affected area~~ epidemic area for the purpose of disease prevention and control as well ~~of~~ as the extent of movements and trade of susceptible animals.

~~2)~~ During ~~the~~ inter-~~epizootic~~epidemic periods:~~, *surveillance* and monitoring of climatic factors predisposing to an epizootic should be carried out in countries or *zones* infected with RVFV.~~

1) the level of virus transmission should be assessed and determined by *surveillance* in sentinel *herds* of susceptible animals;

2) monitoring of ecological and meteorological factors should be carried out.

~~3)~~ Countries or *zones* adjacent to a country or *zone* in which ~~epizootic~~epidemics have been ~~reported~~ notified should determine their RVF status through an on-going specific *surveillance* programme.

~~To determine areas of low *vector* activity (see Articles 8.15.87. and 8.15.98.) *surveillance* for arthropod *vectors* should be carried out in accordance with Chapter 1.5.~~

~~Examination of *vectors* for the presence of RVFV is an insensitive *surveillance* method and is therefore not recommended.~~

The *Veterinary Authority* should coordinate in a timely manner with public health and other relevant authorities and share information to support the *surveillance* outcomes, the use of public health messages to prevent human exposure and the decision-making process for the prevention and control of RVF.

CHAPTER 10.9.

INFECTION WITH NEWCASTLE DISEASE VIRUS

EU position

The EU supports the adoption of this revised chapter.

Article 10.9.1.

General provisions!

1) For the purposes of the *Terrestrial Code*, Newcastle disease (ND) is defined as an *infection* of *poultry* caused by Newcastle disease virus (NDV), which is an avian paramyxovirus serotype 1 (APMV-1) that meets one of the following criteria for virulence:

   a) the virus has an intracerebral pathogenicity index (ICPI) in day-old chicks *(Gallus gallus)* of 0.7 or greater; or

   b) multiple basic amino acids have been demonstrated in the virus (either directly or by deduction) at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term 'multiple basic amino acids' refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test.

   In this definition, amino acid residues are numbered from the N-terminus of the amino acid sequence deduced from the nucleotide sequence of the F0 gene, 113–116 corresponds to residues –4 to –1 from the cleavage site.'

2) ~~*Poultry* is defined as 'all domesticated birds, including backyard *poultry*, used for the production of *meat* or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.~~

   ~~Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions, or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.~~

~~3)~~ For the purposes of the *Terrestrial Code*, the *incubation period* for ND shall be 21 days.

4~~3~~) This chapter deals with NDV *infection* of *poultry* ~~as defined in point 2 above~~ in the presence or absence of clinical signs.

5~~4~~) The occurrence of *infection* with NDV is defined as the isolation and identification of NDV as such or the detection of viral ribonucleic acid specific for NDV.

6~~5~~) A Member Country should not impose bans on the trade in *poultry commodities* in response to information on the presence of any APMV-1 in birds other than *poultry*, including *wild* birds.

7~~6~~) Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. When the use of ND vaccines is appropriate, those vaccines should comply with the standards described in the *Terrestrial Manual*.

[…]

Annex 12

CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

EU position

The EU thanks the Code Commission for the latest version of the revised Chapter 11.4. on bovine spongiform encephalopathy and appreciates the amendments introduced in the draft to address some of the EU comments, in particular regarding Articles 11.4.10. and 11.4.13. on importation of meat and meat products and blood and blood products respectively.

The EU still considers that whenever related to recycling, it would have been better that all BSE agents be considered and not only the classical BSE agent, since the risk of recycling of atypical BSE cannot be ruled out, as stated in point 1 of Article 11.4.1.

The EU can, however, support the adoption of this revised chapter as proposed. A few editorial suggestions are inserted in the text below for consideration before adoption.

Article 11.4.1.

General provisions

1) Bovine spongiform encephalopathy (BSE) is an invariably fatal neurological prion disease of bovines caused by a misfolded form of the prion protein (PrP^{Sc}), which includes both ~~classical (~~C-type (classical BSE) and ~~atypical strains (~~H- and L-type (atypical BSE) agents. ~~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.~~ Oral exposure to contaminated *feed* is the main route of transmission of classical BSE. Atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any ~~cattle~~ bovine population. ~~Oral exposure to contaminated *feed* is the main route of transmission of classical BSE.~~ Given that c~~C~~attle ~~A~~ bovine has~~ve~~ been experimentally infected by the oral route with a low molecular weight type of atypical BSE (L-type BSE~~,~~). ~~Therefore~~ and the potential for recycling of atypical BSE cannot be ruled out~~,is also potentially considered capable of being recycled in a cattle population if cattle are orally exposed to contaminated *feed* but~~ although there is no evidence that it plays a significant role in the epidemiology of BSE.

2) BSE primarily affects ~~cattle~~ bovines. 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~~*protein meal* is not ~~practiced~~practised. The recommendations in this chapter are intended to mitigate the human and animal health risks associated with BSE in bovines only.

3) For the purposes of the *Terrestrial Code*~~,~~:

~~1a) BSE is an invariably fatal neurological prion disease of cattle caused by a misfolded form of the prion protein ($PrP^{BSE}$$PrP^{Sc}$), including which includes both classical (C-type BSE) and atypical strains (H- and L-type BSE). for respectively having, respectively, a protease resistant $PrP^{BSE}$$PrP^{Sc}$ fragment of higher and lower molecular mass than classical BSE). The term 'BSE' includes both classical and atypical forms, unless otherwise specified.~~

~~2b)~~ ~~T~~the occurrence of a ~~BSE~~ *case* of BSE is defined by the ~~immunohistochemical (IHC) or immunochemical~~ detection of the ~~C-type~~classical BSE ~~PrP^{BSE}PrP^{Sc}~~ agent in brain tissue of a ~~bovid~~ bovine ~~of the species *Bos taurus* or *Bos indicus*.~~ , ~~with d~~Discrimination between atypical and classical BSE strains is based on the Western immunoblot banding pattern, as ~~described in the *Terrestrial Manual*~~.

4) For the purposes of this chapter~~:~~

~~3a)~~ , '~~C~~cattlebovine' means ~~a bovids~~ an animal of the species *Bos taurus* or *Bos indicus.*

~~4b) '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~~ bovines, *Veterinary Authorities* should not require any conditions related to BSE, regardless of the BSE risk posed by the ~~cattle~~ bovine population of the *exporting country*, *zone* or *compartment*:

1) *milk* and *milk products*;

2) semen and *in vivo* derived ~~cattle~~ bovine 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;~~

~~7~~6) dicalcium phosphate (with no trace of protein or fat~~).~~);

7) ~~foetal~~ fetal blood.

Other *commodities* of ~~cattle~~ bovines can be traded safely if in accordance with the relevant articles of this chapter.

Article 11.4.2.

~~The~~ General criteria for the determination of the BSE risk ~~of the cattle population~~ of a country, zone or compartment

~~The Due~~ Owing to its specific 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~~A BSE *risk assessment*, in accordance with the provisions of ~~Chapter 1.8.~~the "'Application for official recognition by WOAH of risk status for bovine spongiform encephalopathy"' that evaluates the ~~likelihood~~ risk of the classical BSE agent~~s~~ being recycled within the ~~cattle~~ bovine 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) ~~C~~cattlebovines;

ii) ~~R~~ruminant-derived ~~protein meal~~*protein meal*;

iii) ~~F~~*feed* (except packaged and labelled pet food ~~not intended for pets~~) that contains ruminant-derived ~~protein meal~~*protein meal*;

iv) ~~F~~fertili~~z~~sers that contain ruminant-derived ~~protein meal~~*protein meal*;

v) ~~A~~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~~ bovines being exposed to the classical BSE agent~~s~~ during the preceding eight years, either through imported *commodities* or as a result of the presence of the classical BSE agent~~s~~ ~~in~~ within the indigenous ~~cattle~~ bovine 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~~ bovines from being fed ruminant-derived ~~protein meal~~*protein meal*, taking account of:

- demographics of the ~~cattle~~ bovine population and production and farming systems;
- feeding practices, including the use of fertilisers containing ruminant proteins on land for grazing or harvesting forage;
- slaughtering and waste management practices;
- rendering practices;
- *feed* production, labelling, distribution and storage.

Depending on the outcome from this step, an evaluation of risk 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~~ bovines from being fed ruminant-derived ~~protein meal~~*protein meal*, taking account of:

- the nature and scope of a *feed* ban on feeding ruminants with ~~protein meal~~*protein meal* derived from ruminants;
- the fate of *commodities* with the greatest BSE infectivity ~~(those *commodities* as~~ 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;
- an 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~~ bovines becoming infected ~~with~~ following exposure to the classical BSE agent~~s~~ together with the likely extent and duration of any subsequent recycling and amplification within the ~~cattle~~ bovine 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~~ bovine industry practices or the implementation of ~~BSE~~ 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~~ of the classical BSE agent~~s~~ ~~have been~~ being recycled ~~in~~ within the ~~cattle~~ bovine population ~~through the feeding of ruminant-derived protein meal, with indigenous *cases* arising as a consequence, and to determine the date from which the risk of BSE agents being recycled within the cattle bovine population has been negligible~~.

2) ~~the~~ The ongoing implementation of a *surveillance* programme for ~~classical~~ BSE in the ~~cattle~~ bovine population in accordance with Article 11.4.18.

3) ~~the~~ The history of occurrence and management of ~~BSE~~ *cases* of BSE and bovines affected by atypical BSE.

Determination of the date from which the risk of BSE agents being recycled within the bovine population has been negligible is based on the points 1 to 3 above.

Article 11.4.3.

Negligible BSE risk

The BSE risk of ~~the cattle population of~~ a country~~,~~ or *zone* ~~or *compartment*~~ can be considered to be negligible if all the following conditions for the ~~cattle~~ bovine population are met for ~~at least~~ at least the preceding eight years:

1) A *risk assessment* as described in point 1 of Article 11.4.2. that has identified all potential risk factors associated with ~~the occurrence of~~ classical BSE~~, including feeding ruminants with ruminant derived *protein meal,*~~ has been conducted, and the Member Country has demonstrated through documented evidence that any identified risk factors have been adequately managed and that the ~~likelihood~~risk of the classical BSE agent~~s~~ being recycled ~~in~~ within the ~~cattle~~ bovine population has been negligible as a result of ~~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.~~

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.

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~~ each *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~~either:

i) all *cases* were born ~~at least eight years ago~~ before the date from which the risk of BSE agents being recycled within the ~~cattle~~ bovine population has been negligible;

~~OR~~or

ii) where a *case* was born ~~within the preceding eight years~~ after that date, subsequent investigations have confirmed that any identified source of *infection* has been ~~mitigated~~controlled and the ~~likelihood~~risk of BSE agents being recycled within the ~~cattle~~ bovine population has continued to be negligible.

4) Any *cases* of BSE or any bovines affected by atypical 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 WOAH 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 ~~any identified source of *infection* has been mitigated and the likelihood~~risk ~~of BSE agents 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 or~~,~~ *zone* ~~or *compartment*~~ can be considered to be controlled provided all of the conditions of Article 11.4.3. are met, but ~~at least~~ one or more of these 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 WOAH in accordance with Chapter 1.1.

Article 11.4.4bis.

Compartment with negligible or controlled BSE risk

The establishment and bilateral recognition of a *compartment* posing negligible or controlled BSE risk should follow the relevant requirements of this chapter and the principles laid down in Chapters 4.4. and 4.5.

Article 11.4.5.

Undetermined BSE risk

The BSE risk ~~of the cattle population~~ of a country or~~,~~ *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 11.4.5bis.

Maintenance of BSE risk status

The BSE risk status of a country or *zone* is not affected by imported *cases* of BSE or *cases* of BSE born before the date from which the risk of BSE agents being recycled within the bovine population has been negligible, or by any bovine affected by atypical BSE, as long as managed in accordance with Articles 11.4.3. or 11.4.4.

Should an indigenous *case* of ~~classical~~ BSE in a~~n animal~~ bovine born after the date from which the risk of BSE agents being recycled within the ~~cattle~~ bovine population has been negligible occur in a country or *zone* recognised as posing a negligible or controlled risk for BSE, the status of the country or *zone* is maintained, provided that documented evidence regarding the outcome of subsequent investigations is submitted to WOAH within 90 days demonstrating that any identified source of *infection* has been controlled and the risk of BSE agents being recycled within the ~~cattle~~ bovine population has continued to be negligible.

If no documented evidence is provided or if it is not accepted by WOAH, the provisions of Article 11.4.3. or Article 11.4.4. apply.

EU comment

The EU proposes to make a clear reference to the provisions in the Chapter addressing the handling of any case of BSE or any bovines affected by atypical BSE and suggests that the first sentence reads as follows:

"The BSE risk status of a country or zone is not affected by imported cases of BSE or cases of BSE born before the date from which the risk of BSE agents being recycled within the bovine population has been negligible, or by any bovine affected by atypical BSE, as long as managed in accordance with point 4 of Articles 11.4.3. ~~or 11.4.4.~~"

~~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~~ bovines 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~~The ~~cattle~~ bovines 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*~~ them to be traced throughout ~~its~~ their lifetime~~;~~.

AND EITHER:

2) ~~the~~The ~~cattle~~ bovines selected for export were born and kept in ~~the~~ a country, *zone* or *compartment* posing a negligible or controlled BSE risk after the date from which ~~during the period when~~ the ~~likelihood~~risk of ~~the~~ BSE agents being recycled ~~in~~ within the ~~cattle~~ bovine 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~~ It is demonstrated ~~as having~~that the ~~cattle~~ bovines selected for export have ~~not~~ never been fed ~~protein meal~~*protein meal* derived from ruminants.

Article 11.4.8.

Recommendations for importation of ~~cattle~~ bovines from a country or~~,~~ 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~~The ~~cattle~~ bovines selected for export are identified ~~by a permanent individual~~ through an *animal identification system* ~~from birth~~ enabling ~~each *animal*~~ them to be traced throughout ~~its~~ their lifetime~~;~~.

2) ~~are~~~~it~~ It is demonstrated ~~as having~~ that the ~~cattle~~ bovines selected for export have ~~not~~ never been fed ~~protein meal~~*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~~ bovine 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*;

2) they have been subjected to an ante-mortem inspection with favourable results;

~~AND EITHER:~~

3) they were born and kept in ~~the~~:

a) a country, *zone* or *compartment* posing a negligible BSE risk; or

b) a country, *zone* or *compartment* posing a controlled BSE risk after the date from which the risk of the BSE agents being recycled within the bovine population has been demonstrated to be negligible; or ~~or controlled BSE risk after the date from whichduring the period when the likelihood risk of the BSE agents being recycled in within the cattle population has been demonstrated to be negligible;~~

c) a country, *zone* or *compartment* posing a controlled BSE risk before the date from which the risk of the BSE agents being recycled within the bovine population has been demonstrated to be negligible, and the *fresh meat* and *meat products*:

i) derived from bovines 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

EU comment

The EU suggests inserting the word "were" before "derived" in point i) above for clarity reasons.

ii) were produced and handled in a manner which ensures that such products do not contain and are not contaminated with the *commodities* listed in point 1 of Article 11.4.14. or mechanically separated *meat* from the skull or from the vertebral column of bovines over 30 months of age.

~~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 points 1) *a)* and 1) *b)* of Article 11.4.14.;~~

~~ii) mechanically separated *meat* from the skull andnor or from the vertebral column from of cattle over 30 months of age~~.

Article 11.4.11.

Recommendations for importation of fresh meat and meat products from a country~~,~~ or zone ~~or compartment~~ posing an undetermined BSE risk

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

1) the ~~cattle~~ bovines 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~~ bovines from which the *fresh meat* and *meat products* were derived have ~~not~~ never been fed ~~protein meal~~*protein meal* derived from ruminants;

~~b~~3) the ~~cattle~~ bovines 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 points~~ 1) *a) and 1) b)*~~ of Article 11.4.14.;

b) mechanically separated *meat* from the skull ~~and~~nor or from the vertebral column ~~from~~ of ~~cattle~~ bovines over 30 months of age.

Article 11.4.12.

Recommendations for importation of bovine ~~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~~ bovines from which the ~~protein meal~~*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~~ were ~~are~~ identified through an *animal identification system* and were born and kept in ~~the~~ a country, *zone* or *compartment* posing a negligible BSE risk, and

EITHER

1) they were born after the date from which ~~during the period when~~ the risk of ~~the~~ BSE agents being recycled ~~in~~ within the ~~cattle~~ bovine population has been demonstrated to be negligible

OR

2) the *protein meal* was processed in accordance with Article 11.4.17.

Article 11.4.13.

Recommendations for importation of blood and blood products derived from bovine~~cattle~~ (except ~~foetal~~ fetal 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~~

1~~2~~) ~~the blood and blood products came from a country, *zone* or *compartment* posing a controlled BSE risk and the cattle bovines from which~~ the blood and blood products were derived from bovines that ~~are~~ were identified through an *animal identification system* and were born and kept in ~~the~~ a country, *zone* or *compartment* posing a negligible risk, or a country, *zone* or *compartment* posing a controlled BSE risk after the date from which the risk of BSE agents being recycled within the bovine population has been demonstrated to be negligible ~~after the date from which during the period when the likelihood risk of the BSE agents being recycled in within the cattle population has been demonstrated to be negligible~~;

OR

2~~3~~) the blood and blood products were:

a) collected from ~~cattle~~ bovines 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, or to any other procedure that can contaminate the blood with nervous tissue, 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~~ bovines of any age; ~~*b)*~~ skull, brain, eyes, vertebral column and spinal cord from ~~cattle~~ bovines 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*~~ they are derived from ~~cattle~~ bovines born before the ~~period when~~ date from which the risk of ~~the~~ BSE agents being recycled ~~in~~ within the ~~cattle~~ bovine population has been demonstrated to be negligible.

2) ~~Protein products, f~~Food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, ~~or~~ medical devices or any other product containing proteins prepared using *commodities* listed in point~~s~~ 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~~Bovine-derived ~~protein meal~~*protein meal*~~,~~ or any *commodities* containing such product~~s,~~ 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 11.4.1bis.) ~~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:

1) ~~the tallow~~ came from a country, *zone* or *compartment* posing a negligible BSE risk; or

2) ~~the tallow~~ is derived from ~~cattle~~ bovines which have been subjected to an ante-mortem inspection with favourable results, and has not been prepared using the *commodities* listed in ~~points~~point 1~~) a) and 1) b)~~ of Article 11.4.14.

Article 11.4.15bis.

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* posing 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.

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* posing 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.~~

Article 11.4.17.

Procedures for reduction of BSE infectivity in bovine 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~~*protein meal* containing ~~ruminant~~ bovine proteins~~.~~:

1) ~~T~~the raw material should be reduced to a maximum particle size of 50 mm before heating~~.~~;

~~2)~~ ~~T~~ and 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~~.~~; or

2) an alternative procedure that has been demonstrated to achieve at least an equivalent level of reduction in BSE infectivity.

Article 11.4.18.

Surveillance

The objective of BSE *surveillance* is to detect occurrence of BSE within the ~~cattle~~ bovine population.

~~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~~ bovines that usually has an insidious onset and 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 on a spectrum 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, t~~The~~The~~ final stages of the disease 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~~ bovine 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~~ includes all ~~animals~~ bovines that ~~lie on the continuum of the~~ show ~~symptoms~~ signs of the clinical spectrum of BSE ~~spectrum to the *Veterinary Authority**Veterinary Services* for subsequent investigation and follow-up~~.

In ~~those countries where cattle are intensively reared and~~production and farming systems that allow ~~cattle~~ bovines to be 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~~ which 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~~production and farming systems, ~~however,~~ where ~~cattle~~ bovines are not monitored as closely, situations may ~~inevitably~~ arise where an animal might be considered as a clinical suspect, yet if it ~~was~~ has not been 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* programme~~candidates~~ should take into account that the vast majority of ~~BSE~~ *cases* of BSE arise as single, isolated events. The ~~concurrent occurrence~~ concurrence of multiple animals with behavioural or neurological signs, or non-ambulatory or fallen stock is most likely associated with other causes.

The ~~following~~ animals that lie on ~~the continuum of~~ the ~~disease~~ clinical spectrum of BSE should be targeted for BSE *surveillance* and the following animals should be reported and followed up with appropriate laboratory testing in accordance with the *Terrestrial Manual* to accurately confirm or rule out the presence of BSE agents, including discrimination between atypical and classical BSE strains:

a) those displaying ~~some of the~~ progressive clinical signs suggestive of BSE mentioned in point 1 ~~of Article 11.4.18. suggestive of BSE~~ that are refractory to treatment, and where the presentation cannot be attributed to 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 at ~~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 (i.e. the presentation cannot be attributed to other common causes of recumbency ~~has have been ruled out~~);

d) those found dead (fallen stock), with an appropriate supporting clinical history (i.e. the presentation cannot be attributed to other common causes of death ~~has have been ruled out~~).

EU comment

The EU suggests inserting the word "clinical" before "presentation" in points a) and c) to d) above for clarity reasons and full coherence with the explanations given by the Code Commission in its report of February 2023 and with the provisions contained in Chapter 1.8.

In addition, the EU suggests clarifying the concept of "downers" in point c) by replacing it with the wording used in the current Article 11.4.21. on 'Surveillance: description of cattle subpopulations', as follows:

"c) those which are~~represented as downers (~~non-ambulatory, recumbent, unable to rise or to walk without assistance~~)~~, with an appropriate supporting clinical history (i.e. the clinical presentation cannot be attributed to other common causes of recumbency);"

~~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, cattle~~ bovine breeders, owners and keepers, *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 definition of the target population for BSE *surveillance*,

– ~~the identification and~~ the reporting of ~~potential candidates~~ ~~animals~~ bovines described in points 2 a) to 2 d)~~targeted for BSE *surveillance*~~,

– ~~for~~ the determination of animals to be subjected to laboratory testing,

– ~~for~~ the collection and submission of samples for laboratory testing,

– ~~and for~~the follow-up epidemiological investigations for BSE positive findings.

Annex 13

DRAFT CHAPTER 1.8.

APPLICATION FOR OFFICIAL RECOGNITION BY WOAH OF RISK STATUS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

EU position

The EU thanks the Code Commission for the latest version of the revised Chapter 1.8. on application for official recognition by the WOAH of risk status for bovine spongiform encephalopathy and appreciates the amendments introduced in the draft to address some of the EU comments submitted previously.

The EU still considers that whenever related to recycling, it would have been better that all BSE agents be considered and not only the classical BSE agent, since the risk of recycling of atypical BSE cannot be ruled out, as stated in Chapter 11.4.

The EU can, however, support the adoption of this revised chapter as proposed. An editorial suggestion is inserted in the text below for consideration before adoption.

Article 1.8.1.

~~Guidelines~~General principles

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 the classical BSE agent~~s (classical and atypical)~~ being recycled within the ~~cattle~~ bovine (*Bos indicus* and *Bos taurus*) 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~~.

~~For the purposes of this chapter, '~~A *case* of BSE ~~*case*' means the occurrence of classical BSE, as~~ is defined in point 3 of Article 11.4.1.

The information specified in Articles 1.8.2. to 1.8.6. should be provided by WOAH 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 WOAH website).

Each element of the core document of the dossier provided to WOAH~~,~~ 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:

~~–~~ ~~T~~the history of occurrence and management of BSE ~~*cases*~~ in the country or ~~*zone*~~ ~~(Article 1.8.2.)~~

– ~~L~~legislation ~~(Article 1.8.3.)~~

– ~~V~~veterinary system ~~(Article 1.8.4.)~~

– BSE risk assessment ~~(Article 1.8.5.)~~

– BSE surveillance ~~(Article 1.8.6.).~~

– the history of occurrence and management of BSE in the country or *zone*.

The dossier should indicate the date from which it can be considered that the risk of BSE agents being recycled within the bovine population has been negligible.

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 WOAH 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 *case* 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 *cases* 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.~~

~~2) If there have been *cases* of BSE *cases* or bovines affected by atypical 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 3.2.1.). 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., 3.2. and 3.3.

2) The applicant Member may provide information on any recent (not older than five years) WOAH 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;~~ ~~cattle~~ bovine breeders, owners and keepers; 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~~ bovine 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~~ whether there are any industry associations or organisations involved in ~~cattle~~ bovine 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~~ relevant *Competent Authority~~y~~ies*.

Article 1.8.5.

BSE risk assessment (point 1 of Article 11.4.3.)

1~~.~~) Entry assessment (point 1 a) of Article 11.4.2.)

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:

– ~~C~~cattlebovines~~.~~;

– ~~R~~ruminant-derived ~~protein meal~~*protein meal*~~.~~;

– ~~F~~*feed* (~~not intended for pets~~except packaged and labelled pet food) that contains ruminant-derived ~~protein meal~~*protein meal*~~.~~;

– ~~F~~fertilizers that contain ruminant-derived ~~protein meal~~*protein meal*~~.~~;

– ~~A~~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.~~

a) For each *commodity* listed above indicate ~~if~~ whether 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~~ to, 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~~ bovines 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* and their results 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 (point 1 b) of Article 11.4.2.)

~~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~~ bovines being exposed to the classical BSE agent~~s~~ either through imported *commodities* ~~(classical BSE)~~ or as a result of the presence of classical BSE ~~agents (classical or atypical BSE) in~~ within the ~~indigenous cattle~~ bovine 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~~ period for which they have the information if applying for a controlled risk status) to ~~establish the period when~~ indicate the date from which the ~~likelihood~~ risk of ~~the~~ BSE agents being recycled ~~in~~ within the ~~cattle~~ bovine population has been ~~demonstrated to be~~ negligible ~~(i.e. to determine the period of time~~ date ~~to be attested in point 2 of~~ accordance with ~~Articles 11.4.6., 11.4.7., 11.4.910., 11.4.12., and 11.4.13. and 11.4.14.)~~.

As indicated in point 1 b) 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~~ bovines from being fed ruminant-derived ~~protein meal~~*protein meal* and, depending on the outcome of this step, an evaluation of the impact of specific mitigation measures on preventing ~~cattle~~ bovines from being fed ruminant-derived ~~protein meal~~*protein meal*.

a) Livestock industry practices (point 1 b) i) of Article 11.4.2.)

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~~ bovine population and associated industry practices, with a particular emphasis on: feeding practices; disposal of dead ~~stock~~ animals and waste from slaughtered animals; rendering; and production, labelling, distribution and storage of *feed* that may lead to ~~cattle~~ bovines 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~~ bovine population to BSE agents (such as a legislated *feed* ban) as they will be considered where relevant in ~~Section~~ point *b) An evaluation of BSE specific mitigation measures*. The intention here is to evaluate the likelihood and extent of exposure of the ~~cattle~~ bovine population to the classical BSE agent~~s~~, given the ongoing livestock industry practices in a country or *zone*.

i) Demographics of the ~~cattle~~ bovine population and production and farming systems~~.~~

Describe the composition of the ~~cattle~~ bovine population and how the ~~cattle~~ bovine 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-~~semi-intensive, transhumant, pastoral, agropastoral, and mixed-species farming. The description should include the number and size of *herds* ~~farms~~ in each type of production and farming 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 fertili~~z~~sers containing ruminant-derived ~~protein meal~~*protein meal*, composted materials derived from fallen stock (i.e. ~~cattle~~ bovines of any age which were found dead or were killed on a farm, during transportation, at livestock *markets* or auctions, or at a *slaughterhouse/abattoir*), *slaughterhouse/abattoir* waste or animals condemned at ~~ante~~ ante-mortem inspections or any other materials derived from or that incorporate ruminant protein~~s~~ are applied to land where ~~cattle~~ bovines graze or where forage is harvested for feeding to ~~cattle~~ bovines. Where such fertili~~z~~sers ~~or composted materials~~ are used, provide information on the extent and frequency of use and any risk mitigation measures to prevent accidental ingestion.

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, including ~~cattle~~ bovines euthanised as part of a BSE *surveillance* programme under Article 11.4.18.~~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~~ bovines 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~~ relevant *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~~ 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~~*protein meal* that may be used in animal *feed*. It provides ~~the~~ a pathway for the introduction of ~~the~~ ~~classical~~ 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~~ relevant *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 the 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~~ bovines 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) programmes, *good manufacturing practices*, etc. Include a description of their role, membership and interaction with the *Veterinary Services* or ~~other~~ relevant *Competent Authority~~y~~ies*.

v) Feed production, labelling, distribution and storage~~.~~

Where rendered products are used as ingredients in the production of animal *feed* the exposure of ~~cattle~~ bovines to ~~the classical~~ BSE agents ~~(classical or atypical)~~ may arise as a result of the use of rendered products containing materials of ruminant origin as ingredients in ~~cattle~~ bovine *feed* or as a result of ~~cattle~~ bovine *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 for pets are required to be registered or approved by the *Veterinary Services* or ~~other~~ relevant *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, excluding those listed in Article 11.4.1bis., 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 programmes, *good manufacturing practices*, etc. Include a description of their role, membership and interaction with the *Veterinary Services* or ~~other~~ relevant *Competent Authority~~y~~ies*.

vi) Conclusions for livestock industry practices~~.~~

– Given the livestock industry practices described above, is the likelihood that the ~~cattle~~ bovine population has been exposed to ~~either~~ the classical ~~or atypical~~ BSE agent~~s~~ 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 estimation*.

– Where the likelihood estimate is non-negligible, proceed to *Section b) An evaluation of BSE specific mitigation measures*.

b) An evaluation of ~~BSE~~ BSE-specific risk mitigation measures~~.~~ (point 1 b) ii) of Article 11.4.2.)

For those countries that have reported ~~classical~~ *~~cases~~* of BSE *~~cases~~* in indigenous ~~cattle~~ bovines, it is apparent that their historic livestock industry practices did not prevent the recycling of the classical BSE agent ~~in~~ within their ~~cattle~~ bovine populations. These countries, together with others whose livestock industry practices would have been conducive to recycling, may have implemented specific measures, ~~such as~~notably 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~~these 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~~ whether there is a ban on feeding ruminants with ~~protein meal~~*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 of 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-~~ante-mortem inspection are excluded from rendering and how this is done.

– Where these *commodities* are not ~~excluded~~ removed from fallen stock, animals condemned at ante-mortem inspection, or *slaughter* waste declared as unfit for human consumption, describe their 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~~ relevant *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~~bovine-derived ~~protein meal~~*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~~ relevant *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 an *approved* third party;
- training and accreditation programmes for inspectors;
- the planned frequency of inspections~~,~~ and 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-compliance~~s~~) 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~~ variation and how ~~they~~ it 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~~ 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-compliance~~s~~) that were likely to have led to ~~cattle~~ bovines 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~~ 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~~ 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~~ bovines may contain or has been cross-contaminated with ruminant-derived ~~protein meal~~*protein meal*.
- Given the evaluation of ~~BSE~~ BSE-specific risk mitigation measures and their enforcement as described above, is the likelihood that, during the preceding eight years, the ~~cattle~~ bovine population has been exposed to ~~either~~ the classical ~~or atypical~~ BSE agent 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 (point 1 c) of Article 11.4.2.)

~~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 that for classical BSE.~~

As described in Article 11.4.2., a consequence assessment evaluates the likelihood of ~~cattle~~ bovines becoming infected following exposure to the classical BSE agent~~s~~ ~~(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~~ the classical BSE agent~~s~~, to initiate a cycle of BSE infectivity within a ~~cattle~~ bovine 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~~*protein meal*;

– the rendering process does not destroy BSE infectivity ~~of the BSE agent(s)~~;

– the ruminant-derived ~~protein meal~~*protein meal* is incorporated as an ingredient in ~~cattle~~ bovine *feed*, or ~~cattle~~ bovine *feed* is cross-contaminated during *feed* production, distribution and storage, or ~~cattle~~ bovines are incorrectly fed with *feed* intended for non-ruminant species that includes the ruminant-derived ~~protein meal~~*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 classical 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~~*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~~ bovine population are non-negligible.

a) Factors to consider when evaluating the likely extent of recycling of the classical BSE agent~~s~~ within a ~~cattle~~ bovine 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~~ Bovines exposed to the classical BSE agent~~s~~ 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 classical 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~~ bovine *feed*, it is highly likely that some level of recycling would occur.

– Feedlot ~~cattle~~ bovines~~.~~

Even if ~~cattle~~ bovines 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 classical 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~~ bovines 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~~ bovine *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 classical BSE agent~~s~~ ~~in~~ within the ~~cattle~~ bovine 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.

b) Conclusions for the consequence assessment~~.~~

Where the outcome of the evaluation of livestock industry practices or the evaluation of ~~BSE~~ 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~~ bovine population has been exposed to the classical BSE agent~~s~~, what is the likelihood that they have been recycled within the ~~cattle~~ bovine population during the preceding eight years?

Clearly describe the rationale leading to the conclusions reached.

4~~.~~) Risk estimation (point 1 d) of Article 11.4.2.)

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~~ of the classical BSE agent~~s~~ ~~have been~~ being recycled ~~in~~ within the ~~cattle~~ bovine 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 Indicate the period of time fordate from which it can be considered that the risk of classical BSE agents being recycled in within the cattle bovine population has been negligible. Provide explanations and clearly describe the rationale leading to the conclusions reached.~~

Article 1.8.6.

~~BSE s~~Surveillance (point 2 of Article 11.4.3.)

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~~ bovines affected by BSE are likely to exhibit.

Requirements under point 2 of Article 11.4.18. are focused on subsets of the ~~cattle~~ bovine population where ~~disease~~ BSE 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 show symptoms signs of the clinical disease spectrum of BSE (i.e. from clinically ill to non-ambulatory to fallen stock) should be targeted for BSE *surveillance* and should include those animals described in points 2(a) to 2(d) of Article 11.4.18.~~

1~~.~~) Awareness and training programmes (point 3 a) of Article 11.4.18.)

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 geographical coverage ~~for~~ of these activities.

d) Provide a description including examples of materials used in the awareness programme ~~including~~ such as training manuals, supporting documents such as publications in local newspapers and farming magazines, pamphlets and videos (weblinks to supporting documents in one of the WOAH official languages 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~~.~~) ~~Compulsory notification~~ BSE reporting system (point 3 b) of Article 11.4.18.)

~~To ensure the reporting and further investigations of any animals that lie on the continuum show symptoms signs of the clinical BSE spectrum of BSE, appropriate legislation, policies and incentives to support compulsory notification, investigation and verification should be in place.~~

a) ~~Indicate whether~~ Describe the BSE reporting system, including the date of implementation of any supporting legislation and associated policies making BSE a *notifiable disease* ~~notification of BSE compulsory~~. Indicate if a definition for a "suspicion of ~~'~~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~~ targeting animals that ~~lie on the continuum~~ show ~~symptoms~~ signs of the clinical ~~BSE~~ spectrum of BSE and for reporting of animals described in points 2 a) to 2 d) of Article 11.4.18., 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,~~ ~~cattle~~ bovine breeders, owners and keepers, *veterinarians*, transporters, and workers at livestock *markets*, auctions and *slaughterhouses/abattoirs* in terms of the criteria for reporting ~~animals that lie on the continuum show symptoms signs of the clinical BSE spectrum of BSE~~. What mechanisms are in place to ensure that these guidelines reach those stakeholders?

d) Describe the evaluation of the reporting system~~framework for animals that lie on the continuum show symptoms signs of the clinical BSE spectrum of BSE for evaluation~~. Has this ~~framework~~ reporting system evolved over time and, if so, how?

3~~.~~) Laboratory testing (point 3 c) 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*~~ *laboratories* 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 *laborator*~~*ies* in the country ~~or *zone*~~ for testing, or if suspicious or positive samples are referred to ~~a *laboratory*~~ *laboratories* 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 arise between primary and secondary tests ~~arise~~ (e.g. primary positive result followed by a secondary negative result)~~?~~; and tests undertaken to discriminate classical BSE from atypical BSE.

~~4.~~) Evaluation procedures and protocols to identify ~~and report potential candidates~~animals targeted for BSE surveillance, to determine animals to be subjected to laboratory testing, to collect and submit samples for laboratory testing, and to follow up BSE positive findings with epidemiological investigation ~~BSE positive findings~~ (point 3 d) of Article 11.4.18.)

~~Because~~ Given that 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~~ bovine population where disease is more likely to be detected~~, if it is actually present. Hence, those animals described in points 2(a) to 2(d) 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~~ showing ~~symptoms~~ signs of the clinical ~~BSE~~ spectrum of BSE (e.g. by the ~~farmer~~ breeder, owner or keeper, *animal handler*, *veterinarian*, etc.)~~,~~; (2) the criteria to determine which of these ~~reported~~ animals need to be reported and 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.

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~~ bovine 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 showing symptoms signs of the clinical BSE spectrum of BSE (those~~ described in points 2 a) to 2 d) of Article 11.4.18.~~) to the *Competent Authority*.~~ For example, these procedures and protocols may include the steps that a ~~farmer~~ breeder, owner or keeper 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 showing symptoms signs of the clinical BSE spectrum of BSE (those described in points 2(a) to 2(d) 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.

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~~ bovine 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.

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 2 a) to 2 d) 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~~ Bovines displaying progressive behavioural or neurological signs suggestive of BSE that are refractory to treatment		
(B) ~~Cattle~~ Bovines showing behavioural or neurological signs that did not pass the ante-mortem inspection at slaughterhouses/abattoirs		
(C) ~~Cattle~~ Bovines presented as downers (non-ambulatory) with an appropriate supporting clinical history		
(D) ~~Cattle~~ Bovines found dead (fallen stock) with an appropriate supporting clinical history		

EU comment

The EU suggests clarifying the concept of "downers" in line (C) by replacing it with the wording used in the current Article 11.4.21. on 'Surveillance: description of cattle subpopulations', as follows:

"(C) Bovines which are~~represented as downers (~~non-ambulatory, recumbent, unable to rise or to walk without assistance~~)~~ with an appropriate supporting clinical history"

5.) Animals subjected to laboratory testing

~~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	Age (in months) at the	Type of production system (dairy,	Description of observed clinical signs	Clinical presentation (A, B, C or D)	Final diagnosis (if BSE, specify ~~the strain~~ if	For a *case* of BSE ~~*case*~~, indicate the origin

	identification number	time of reporting ~~first detection~~	beef, mixed, etc.)			C, L or H type)	(indigenous or imported; if imported, indicate the country of birth)

Article 1.8.6bis.

History of occurrence and management of BSE in the country or zone (points 3 and 4 of Article 11.4.3.)

Describe the history of occurrence and management of BSE 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 *cases* of BSE, and:

   a) Provide a table of aggregated data on all *cases* of BSE encountered in the country or *zone*, 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), and the year of birth of each indigenous *case*.

2) If there have been *cases* of BSE or bovines affected by atypical BSE, confirm that they were completely destroyed or disposed of to ensure they are excluded from the *feed* chain and describe how this was achieved. In the table under Article 1.8.2. provide details of the national legislation, regulations and *Veterinary Authority* directives that describe these procedures.

Article 1.8.7.

~~Recovery~~ Maintenance of BSE risk status

Following the occurrence of an indigenous *case* of ~~classical~~ BSE in a~~n animal~~ bovine born ~~within the preceding eight years~~ after the date from which the risk of BSE agents being recycled within the ~~cattle~~ bovine population has been negligible occur in a country or *zone* with a negligible or controlled 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 agents being recycled within the ~~cattle~~ bovine 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.

CHAPTER 12.2.

INFECTION *WITH TAYLORELLA EQUIGENITALIS* (CONTAGIOUS EQUINE METRITIS)

EU position

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

As a general comment, the EU reiterates its suggestion that this chapter should apply to all equids, instead of just to horses as is currently the case (with the exception of the parts relating to temporary importation of horses). This would be consistent with other chapters currently being revised (e.g. equine influenza).

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 as such from a genital swab sample from a horse; or

2) nucleic acid specific to *T. equigenitalis* has been ~~identified~~ detected in a sample from a horse; or

3) ~~antigen or genetic material~~antigen specific to *T. equigenitalis* has been ~~identified~~ detected in a sample from a ~~mare~~ horse 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, in the absence of effective treatment, 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*.

For the purposes of this chapter, a temporary importation refers to the introduction of horses 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 the importation 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*~~*herd*.

Article 12.2.2.

Safe commodities

When authorising importation or transit of the following *commodities*, *Veterinary Authorities* should not require any *T. equigenitalis*-related conditions, regardless of the ~~*T. equigenitalis infection*~~ *animal health status* of ~~the *animal population* of~~ the *exporting country*, *zone* or ~~*establishment*~~*herd*:

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~~Herd 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*, a~~n *establishment*~~ *herd* 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*~~*herd* have been subjected to *T. equigenitalis* tests, with negative results, on samples collected ~~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 tests~~sample collections. Horses must have not been treated with antibiotics for at least 7 days prior to the first sampling, nor subjected to antiseptic washing of genital mucous membrane for at least 21 days ~~before~~ prior to the first sampling;

d) any stored semen was subjected to a test for detection of ~~genetic material~~nucleic acid of ~~to detect~~ *T. equigenitalis* with negative results, carried out on an aliquot of the stored semen.

3) Maintenance of freedom

a) the requirements in points 1 ~~and~~, 2(a) and 2(b) 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~~ germinal products into the ~~*establishment*~~*herd* is carried out in accordance with the importation conditions for these *commodities* listed in this chapter.

4. Recovery of freedom

When a *case* is detected in a previously free ~~*establishment*~~*herd* 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) not before 21 days after the last removal or the last treatment of an infected horse, all horses have been subjected to a ~~*T. equigenitalis*~~ test for the detection of the agent, with negative results, on samples collected on three occasions, within a 12-day period with an interval of no less than three days ~~apart~~ between ~~each tests~~sample collections;

c) any fresh semen from all infected horses in the *herd* has been destroyed; aliquots of each collection of stored semen from all infected horses in the *herd* ~~was~~ were subjected to a test ~~to detect~~ for detection of ~~genetic material~~nucleic acid of *T. equigenitalis* with negative results~~ in accordance with Article 12.2.8., carried out on an aliquot of the stored semen~~; and all positive stored semen has been destroyed;

d) the introduction of horses and their ~~germplasm~~ germinal products into the ~~*establishment*~~*herd* is carried out in accordance with the importation 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) kept since birth or for at least two years prior to shipment in a~~n *establishment*~~*herd* that has been free from *infection* with *T. equigenitalis* ~~since birth or for at least two years prior to shipment~~;

OR

b)

i) kept for at least the last 60 days in a~~n *establishment*~~*herd* in which no *case* has been reported during that period ~~the 60 days prior to shipment~~**;**

AND

ii) ~~were~~ subjected to tests for the detection of the agent ~~*T. equigenitalis* tests~~, with negative results, carried out on samples collected on three occasions~~,~~ within a 12-day period, with an interval of no less than three days ~~apart~~ between ~~each tests~~sample collections, ~~being~~ the last ~~test~~one being carried out within ~~the~~ 30 days prior to shipment. Horses ~~must not~~ have not been treated with antibiotics for at least ~~21~~ 7 days nor subjected to antiseptic washing of genital mucous membranes for at least 21 days prior to the first sample collection~~,ing~~ and have not been mated or inseminated after the first sampling.

Article 12.2.5.

Recommendations for temporary importation of stallions and mares~~orses~~

When importing on a temporary basis stallions or mares ~~horses~~ that do not comply with recommendations in Article 12.2.4. for purposes ~~different~~ other than breeding and rearing, *Veterinary Authorities* should:

1) require:

a) the ~~animals~~horses ~~to~~ 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* ~~to~~ be defined;

2) ensure that during their stay in the country or *zone*, the ~~animals~~horses:

a) are not used for breeding (including artificial insemination, semen collection, use~~d~~ as teasers ~~stallions~~) and do not have any sexual contact with other horses;

b) ~~do not undergo any genital examinations~~are not subjected to any practice that may represent a risk of transmission of *infection* with *T. equigenitalis*;

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~~ from ~~horses~~stallions

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~~ were done in accordance with Chapter 4.6; and

EITHER

2) the donor stallion was kept in a~~n~~ ~~*establishment*~~*herd* free from *infection* with *T. equigenitalis*;

OR

3)

a) the donor stallion was kept for at least 60 days prior to semen collection in a~~n~~ ~~*establishment*~~*herd* in which no *case* has been reported during that period~~the 60 days prior to semen collection~~; and

b) the donor stallion was subjected to tests for the detection of the agent ~~*T. equigenitalis* tests~~, with negative results, carried out on samples collected on three occasions, within a 12-day period with an interval of no less than three days ~~apart~~ between ~~each tests~~sample collections, ~~being~~ the last ~~test~~one being 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~~ Horses have not been treated with antibiotics for at least ~~21~~ 7 days nor subjected to antiseptic washing of genital mucous membranes for at least 21 days prior to the first sample collection, ~~ing~~ and have not been mated or inseminated after the first sampling;

OR

4) aliquots of fresh semen were subjected to culture and a test for detection of ~~genetic material~~nucleic acid ~~for~~ of *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~~ stored semen corresponding to the ~~earliest~~ oldest and the most recent collection were subjected to culture and a test for detection of ~~genetic material~~nucleic acid 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 4.8. 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 Article 12.2.6. and 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 being 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~~ owners, breeders 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 an *early warning system* in accordance with Article 1.4.5. and ~~:~~

~~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~~ reproductive performance. However, clinical *surveillance* should be complemented by culture for *T. equigenitalis* ~~bacteriological~~ and molecular ~~tests~~testing, 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 *cases* should be implemented to establish the status of a country, *zone* or ~~*establishment*~~*herd*. Culture for *T. equigenitalis* and molecular testing are the most effective methods of detection of ~~the~~ a *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~~ done in conjunction with agent identification ~~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*.

CHAPTER 12.6.

INFECTION WITH EQUINE INFLUENZA VIRUS

EU position

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

Article 12.6.1.

General provisions

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an *infection* of domestic and c*aptive wild* equids with equine influenza virus (EIV), i.e. subtypes H3N8 and H7N7 of influenza A viruses ~~(H7N7 and H3N8)~~.

This chapter deals not only with the occurrence of clinical signs caused by *infection* with ~~equine influenza virus (~~EIV~~)~~, but also with the presence of *infection* with EIV in the absence of clinical signs.

The following defines the occurrence of *infection* with EIV:

1) EIV, excluding modified-live virus vaccine strains following recent *vaccination*, has been isolated and identified as such ~~from~~ in a sample from a domestic or *captive wild* equid; or

2) antigen or ~~ribo~~nucleic acid ~~or antigen~~ specific to EIV has been detected in a sample from a domestic or *captive wild* equid showing clinical signs or pathological lesions ~~suggestive of~~ consistent with equine influenza, or epidemiologically linked to a confirmed or suspected ~~or confirmed~~ *case* of equine influenza; or

3) seroconversion due to recent exposure to EIV ~~virus, demonstrated by a significant increase in antibody titres which are~~which is not the consequence of *vaccination*, ~~have~~ has been detected in paired samples from a domestic or *captive wild* equid showing clinical signs or pathological lesions ~~consistent with !suggestive of~~consistent with equine influenza, or epidemiologically linked to a confirmed or suspected ~~or confirmed~~ *case* of *infection* with EIV.

~~For the purposes of this chapter, isolation is defined as 'the separation of domestic equids from domestic equids of a different EI health status, utilising appropriate *biosecurity* measures, with the purposes of preventing the transmission of *infection*'.~~

For the purposes of the *Terrestrial Code*, the *infective period* for EI shall be ~~21~~ ~~10~~ 14 days.

For the purposes of this chapter, a temporary importation refers to the introduction of horses 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 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 the importation or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 12.6.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the EI status of the equine population of the *exporting country*, *zone* or *compartment*.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 12.6.2.

Safe commodities

When authorising the importation or transit of the following *commodities*, *Veterinary Authorities* should not require any EIV-related conditions, regardless of the ~~EI~~ *animal health status* of ~~the equine~~animal ~~population of~~ the *exporting country*, *zone* or *compartment*:

1) equine semen;

2) *in vivo* derived equine embryos collected, processed and stored in accordance with Chapters 4.8. and 4.10., as relevant; ~~(under study).~~

3) *meat* and *meat products* from equids that have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 12.6.3.

Determination of the EI status of a country, a zone or a compartment

The EI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1) the outcome of a *risk assessment* identifying all risk factors and their historic relevance;

2) whether EI is notifiable in the whole country, an ongoing EI awareness programme is in place, and all notified suspect occurrences of EI are subjected to field and, where applicable, *laboratory* investigations;

3) appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in domestic and *captive wild* equids.

Article 12.6.4.

~~EI free c~~Country, zone or compartment free from EI

A country, *zone* or *compartment* may be considered free from EI provided ~~the disease~~ that *infection* with EIV is notifiable in the whole country and it shows evidence, through an effective *surveillance* programme, planned and implemented in accordance with the general principles in Chapter 1.4., that no *case* of ~~EI~~ *infection* with EIV occurred in the past two years. The *surveillance* may need to be adapted to parts of the country, *zone* or *compartment* depending on historical or geographical factors, industry structure, population data, movements of equids within and into the country, *zone* or *compartment*, *wild* equine populations or proximity to recent *outbreaks*.

A country, *zone* or *compartment* seeking freedom from EI, in which *vaccination* is practised, should also demonstrate that EIV has not been circulating in the population of domestic, *captive wild, feral,* and *wild* equids during the past 12 months, through *surveillance*, in accordance with Chapter 1.4.

In a country in which *vaccination* is not practised, *surveillance* may be conducted using serological testing alone. In countries where *vaccination* is practised, the *surveillance* should include agent identification methods described in the *Terrestrial Manual* for evidence of *infection*.

A country, *zone* or *compartment* seeking freedom from EI should apply appropriate movement controls to minimise the risk of introduction of EIV in accordance with this chapter and should be in accordance with relevant requirements and principles described in Chapter 4.4. and Chapter 4.5.

~~If an *outbreak* of clinical EI occurs in a previously free country, *zone* or *compartment*, free status can be regained 12 months after the last clinical *case*, providing that *surveillance* for evidence of *infection* has been carried out during that twelve month period in accordance with Chapter 1.4.~~

Article 12.6.4bis.

Recovery of free status

If a *case* of *infection* with EIV occurs in a previously free country, *zone* or *compartment*, free status can be regained 12 months after the last *case*, provided~~ing~~ that *outbreaks* were managed in accordance with Chapter 4.19. and that *surveillance,* in accordance with ~~Chapter 1.4.~~Article 12.6.4., has been carried out during that 12-month period, with negative results.

Article 12.6.5.

Recommendations for the importation of domestic and captive wild equids for immediate slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the domestic ~~and~~ or *captive wild* equids showed no clinical sign of EI on the day of shipment.

Article 12.6.6.

Recommendations for the importation of domestic and captive wild equids ~~for unrestricted movement~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the domestic or *captive wild* equids :

1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least ~~21~~ ~~10~~ 14 days; in the case of vaccinated ~~domestic~~ equids, information on their *vaccination* status should be included in the veterinary certificate;

OR

2) a) ~~came from a country, *zone* or *compartment* not known to be free from EI,~~ were subjected to pre-export isolation for ~~21~~ ~~10~~ 14 days and showed no clinical sign of EI during isolation nor on the day of shipment; and

~~AND~~

~~3~~b) 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~~i) between 14 and 90 days before shipment ~~either~~ with either a primary course or a booster; or

~~b~~ii) 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 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.

Article 12.6.7.

Recommendations for the temporary importation of ~~domestic~~ ~~equid~~ ~~which will be kept in isolation (see Article 12.6.1.)~~ horses

If the importation of horses on a temporary basis does not comply with the recommendations in Article 12.6.6., *Veterinary Authorities* of *importing countries* should ~~require the presentation of an *international veterinary certificate* attesting that the domestic equids~~:

1) require ~~that~~:

a) that the horses 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 horses:

~~1~~i) came from a~~n EI free~~ country, *zone* or *compartment* free from EI, in which they had been resident for at least ~~21~~ 14 days; in the case of ~~a~~ vaccinated ~~domestic equid~~ horses, information on ~~its~~ their *vaccination* status should be included in the veterinary certificate;

OR

~~2~~ii) showed no clinical sign of EI in any premises in which the ~~domestic equids~~ horses had been resident for the ~~21~~ 14 days prior to shipment nor on the day of shipment; and

~~3~~iii) were ~~immunised in accordance~~ vaccinated with ~~the recommendations of the manufacturer with~~ a vaccine complying with the standards described in the *Terrestrial Manual*; information on their *vaccination* status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12.;

2) ensure that during their stay in the country or *zone* ~~domestic equids~~ horses are kept separated from domestic and *captive wild* equids of a different EI health status through appropriate *biosecurity*.

~~Article 12.6.8.~~

~~Recommendations for the importation of fresh meat of equids~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *fresh meat* came from equids which had been subjected to ante- and post-mortem inspections as described in Chapter 6.3.~~

CHAPTER 12.7.

~~EQUINE PIROPLASMOSIS~~ INFECTION WITH *THEILERIA EQUI* AND *BABESIA CABALLI* (EQUINE PIROPLASMOSIS)

EU position

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

Article 12.7.1.

General provisions

The *infection* with ~~use of the term equine piroplasmosis indicates clinical diseases caused by the transmission of~~ *Theileria equi* (*T. equi*) or *Babesia caballi* (*B. caballi*) established after transmission of these pathogenic agents through competent ticks or iatrogenic practices may be asymptomatic or may cause a clinical disease known as equine piroplasmosis. Vertical transmission from mares to foals has also been reported. This chapter deals not only with ~~the occurrence of~~ clinical disease ~~signs caused by infection with T. equi or B. caballi~~, but also with asymptomatic infections ~~the presence of infection with T. equi or B. caballi in the absence of clinical signs~~.

~~Susceptible a~~Animals ~~for~~ susceptible to *infection* with *T. equi* or *B. caballi* are primarily domestic and *wild* equids. Although old-world camelids are susceptible to *infection* and are 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*, including species 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) *T. equi* or *B. caballi* has been observed and identified as such ~~identification of the parasite by microscopic examination of~~ in a sample from an equid ~~which may be 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~~ nucleic acid specific ~~for~~ to *T. equi* or *B. caballi* has been ~~identified~~ detected in a sample from an equid ~~which may be~~ 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~~ detected in a sample from an equid ~~which may be~~ 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~~horses 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 the importation 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*.

Article 12.7.2.

Safe commodities

When authorising importation or transit of the following *commodities*, *Veterinary Authorities* should not require any conditions related to ~~conditions related with~~ *infection* with *T. equi* or *B. caballi* ~~related conditions~~, regardless of the ~~*infection*~~ *animal health status* of ~~the *animal population* 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 in accordance with the relevant chapters of the *Terrestrial Code*;

7) sterile filtered horse serum;

8) embryos collected, processed and stored in accordance with Chapters 4.8., 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~~for the past six years and has considered the presence or absence of competent *vectors* in the epidemiological situation;

      ~~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) importation~~s~~ of equids into the country or *zone* ~~are~~ is carried out in accordance with this chapter. A country or *zone* free from *infection* with *T. equi* and *B. caballi* in which ~~an epidemiological investigation has been conducted with favourable results 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~~horses were imported temporarily in accordance with Article 12.7.6. will not lose its free status provided an epidemiological investigation demonstrates that there has been no transmission of *infection*;

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.

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~~ and agent identification tests 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. and not subjected to any practice that may present a risk of iatrogenic transmission of *infection* with *T. equi* or *B. caballi* during the 30 days prior to sampling and after sampling until shipment ~~and throughout the transport to the destination country or *zone*.~~; and

iii) have not been treated with antiparasitic drugs capable of masking an *infection* with *T. equi* and *B. caballi,* for at least six months prior to sampling.

Article 12.7.~~3~~6.

Recommendations for the temporary importation of ~~equids~~ horses ~~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~~horses 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~~ that the ~~animals~~horses 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~~horses:

~~a.~~i) showed no clinical sign of ~~equine piroplasmosis~~ *infection* with *T. equi* or *B. caballi* on the day of shipment;

~~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) that 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~~horses are protected from ticks in accordance with Article 12.7.7.;

b) ~~equids~~horses 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~~horses 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

1) Under the direct supervision of the *Veterinary Authority*:

~~a1~~) equids are kept in tick-protected facilities and transported in protected ~~vehicles~~ *vehicles/vessels* according to ~~Article 12.7.8.~~point 3;

b~~2~~) equids have ~~been preventively treated according to~~ received preventive treatment in accordance with the manufacturer's recommendations with an acaricide effective against the competent ticks.

~~Article 12.7.8.~~

~~Protecting facilities and transports from ticks~~

2) The *establishment* or facility should be approved by the *Veterinary Authority* and the means of protection should at least comprise the following:

~~a 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;

b~~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) W~~w~~hen transporting ~~animals~~ equids through infected countries or *zones*:

a) the *vehicle/vessel* should be treated with an effective acaricide before transporting the animals;

b) preventive treatment of the equids with an acaricide with an extended residual effect that lasts at least for the duration of any stopover during the trip should be conducted.

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 breeders, owners, keepers, and 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 an *early warning system* in accordance with Article 1.4.5. and~~:~~

~~–~~ ~~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 testing 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 competent ~~Ixodid~~ ticks including species of the genera *Dermacentor*, *Rhipicephalus*, *Hyalomma,* and *Amblyomma*.

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~~ collection methods 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 competent ~~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. Rather, ~~A~~animal-based *surveillance* strategies are preferred to detect *T. equi* or *B. caballi* transmission ~~than entomological *surveillance*~~.

Annex 17

CHAPTER 14.X.

INFECTION WITH *THEILERIA LESTOQUARDI, T. LUWENSHUNI* AND *T. UILENBERGI*

EU position

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

Article 14.X.1.

General provisions

~~*Animals* susceptible to *infection* with *Theileria* are~~ Theileriosis is a disease of bovines (*Bos indicus*, *B. taurus*, ~~and~~ *B. grunniens*~~)~~, ~~water buffaloes (~~*Bubalus bubalis*~~),~~ and ~~African buffaloes (~~*Syncerus caffer*), sheep *(Ovis aries)*, goats *(Capra hircus),* camels (*Camellus dromedarius* and *C. bactrianus*) and some *wild* ruminants.

~~*Infection* with Theileria~~Theileriosis can give rise to disease of variable severity and ~~to *Theileria* transmission. *Theileria*~~ the pathogenic agent may persist in ruminants for their lifetime. Such animals are considered carriers.

Only sheep and goats play a significant epidemiological role in the *infection* with *Theileria lestoquardi, T. luwenshuni* and *T. uilenbergi.*

For the purposes of the *Terrestrial Code*, *infection* with *Theileria lestoquardi, T. luwenshuni* and *T. uilenbergi* are defined as a tickborne *infection* of sheep and goats with *T. lestoquardi, T. luwenshuni* and *T. uilenbergi*.

For the purposes of this chapter, *Theileria* means *T. lestoquardi, T. luwenshuni* and *T. uilenbergi.*

The following defines the occurrence of *infection* with *Theileria*:

1) *Theileria* has been ~~identified~~ observed and identified as such in a sample from a sheep or goat; or

2) ~~antigen or~~ nucleic acid specific to *Theileria* has been ~~identified~~ detected in a sample from a sheep or goat showing clinical signs consistent with *infection* with *Theileria*, or epidemiologically linked to a confirmed or 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 sheep or goat ~~that either shows~~showing clinical signs consistent with *Theileria*, or ~~is~~ epidemiologically linked to a confirmed or 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 14.X.2.

Safe commodities

When authorising the importation or transit of the following *commodities*, *Veterinary Authorities* should not require any *Theileria*-related conditions regardless of the ~~*Theileria infection*~~ *animal health status* of ~~the *animal population* of~~ the *exporting country* or *zone*:

1) *meat* and *meat products*;

2) *casings*;

3) *milk* and *milk products*;

4) gelatine and collagen;

5) tallow;

6) semen and embryos collected in accordance with the relevant chapters of the *Terrestrial Code*;

7) hooves and horns;

8) bones.

Article 14.X.3.

Country or zone free from infection with *Theileria* in sheep and goats

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 sheep and goats 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 sheep and goats from infected countries or *zones*.~~

~~3~~2) A country or *zone* free from *infection* with *Theileria* will not lose its status as a result of introduction of seropositive ~~or vaccinated~~ sheep and goats or their *commodities*, provided they were introduced in accordance with this chapter.

Article 14.X.4.

Recommendations for importation of sheep and goats from countries or zones free from infection with *Theileria*

~~For sheep and goats~~

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 14.X.5.

Recommendations for importation of sheep and goats from countries or zones not free from infection with *Theileria*

~~For sheep and goats~~

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 time of entry into 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 immediately prior to ~~on~~ entry and at least 25 days after entry into ~~to~~ the isolation *establishment* ~~and five days before shipment~~.

Article 14.X.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 14.X.7.

Recommendations for importation of wool and fibre of sheep and goats 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 were subjected to:

1) industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide or potassium hydroxide; or

2) industrial scouring, which consists of the immersion of wool in a water-soluble detergent held at 60–70°C.

Article 14.X.8.

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 18

CHAPTER ~~X~~ 16. ~~X~~ 1.

INFECTION WITH MIDDLE EAST RESPIRATORY SYNDROME CORONAVIRUS

EU position

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

Article ~~X.X~~16.1.1.

General provisions

Middle East respiratory syndrome (MERS) is a viral respiratory infection of humans and dromedary camels (*Camelus dromedarius*) which is caused by a coronavirus called Middle East Respiratory Syndrome Coronavirus (MERS-CoV).

Dromedary camels ~~(*Camelus dromedarius*) have been confirmed by several studies to be~~ are the natural host and zoonotic source of the MERS-CoV infection in humans. Other species may be susceptible to *infection* with MERS-CoV. However, their epidemiological significance has not been demonstrated.

MERS-CoV has been associated with mild upper respiratory signs in some dromedary camels. While the impact of MERS-CoV on animal health is very low, ~~human infections have a significant public health impact~~it can cause~~s~~ severe and sometimes fatal disease in humans.

For the purposes of the *Terrestrial Code*, MERS is defined as an *infection* of dromedary camels with MERS-CoV.

The following defines the occurrence of *infection* with MERS-CoV:

1) MERS-CoV has been isolated and identified as such in a sample from a dromedary camel~~;~~ or

2) ~~ribo~~nucleic acid specific to MERS-CoV has been ~~identified~~ detected in a sample~~s~~ from a dromedary camel showing clinical signs or pathological lesions ~~suggestive of~~ consistent with MERS~~-CoV~~, or ~~epidemiologically linked~~ with epidemiological links either to a ~~suspected or~~ confirmed or suspected *case* ~~of MERS-CoV~~ or to a human infected with MERS-CoV, or ~~from a dromedary camel~~ giving cause for suspicion of previous association or contact with MERS-CoV.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Annex 19

CHAPTER ~~X~~ 8. Y.

INFECTION WITH *LEISHMANIA* SPP. (LEISHMANIOSIS)

EU position

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

Article ~~X~~8.Y.1.

General provisions

For the purposes of the *Terrestrial Code*, ~~*infection* with *Leishmania spp.*~~ leishmaniosis is defined as an *infection* of dogs and cats (hereafter 'susceptible animal') by protozoan parasites of the genus *Leishmania*, family *Trypanosomatidae*, order *Kinetoplastida*.

The *infection* is usually transmitted by the bite of an infected ~~*Phlebotomus* sandfly~~phlebotomine sand fly belonging to the genera *Phlebotomus* (Old World) or *Lutzomyia* (New World).

The following defines the occurrence of *infection* with *Leishmania* spp.:

1) *Leishmania* spp. amastigotes have been observed and identified as such in a sample~~s~~ from a ~~dog or a cat~~ susceptible animal; or

2) nucleic acid specific to *Leishmania* spp. has been detected in a sample from a ~~dog or a cat~~ susceptible animal showing clinical signs or pathological lesions consistent with *infection* with *Leishmania* spp., or epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with *Leishmania* spp.; or

3) antibodies specific to *Leishmania* spp. that are not the consequence of *vaccination* have been detected in a sample from a ~~dog or a cat~~ susceptible animal showing clinical signs or pathological lesions consistent with *infection* with *Leishmania* spp., or epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with *Leishmania* spp.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Annex 20

TERMINOLOGY: USE OF THE TERMS 'FETAL', 'FOETAL', 'FETUS' AND 'FOETUS'

EU position

The EU supports the adoption of this revised article.

Article 4.10.3.

Procedures for micromanipulation

The term "micromanipulated" covers several different procedures and a variety of specialised microsurgical instruments and other equipment may be used. However, from the standpoint of animal health, any cutting, penetrating or breaching of the integrity of the zona pellucida is an action that can alter the health status of an embryo. To maintain health status during and after micromanipulation, the following conditions should apply:

1. Media

   Any product of animal origin, including co-culture cells and media constituents, used in the collection or production of oocytes, embryos or other cells, and in their micromanipulation, culture, washing and storage should be free from pathogenic agents (including transmissible spongiform encephalopathy agents, sometimes called prions). All media and solutions should be sterilised by approved methods in accordance with the Manual of the IETS and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the Manual of the IETS.

2. Equipment

   Equipment (e.g. microsurgical instruments which have direct contact with embryos) should either be of the single-use type (disposed of after each oocytes or embryos batch) or should be effectively sterilised between oocytes or embryos batch in accordance with recommendations in the Manual of the IETS.

3. Nuclei for transplantation ("nuclear transfer")

   a) Where it is intended to transplant nuclei derived from pre-hatching stage (i.e. zona pellucida intact) embryos, the parent embryos from which those nuclei are derived should fulfil the conditions of this chapter. Where nuclei derived from other types of donor cell (e.g. post-hatching stage embryos, embryonic, ~~foetal~~ fetal and adult cells, including spermatozoa or spermatids for ICSI) are to be transplanted, the parent embryo, ~~foetus~~ fetus or animal from which those donor cells originate, and the methods whereby they are derived, including cell culture, should comply with the relevant animal health standards recommended elsewhere in this *Terrestrial Code* and in the *Terrestrial Manual*.

   b) Where it is intended to transplant a nucleus into an intact oocyte (e.g. for ICSI), or into an enucleated oocyte (for nuclear transfer), those oocytes should be collected, cultured and manipulated in accordance with the recommendations in this chapter.

Annex 21

T E R M I N O L O G Y

EU position

The EU supports the adoption of these revised texts.

[...]

SECTION 9. ~~APIDAE~~ APINAE

SECTION 11. ~~BOVIDAE~~ BOVINAE

SECTION 16. CAMELIDAE

Chapter 16.1. Infection with Middle East respiratory syndrome coronavirus

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Annex 22

TERMINOLOGY: USE OF THE TERMS 'ENZOOTIC', 'ENDEMIC', 'EPIZOOTIC' AND 'EPIDEMIC'

EU position

The EU supports the adoption of these revised articles.

Article 4.19.1.

Introduction

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

The *Veterinary Authority* should determine the diseases against which *official control programmes* are to be prepared, developed and implemented, according to an evaluation of the actual or likely impact of the disease. *Official control programmes* should be prepared by the *Veterinary Authority* and *Veterinary Services* in close collaboration with the relevant stakeholders and other authorities, as appropriate.

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

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

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

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

1) a plan of the programme to control or eradicate the relevant *infection* or *infestation* in the country or *zone*;

2) appropriate *veterinary legislation*;

3) emergency preparedness plans and emergency response plans;

4) *surveillance* of the relevant *infection* or *infestation* in accordance with Chapter 1.4.;

5) regular and prompt animal disease reporting;

6) detection and management of *cases* of the relevant *infection* or *infestation*, to reduce the *incidence* and the *prevalence* by minimising transmission;

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

8) a *vaccination* programme, if appropriate;

9) measures to protect public health, if appropriate;

10) communication and collaboration among all relevant *Competent Authorities*;

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

The critical components of *official control programmes* for diseases that are not present in the country or *zone* are measures to prevent their introduction, an *early warning system*, and a plan for rapid response and effective action, possibly followed by long-term measures. Such programmes should include options for revising or ending them.

Official control programmes and the application of their components should be regularly evaluated. Learning from past *outbreaks*, from both ~~epizootic~~ epidemic or ~~enzootic~~ endemic situations, reviewing the response sequence and revising the methods are critical for adaptation to evolving circumstances and for better future performance. Experiences of the *Veterinary Services* of other Member Countries may also provide useful lessons. Plans should be tested regularly to ensure that they are fit-for-purpose, practical, feasible and well understood, and that staff are proficient and other stakeholders are fully aware of their respective roles and responsibilities.

Article 9.3.1.

General provisions

For the purposes of the *Terrestrial Code*, European foulbrood is a disease of the larval and pupal stages of honey bees (species of the genus *Apis*), caused by *Melissococcus plutonius* (*M.plutonius*), a non-sporulating bacterium, which is widely distributed. Subclinical *infections* are common and require *laboratory* diagnosis. *Infection* remains ~~enzootic~~ endemic because of mechanical contamination of the honeycombs. Recurrences of disease can therefore be expected in subsequent years.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the European foulbrood status of the honey bee population of the *exporting country* or *zone*.

Standards for diagnostic tests are described in the *Terrestrial Manual*.
