

Report of the Meeting of WOAH Terrestrial Animal Health Standards Commission

Annex 1

Original: English (EN)

13 to 22 September 2022
Paris

EU comment

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

A number of general comments on this report of the September 2022 meeting of the Code Commission are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report.

The EU welcomes the new format of the report. However, the small font makes it extremely difficult to read, especially when printed. A minimum font of 11 should preferably be used.

In addition, the late publication of the report this year, combined with an early deadline for submission of comments, may impede the quality and numbers of comments submitted.

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

Introduction and Member contribution

The WOAHA Terrestrial Animal Health Standards Commission (hereafter the 'Code Commission') thanked the following Members for providing comments: Argentina, Australia, Brazil, Canada, Chile, China (People's Republic of), Chinese Taipei, Japan, New Caledonia, New Zealand, Mexico, Norway, Republic of Korea, Singapore, South Africa, Switzerland, Thailand, the United Kingdom (UK), the United States of America (USA), Members of the WOAHA Americas Region, the Member States of the European Union (EU), the African Union Inter-African Bureau for Animal Resources (AU-IBAR) on behalf of African Members of WOAHA. The Commission also thanked the following organisations for providing comments: the Global Alliance of Pet Food Associations (GAPFA), the International Coalition for Farm Animal Welfare (ICFAW), the World Renderers Organization (WRO), as well as various experts of the WOAHA scientific network.

The Code Commission reviewed all comments that were clear, submitted prior to the deadline and were supported by a rationale. Due to the large number of comments, the Commission was not able to provide a detailed explanation on the reasons for accepting or not each of the comments considered, and focused its explanations on significant issues. 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 **Annexes 4 to 21** are presented for comments and will be proposed for adoption at the 90th General Session in May 2023. Texts in **Annexes 3 and 22 to 28** are presented for comments.

How to submit comments

The Code Commission strongly encourages Members and International Organisations that have a Cooperative Agreement with WOAHA to participate in the development of WOAHA International Standards by submitting comments on this report and on relevant annexes of this report. All comments should be submitted to WOAHA through the WOAHA Delegates of Members or from organisations with which the WOAHA 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 in the relevant annex, and include any amendments to the proposed text, supported by a rationale or by published 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 Word processing software, as such changes may be lost in the process of collating submissions into working documents.

Deadline for comments

Comments on relevant texts in this report must reach the Headquarters by **30 December 2022** to be considered at the February 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: **7 to 17 February 2023**.



Table of Contents

1. Welcome	5
1.1. Deputy Director General-International Standards and Science	5
1.2. Director General	5
2. Adoption of the agenda	5
3. Cooperation with Other Specialist Commissions	5
3.1. Scientific Commission for Animal Diseases	5
3.2. Biological Standards Commission	6
3.3. Aquatic Animals Health Standards Commission	7
4. Work Programme and priorities	7
4.1. Ongoing priority topics (other than texts circulated for comments)	7
4.1.1. New chapter on biosecurity (Chapter 4.X.).....	7
4.1.2. Revision of Chapters 5.4. to 5.7.	8
4.1.3. New chapter on Animal welfare and laying hen production systems (Chapter 7.Z.).....	9
4.1.4. Revision of Chapter 7.5. Slaughter of animals (Chapter 7.5.) and Glossary definitions for 'death', 'distress', 'euthanasia', 'pain', 'slaughter', 'stunning' and 'suffering'.	9
4.1.5. Revision of Chapter 7.6. 'Killing for disease control purposes'.....	9
4.1.6. New chapter on infection with <i>Trypanosoma evansi</i> (<i>Surra</i>).....	10
4.1.7. Harmonisation Code chapters related to official recognition of status by the WOAHP	10
4.1.8. Terminology	11
4.1.8.1. Use of terms 'animal-based measures' and 'measurables'	11
4.1.8.2. Use of terms 'Competent Authority', 'Veterinary Authority', 'Veterinary Services'	11
4.2. Items under consideration for inclusion in the work programme	12
4.2.1. Surveillance of diseases of wildlife (from Wildlife Working Group)	12
4.2.2. Infection with <i>Brucella abortus</i> , <i>B. melitensis</i> and <i>B. suis</i> (Chapter 8.4.)	12
4.2.3. Infection with peste des petits ruminants virus (Chapter 14.7.).....	13
4.2.4. Melioidosis	13
4.3. New proposals and requests for inclusion in the work programme.....	13
4.3.1. Electronic certification (Chapter 5.2. Certification procedures)	13
4.3.2. Request to revise <i>Terrestrial Code</i> Chapter 5.8. International transfer and Laboratory containment of animal pathogenic agents	14
4.3.3. Use of antiparasitic drugs	14
4.3.4. The 'Five domains' as an animal welfare concept.....	15
4.3.5. Requests to revise Chapter 8.10. 'Japanese encephalitis' and Chapter 12.11. 'Venezuelan equine encephalomyelitis'.....	15
4.3.6. Avian mycoplasmosis (Chapter 10.5.).....	16
4.4. Follow-up on chapters recently adopted.....	16
4.4.1. Infection with <i>Theileria annulata</i> , <i>T. orientalis</i> and <i>T. parva</i> (Chapter 11.10.).....	16
4.5. Prioritisation of items in the work programme	17

5. Texts circulated for comments and proposed for adoption in May 2023	18
5.1. User's Guide	18
5.2. Glossary definition for 'poultry'	18
5.3. Infection with foot and mouth disease virus (Chapter 8.8.)	19
5.4. Infection with rabies virus (Articles 8.14.6bis. and 8.14.7. of Chapter 8.14)	25
5.5. Infection with Rift Valley fever virus (Chapter 8.15.)	27
5.6. Infection with Newcastle disease virus (Article 10.9.1.)	28
5.7. Bovine spongiform encephalopathy (Chapter 11.4.; Chapter 1.8.; Glossary definition for 'protein meal' and use of related terms)	28
5.8. Contagious equine metritis (Chapter 12.2.)	35
5.9. Infection with equine influenza virus (Chapter 12.6.)	36
5.10. Equine piroplasmiasis (Chapter 12.7.)	38
5.11. Infection with <i>Theileria lestoquardi</i> , <i>T. luwenshuni</i> and <i>T. uilenbergi</i> (New Chapter 14.X.) and revision of Article 1.3.3.	41
5.12. Middle East Respiratory Syndrome Coronavirus (MERS-CoV) (New Chapter X.X.)	42
5.13. Infection with leishmania spp. (leishmaniasis) (New Chapter X.Y.)	42
5.14. Terminology: Use of terms 'fetal', 'foetal', 'fetus' and 'foetus'	43
5.15. Terminology: Use of terms 'bovid', 'bovidae', 'bovine' and 'cattle'	43
5.16. Terminology: Use of terms 'enzootic', 'endemic', 'epizootic' and 'epidemic'	44
6. Texts circulated for comments	45
6.1. Revision of Chapter 4.6. 'Collection and processing of semen of animals'	45
6.2. Responsible and prudent use of antimicrobial agents in veterinary medicine (Chapter 6.10.)	46
6.3. Infection with <i>Coxiella burnetii</i> (Q fever) (New Chapter 8.X.)	47
6.4. Infection with <i>Mycoplasma mycoides</i> subsp. <i>Mycoides</i> SC (Contagious bovine pleuropneumonia) (Chapter 11.5.)	48
6.5. Infection with bovine pestiviruses (bovine viral diarrhoea) (New Chapter 11.X.)	48
6.6. African horse sickness (Chapter 12.1)	49
6.7. Infection with Camelpox virus (New Chapter X.Z.)	49
7. Updates on WOAHP initiatives relevant to the Code Commission	50
7.1. WOAHP Observatory	50
7.2. Global Burden of Animal Diseases (GBADs)	50
7.3. WOAHP Wildlife health framework	50
7.4. WOAHP Global animal welfare strategy	51
7.5. <i>Terrestrial Code</i> data standardisation	51
7.5.1. Framework for <i>Terrestrial Code</i> standards	51
7.5.2. Commodities	52
7.5.3. Codification	52
8. Updates on other standard-setting bodies and international organisations	52
8.1. Update on Codex's works	52
8.2. IATA Live Animal Regulation amendments	53

List of Annexes

- Annex 1. Adopted Agenda
- Annex 2. List of Participants
- Annex 3. Item 4.5. – Work programme
- Annex 4. Item 5.1. – User’s guide
- Annex 5. Items 5.2. and 5.7. – Glossary definitions
- Annex 6. Item 5.3. – Chapter 8.8. Infection with foot and mouth disease virus
- Annex 7. Item 5.4. – Articles 8.14.6bis, 8.14.7. and 8.14.11bis of Chapter 8.14. Infection with rabies virus
- Annex 8. Item 5.5. – Chapter 8.15. Infection with Rift Valley fever virus
- Annex 9. Item 5.6. – Article 10.9.1. of Chapter 10.9. Infection with Newcastle disease virus
- Annex 10. Item 5.7. – Chapter 11.4. Bovine spongiform encephalopathy
- Annex 11. Item 5.7. – Chapter 1.8. Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy
- Annex 12. Item 5.8. – Chapter 12.2. Contagious equine metritis
- Annex 13. Item 5.9. – Chapter 12.6. Infection with equine influenza virus
- Annex 14. Item 5.10. – Chapter 12.7. Equine piroplasmiasis
- Annex 15. Item 5.11. – Chapter 14.X. Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi*
- Annex 16. Item 5.11. – Article 1.3.3. of Chapter 1.3. Diseases, infections and infestations listed by the OIE.
- Annex 17. Item 5.12. – Chapter X.X. Infection with Middle East respiratory syndrome coronavirus (MERS-CoV)
- Annex 18. Item 5.13. – Chapter X.Y. Infection with *Leishmania* spp. (Leishmaniasis)
- Annex 19. Item 5.14. – Terminology ‘fetal’, ‘foetal’, ‘fetus’ and ‘foetus’
- Annex 20. Item 5.15. – Terminology ‘bovid’, ‘bovidae’, ‘bovine’ and ‘cattle’
- Annex 21. Item 5.16. – Terminology ‘enzootic’, ‘endemic’, ‘epizootic’ and ‘epidemic’: Articles 4.19.1 & 9.3.1.
- Annex 22. Item 6.1. – Chapter 4.6. General hygiene in semen collection, processing and storage
- Annex 23. Item 6.2. – Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine
- Annex 24. Item 6.3. – Chapter 8.X. Infection with *Coxiella burnetii* (Q fever)
- Annex 25. Item 6.4 – Chapter 11.5. Infection with *Mycoplasma mycoides* susp. *Mycoides* SC (Contagious Bovine Pleuropneumonia)
- Annex 26. Item 6.5. – Chapter 11.X. Infection with Bovine Pestiviruses (Bovine viral diarrhoea)
- Annex 27. Item 6.6. – Chapter 12.1. Infection with African horse sickness virus
- Annex 28. Item 6.7. – Chapter X.Z. Infection with Camelpox virus

1. Welcome

1.1. Deputy Director General-International Standards and Science

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

Dr Arroyo briefed the Commission on the intent to host the 90th General Session as a physical meeting with a focus on reconnecting after the previous virtual and hybrid General Sessions. She encouraged Commission members to present highlights of its September 2022 report in regional webinars as this was proving to be an excellent mechanism to strengthen the engagement of Members. She also informed the Commission that the new WOAHA acronym will be introduced progressively in WOAHA Standards. Dr Arroyo provided a summary of ongoing WOAHA initiatives for digitalisation, including the development and planning for new digital tools. Dr Arroyo updated the Commission on the new WOAHA Research Coordination Group aiming at enhancing WOAHA coordination on related research activities by sharing available information, collecting, and disseminating research needs. Dr Arroyo also highlighted the establishment of a WOAHA Coordination for Terrestrial Standards aiming to achieve efficient and integrated management of the process to develop new or revised standards for terrestrial animals, by integrating the planning of activities of WOAHA teams providing technical support, coordination, and input to WOAHA Standard-setting work for terrestrial animals.

Dr Arroyo informed the Code Commission of the development of a new dedicated access point to provide access to previous editions of the *Terrestrial Code* which includes also the relevant amendments introduced over time. Dr Arroyo noted that this access point is accessible at the [WOAHA website](#) and was built from resources of the WOAHA Documentary portal, highlighting that all contents were fully available to the public

Dr Arroyo also updated the Commission on the progress on specific topics discussed at their previous meeting, in February 2022, and informed the Commission that WOAHA Standard Operating Procedure for determining whether a disease is emerging had been revised in response to the comments discussed with the Code Commission and the Scientific Commission and the revised version was already available on the [WOAHA website](#).

The members of the Code Commission thanked Dr Arroyo for the excellent support provided by the WOAHA Secretariat, and strongly supported the new initiatives.

1.2. Director General

Dr Monique Eloit, the WOAHA Director General, met the Code Commission and thanked its members for their support and commitment to achieving WOAHA objectives. She informed the Commission that supporting and strengthening regional activities and capacity building will be increasingly important moving forward. Dr Eloit updated the Commission on the review of the WOAHA Science System currently underway and emphasised that the science system needs to align with current best practices and be an agile and responsive system. Dr Eloit discussed WOAHA's role in the prevention of disease, specifically in the context of wildlife and explained some of WOAHA's work under the Wildlife Health Framework. The Code Commission thanked Dr Eloit, highlighted the importance of meeting face-to-face again, and provided feedback on these updates.

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 ongoing activities of the Scientific Commission, including the plans to develop guidelines on BSE surveillance and to conclude the assessments of the potential impact of the revision of the BSE standards on the official status recognition.

The Code Commission considered the conclusion of the Scientific Commission provided in its February 2022 report on the assessment of paratuberculosis against the listing criteria, which had been requested by the Code Commission. The Commission noted that the experts who performed the assessment and the Scientific Commission similarly concluded that if the criteria were strictly applied, the disease would have to be delisted, but recommended to keep the disease on the list and recommended rather to revise the criteria in Chapter 1.2. of the *Terrestrial Code*.

The Code Commission expressed strong concerns about this conclusion and stressed that the current criteria had been developed to assist the decision-making process regarding listing diseases through the standards-setting process and had been adopted by Members. The Commission agreed not to propose delisting paratuberculosis at this stage but stressed that the current criteria should be applied in any assessment, or no assessment should be done until the issues with the current criteria are discussed.

The Code Commission was also updated on the progress of the work to develop case definitions to support Member's notification which was being led by the Scientific Commission. The Code Commission thanked the Scientific Commission for progressing this work and highlighted the commitment of the Code Commission to consider the prioritisation of the case definitions for inclusion in the *Terrestrial Code*. The Code Commission reaffirmed the importance of providing Members with standards for them to comply with their notification obligations, and encouraged Members to comment on the relevant texts currently being circulated (See items 5.12, 5.13, 6.3, 6.5 and 6.7 of this report).

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](#).

3.2. Biological Standards Commission

The Secretariat updated the Code Commission on relevant ongoing activities of the Biological Standards Commission.

The Secretariat also updated the Code Commission on chapters in the *Terrestrial Manual* that were identified, by the Biological Standards Commission, for update in 2022/2023 and 2023/2024 review cycle. Given that the revision of the chapters could have potential impacts on the corresponding chapters in the *Terrestrial Code*, the Code Commission emphasised the importance of close interaction with the Biological Standards Commission to ensure early identification of coordination needs and strive for efficient and complementary processes for the development and review of the *Terrestrial Code* and *Terrestrial Manual*.

On the margin of this meeting, the Bureaus (i.e., the President and the two Vice-Presidents) of the Code Commission and the Biological Standards Commission held a meeting chaired by WOAHH DDG ISS. The purpose of the meeting was for the Secretariat and the two Bureaus to update on the work of each Commission on relevant topics of common interest, and to discuss and agree on the planning and coordination of those relevant topics.

The Bureaus discussed the following topics:

- the *Terrestrial Manual* chapters to be reviewed in the 2022/2023 and 2023/2024 review cycle, and the progress of development and revision of *Terrestrial Code* chapters
- the Biological Standards Commission's work to develop a new section that would describe the rationale for the selection of tests for different purposes given in a table in all disease chapters of the *Terrestrial Manual*
- considerations on the Glossary definition for 'case'
- specific comments received on the revised Chapter 12.7. Equine piroplasmiasis (See item 5.10 of this report)
- specific comments received on the revised Chapter 11.4. Bovine spongiform encephalopathy (See item 5.7 of this report)
- clarifications regarding testing for confirmation of occurrence of FMD (See item 5.3 of this report).

The Bureaus noted that the Manual chapters were regularly updated to reflect advances in scientific knowledge and that these updates should be an opportunity to identify needs to update the Code, in terms of changes in diagnostic tests and vaccines available or other relevant points. Both Bureaus agreed that experts undertaking the review of a Manual chapter could be requested to provide advice on potential need to consequentially amend an existing Code chapter, for the Biological Standards Commission to consider and eventually make high-level recommendations in this regard to the Code Commission, when appropriate.

Following the discussion with the Biological Standards Commission, the Code Commission acknowledged that there was no need to review the Glossary definition for 'case' and agreed to remove this item from their work programme.

The Code Commission wished to thank the Biological Standards Commission for providing inputs to support the decisions of the Code Commission on relevant comments received. The Code Commission reminded Members that its consideration of the Biological Standards Commission's responses is noted under the relevant agenda items of its report and encouraged Members to read its report together with [the Biological Standards Commission's reports](#).

3.3. Aquatic Animals Health Standards Commission

On the margin of this meeting, the Bureaus (i.e., the President and the two Vice-Presidents) of the Code Commission and the Aquatic Animals Commission held a meeting chaired by WOAH DDG ISS. The purpose of the meeting was for the Secretariat and the two Bureaus to update on the work of each Commission on relevant topics of common interest, and to discuss and agree on the planning and coordination of those topics and to exchange experiences and harmonise approaches to horizontal chapters. Both Commissions committed to continue meeting through this avenue on an annual basis to ensure enhanced coordination in the future. The Bureaus discussed issues of mutual interest in the *Aquatic Code* and the *Terrestrial Code* notably:

- the approach taken by both Commissions in the development of their work plan/work programme and prioritisation of items;
- the approach for the review of the use of Glossary definitions for 'Competent Authority', 'Veterinary Authority', 'Veterinary Services' and 'Aquatic Animal Health Services' in the *Terrestrial Code* and the *Aquatic Code* (See item 4.1.8.2 of this report);
- electronic certification (See item 4.3.1 of this report);
- progress on Section 4 and specifically the work to develop a new chapter on biosecurity in the *Terrestrial Code* (to exchange the Aquatic Animals Commission's experience in the development of Chapter 4.1. Biosecurity for Aquaculture establishments in the *Aquatic Code* (adopted in May 2021) with the Code Commission);
- revision of Chapters 5.4. to 5.7. in the *Terrestrial Code* (to inform the Aquatic Animals Commission of the status);
- revision of Chapter 4.3. Application of Compartmentalisation in the *Aquatic Code* (to exchange the Code Commission's experience in the last revision of Chapter 4.4. Zoning and compartmentalisation and development of Chapter 4.5. Application of compartmentalisation in the *Terrestrial Code* with the Aquatic Animals Commission);
- revision of Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine in the *Terrestrial Code* (to inform the Aquatic Animals Commission of the status).

4. Work Programme and priorities

Comments were received from Australia, the USA, Members of the WOAH Americas Region, the EU and GAPFA.

The Code Commission discussed ongoing priority topics on its work programme and pending issues with recently adopted chapters and considered comments and new requests received. The specific discussion is captured in the relevant items of this section of the report.

The Commission acknowledged a comment from the GAPFA, with reference to a Commission's agreement to consider the inclusion of 'extruded dry pet food' and 'heat-treated meat products in a hermetically sealed container with an F0 value of 3 or above' in the list of safe commodities each time a disease-specific chapter is reviewed. The Commission agreed not to initiate the revision of Code chapters only to address this request, noting that most of the indicated priority diseases' chapters had recently been revised. Nonetheless, the Commission highlighted that this would be considered, as appropriate, when chapters are revised. (See items 5.3 and 5.5 of this report).

The Commission reminded Members that this 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.

4.1. 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.

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

Background

In September 2017, the Presidents of the Code Commission and Aquatic Animals Commission discussed the proposed changes to the *Aquatic Code*'s Glossary definitions for 'biosecurity' and 'biosecurity plan' with a view to developing a new chapter on biosecurity in aquatic establishments. Considering the importance of biosecurity for disease prevention and control and the lack of a dedicated chapter in the *Terrestrial Code* describing the standards on biosecurity, the Code Commission agreed to develop a new chapter on biosecurity and added this to its work programme.

In September 2021, the Code Commission reiterated the importance of having a chapter on biosecurity in the *Terrestrial Code*, and in February 2022 asked the Secretariat to progress work to define the scope and structure of a draft chapter.

The Secretariat prepared a discussion paper, which was presented to the Scientific Commission and the Code Commission for consideration at their September 2022 meetings, as the basis for their discussions on the scope of the new chapter.

Discussion

The Code Commission considered the discussion paper and the input from the Scientific Commission.

The Commission discussed in length the meaning of 'biosecurity' and how the term is used in the *Terrestrial Code*. It agreed that currently, the scope of 'biosecurity' in the *Terrestrial Code* is wider than biosecurity only at establishment level. The Commission agreed with the opinion of the Scientific Commission that the scope of the new chapter should be at a high level describing the overarching principles of biosecurity, using the Glossary definition and how the concept is used throughout the *Terrestrial Code* as a starting point. The Commission requested that an *ad hoc* Group be convened to draft an outline of a new chapter on Biosecurity in terrestrial animals, including a description of what each article may cover, and to review current, or add new, Glossary definitions as deemed necessary.

The Commission requested that a progress report from the *ad hoc* Group be presented to the Scientific Commission and the Code Commission at their February 2023 meetings.

4.1.2. Revision of Chapters 5.4. to 5.7.

Comments were received from Argentina and the EU.

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 develop the Terms of Reference of the *ad hoc* Group to be convened for this work, and encouraged Members to submit comments, and emphasised the importance of Members' active participation at this early stage to ensure that the revised chapters meet Members' needs.

Discussion

In September 2022, the Code Commission considered comments received and reviewed the draft Terms of Reference for the *ad hoc* Group.

The Code Commission noted comments that the scope of these chapters may no longer be limited to animal health, as experiences and current practices have indicated that other aspects such as animal welfare also need to be addressed. The Commission agreed that the potential inclusion of veterinary public health or animal welfare aspects in the revised chapter(s) could be considered by the *ad hoc* Group, while acknowledging that Chapters 7.2. to 7.4. of Section 7. Animal Welfare provide specific recommendations on transport of livestock. The Commission agreed that any provisions included in the revised Chapters 5.4. to 5.7. should be general in nature to avoid duplication.

The Code Commission requested that all relevant proposals and comments of Members be provided to the *ad hoc* Group for its consideration. The Commission did not agree with a comment to include model international veterinary certificates in Chapter 5.4, and explained that the model veterinary certificates are currently provided in Chapters 5.10. to 5.13. of the *Terrestrial Code*, and a revision of these chapters is not included in the current work programme.

The Code Commission agreed that the revised chapters should focus on procedural aspects, i.e., who does what and when, in the entire process of international trade, including measures taken at origin, from the farm/premises of origin to the point of international departure in the exporting country; in transit; and on arrival (import inspection and possible on-farm post-arrival follow-up). The Commission reminded Members that recommendations on certification procedures (including recommendations on electronic certification) are described in Chapters 5.1 and 5.2. The Commission also agreed that the revised chapters should not go into the details of specific measures that would be addressed in the veterinary certificates for importation.

The Code Commission requested that the report of the first meeting of the *ad hoc* Group that will be held in November 2022 be presented for consideration at its February 2023 meeting.

4.1.3. 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.

Since May 2021, a number of Members and partner organisations have submitted comments noting the importance of having a WOA standard for animal welfare and laying hen production systems.

Update

The Secretariat informed the Code Commission that headquarters has undertaken a number of activities to understand better the different points of view and to determine the feasibility of possible future work. The Commission requested to be kept informed to consider the next steps when relevant.

4.1.4. Revision of Chapter 7.5. Slaughter of animals (Chapter 7.5.) and Glossary definitions for 'death', 'distress', 'euthanasia', 'pain', 'slaughter', 'stunning' and 'suffering'.

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

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 proposed for comments the revised definitions for 'euthanasia', 'slaughter', 'stunning', 'death', 'distress', 'pain' and 'suffering' which arose from the work of the *ad hoc* Group on the revision of Chapters 7.5. and 7.6.

The *ad hoc* Group has been convened on several occasions to draft the revised Chapter 7.5. and to consider comments. A revised draft chapter has been circulated for comments three times: in February 2020, February 2021 and February 2022.

Discussion

The Code Commission reviewed comments received on the draft Chapter 7.5. and on the related Glossary definitions used in Chapters 7.5 and 7.6., i.e., 'euthanasia', 'slaughter', 'stunning', 'distress', 'pain', and 'suffering', and requested that the *ad hoc* Group be reconvened to consider the comments and report back to the Commission at its February 2023 meeting. The Commission agreed with the *ad hoc* Group's proposal to delete the definition of 'death' as this term is deemed to be aligned with the common use of this term and therefore there is no need for a specific Glossary definition.

4.1.5. Revision of Chapter 7.6. 'Killing for disease control purposes'

Background

In February 2018, the Code Commission agreed to revise Chapter 7.6. 'Killing of animals for disease control purposes', together with a revision of Chapter 7.5. 'Slaughter of animals' and requested that an *ad hoc* Group

be convened to undertake this work. The *ad hoc* Group met virtually in June 2022 to commence work on the revised Chapter 7.6., now that work on the revision of Chapter 7.5. was well advanced.

Discussion

In September 2022, the Secretariat presented an update on the progress made by the *ad hoc* Group on the revision of Chapter 7.6. The Commission agreed with the approach taken, thanked the *ad hoc* Group for its diligence and requested that it be reconvened to continue the work and present a revised draft chapter to the Commission at its February 2023 meeting.

4.1.6. New chapter on infection with *Trypanosoma evansi* (Surra)

Background

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

In addition to the new Chapter 8.18. Infection with *Trypanosoma brucei*, *T. congolense*, *T. simiae* and *T. vivax* adopted in May 2021, a draft new Chapter 8.X. Infection with *Trypanosoma evansi* (Surra) and a revised Chapter 12.3. Dourine had been proposed and extensively discussed since 2015. 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.X. and 12.3. on hold to progress first the discussions related to Chapter 8.18. Both Commissions had also agreed that, notwithstanding the diagnostic issues, the scope of the new Chapter 8.X. should address surra of multiple species including horses and that the scope of Chapter 12.3. should remain as dourine of equids, 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.X. Infection with *T. evansi* (Surra), and revise Chapter 12.3. Dourine. The Code Commission requested the *ad hoc* Group to 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.X. 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.

Discussion

The Code Commission reviewed the draft new Chapter 8.X. and [the *ad hoc* Group report](#), together with the opinion of the Scientific Commission.

The Code Commission identified a range of critical points that were not clearly explained in the supporting reports, including the lack of information on the epidemiological significance of susceptible species that should be addressed in this chapter and on the rationale for addressing commodities, either as 'safe commodities' or through articles containing risk mitigation measures for importation.

The Code Commission requested that advice on these points be sought from the subject-matter experts. The Commission also requested that the wording and structure of the draft text be reviewed to ensure alignment with other chapters of the *Terrestrial Code*, where relevant.

The Commission agreed not to circulate the proposed draft text for comments yet and requested the Secretariat to prepare a revised draft addressing the abovementioned points, to be considered by the Commission together with the additional information from the experts, at its next meeting.

4.1.7. Harmonisation Code chapters related to official recognition of status by the WOA

Background

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

Common provisions concerning procedures applicable to the diseases for which WOAH grants official recognition of status were addressed in Chapter 1.6. 'Procedures for self-declaration and for official recognition by the OIE', instead of being repeated in relevant disease-specific chapters. The revised Chapter 1.6. was adopted at the 88th General Session in May 2021.

In February 2019, the Code Commission agreed to use Chapter 14.7. 'Infection with peste des petits ruminants virus (PPR)', as the 'model chapter' to present relevant amendments to Members. The revised articles of Chapter 14.7. were circulated four times and adopted at the 88th General Session in May 2021. Similar changes were also included in a revised Chapter 15.2. 'Classical swine fever' which was adopted in May 2022, and as part of the ongoing revision of Chapter 8.8. 'Foot and mouth disease'.

Discussion

The Commission considered the amendments proposed by the Secretariat and endorsed by the Scientific Commission to Chapter 11.5. Infection with *Mycoplasma mycoides* subsp. *Mycoides* SC (Contagious bovine pleuropneumonia) and to Chapter 12.1. Infection with African horse sickness virus (see items 6.4 and 6.6 of this report, respectively).

The Commission noted that once the revised Chapters 11.5, 12.1., and 8.8. are adopted, the work to harmonise the provisions for official recognition will be completed.

4.1.8. Terminology

4.1.8.1. Use of terms 'animal-based measures' and 'measurables'

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'.

Discussion

The Commission considered the discussion paper prepared by the Secretariat and agreed that the terminology used should be harmonised throughout the animal welfare chapters. It agreed that 'measures' should be used instead of 'measurables'. The Commission requested that the Secretariat propose some explanatory text on these terms ('animal-based measures', 'resource-based measures', 'management-based measures' and 'outcome') to add to Chapter 7.1. 'Introduction to the recommendations for animal welfare'. This text will clarify the meanings of these terms for the purposes of the *Terrestrial Code* and explain how they should be used in Section 7. 'Animal Welfare'. This assessment, including a proposed process to subsequently amend the relevant chapters, will be presented to the Commission at a future meeting.

4.1.8.2. Use of terms 'Competent Authority', 'Veterinary Authority', '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.

Discussion

The Code Commission considered an analysis prepared by the Secretariat on 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](#).

The Commission discussed and considered different issues observed and, while noting that in general the terms were consistently used, it agreed on a number of amendments that would need to be addressed.

The Commission agreed on the need for a number of amendments. However, 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.

Nonetheless, the Commission agreed to propose amendments to the use of these terms in the User's Guide at this meeting (See item 5.1 of this report)

4.2. Items under consideration for inclusion in the work programme

The Code Commission discussed a number of topics 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.

4.2.1. Surveillance of diseases of wildlife (from Wildlife Working Group)

Background

At its September 2021 meeting, the Code Commission discussed a proposal from the WOA Working Group on Wildlife to develop a new chapter in the *Terrestrial Code* on surveillance of disease of wildlife (as reported in its December 2020 report). The Commission discussed and provided feedback on this proposal and requested the Working Group on Wildlife to consider its comments before progressing with this work.

In February 2022, the Code Commission was informed of the progress of different work relevant to this request and agreed to continue discussing the possible inclusion of new items related to wildlife health management in its work programme at its next meeting.

Discussion

Considering the update provided by the Secretariat on the WOA Wildlife health framework (see item 7.3. of this report), the Commission agreed to include a new item to its work programme with a focus to consider how the *Terrestrial Code* addresses wildlife health, based on the further recommendations from the Working Group on Wildlife.

The Commission highlighted the need of close coordination with all the Specialist Commissions to ensure a consistent approach is taken for all WOA Standards.

4.2.2. Infection with *Brucella abortus*, *B. melitensis* and *B. suis* (Chapter 8.4.)

Background

At its February 2021 meeting, the Code Commission considered a request to prioritise the revision of Chapter 8.4. Infection with *Brucella abortus*, *B. melitensis* and *B. suis*, notably Articles 8.4.4. and 8.4.5. which include the provisions on country or zone free from infection with Brucella in bovids with vaccination and without vaccination. The Code Commission had noted that the Biological Standards Commission had been working to update the corresponding *Manual* Chapter 3.1.4. and agreed to wait until that work progressed to consider the inclusion of the revision of this chapter in its work programme.

Discussion

Given that the updated *Manual* Chapter 3.1.4. was adopted at the May 2022 General Session, the Code Commission discussed the request again. The Commission noted the global situation of the disease, including the situation on Members' self-declaration of freedom from the disease, but considered there was no new element justifying the revision of the chapter, especially in terms of potential alternatives to the current provisions. The Commission decided not to include the revision of Chapter 8.4. Infection with *Brucella abortus*, *B. melitensis* and *B. suis* in its work programme at this stage, but invited Members to submit any proposal with a scientific justification to amend the current Articles 8.4.4. and 8.4.5.

4.2.3. Infection with peste des petits ruminants virus (Chapter 14.7.)

Background

At its September 2021 meeting, noting a new publication of the '[FAO/OIE Guidelines for the Control and Prevention of Peste des Petits Ruminants \(PPR\) in Wildlife Populations \(2021\)](#)', the Code Commission requested that the Secretariat assess whether amendments regarding wildlife should be considered for Chapter 14.7.

Discussion

The Code Commission was informed that the PPR Global Research and Expertise Network (GREN), at its December 2021 meeting, had considered that there is still no evidence to recognise the wildlife species as epidemiologically significant and current scientific evidence still did not confirm maintenance and reinfection from wildlife back to domestic animals.

Considering the GREN's position, the Code Commission decided not to propose any amendment to Chapter 14.7. at the moment and requested that the Secretariat follow this topic and report back to the Commission when new relevant information became available.

4.2.4. Melioidosis

Background

At its February 2021 meeting, the Code Commission noted a comment on its Work programme requesting recommendations on Melioidosis and asked the Secretariat to follow up on the issue and collect relevant information.

Discussion

The Commission considered additional information provided by the Secretariat and acknowledged that there was no specific request to develop a *Code* chapter, and that no relevant notifications of the disease had been recently submitted to WOAHA as per Article 1.1.5. of the Code.

The Commission noted that Melioidosis (infection with *Burkholderia pseudomallei*) was not a listed disease and that the *Terrestrial Manual* Chapter 3.6.11. had been recently revised in 2018 to include provisions on this disease, and the title of the chapter was changed from 'Glanders' to 'Glanders and melioidosis'. This was mainly linked to the need for recommendations for differential diagnosis.

The Commission encouraged Members to refer to the *Terrestrial Manual* Chapter for recommendations on the diagnosis of this disease and decided not to include a new item in its work programme in response to this request.

4.3. 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*.

4.3.1. Electronic certification (Chapter 5.2. Certification procedures)

The Secretariat updated the Code Commission on the activities that WOAHA had recently implemented to gain a better understanding of e-certification practices implemented by WOAHA Members, including the completion of a WTO Standards and Trade Development Facility project on [Electronic veterinary certification](#). The Secretariat also informed the Commission of the relevant work of other international organisations on e-certification and Single Window and noted that the implementation of e-certification for animals and animal products was still limited while the use of electronic phytosanitary certificates was well established in many countries. The Secretariat also reported that in 2021 Codex adopted revised [Guidelines for design, production, issuance and use of generic official certificates \(CXG 38-2011\)](#), specifically related to transitioning to paperless certification.

Given that in practice a single veterinary certificate may contain information relevant to food safety and animal health for products of animal origin, the Secretariat proposed that the Commission consider developing similar guidance to that of Codex to ensure alignment of standards for e-certification

The Code Commission agreed to revise Chapter 5.2, Certification procedures, of the *Terrestrial Code* to address e-certification in more detail, and to align, as relevant, with the Codex Guidelines. The Commission was informed that WOAAH would also develop Reference data models for the WOAAH model certificates for international trade in live animals and animal products, to align with Reference data models for food products that are included in the Codex Guidelines.

The Commission noted that the implementation of electronic veterinary certification can contribute to facilitating international trade, lowering administrative costs, minimising human errors when certifying, and also minimising the risk of trade fraud.

The Code Commission agreed to include the revision of Chapter 5.2. in its work programme, and to undertake this work in collaboration with the Aquatic Animals Commission, to address jointly the corresponding Chapter 5.2. in the *Aquatic Code*.

4.3.2. Request to revise *Terrestrial Code* Chapter 5.8. International transfer and Laboratory containment of animal pathogenic agents

The Commission considered a new request from a Member to improve clarity within the *Terrestrial Code* on the ability of Members to hold pathogenic agents within laboratories without affecting their animal health status.

The Code Commission discussed how this concept was currently addressed in the *Terrestrial Code* and noted that in addition to Chapter 5.8., references relevant to this concept were already included among the recommendations for laboratories in Chapter 3.2. Quality of Veterinary Services (Article 3.2.10.), and in Chapter 3.4. (Article 3.4.7.), and acknowledged that Chapters 1.7. to 1.12., containing the questionnaires for official recognition of status by WOAAH, included specific requests for Members to provide information regarding the handling of live pathogenic agents in laboratories. The Commission noted that there were currently no articles specific to this concept in the disease-specific chapters.

The Commission also noted that the *Terrestrial Manual* Chapter 1.1.4. outlined the principles on which the specific management of biological risks associated with veterinary laboratories and experimental animal handling facilities should be based, and *Terrestrial Manual* Chapter 1.1.3. described the transport of biological materials.

Based on the abovementioned considerations, the Code Commission agreed that this specific request should be addressed in the context of official status recognition by WOAAH, 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.

4.3.3. Use of antiparasitic drugs

The Code Commission considered the document [“Responsible and prudent use of anthelmintic chemicals to help control anthelmintic resistance in grazing livestock species”](#), developed by the WOAAH Expert Group on Antiparasitic Resistance (EEG-APR) and published on the WOAAH website in December 2021, and discussed the merits of developing the *Terrestrial Code* standards related to the use of antiparasitic drugs.

The Code Commission acknowledged the importance of parasitic diseases for animal and public health and the relevance of the use of antiparasitic drugs in veterinary medicine. The Commission agreed on the need for WOAAH to consider addressing this issue in collaboration with other international organisations. The Commission considered that it could be valuable to consider extending the scope to cover not only anthelmintics but also the use of, and the resistance to, other antiparasitic agents, notably ectoparasiticides, and noted that the use of these veterinary medicinal products was critical for the prevention and management of parasitic diseases and vector-borne diseases listed in the *Terrestrial Code*.

The Commission highlighted that anthelmintics and other ectoparasiticides are outside of the Glossary definition of antimicrobial agents but welcomed the initiative and recommended that WOAAH focus on how to build on the work done to develop the document before considering the development of an international standard. In addition, the Commission stressed the importance of having a good representation of experts from different regions of the world on the EEG-APR, especially from regions where parasitic diseases are highly significant due to their geographical and climatic conditions. The Commission also highlighted the importance of ensuring that sound scientific evidence is available to support the potential development of standards.

The Commission expressed its willingness to contribute to any future work on this topic and requested the Secretariat to report back, as relevant.

4.3.4. The 'Five domains' as an animal welfare concept

Background

In February 2022, the Code Commission considered a comment to add the 'five domains' concept in Chapter 7.7. Dog population management. Although the Commission recognised the importance of the 'five domains' concept, it agreed not to make any changes until it could consider this concept in more detail. The Commission requested that the Secretariat works with the WOAAH Animal Welfare Collaborating Centres to provide more information about this proposal for consideration at its September 2022 meeting.

Discussion

The Code Commission reviewed a document drafted by the Secretariat and the WOAAH Animal Welfare Collaborating Centres.

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 Code Commission requested the Secretariat to continue to work with the WOAAH Collaborating Centres to develop 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 Code.

The Code Commission agreed that more information was required to explain the concept to Members and to clarify how it is linked to the 'five freedoms' concept and requested the Secretariat to work in collaboration with WOAAH Collaborating Centres to develop an explanatory note for consideration at its February 2023 meeting.

4.3.5. Requests to revise Chapter 8.10. 'Japanese encephalitis' and Chapter 12.11. 'Venezuelan equine encephalomyelitis'

The Code Commission considered requests to review Chapters 8.10. Japanese encephalitis and 12.11. Venezuelan Equine Encephalomyelitis which were raised during the 89th General Session in May 2022, as well as comments from Members.

The Code Commission reviewed and discussed a paper prepared by the Secretariat presenting an analysis of the different elements presented in these requests, such as the impact on trade for the movement of horses from infected countries, the discrepancies observed between the chapters of the *Terrestrial Code* and *Terrestrial Manual*, as well as the opinion of the International Horse Sports Confederation (IHSC) and discussions of the Scientific Commission at [its September 2015 meeting](#).

The Commission noted that Chapter 8.10. Japanese encephalitis was first adopted in 1992, and the most recent update was adopted in 2000, but the corresponding *Terrestrial Manual* Chapter 3.1.10. was updated in 2021.

The Commission agreed that the current Chapter 8.10. Japanese encephalitis was partly obsolete given the latest information provided in Chapter 3.1.10 of the *Terrestrial Manual*. The Commission agreed to include the revision of Chapter 8.10 in its work programme.

The Commission also noted that the revisions of Chapter 12.4. Equine encephalitis (Eastern and Western) (no update since its first adoption in 1968) and Chapter 12.11. Venezuelan equine encephalomyelitis (the most recent update adopted in 1998) had been included in its work programme in February 2020 but that work had not been yet initiated.

Considering the epidemiological similarities across these three diseases, the Commission agreed to approach the revisions of these three disease-specific chapters together, to ensure a consistent logic is applied to all three chapters. The Commission also agreed that Chapter 8.20. West Nile fever, even if more recently updated, should also be taken into consideration.

While acknowledging that a major revision of these chapters will be needed, the Code Commission requested the Secretariat to first undertake, in consultation with subject matter experts and the Scientific Commission, a scientific assessment of the susceptible animals, their epidemiological role and their relevance for surveillance and disease prevention and control, to further discuss the approach for the different chapters and then identify the next steps and priorities. In this regard, the Commission suggested assessing these diseases against the criteria for the inclusion of diseases, infections and infestations in the WOAAH list of notifiable terrestrial animal diseases in accordance with Chapter 1.2. of the *Terrestrial Code*.

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

4.3.6. Avian mycoplasmosis (Chapter 10.5.)

Background

The Code Commission considered a comment at the 89th General Session in May 2022 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 Manual chapter addressed both pathogens.

Discussion

The Code Commission noted that until 2004, only *Mycoplasma gallisepticum* had been dealt with in the *Terrestrial Code* (both as a Listed disease and in the disease-specific chapter) and that the current Chapter 10.5. was first adopted in 1982, and last updated in 2021. The Commission also noted that *M. synoviae* was added to the list in 2005, based on recommendations of [the ad hoc Group on diseases/pathogenic agent notification \(November 2004\)](#), but it had not been addressed in any disease-specific chapter.

The Code Commission acknowledged that the corresponding *Terrestrial Manual* Chapter 3.3.5. Avian mycoplasmosis (*M. gallisepticum*, *M. synoviae*) was first adopted in 1991 focusing on *M. gallisepticum*, and *M. synoviae* was added later, in 2008. The Commission noted that the *Manual* chapter was last updated in 2021 and addressed both pathogens.

The Code 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*, and agreed to include this item in its work programme, as priority 3.

The Commission considered that while other mycoplasma species are mentioned in the *Manual* chapter, it was also clear that only *M. gallisepticum*, and *M. synoviae* are considered relevant for the *Terrestrial Code*, and agreed that it was not necessary to review the current listing.

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.

4.4. Follow-up on chapters recently adopted

The Code Commission discussed the following topics related to texts which were adopted at the last General Session in May 2022.

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

Comments received from Australia and the AU-IBAR.

Background

In September 2017, the revised Chapter 11.10. Infection with *Theileria annulata*, *T. orientalis* and *T. parva* was first circulated for comments, but it was put on hold while expert advice was sought regarding the listing assessment, in response to comments received in February 2018 meeting.

In September 2019, the Code Commission was informed that *T. orientalis* (Ikeda and Chitose) meets the criteria for listing in accordance with the criteria in Chapter 1.2. of the *Code* based on the assessment by experts.

The revised Chapter was adopted during the 89th General Session in May 2022, but, at the time of adoption, the President of the Code Commission noted that some comments raised during or submitted before the General Session would be considered at the Code commission's September 2022 meeting.

Discussion

The Code Commission did not agree with a comment that *T. orientalis* should be delisted, noting that the listing assessment had been well justified and that the chapter only refers to *T. orientalis* Ikeda and *T. orientalis* Chitose and not the other strains of *T. orientalis*.

The Commission did not agree with a comment that African buffaloes should be covered in the chapter as epidemiologically significant hosts, as it considered that only bovines (including water buffaloes) were referred to in [the report of February 2017 ad hoc Group on theileriosis](#).

Nevertheless, the Commission 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.

4.5. Prioritisation of items in the work programme

Based on a number of 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 include and remove the items as presented below:

Added items:

- Wildlife Health (preliminary discussions – overarching work)
- Consideration of inclusion of the ‘Five Domains’ concept
- Consideration of use of terms: Competent Authority / Veterinary Authority / Veterinary Services
- Consideration of use of terms: fetal / foetal/ fetus / foetus
- Consideration of use of terms: bovid / bovidae / bovine / cattle
- 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 the OIE
- Revision of Chapter 5.2. Certification procedures
- Revision of Chapter 8.10. Japanese encephalitis
- Revision of Chapter 10.5. Infection with *Mycoplasma gallisepticum* (Avian mycoplasmosis)
- Development of new Chapter 8.X. Q fever
- Development of new Chapter 11.X. Infection with bovine pestiviruses (bovine viral diarrhoea)

Removed items

- All texts adopted at the 89th General Session, in May 2022
- Revision of the Glossary definition for ‘case’
- Listing assessment of Paratuberculosis

The Code Commission updated its work programme accordingly.

The Commission reminded that the prioritisation order 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.

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. This decision as to when to commence each work depends on an overall consideration of priorities, the progress of ongoing work and the resources 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 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 updated work programme is presented in [Annex 3](#), for comments.

EU comment

The EU thanks the Code Commission for having taken into consideration comments submitted previously and fully supports the revised work programme and its prioritisation. Comments and a request to urgently revise Chapter 14.19. *Sheep pox and goat pox* are inserted in the text of Annex 3.

5. Texts circulated for comments and proposed for adoption in May 2023

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

5.1. User's Guide

Background

At this meeting, following the recent adoption of a revised definition for the terms 'Veterinary Authority', 'Competent Authority' and 'Veterinary services', the Commission discussed their use across the Code (See item 4.1.8.2 of this report), and agreed to address the amendments needed in the Users' Guide.

Discussion

The Commission noted that, in the User's guide, in the last sentence of Point C(6), 'Veterinary Services' was used in the context of issuing veterinary certificates and WOH Members' obligations of disease notification, and noticed that this was not in line with the revised Glossary definition. The Commission decided to replace 'Veterinary Services' with 'Veterinary Authority', and circulate this proposal to Members at this meeting.

The Commission reminded Members that the proposed changes to these texts referred only to this specific terminology issue for consistency purposes and did not intend to open the discussion of other aspects or parts of the texts.

The revised point C(6) of the User's guide is presented as [Annex 4](#) for comments and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU supports the proposed change to the User's guide.

5.2. Glossary definition for 'poultry'

Comments were received from Japan, 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" in the current definition, could be considered as '*poultry*', depending on the epidemiological situation of each event.

The Code Commission noted that the definition for poultry clearly states that pet birds are excluded, provided that they have no direct or indirect contact with *poultry* or *poultry* facilities. On the other hand, the Commission acknowledged that it was not clear whether populations of pet birds for breeding or selling are included or not in the definition. To address this point, the Commission agreed to amend the definition to make it clear that populations of pet birds for breeding or selling are excluded from the definition of poultry.

The proposed revised definition was circulated for comments in the Commission's February 2022 report.

Discussion

The Code Commission considered the comments received.

The Code Commission reminded Members that the definition of 'poultry' had been adopted at the 88th General Session in 2021 and considered it appropriate for its objectives.

The Commission did not agree with a comment to replace 'exclusively' with 'primarily', as it would change the intended rigour of the definition. It did not agree either with a comment that pet birds kept in a commercial operation for breeding or selling should be considered poultry due to its higher risk of virus transmission and the subsequent animal and public health risks. While acknowledging that there may be a disease spread risk, albeit not deemed high, from such bird populations, the Commission agreed that this was also the case for any other category of specific bird populations currently listed in the last paragraph of the Glossary definition.

The revised Glossary definition for 'poultry' is presented as part of [Annex 5](#) for comments and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU supports the proposed changes to the Glossary.

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

Comments were received from Australia, Brazil, Canada, China (People's Rep. of), Japan, Mexico, New Zealand, South Africa, Thailand, the UK, the USA, the AU-IBAR, the EU and the IMS.

Background

A revised Chapter 8.8. Infection with foot and mouth disease virus has been circulated four times for comments, the last time in the Code Commission's September 2021 report.

At its September 2021 meeting, the Code Commission also considered recommendations of the joint Code Commission-Scientific Commission Taskforce, which met between June and July 2021 and a proposal from the Secretariat on the harmonisation of requirements for official recognition and maintenance of free status and endorsement and maintenance of official control programmes to align with recently adopted amendments in Chapters 14.7. Infection with peste des petits ruminants virus and 15.2. Infection with classical swine fever virus.

At its February 2022 meeting, the Code Commission considered the comments received. It discussed selected comments and identified those comments which required further advice from experts, including the Biological Standards Commission and the Scientific Commission. The Code Commission decided to defer the review of the remaining comments until its September 2022 meeting so it could consider all comments together with expert inputs. The Commission also considered draft provisions for the importation of meat of susceptible captive wild animals and wild animals, and meat of domestic small ruminants and pigs from countries or zones infected with FMD virus, where a WOAHP endorsed official control programme for FMD exists, which were developed by the *ad hoc* Group on Foot and mouth disease virus (June 2020) and endorsed by the Scientific Commission at its February 2021 meeting. The Commission considered that the proposed text by the *ad hoc* Group required further work and appointed members from the Commission to review the recommendations of the *ad hoc* Group to prepare a proposal to be considered by the Commission for incorporation into the revised chapter.

Discussion

General Comments

The Code Commission acknowledged a comment regarding the use of the term 'Member Country', noted that this term is used in other chapters for diseases for which WOAHP grants official recognition of status and agreed that this should be considered by WOAHP Headquarters.

In response to comments that the proposed amendments to the chapter seem to promote the use of vaccines in FMD prevention and control rather than pursuing FMD eradication, the Code Commission explained that the objective of these changes was to promote the safe movement and trade of animals and animal products and highlighted that: i) vaccination is a key tool for FMD control programmes and many countries had already achieved eradication through vaccination and ii) the chapter was also a key tool for Members wanting to progress towards the cessation of vaccination while possibly using a zoning approach. The Commission emphasised that recommended measures for the movement of vaccinated animals take into consideration the fact that these animals originate from FMD free countries, zones or compartments, and referred to the discussions below on the relevant articles.

The Code Commission noted a comment requesting that WOAHA consider extending the official recognition of disease status to compartments free from FMD and acknowledged that this was not under its mandate and referred it to WOAHA Headquarters.

Article 8.8.1.

General provisions

In point 2, in response to comments on the taxonomy of the susceptible animals, the Code Commission proposed amendments to clarify the families and subfamilies concerned, i.e., 'families Suidae and Cervidae, the subfamilies Bovinae and Caprinae of the family Bovidae, and *Camelus bactrianus*'. The Code Commission also proposed to amend the text to clarify that these are to be referred to in the chapter as 'susceptible animals' and applied this term throughout the text where relevant.

In point 2bis, the Code Commission noted the specific discussion and agreement reached at this meeting with regard to the use of the term 'cattle' in the *Terrestrial Code* (See item 5.15 of this report) and proposed to replace 'cattle' with 'bovine', and applied this change throughout the chapter. The Commission did not agree with a comment to modify the taxonomy reference as it considered the text correct as currently proposed.

In point 3, the Commission also considered a new proposal from the Biological Standards Commission, which was discussed at its September 2022 meeting, to reformulate the structure of point 3, because the process for virus isolation requires confirmatory testing with an antigen or a ribonucleic acid detection test to confirm the identity of the isolated virus. The Commission did not agree with the proposed amendments, because it considered that, irrespective of laboratory techniques required to confirm the identity of the pathogenic agent or any clinical or epidemiological consideration, the recovery of infective virus identified as FMDV in a sample from an animal was sufficient to confirm the occurrence of infection with FMDV while that was not the case when the diagnosis was only based on the direct detection of antigen or ribonucleic acid from a sample.

In point 3(a), in reference to previous discussions of the Biological Standards Commission and the Scientific Commission, the Code Commission noted that the three Commissions had agreed that it was not necessary to refer to the characterization of the agent as part of the definition of occurrence of the disease. Nonetheless, in response to comments received on this point in this chapter and others, and in agreement with the Biological Standards Commission, the Code Commission agreed to add 'and identified as such' after 'isolated' to ensure understanding that adequate confirmation of the diagnosis is always required.

In point 4, the Code Commission agreed with a comment that transmission of FMDV would constitute a case as defined in point 3 and would thus need to be notified to WOAHA within 24 hours of detection. Therefore, it proposed to add a new sentence 'Transmission of FMDV shall be notified to the OIE' at the end of the point for clarity.

In point 5, the Code Commission noted a comment on defining the latent period and requested the Secretariat to refer this comment to the Biological Standards Commission for its consideration, explaining that such detail should be in the *Terrestrial Manual* and not the *Terrestrial Code*.

In point 6, the Code Commission proposed to replace 'this species' with 'African buffalo' for clarity. In response to a comment seeking clarification about the use of the term 'rare', the Commission, in agreement with the opinion of the Scientific Commission at its February 2022 meeting, explained that it referred to the frequency of the event, and not to its epidemiological impact, which would certainly depend on many other factors.

At the same point, the Code Commission did not agree with a comment to provide a more detailed definition for the length of the carrier state of all susceptible animals and reiterated its rationale described in its September 2020 report that this was detailed for a chapter of the *Terrestrial Code*.

Article 8.8.1bis.

In response to a comment disagreeing with the addition of point 1, the Code Commission reiterated that it considered UHT sufficient to destroy the FMDV, and this was aligned with the current version of the WOAHA Technical Disease Card on FMD. The Code Commission explained that if a commodity is considered safe, whether it is for human or animal consumption or other usage is irrelevant. It reminded Members that this was the reason for the proposed deletion of Article 8.8.36.

In point 3, in response to a comment to remove protein meal as a safe commodity in view of EC1069/2009 regulation stating that selected by-products originating from animals including protein meal should not enter the feed chain for human consumption, the Commission reminded Members that the Code does not address specific Members' regulations, but provides international standards applicable to all Members, which are expected to implement them in their national context. Furthermore, it also noted that protein meal is a commodity which uses standardized

protocols in its processing and treatment, and therefore would meet the criteria in Chapter 2.2. of the *Code*. The Commission acknowledged a separate comment requesting to define the standard process for rendering and requested Secretariat to consult the industry in this regard.

In response to a comment requesting the addition of 'gamma irradiated foetal bovine serum (irradiated at 25 kGy while in a frozen state of $-10\text{ }^{\circ}\text{C}$ or below)' to the list of safe commodities, the Code Commission requested the Secretariat to consult the industry on whether the proposed treatment is a standardised protocol for irradiated foetal bovine serum.

In response to comments on the inclusion of fresh matured deboned meat on the list of safe commodities, the Code Commission noted that 'matured meat' involves a series of processing steps that may differ between countries. As there is no universally standardised agreement on these steps and specifications on the time-pH holding conditions that have to be prescribed, the Code Commission did not consider matured deboned meat' to meet the criteria to be defined as a safe commodity.

Considering the wording of the last paragraph of Article 8.8.27., the Code Commission agreed to add a new point 6), to include 'limed hides, pickled pelts, and semi-processed leather' to the list as safe commodities, and to remove that paragraph from Article 8.8.27.

Following up on its agreement in its February 2022 meeting, the Code Commission also considered the inclusion of 'extruded dry pet food' and 'heat-treated meat products in a hermetically sealed container with an F0 value of 3 or above' in the list of safe commodities. The Commission agreed that these commodities complied with the criteria in Chapter 2.2. and agreed to add a new point 7) 'extruded dry pet food' to the list as safe commodities, and to amend point 2) for consistency with other chapters.

Article 8.8.2.

The Code Commission did not agree with a comment to reinstate 'measures' after '*biosecurity*', and it reiterated that it would be redundant considering the Glossary definition for '*biosecurity*', which means 'a set of measures'.

The Code Commission agreed with a comment to remove the first three paragraphs for consistency with other chapters, noting that the content of these paragraphs is already covered by the relevant horizontal chapters.

In response to a comment on whether the reference in point 2 of Article 1.4.6 excludes countries having wild African buffalo populations from acquiring free status because this species is known to be persistently infected, the Code Commission noted that point 2 of Article 1.4.6. states 'unless otherwise specified in the relevant chapters of the *Terrestrial Code*', and for FMD, having known infected susceptible animals, whether wild or not, would indeed preclude freedom status.

In point 2, a comment was received on defining 'current knowledge of' and 'authority over', with the rationale that difficulties were encountered in the annual reconfirmation submitted for another disease for the same point. The Code Commission clarified that this requirement was harmonized across the chapters of diseases for which WOAHS grants official status recognition, and refers to the knowledge and competency that the Veterinary Authority has over domestic and captive wild animal populations in its jurisdiction. In the same point, the Code Commission did not agree with a comment to add 'all susceptible species in the country or zone' after 'current knowledge of', as this addition would not provide any added value.

In point 3, the Code Commission did not agree with a comment requesting to delete the point, in agreement with the Scientific Commission's opinion that the presence of wild and feral susceptible animals may have an impact on the animal health status of the country or zone and should be monitored. The Commission noted that this response was also relevant for a similar comment on point 1 d) of Article 8.8.3.

In the same point, the Commission noted a comment questioning if the current wording implied that a dedicated surveillance system should be established for wild and feral susceptible animals, noting that the range of susceptible animals of FMD is much wider than other diseases and that the clinical signs of FMD in wild animals may be unclear to be detected. The Commission noted the opinion of the Scientific commission at its February 2022 meeting that the intention of this provision was not to require active surveillance but to ensure that a passive surveillance system is in place to support and maintain the FMD free status of a country or zone, and considering that this is already covered by point 4) of this article and the general principles for surveillance in Chapter 1.4., it proposed to delete 'and indication of disease occurrence through passive surveillance' for clarity.

In point 4(b)(ii), the Code Commission did not agree with a comment that the amended provisions allowing the importation of vaccinated animals into a country or zone officially free from FMD where vaccination is not practised implied an unjustified additional burden on FMD-free importing countries to maintain its animal health status. The Commission highlighted that these provisions aimed at providing recommendations for the safe movement of animals,

and that importing countries had to implement them based on risk analysis. Nonetheless, the Commission agreed with the opinion of the Scientific Commission at its February 2022 meeting, and considering the concerns raised by Members and the significance of the change, the Commission proposed amendments in point 5) to limit the introduction of vaccinated animals only to those from FMD-free countries/zones where vaccination is practised (and not from infected countries/zones). The Commission also noted that the Scientific Commission would develop guidelines on FMD surveillance to assist Members in this regard.

In the last paragraph, the Code Commission did not agree with a comment to delete the paragraph and reinstate the requirement to establish a protection zone in the case of an incursion of stray African buffalo. The Code Commission reiterated that the Taskforce did not consider this to be necessary and referred the Member to the September 2021 report of the Scientific Commission for further information. In the same paragraph, the Code Commission agreed with a comment to clarify the conditions to maintain the free status despite an incursion of African buffalo and proposed to change 'the relevant conditions are' with 'it is demonstrated that the provisions in this article continue to be' and to add 'where vaccination is not practised' after 'free from FMD'.

Article 8.8.3.

In the third paragraph, the Code Commission agreed to delete the paragraph to align the structure of the article with similar articles (status definition) in other chapters. Nonetheless, the Commission agreed that the content of the paragraph was important and moved it to the end of point 1(e) of this article.

In response to a comment on whether the reference in point 2 of Article 1.4.6. excludes countries having wild African buffalo populations known to be persistently infected from acquiring free status where vaccination is practised, the Code Commission reiterated its explanation given above, under Article 8.8.2.

In point 1(b) the Code Commission did not agree with a comment that the point was redundant.

In point 1(c), the Code Commission did not agree with a comment to add 'all susceptible species in the country or zone' after 'current knowledge of' as this addition would not provide any added value.

In point 1(d), the Code Commission amended the text to follow the changes introduced in point 3 of Article 8.8.2.

In point 1(g), the Code Commission did not agree with a comment that this point appears to be redundant if the country or zone complies with point 2 of Article 1.4.6. and explained that point 1(g) complements point 2(a)(iii) of Article 1.4.6. with reference to the specific recommendations of this chapter on FMD.

In point 2, the Code Commission did not agree with a comment to amend the text as considered it was clear as written that the duration for which surveillance should be undertaken is 24 months.

Article 8.8.3bis.

In the first paragraph, the Code Commission agreed with comments to amend the text for clarity.

In response to a comment querying why the last paragraph was proposed to be deleted, the Code Commission explained that it was for harmonisation purposes for all disease-specific chapters for which WOAHA grants official recognition of status (See item 4.17 of this report) and noted that it was covered by Article 1.6.1.

Article 8.8.4.bis

In point 2(c) the Code Commission did not agree with a comment to delete 'population immunity is closely monitored', as it considered this a critical point for a compartment free with vaccination to be established and approved.

Article 8.8.5bis.

In response to a comment questioning the level of detail in this new article, the Commission highlighted that while a dedicated horizontal Article 4.4.6. provides general recommendations, these disease-specific provisions are relevant due to the importance of this disease and are necessary for the purposes of official status recognition.

In the fourth paragraph, the Code Commission agreed with comments that the two options for recovery of free status after vaccination is implemented in a protection zone, established in a free country or zone where vaccination was not practised (i.e., towards free with or without vaccination) needed to be clarified and proposed amendments to the text for clarity.

In the fifth paragraph, in response to comments that the establishment of a containment zone is optional, the Code Commission proposed to add 'If the Veterinary Authority establishes' at the beginning of the second sentence to clarify this.

In the same paragraph, the Code Commission did not agree with a comment that if FMD occurred in a protection zone, the significance of protection will be lost. The Code Commission clarified that a protection zone *per se* is not a protected area, and the objective of the protection zone is to prevent the entry of the pathogenic agent into the rest of a free country or zone.

In the last paragraph, the Code Commission did not agree with a comment that requested to add 'established as a temporary measure in response to an increased risk of disease' after 'protection zone', as it considers that the text clearly defines that the protection zone should be limited to less than 24 months from the date of its approval by the WOA. H.

In the same paragraph, the Code Commission did not agree with a comment to replace 'Member Country' with 'Veterinary Authority', as a status is requested by and granted to a Member. The Commission noted that this response also applied to similar comments received in other points of the chapter.

Article 8.8.6.

In the first paragraph, the Code Commission agreed with a comment to amend the text for consistency of terminology.

In the last paragraph, the Commission agreed with a comment to review the time limit for recovery of free status of the containment zone. The Commission acknowledged that its previous response, at its September 2021 meeting, focused on the recovery of free status of the entire country or zone, but did not necessarily address the possibility for a Member to follow the official process to have two different zones with distinct animal health statuses, one for the area inside of the containment zone and the other for the area outside of the containment zone. In agreement with the Scientific Commission and acknowledging that these changes would require yearly adoption by the World Assembly, the Commission proposed to amend this period from 18 months to 24 months, which would also align with that of the protection zone.

In the same paragraph, in response to a comment querying about the consequences of recovery not being achieved within that time limit, the Commission explained that even if no consequences are described in this paragraph, it should be understood that the officially recognised status for the country or zone would be suspended in such a case. The Commission referred to the opinion of the Scientific Commission on this point at its February 2022 meeting.

Article 8.8.7.

The Code Commission acknowledged a comment regarding the processes to demonstrate freedom and noted that it had been forwarded to the Scientific Commission for consideration at its February 2022 meeting.

In point 3, in response to a comment, the Code Commission proposed to add 'or transmission of FMDV' as the transmission of FMDV in vaccinated populations would also affect freedom status. The Commission applied this addition throughout the text where relevant.

In point 3(a), the Code Commission did not agree with a comment to add 'or without' before emergency vaccination and explained that the shortened waiting period of 6 months was to take into account the application of emergency vaccination. For the same reason, in the last paragraph of the point, the Code Commission did not agree to add 'neither stamping-out policy nor' before 'emergency vaccination'. The Commission clarified that reduced waiting periods apply only if emergency vaccination is practised, and if emergency vaccination is not applied, the waiting periods in this article do not apply and Article 8.8.3. applies.

In point 3, in the third paragraph, the Code Commission did not agree with a comment to replace 'Article 8.8.3' with 'Article 8.8.2', explaining that point 3 refers to a country or zone previously free from FMD where vaccination is practised, and therefore the correct reference for recovery is Article 8.8.3.

In point 5, the Code Commission agreed with a comment to amend the text to clarify the requirements for lifting restrictions, noting these were not described elsewhere in this article.

In the last paragraph of point 5, the Commission agreed with a comment to include a reference to Article 8.8.4bis for completeness and consistency with point 4.

Article 8.8.9bis.

In the title, the Code Commission did not agree with a comment to remove 'or not' after 'practised' because this article deals specifically with animals which had been vaccinated, as such animals may still exist in a zone free from vaccination where vaccination is not practised, and referred the Member to the different provisions in this chapter for the conditions for determination of status at origin.

Article 8.8.11.

The Code Commission noted a comment to reorganise the articles containing trade provisions and, following its agreement regarding the standardisation of content across the *Terrestrial Code*, the Commission agreed to include the relevant commodity in the title of the article and applied this change across the chapter.

In points 3 and 4, the Code Commission acknowledged diverging comments requesting on one side to use only one test (i.e., either a virological test or serological test for FMD), and on the other, requesting additional measures to the proposed scheme. Noting the opinions of the Biological Standards Commission (September 2022 meeting) and the Scientific Commission (February 2022 meeting), the Commission agreed that while the tests individually may have limitations, the application of two tests in parallel would improve the sensitivity of the process, which added to the other complementary mitigation measures. The Commission also highlighted that these provisions were meant for the importation of animals from FMD free countries, which implies that the absence of the pathogenic agent in the population has been duly demonstrated in compliance with the relevant provisions of this chapter and officially recognized by WOAHA, and hence the risks of the animals being either infected with FMD or previously exposed would be marginal. The Commission agreed not to further amend the text.

In point 6, in response to a comment querying what is meant by place of shipment, the Code Commission clarified that this meant the place where the animals leave the exporting country for international trade.

The Code Commission acknowledged a comment providing the experience of countries in the South American region regarding vaccination and the evaluation of transmission in vaccinated animals.

Article 8.8.11bis.

In point 4, in response to a comment, the Code Commission referred to its explanation in Article 8.8.11. regarding the place of shipment.

Article 8.8.12.

In point 5, the Code Commission agreed with a proposal of the Scientific Commission at its February 2022 meeting, and proposed amendments to the text to clearly explain the two different options (a quarantine station or an establishment in an area with no occurrence of FMD), while the testing procedures are the same.

Article 8.8.14.

In point 1(c), the Code Commission did not agree with a comment to provide further details regarding the time period in which animals are required to be kept in an artificial insemination centre before collection, noting that this article applies to FMD free countries or zones. The Commission also noted the alignment with Chapters 4.6. and 4.7. will be addressed by the ongoing work to update those chapters.

Article 8.8.18.

In point 3, the Code Commission agreed with a comment to include a reference to Chapter 4.10, as *in vitro* produced embryos are also micromanipulated. The amendment also applied to Article 8.8.19.

Article 8.8.19.

In point 1(c)(ii), the Code Commission agreed with a comment to add 'and not more than 60 days' to align with the requirements for semen donors.

Article 8.8.22ter.

The Code Commission proposed a new article for the importation of fresh meat of domestic small ruminants (excluding feet, head, and viscera) from FMD infected countries and zones where an official control programme exists, based on the proposed draft texts and rationale developed by [the *ad hoc* Group on foot and mouth disease virus \(June 2020\)](#). The Commission agreed that the maturation process described for the meat of small ruminant carcasses was comparable to that for the meat of bovines and could be used in the same way as one of the risk mitigation measures required.

While acknowledging that the original request from the Commission to this *ad hoc* group was also to consider recommendations for the trade of wild animal meat from infected countries or zones, the Commission decided not to include such draft provisions as it would be difficult to provide for such commodities, standard recommendations compatible with current export supply chains, feasible from practical and cost perspectives and simple to be certified by Veterinary Authorities. The Commission considered that for the time being, such trade would be managed bilaterally based on a specific risk analysis.

Article 8.8.25.

In point 1(b) the Commission agreed to delete the reference to Article 8.8.36, as it was no longer applied.

Article 8.8.27.

The Commission agreed to delete the last paragraph as the relevant commodities were added to Article 8.8.1bis.

Article 8.8.28.

In point 1, the Commission did not agree with a comment to add “or come from areas where animal grazing is not allowed for this type of commodity” in the end, as it considered this excessive as all other measures provided in this article were sufficient to mitigate risks related to straw and forage.

Article 8.8.35.

In point 1, the Commission did not agree with a comment to reinstate the point and reiterated its response provided in its September 2020 report, that this was a consequence of the addition of UHT milk to the list of safe commodities in Article 8.8.1bis and referred to the February 2020 report of the Scientific Commission for further information.

The Code Commission did not agree with a comment regarding this article and the deleted Article 8.8.36., requesting that two separate articles be retained with appropriate measures to inactivate FMDV to the level of confidence dependent on end use. The Commission reiterated that the provisions in disease-specific chapters are intended to deal with the risk of the commodity itself regardless of its usage. The Commission also highlighted that the current draft article provides measures equivalent to those in the previous article 8.8.36.

Article 8.8.40.

In response to a comment regarding the surveillance requirements related to the introduction of vaccinated animals, the Code Commission referred Members to the responses provided to comments in Article 8.8.2.

Article 8.8.41.

In the first paragraph, the Code Commission did not agree with a comment to add ‘field samples or’ before ‘FMDV isolates’, as it considered it was not practical to include this as a standard requirement. Nonetheless, the Commission acknowledged that field samples could be helpful to establish the molecular, antigenic and other biological characteristics of the causative virus notably when the national laboratories might not have all the necessary capacities.

Article 8.8.42.

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

The revised Chapter 8.8. Infection with foot and mouth disease virus is presented as [Annex 6](#) for comments and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU thanks the Code Commission and in general supports most of the proposed changes to this chapter. However, important comments are inserted in the text of Annex 6.

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

Comments were received from Argentina, Chinese Taipei, Singapore, Switzerland and the EU.

Background

Following the adoption of revised Chapter 8.14. Infection with rabies virus, in May 2019, the Code Commission, at its September 2019 meeting, acknowledged that there was still some work pending on the chapter given that the priority had been to adopt amendments to support the global strategic plan to end human deaths from dog-mediated rabies by 2030 (i.e., the “Zero by 30 initiative”). The pending issues concerned the provisions for vaccination, testing and the shipment of animals (in Article 8.14.7.) and the provisions on risk mitigation measures for the importation of mammals outside of the Orders *Carnivora* and *Chiroptera* (in Articles 8.14.8. and 8.14.10.). In addition, the Code Commission and the Scientific Commission had agreed to seek advice on the relevance of including specific provisions on the control of rabies in wildlife, including oral vaccination.

At its September 2020 meeting, the Code Commission considered the advice of the *ad hoc* Group on Rabies and the Scientific Commission (October 2019 report) 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 requested the advice of the Scientific Commission for some comments. The Code Commission also decided, in agreement with the Scientific Commission, not to propose any amendment to Articles 8.14.8. to 8.14.10. until new scientific evidence becomes available.

Between February and September 2021, the Scientific Commission requested additional advice from the WOA/Rabies Reference Laboratory network (RABLAB), which was endorsed by the Scientific Commission at its September 2021 meeting.

At its February 2022 meeting, the Code Commission considered the comments received, together with the advice from the RABLAB and the Scientific Commission. The Commission also considered a draft new article developed by the RABLAB experts providing provisions for the control of rabies in wildlife, and a new draft article on recommendations for implementing a rabies vaccination programme for dogs, which had been endorsed by the Scientific Commission.

Discussion

In preparation for this meeting, the Secretariat requested the advice of the Scientific Commission on selected comments received on the circulated texts. The Scientific Commission, at its September 2022 meeting, considered the opinion of experts of the RABLAB to address those points.

The Code Commission considered the comments received on the new Article 8.14.6bis. and the revised Article 8.14.7., together with the opinion of the Scientific Commission at its September 2022 meeting.

General comments

The Code Commission noted a first comment not supporting the proposed reduction in the waiting period from 3 months to 30 days for the importation of vaccinated dogs from infected countries or zones, but agreed that no specific evidence or reference had been provided.

The Code Commission also acknowledged another comment not supporting the proposed changes, based on a risk assessment conducted to assess the risks related to a possible reduction of the waiting period after rabies antibody titration test to 30 days compared with 90 days of the current EU legislation, for dogs moving from certain non-EU countries to the EU. The Commission thanked the Members for the information provided and referred to the opinion of the Scientific Commission on this assessment (see SCAD’s September 2022 meeting report for details). The Commission highlighted that such risk assessments that were based on assumptions and modelling may be relevant to a specific context and could support a Member wishing to apply more stringent sanitary measures than those recommended in the Code, if scientifically sound and conducted in accordance with Chapter 2.1., while it was not fit for extrapolation to the global context.

Article 8.14.6bis.

In view of the above, and of the fact that any dog naturally infected and presenting a serology titer as described in the article should show signs of rabies at the time of, or less than ten days after the test the Code Commission did not agree to modify the waiting period for the importation of vaccinated dogs from infected countries or zones from 30 days to 3 months, and encouraged the Members to refer to the rationale provided in previous reports of this Commission, the Scientific Commission and the RABLAB experts.

Article 8.14.11bis.

In point 2(a) the Code Commission did not agree with a comment to include cats, as it considered the article was focused on dogs and was aimed at addressing vaccination programmes for dog-mediated rabies for which cats were not considered to play a significant epidemiological role.

In point 3(a) the Code Commission agreed with a comment to replace “a database” with “an animal identification system”, for consistency with related text in Chapter 7.7. Dog population management.

At the same point, it acknowledged a comment stating that this requirement may not be feasible when using an oral rabies vaccine but considered that it was not needed to change the text, since, as stated in the *Terrestrial Manual*, parenteral vaccination should remain the foundation of mass vaccination campaigns of dogs.

Recommendations for the control of rabies in wildlife

The Code Commission reviewed a draft new article developed based on the previous discussions between the Code Commission, the Scientific Commission and the WOA Working Group on wildlife about specific provisions on the control of rabies in wildlife in the chapter.

The Code Commission acknowledged the proposed article providing recommendations for an official control programme for wildlife-mediated rabies and thanked the RABLAB experts and the Scientific Commission for their work.

Noting that the chapter is focused on dog-mediated rabies, the Commission decided that it was premature to include control of wildlife-mediated rabies and not to propose this addition to the Members for the time being. The Commission agreed to continue working on the current revision and come back to this topic upon Members' request, after the adoption of the currently proposed amendments.

The revised new Article 8.14.6bis., the revised Article 8.14.7., and the new Article 8.14.11bis. are presented as [Annex 7](#), for comments, and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU thanks the Code Commission but cannot support the chapter as presented. Comments are inserted in the text of Annex 7.

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

Comments were received from Australia, China (People's Rep. of, Chinese Taipei, New Zealand, Switzerland 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 the 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, and made additional amendments, and circulated the revised chapter for comments.

Discussion

The Code Commission considered the comments received.

Article 8.15.1.

In point 4(b), in response to a comment to add 'locally acquired' before 'human infected with RVFV', the Code Commission agreed that humans are dead-end hosts, and thus infection in humans that has been acquired in a different geographical area would not be linked to infection in animals. However, the Commission did not agree to amend the text as it considered the draft text adequately addressed this scenario.

Article 8.15.2.

The Code Commission reminded Members that the Commission, at its February 2022 meeting, had agreed to consider the inclusion of 'extruded dry pet food' and 'heat-treated meat products in a hermetically sealed container with an F0 value of 3 or above' in the list of safe commodities, as appropriate, when a disease-specific chapter was under review. The Commission reviewed a number of scientific references¹ regarding virus inactivation, together with information provided by the GAPFA, and agreed that these two products met the criteria for safe commodities and should be added to the list of safe commodities in this article.

Article 8.15.6.

In point 2(b), the Code Commission did not agree with a comment to add 'where RVF exists' at the end of the point, and noted that "epidemic area" was defined in Article 8.15.1 for the purposes of this chapter.

Article 8.15.8.

In response to a comment that there were no recommendations for *in vitro* produced embryos for sheep, goat or cattle, the Code Commission requested that WOAHS Secretariat seek experts' advice on the inclusion of *in vitro* embryos in this article.

The Commission also discussed the trade in *in vitro* produced embryos in a broader context, and agreed that there was a need to consider how to address risks posed by *in vitro* produced embryos in international trade in some other chapters of the *Terrestrial Code*, recognising that this may be difficult in some cases due to a lack of scientific data. In point 2b, the Code Commission did not agree with a comment to add 'with animal vaccinated against RVF' after 'subjected to a serological test'. The Commission reminded Members that [the ad hoc Group on RVF \(June 2021\)](#), had noted that there was insufficient scientific evidence to indicate that semen remains infective following recovery of infected animals and had concluded that the risk mitigation measures in the current article should be sufficient to prevent disease transmission. At the same point, the Commission did not agree to add 'and RT-PCR negative results from the semen' at the end of the point, again noting that there was insufficient scientific evidence to indicate that semen remains infective following recovery of infected animals. The Commission encouraged Members to provide scientific references to support the proposed amendments for the Commission's future consideration.

Article 8.15.9.

The Code Commission did not agree with a comment to add 'by-products' in this article, given that no scientific evidence was provided to support this proposal. Further, the Commission emphasised that the Glossary definition for meat and meat products did not cover inedible foodstuff, and thus they could not include all "by-products". The Commission also reminded Members of the ongoing work on the use of the term 'animal by-products' in the *Terrestrial Code* and that the possible development of a specific definition has been included in the Commission's work programme.

Article 8.15.11.

The Code Commission did not agree with a comment to add a sentence referring to surveillance for high vector activity and noted that this is already addressed in the second paragraph. The Commission considered that 'low vector activity' was more relevant than 'high vector activity' in the provisions of this chapter.

In the third paragraph, the Code Commission proposed to add 'indigenous' before 'infections in humans' to ensure alignment with point 2(b) of Article 8.15.3.

The revised Chapter 8.15. Infection with Rift Valley fever virus is presented as [Annex 8](#) for comments and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU thanks the Code Commission and in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 8.

5.6. Infection with Newcastle disease virus (Article 10.9.1.)

¹ Daouam et al. (2014). Heat stability of the Rift Valley Fever Virus Clone 13 live vaccines. *Trials in Vaccinology*, 3 (2014), 61-64.; [ICTV 9th Report. Family: Bunyaviridae; WOAHS Technical disease card for Rift Valley fever.](#)

Comments were received from New Zealand, Switzerland, the UK 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, and that there was no need to include a definition in disease-specific chapters such as Chapter 10.4. Infection with highly pathogenic avian influenza viruses or Chapter 10.9. Infection with Newcastle disease virus.

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.

Discussion

The Code Commission considered the comments received.

Article 10.9.1.

In point 3, the Code Commission agreed to delete 'as defined in point 2 above' as it was not relevant anymore.

The revised Article 10.9.1. of Chapter 10.9. Infection with Newcastle disease virus is presented as [Annex 9](#) for comments and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

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

5.7. Bovine spongiform encephalopathy (Chapter 11.4.; Chapter 1.8.; Glossary definition for 'protein meal' and use of related terms)

Background

In February 2018, following preliminary work and discussions, the Code Commission and the Scientific Commission agreed to an in-depth review of Chapter 11.4. Bovine spongiform encephalopathy (BSE). WOAHP convened four *ad hoc* Group 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 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 the OIE 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 draft revised Chapters 11.4. and 1.8. and made some additional amendments and circulated the revised chapters for comments in its September 2020 report.

At its February 2021 meeting, the Code Commission considered comments received and amended the chapters, as appropriate, and circulated the revised chapters.

In preparation for the September 2021 meetings, nominated members of the Code Commission and the Scientific Commission met to discuss key aspects of the revision of Chapters 11.4. and 1.8. to ensure agreement on how to address the main concerns raised by Members, the decisions made on the revised chapters and their impact on the WOAHP official status recognition, as well as on the adapted procedures that will be required. Both Commissions addressed specific issues of relevance at their respective September 2021 meetings.

At its September 2021 and February 2022 meetings, the Code Commission considered comments received and amended the chapters, as appropriate, and circulated the revised chapters, proposing the chapters for adoption at the 89th General Session in May 2022.

In the 89th General Session held in May 2022, 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 noted that some

Members had submitted very detailed comments, and acknowledged that significant amendments had been made to the text at the last two Commission meetings and therefore Members might not have had enough time to adequately review the amended text. Therefore, he proposed that the Assembly withdraw the proposed revised Chapter 11.4. (as well as Chapter 1.8.) from adoption. He emphasised that the revision of the chapter was not a matter of urgency and that it was important to make every effort to reach an agreement by consensus. He also explained that the postponement would provide WOAAH with more time to further review the impact on the assessment of official BSE status already recognised and to develop guidelines on surveillance that would help Members adapt the proposed new provisions on BSE surveillance. He indicated that the Code Commission would consider comments received prior to this General Session, as well as any additional comments submitted at its next meeting in September 2022 and explained that revised chapters would be presented to the Assembly at the 90th General Session in May 2023.

Discussion

Chapter 11.4. Bovine spongiform encephalopathy

Comments were received, prior to the 89th General Session, from Australia, Brazil, China (People's Republic of), France (on behalf of the 27 Member States of the EU), Japan, New Caledonia, New Zealand, Republic of Korea, the UK, the AU-IBAR and the WRO.

Additional comments were received prior to this meeting, from Australia, Japan, New Zealand, Republic of Korea, Singapore, South Africa, the UK, the AU-IBAR and the WRO.

General comments

The Code Commission acknowledged various comments reiterating concerns on how the revised chapter addressed atypical BSE, and noted that new detailed comments were received in that regard. The Commission reviewed its previous discussions and reminded that at its September 2020 meeting it had recognised the difficulties of strictly applying the criteria in Article 1.2.2. to atypical BSE and that there were still gaps in scientific knowledge regarding atypical BSE, and therefore the Commission had agreed that keeping atypical BSE as a listed disease was an interim solution. The Commission noted that no new scientific evidence had become available since 2020, and decided to seek the Scientific Commission's opinion on whether atypical BSE should continue to be notifiable to WOAAH, and whether and how atypical BSE should be considered in the risk assessment, as these two points were critical to address Members' concerns.

The Scientific Commission discussed these issues at its September 2022 meeting and concluded that there was no evidence to consider that point 1 of Article 1.2.2. was met for atypical BSE, but whilst there was no evidence to date that atypical BSE was transmissible under natural conditions, the potential for recycling of the atypical BSE agent could not be ruled out and should be avoided. It also concluded that there was no evidence that atypical BSE was an indicator of a BSE agent being recycled in a bovine population and it should not be part of the exposure assessment in Article 11.4.2. of the revised BSE Code chapter, and noted that risk mitigation measures put in place for classical BSE would also likely be relevant for preventing recycling and amplification of atypical BSE in a bovine population.

The Code Commission considered the Scientific Commission's conclusions and proposed relevant amendments to the revised Chapter 11.4., based on the following positions:

- Since atypical BSE does not meet the criteria for listing, reference to atypical BSE is not justified in this chapter in the context of notification obligation to WOAAH in accordance with Chapter 1.1. of the *Terrestrial Code*;
- Since there is no scientific evidence that atypical BSE is an indicator of a BSE agent being recycled in a bovine population, reference to atypical BSE is not justified in the BSE risk assessment described in Article 11.4.2.;
- Nevertheless, since the potential for recycling of atypical BSE agent cannot be ruled out and should be avoided, reference to BSE (i.e., including both classical and atypical) is justified in the contexts of general reference to the disease, of risk mitigation measures for BSE, and of BSE surveillance.

The Code Commission noted comments expressing concerns with the proposed approach for some of the trade provisions: one stated that it was essential that any changes to the chapter do not increase the administrative burdens or trade barriers for countries that hold a negligible BSE risk status, given the global context and epidemiology with respect to diminishing overall BSE and vCJD risks; and another comment argued that it would be more proportionate to have different trade recommendations for different commodities, and that taking into account the two subpopulations as currently proposed for the trade provisions would not be justified for countries that hold a negligible BSE risk status due to the additional costs and difficulty to implement compared with the expected risk mitigation results. The Commission discussed at length these comments and agreed that the BSE risk posed by bovines born

before the date from which the risk of BSE agents being recycled within the bovine population has been negligible (here after referred to as 'the date') was not considered to be significant for meat and blood, and consequently proposed to delete the reference to different subpopulations in Articles 11.4.10. (on recommendations for importation of fresh meat and meat products) and 11.4.13. (on recommendations for importation of blood and blood products). On the other hand, the Commission agreed not to modify Articles 11.4.7. (on recommendations for importation of live bovines) and 11.4.12. (on recommendations for importation of bovine-derived protein meal) on this regard as it considered that a relatively higher BSE risk in these commodities should be properly managed.

The Code Commission noted concerns raised by some Members on the potential impact on official status recognition and the determination and publication of the date. The Code Commission noted these had been addressed by the Scientific Commission at its February 2022 meeting and encouraged Members to follow the discussions on procedures related to official status recognition in the [reports of the Scientific Commission](#). The Code Commission also noted comments expressing interest in the guidelines for BSE surveillance which was being developed by WOA. The Code Commission encouraged Members to refer to the relevant reports of the Scientific Commission for further details on these and other matters relevant to this work. The Code Commission reiterated that these guidelines would not create a need for any further modifications to the chapter.

In response to a comment that the BSE surveillance described in the proposed Article 11.4.18. did not change the testing requirement nor substantially reduced the cost of testing, the Code Commission explained that the proposed surveillance (passive surveillance) targeted only the risk populations, including clinical suspects, casualty slaughter and fallen stock as described in the article, and did not target 'routine slaughter bovines', which is one of the subpopulations that the current point-based surveillance focused on. Nevertheless, the Commission modified some terms of Article 11.4.18., for clarity, and encouraged members to review [the October 2018 report of ad hoc Group on BSE surveillance](#), which provides a clear rationale for the need of new surveillance provisions, including the fact that the new proposed method would be much less burdensome and costly.

The Code Commission proposed to replace 'cattle' with 'bovine(s)' throughout this chapter for consistency (See item 5.15 of this report).

Article 11.4.1.

In the first paragraph, in line with the above-mentioned considerations, and in agreement with the conclusions of the Scientific Commission, the Code Commission amended the text accordingly, notably to specify that 'BSE' is a disease caused by both classical and atypical BSE agents, and to clarify the epidemiological role of atypical BSE agents.

In point 1, the Code Commission did not agree with a comment to replace 'contaminated feed' with 'feed contaminated with prions from bovines' as it considered the text clear as currently written.

In point 2, the Code Commission proposed to add a sentence to clarify the purpose of the chapter, for harmonisation with other chapters on zoonotic diseases, such as Chapter 8.14. Infection with rabies virus and Chapter 8.15. Infection with Rift Valley virus.

In point 3, in line with the above-mentioned considerations and in agreement with the recommendations of the Scientific Commission, the Code Commission amended point 3 of Article 11.4.1. to clarify that a 'case of BSE' meant only the occurrence of classical BSE. At the same point, in agreement with the Biological Standards Commission and [the ad hoc Group on the revision of BSE standards and the maintenance of official BSE risk status \(June 2022\)](#), the Commission maintained its position on the use of the abbreviation 'PrP^{Sc}' in line with the *Terrestrial Manual*.

Article 11.4.1bis.

The Code Commission disagreed with a comment that gelatine and collagen made from certain bovines cannot be regarded as safe commodities, and encouraged Members to refer to [the June 2020 report of ad hoc Group on BSE risk assessment and surveillance](#) for the detailed rationale to include them as safe commodities.

Article 11.4.2.

In point 1(a), the Commission did not agree with a comment to add 'Depending on the outcome of the entry assessment, an exposure assessment (in point 1(b) below) may not be required'. The Commission explained that even when it could be demonstrated that there had been no imported commodities that could lead to exposure to classical BSE agents and that classical BSE agents had not been detected within the bovine population of a country, zone, or compartment, the exposure assessment itself should always be carried out to ensure compliance with point 1 of draft Article 11.4.3., so as to conclude that the likelihood of bovines being exposed to BSE is negligible, in particular through overall risk mitigation measures.

Article 11.4.3.

The Commission did not agree with a comment to maintain a condition on age for indigenous classical BSE cases (e.g., as in point 3 (b) of current Article 11.4.3.), the Code Commission reiterated that such requirements were neither considered proportionate to the risk nor supported by robust scientific evidence.

In point 1, based on the position explained in the general comments above, particularly the fact that the potential for recycling of the atypical BSE agent could not be ruled out and should be avoided, the Code Commission proposed to reinstate the deleted point 1(a) and point 1(b), given that in any country seeking recognition of negligible or controlled risk status, any risks posed by BSE should be properly mitigated either by livestock industry practices described in point 1(a), or by a ruminant-to-ruminant feed ban described in point 1(b).

In point 3(a), in response to comments to refer to both classical BSE and atypical BSE, the Code Commission clarified that, based on the above-mentioned position, a 'case of BSE' now referred only to classical BSE and amended the text of this point and of point 3(b) accordingly.

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

In response to a comment to add 'identified all cases and' before 'confirmed', the Code Commission reiterated that the occurrence of a limited number of indigenous cases of BSE in bovines 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 breakdown of effective control measures, and that isolated pockets of residual infectivity in a complex network of rendering, feed production, distribution and storage may account for rare, sporadic opportunities of exposure to contaminated protein meal. The Commission considered that the 'subsequent investigations' could lead to finding other cases of BSE if the source of infection was identified, recognising that the source of infection may not necessarily be identified.

In point 4, based on the position explained in the general comments paragraph above, the Code Commission proposed to add 'or bovines affected with atypical BSE' as this point provides for overall BSE risk mitigation measures that should apply both for classical and atypical BSE.

Article 11.4.5bis.

In the first paragraph, the Code Commission did not agree with a comment to provide further clarification on the contents and requirements of the 'investigation report', as it considered that the text was clear as currently written.

The Code Commission did not agree with a comment that if the investigations could not identify the BSE agent, environmental BSE risks posed by persistent infectivity in pockets should be removed through measures such as replacement of the feed line of the infected farm. The Commission considered that such measures would not necessarily be justified, emphasising 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 reiterated that the 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.

Article 11.4.10.

Based on the considerations explained for the General comments above, the Code Commission proposed to delete the reference to the subpopulations of bovines born before or after the date.

The Commission also proposed to delete point 4, as it considered that the implementation of these measures was assessed in the BSE risk assessment when the official BSE risk status was recognised.

Article 11.4.12.

In response to comments that protein meal should not be traded because inadequate treatment of protein meal could result in BSE agents being recycled and amplified, resulting in countries losing a previously acquired negligible risk status due to outbreaks of BSE, the Code Commission explained that the risk of BSE agents being recycled within the bovine population in an importing country would be managed to a negligible level by implementing the multi-layered recommendations provided in this chapter.

In the first paragraph, the Code Commission did not agree with comments to delete the reference to 'animal identification system' or to move it to point 1. The Commission reiterated that this point referred to an animal identification system, as defined in the Glossary, meaning that it could involve identification and registration by

animals individually or collectively by epidemiological unit or group, and thus it considered the point relevant and feasible as written.

In point 2, in response to comments opposing the addition of the point because it could result in unnecessary trade restrictions, the Code Commission noted that the concern would be addressed by the amendments proposed to Article 11.4.17.

Article 11.4.13.

Based on the considerations explained in the general comments above, the Code Commission proposed to delete the reference to subpopulations of bovines born before or after the date from which the risk of BSE agents being recycled within the bovine population has been demonstrated to be negligible.

Article 11.4.14.

The Code Commission proposed to delete 'for the preparation of...medical devices' in point 1, as it was covered by point 2 and the destination or end-use of the commodities was not the responsibility of the exporting countries.

In response to a comment to restrict the trade of all commodities with the greatest BSE infectivity from countries with controlled BSE risk, the Code Commission reiterated that in these countries, the BSE risk of commodities derived from bovines born after the date from which the risk of BSE agents being recycled within the bovine population has been demonstrated to be negligible was negligible.

In point 1, the Code Commission did not agree with comments to add 'and tonsils', noting that the *ad hoc* Group had proposed that the restriction applicable to tonsils be removed based on scientific evidence ([EFSA Journal 2011;9\(1\):1947](#)). The Commission encouraged Members to refer to [the March 2019 report of ad hoc Group on BSE risk assessment and surveillance](#).

In point 1(b), in response to a comment to reinstate the deleted 'or a negligible BSE', the Code Commission reiterated that the stricter recommendations than those provided in the current chapter for countries, zones or compartments posing a negligible BSE risk would not be proportionate or justified.

In points 1 and 2, the Code Commission agreed with comments and amended the text for clarify, as the meaning of the term 'protein products' was unclear.

In point 3, in response to a comment querying how this recommendation related to Article 11.4.17. (Procedures for reduction of BSE infectivity in bovine-derived protein meal), the Code Commission explained that the recommendations in Article 11.4.17. were not for 'inactivation' but for 'reduction' of BSE infectivity in bovine protein meal, and they could not guarantee a complete inactivation of BSE agents. The Commission highlighted that measures should not be considered in isolation, but rather be taken in combination with other requirements, such as the consideration of the BSE risk at origin. The Commission also noted that 'protein meal' was a commodity for which it was extremely difficult to demonstrate the exact components and origins (e.g. age of animals, birth date of the animals, or whether commodities with the greatest BSE infectivity were excluded) and that was the reason why the chapter recommended it not to be traded from countries, zones or compartments posing an undetermined BSE risk or controlled BSE risk (as described in Article 11.4.14.).

Article 11.4.15bis.

In point 3, the Code Commission did not agree with a comment to add the same parameters for temperature, time and pressure as those in Article 11.4.17. for protein meal and reminded that the transesterification process of fat was not the same as that used for protein meal, and that the proposed treatment was deemed sufficient to mitigate any risk. The Commission encouraged Members to refer to [the June 2021 report of ad hoc Group on the revision of BSE standards and its impact on the official status recognition](#).

Article 11.4.17.

The Code Commission agreed with a comment to clarify the animal origin of protein meal referred to in the article and made necessary amendments.

In response to comments questioning the intent or needs of this article, the Code Commission explained that it aimed at providing recommendations to mitigate the BSE risk associated with protein meal and reminded Members that this article was referred to in Article 11.4.12. and point 2(b)(iii) of Article 1.8.5.

The Code Commission agreed with comments and added a new point 2 to allow alternative procedures to achieve at least an equivalent level of reduction in BSE infectivity. The Commission noted that, as is the case for other disease-

specific chapters, this would allow proper consideration of equivalent measures and potential future technical innovation.

Article 11.4.18.

In response to comments requesting clarification on this article, the Code Commission explained that the goal of BSE surveillance was to detect a potential emergence or re-emergence of classical BSE within the bovine population, and the objective of the provisions in Article 11.4.18. as proposed were to detect classical BSE agents within the bovine population through passive surveillance and laboratory confirmation of suspicions, including discrimination between classical and atypical BSE strains.

The Code Commission did not agree with comments to set a minimum number of clinical suspects to be tested or an age limit for testing or to maintain current provisions on BSE surveillance (i.e. point-based active surveillance). The Commission explained that the current point-based surveillance was no longer justified, as pointed out in [the October 2018 report of the ad hoc Group on BSE surveillance](#). The Commission explained that the rationale not to set a minimum number of clinical suspects to be tested or age limit for testing had been provided in detail in the reports of relevant *ad hoc* Group meetings and encouraged Members to refer to the relevant parts of [the October 2018 report of the ad hoc Group on BSE surveillance](#) and [the June 2020 report of the ad hoc Group on BSE risk assessment and surveillance](#).

In point 1, the Code Commission did not agree with a comment to propose some amendments to the summary of clinical signs associated with BSE, as it considered that more detail was not needed in the Code, and noted that more detailed clinical signs could be described in the future guidelines on BSE surveillance.

In point 2, in response to a comment the Code Commission amended the first and fourth paragraphs to clarify 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.

In point 3(b), the Code Commission deleted the word 'compulsorily' as it was redundant since already implied in the Glossary definition of 'notifiable disease'.

The revised Chapter 11.4. Bovine spongiform encephalopathy is presented as [Annex 10](#) for comments and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU thanks the Code Commission for the latest version of the revised Chapter 11.4. on bovine spongiform encephalopathy and for having reintroduced paragraphs a) and b) on the feed ban in point 1 of Article 11.4.3., as requested in the EU comments provided in May 2022.

The EU requests the Code Commission to address the comments and suggestions inserted in Annex 10.

Chapter 1.8. Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy

Comments were received, prior to the 89th General Session, from Australia, France (on behalf of the 27 Member States of the EU), New Caledonia and USA (on behalf of Argentina, Bolivia, Brazil, Canada, Chile, Curacao, Mexico, Paraguay, Peru, Saint Lucia, Uruguay).

Additional comments were received, prior to this meeting, from New Zealand, the UK and the AU-IBAR.

General comments

With regard to comments expressing concerns on the way the revised chapter addressed atypical BSE, the Code Commission made amendments to the revised Chapter 1.8., for it to be in line with the amendments proposed in this meeting to the revised Chapter 11.4.

In accordance with the rationale explained for Chapter 11.4., the Code Commission amended the second paragraph in Article 1.8.1. to clearly define that the term 'case of BSE' used in this chapter means only the occurrence of classical BSE. The Commission explained that, when reference to both the occurrence of classical BSE and the occurrence of atypical BSE is necessary, atypical BSE would be explicitly mentioned (e.g. in point 2 of Article 1.8.2.).

Article 1.8.5.

In point 2, the Code Commission agreed to delete the first paragraph, as it considered that the content was not correct anymore, following the amendments proposed in this meeting to the revised Chapter 11.4. Similarly, in point 3, the Code Commission agreed to delete the first paragraph.

In point 2, in the third paragraph, the Code Commission proposed to delete the references to articles in Chapter 11.4., as it considered it unnecessary in this chapter which should only provide a questionnaire for official status recognition.

Article 1.8.6.

In the fifth paragraph, the Code Commission proposed to delete the paragraph referring to point 2 of Article 11.4.18. for a more logical flow, given that the requirements described in the point were also referred to in the second paragraph.

In point 2, the Code Commission proposed to change the title from 'Compulsory notification' to 'BSE reporting system' as the term 'notification' was defined in the Glossary of the *Terrestrial Code* with the meaning of notification of a listed disease to the WOAAH, which was not the intent of this point. The Commission explained that 'reporting' means reporting of animals described in points 2(a) to 2(d) of Article 11.4.18. to the Veterinary Services. The Commission also proposed to delete the first paragraph as it considered it unnecessary in this chapter, which should only provide a questionnaire for official status recognition.

In point 3(b), the Code Commission did not agree with a comment that an applicant member should provide the same level of information on laboratories located outside of the country as the one inside the country, as it considered that it would be difficult to implement.

In point 4, in the second paragraph and in point 4(b), the Code Commission agreed with a comment and replaced 'farmer' with 'bovine breeder, owner or keeper' to align with other uses of the terms in the *Terrestrial Code*.

The revised Chapter 1.8. Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy is presented as [Annex 11](#) for comments and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU thanks the Code Commission for the latest version of the draft Chapter 1.8. Comments are inserted in the text of Annex 11.

Glossary definition for protein meal and use of related terms

No Member comments were received for the Glossary definition for protein meal.

The use of terms 'meat-and-bone meal' and 'greaves' throughout the *Terrestrial Code*:

Background

At its September 2021 meeting, the Code Commission requested the Secretariat to review the use of terms 'meat-and-bone meal' and 'greaves' throughout the *Terrestrial Code* to determine where these terms would need to be replaced with 'protein meal', should the new proposed definition for 'protein meal' be adopted.

At its February 2022 meeting, the Code Commission acknowledged that six disease-specific chapters (Chapter 8.1., Chapter 8.4., Chapter 8.11., Chapter 10.4., Chapter 14.8. and Chapter 15.3.) used the terms 'greaves' or 'meat-and-bone meal' and considered the context where the terms were used. The Commission agreed to propose the Glossary definition for protein meal for adoption in May 2022 and to propose the deletion of the definition described in point 4(b) of Article 11.4.1. However, due to time constraints, the Commission agreed to postpone the discussion on the potential replacement of the terms 'greaves' or 'meat-and-bone meal' in other chapters until its next meeting.

Discussion

The Code Commission reviewed the *Terrestrial Code* chapters in which the terms 'meat-and-bone meal' and 'greaves' were used, and considered whether the terms should be replaced with 'protein meal'.

The Commission noted that the term 'greaves' appears only in Chapter 14.8. Scrapie, apart from Chapters 11.4. and 1.8. currently under revision, and the revision of the chapter was included in the Commission's work programme. The

Commission agreed to address this issue when the chapter on scrapie would be revised and not to delete the definition of 'greaves' from the Glossary until then.

The Code Commission agreed to propose the deletion of the Glossary definition for 'meat-and-bone meal' if the proposed definition for 'protein meal' was adopted in May 2023, and to replace the term 'meat-and-bone meal' with 'protein meal' throughout the *Terrestrial Code* for the 2023 edition of the *Terrestrial Code*.

The Glossary definition for 'protein meal' (and deletion of the definition for 'meat-and-bone meal') is presented as part of [Annex 5](#) for comments and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU supports the proposed changes to the Glossary.

5.8. Contagious equine metritis (Chapter 12.2.)

Comments were received from China (People's Republic of), New Zealand, South Africa, 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 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 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, and 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.

Discussion

General comments

In response to a comment opposing the Commission's decision not to replace 'asymptomatic' with 'subclinical', the Commission reiterated that 'subclinical' refers to a state where a disease is not detectable by clinical observations, while 'asymptomatic' refers to a disease not causing any sign of infection, illness, or disease, and that 'subclinical' was the correct term in the context of this chapter

Article 12.2.1.

In the first paragraph, in point 1, the Code Commission considered a comment to remove 'and identified' because *T. equigenitalis* is noted at the beginning of the sentence and therefore it was implied that *T. equigenitalis* has been identified. While agreeing with the rationale provided, the Commission, in agreement with previous discussions with the Biological Standards Commission and the Scientific Commission for other disease-specific chapters, agreed that there was value in maintaining the reference to avoid misunderstanding. It amended the text for consistency with other chapters.

The Code Commission agreed with a comment opposing the proposed deletion of the previous point 3 because Chapter 3.6 2. Contagious Equine Metritis of the *Terrestrial Manual* includes PCR as a recommended test. The Commission also agreed that as infection with *T. equigenitalis* is always asymptomatic in stallions, and some cases in mares, the detection of nucleic acid should be enough, to define the occurrence of the disease. Consequently, the Commission added a new point 2) to reflect this.

In the new point 3, the Commission removed the reference to genetic material to avoid duplication with the new point 2). In response to comments, the Code Commission agreed to reinstate the detection of antigen, noting that while the *Terrestrial Manual* considers these tests suitable with limitations and not commonly used, a positive result would still be valid.

In the tenth paragraph, the Commission acknowledged a comment proposing that “temporary importation” be considered for inclusion in the Glossary given that it is now being proposed in more than one chapter. The Commission explained that this text does not define a term, but rather presents a set of conditions to contextualise specific provisions contained in the chapter and therefore did not agree to create a glossary definition.

Article 12.2.2.

The Code Commission did not agree with a comment to exclude ‘geldings’ from the list of safe commodities because they could be infected with *T. equigenitalis* and this could pose a risk of transmission of the disease through some manipulations. The Commission explained that ‘geldings’ met Criterion 1 of Article 2.2.2 of Chapter 2.2. of the *Code*, namely ‘the pathogenic agent is not present in the tissues from which the animal product is derived in an amount able to cause infection in a human or animal by a natural exposure route’. The Commission also highlighted that the objective of this article was to ensure the safe trade of animals, which in this case was successfully achieved.

Article 12.2.3.

In point 2(c), in response to a comment, the Code Commission confirmed that all horses, including foals and other juvenile horses, should be tested. The Commission explained that this was in accordance with Chapter 3.6.2. Contagious Equine Metritis of the *Terrestrial Manual*, which states that foals born from carrier mares may also become carriers. The Commission also noted that even though geldings are considered safe for trade (i.e., listed as safe commodities) they should be tested for surveillance purposes as it could provide evidence on the presence of the pathogenic agent in the herd.

At the same point, the Commission agreed with a comment to amend the text for alignment with Chapter 3.6.2. of the *Terrestrial Manual* and added ‘nor subjected to antiseptic washing of genital mucous membrane’ after ‘antibiotics’

In point 2(d), the Code Commission did not agree with a comment to elaborate the reference to aliquots in terms of straws, batches and dates of collection, because it would not be possible to provide a reference that would apply to all situations. The Commission also noted that this would be too prescriptive and highlighted that this measure should not be considered in isolation and should be understood as being part of a set of measures to demonstrate freedom of the herd.

In point 4(c), the Code Commission agreed with a comment to align the wording, as appropriate, with Chapter 3.6.2. of the *Terrestrial Manual* and other relevant Code chapters.

At the same point, the Commission agreed with a comment to amend the text for clarity and to specify that sampling should be done for each collection of semen. The Commission also agreed to remove the reference to Article 12.2.8. as it was not relevant to this point.

Article 12.2.8.

In point 1(c), the Code Commission agreed with a comment to simplify wording by referring to the provisions for early warning systems in Article 1.4.5.

The revised Chapter 12.2. Contagious equine metritis is presented as [Annex 12](#), for comments and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU thanks the Code Commission and in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 12.

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

Comments were received from Australia, New Zealand, 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 the outcomes of work by a WOA Reference Laboratory on equine influenza vaccination protocols prior to shipment of horses, and circulated the revised article for comments.

At its February 2021 meeting, the Code Commission reviewed the comments received on the revised Article 12.6.6. and agreed with a proposal to revise the case definition which had been endorsed by the Scientific Commission at

its February 2021 meeting. The Commission noted that the proposed amendments to the case definition would require consequential changes in other articles and agreed to defer its discussion due to time constraints.

At its February 2022 meeting, the Code Commission considered the comments received on the revised Article 12.6.6. circulated in its September 2021 report, reviewed 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 two times for comments, the last time in the Commission's February 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 include 'feral and wild equids' in the definition of the disease. The Commission noted that while feral and wild equids are susceptible, they were not considered to play a significant role in the epidemiology of the disease, and their inclusion would not be relevant to the purpose of this chapter.

In the same paragraph, the Code Commission did not agree with a comment to remove the reference to the serotype H7N7. It noted that even if no cases have been recently reported, serotype H7N7 is considered to be part of the pathogenic agent, in accordance with Chapter 3.6.7. 'Equine influenza (infection with equine influenza virus)' of the *Terrestrial Manual*. However, the Commission did agree with a comment to amend the text to align better with the corresponding chapter of the *Terrestrial Manual*.

In points 1 and 2, the Code Commission did not agree with a comment to add 'in the absence of clinical signs or' before 'showing'. The Commission considered that detection of antigen or genetic material, or the demonstration of seroconversion, in an animal not showing clinical signs, should only be considered a case if associated with pathological lesions or epidemiologically linked to a suspected or confirmed case of infection with EIV, as stated in the current text.

After point 3, the Code Commission did not agree with a proposal to reinstate the definition of 'isolation' for the purposes of this chapter, as it considered it unnecessary because the term could be understood as a common dictionary definition. Nonetheless, the Commission noted that the upcoming work on the revision of Code Chapters 5.4. to 5.7. should consider whether provisions should be provided on 'isolation' as a pre-export or post-arrival measure.

In the seventh paragraph, in response to a comment, the Commission agreed to modify the infective period from 21 days to 10 days, based on the scientific references reviewed, which specified that the incubation period is 1–3 days and that infected horses have been found to shed the virus up to 10 days via nasal discharge. The Commission reviewed the chapter and amended the text where relevant to apply this change. The Commission noted that this information was not specified in Chapter 3.6.7. 'Equine influenza' of the *Terrestrial Manual* and requested the Secretariat to seek the opinion of the Biological Standards Commission.

In the eighth paragraph, the Commission acknowledged a comment that, as the description of "temporary importation" is now being proposed in more than one chapter, it should be considered for inclusion in the Glossary. The Commission reiterated its explanation provided in the discussion for Chapter 12.2., that this text does not define a term, but rather presents a set of conditions to contextualise specific provisions contained in the chapter and agreed not to modify the text.

Article 12.6.2.

In point 3, the Code Commission did not agree with a comment to add 'excluding respiratory track offal' after 'equids', as it considered that while this material could potentially be a source of infection for dogs it does not represent a significant risk for international trade.

Article 12.6.4.

In the third paragraph, in response to a comment questioning the inclusion of a reference to the relevant requirements and principles described in Chapter 4.4. and Chapter 4.5., the Commission explained that is a standard approach for

some of the disease-specific chapters (e.g., Chapters 8.8. Infection with foot and mouth disease virus and 10.4. Infection with high pathogenicity avian influenza viruses) to include recommendations for free compartments.

Article 12.6.6.

In response to a comment, the Code Commission amended the text where relevant to ensure that the use of the term 'wild equids' was appropriate.

In points 2 and 3, the Code Commission agreed with a comment to amend the text to clarify the hierarchy and connection between the different points and subpoints.

In point 3(b), the Code Commission did not agree with a comment to replace '180 days' with '365 days'. The Commission noted that Chapter 3.6.7. Equine influenza of the *Terrestrial Manual* specifies that, while immunity after infection or vaccination could last more than 1 year, more frequent booster vaccinations are recommended. The Commission highlighted that while recommendations for vaccination could vary in different situations, the provisions in the current text were needed to ensure the safe importation of animals.

Article 12.6.7.

The Code Commission agreed with a comment to delete 'domestic' from the title of the article, as horses *per se* are domestic animals. The Commission made this amendment where relevant throughout the article.

The Code Commission did not agree with a comment to add 'OR' between points 1(a) and (b), because both conditions were needed for the temporary importation of horses. The Commission reminded Members that the objective of this article is to facilitate the international movement of "high health status horse subpopulation", and these horses need to be identified and registered as defined in Chapter 4.17.; for other cases, Article 12.6.6. applies.

The revised Chapter 12.6. Infection with equine influenza virus is presented as **Annex 13**, for comments and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU thanks the Code Commission and in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 13.

5.10. Equine piroplasmiasis (Chapter 12.7.)

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

Background

At its February 2019 meeting, the Code Commission agreed to amend Chapter 12.7. Equine piroplasmiasis 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 reviewed the comments received and agreed to defer its discussion until its September 2021 meeting, given that time constraints did not allow for a detailed discussion. The Secretariat 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 piroplasmiasis (and contagious equine metritis) was consulted electronically between May and July 2021, the outcome of which was discussed at its September 2021 meeting.

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

Discussion

The Code Commission considered the comments received.

General

In response to a comment to recommend that 'equid' be retained, the Code Commission explained that in Articles 12.7.1. and 12.7.6. 'equids' had been replaced with 'horses' as the temporary importation described in the articles should only apply to horses, not other equids such as donkeys and mules.

In response to a comment requesting to replace 'asymptomatic' with 'subclinical', the Commission reiterated its position and explained that 'subclinical' refers to a state where a disease is not detectable by clinical observations, while 'asymptomatic' refers to a disease not causing any sign of infection, illness, or disease. This response applies to similar comments received for Articles 12.7.1. and 12.7.9. in this chapter.

Article 12.7.1.

In the third paragraph, the Code Commission agreed with a comment to include other competent tick vectors to avoid potential conflicts with the corresponding *Terrestrial Manual* chapter (most recent updates were adopted in May 2021). This response applied to similar comments received for other articles in this chapter.

In points 1 to 3, the Code Commission did not agree with a comment to add 'or may not' after 'may' and rather proposed to delete 'which may be' to ensure alignment with other disease-specific chapters, notably chapters on Theileriosis.

In point 1, the Code Commission proposed to amend the point to align with other disease-specific chapters.

In point 2, the Code Commission proposed to delete 'antigen or' as the corresponding Manual chapter did not provide any references to the antigen tests.

In the ninth paragraph, the Commission acknowledged a comment proposing that "temporary importation" should be defined in the Glossary as it was now being proposed to be included in more than one chapter. The Commission explained that this text did not define a term, but rather presented a set of conditions in a specific context, so it is not appropriate to define such term.

The Commission also proposed additional amendments to align the text of the article with other disease-specific chapters.

Article 12.7.2.

The Code Commission proposed to amend the first paragraph to improve readability and agreed to propose similar amendments in other disease-specific chapters.

In point 6, the Code Commission agreed with a comment and proposed to add 'in accordance with the relevant chapters of the *Terrestrial Code*'.

Article 12.7.3.

In point 1, the Code Commission did not agree with a comment that the option to self-declare historical freedom should remain. The Commission reiterated that the vast majority of the cases of infection was asymptomatic, and thus it would not comply with point 2(b)(ii) of Article 1.4.6.

In point 2(a), the Code Commission did not agree with a comment that the presence of equids should be considered when recognizing the free country or zone and thus 'for at least the past 10 years' should be deleted and 'six years' should be replaced with 'two years'. The Commission considered that specific situations such as the absence of equids in an area should not be described in the *Terrestrial Code* and rather should be dealt with in bilateral discussions between trading partners.

In point 2(b), in response to a comment requesting clarification on the meaning of "an epidemiological investigation has been conducted with favourable results", the Code Commission proposed to amend the text for clarity.

Article 12.7.5.

In point 2(b)(i), the Code Commission, in agreement with the Biological Standards Commission, did not agree with a comment to remove the requirement for an agent identification test and to clarify that the serological test is validated to international standards. The Commission emphasised that the *Terrestrial Code* refers only to *Terrestrial Manual* as a reference for diagnostic tests. The Commission noted that the requirement to use a combination of PCR and serological tests was based on expert advice and stressed that the use of PCR alone is not recommended. A

comment to reinstate complement fixation test (CFT) in Table 1 of the corresponding *Manual Chapter 3.6.8*. was considered by the Biological Standards Commission at its September 2022 meeting and it agreed that the CFT was not sensitive enough and did not detect subclinically infected carriers and thus was not suitable for certifying animals for movement.

The Code Commission agreed with a comment previously discussed to add point 2(b)(iii) "Horses have not been treated with antiparasitic drugs capable of masking an infection with *T. equi* and *B. caballi* for at least 6 months prior to sampling". The Commission noted that while it could be a challenge for Veterinary Authorities to certify the requirement related to the absence of such treatment, the Commission had agreed with the Biological Standards Commission, that such treatment, for example with imidocarb dipropionate, prior to exportation, would transiently suppress parasitemia and consequently the antibodies titers would decrease, and could interfere with a diagnosis, consequently entailing a risk of importing carrier horses. The Commission explained that the withdrawal period of '6 months' was suggested by a subject matter expert based on due consideration of the available published evidence, listed below.

- UETI MW, MEALEY RH, KAPPEMEYER LS, et al. (2012) Re-emergence of the apicomplexan *Theileria equi* in the United States: elimination of persistent infection and transmission risk. PLoS ONE. 2012; 7(9), e44713.
- GRAUSE JF, UETI MW, NELSON JT, et al. (2013) Efficacy of imidocarb dipropionate in eliminating *Theileria equi* from experimentally infected horses. Vet. J. 2013 Jun; 196(3), 541-6.
- THANKGOD E. ONYICHE, KEISUKE SUGANUMA, IKUO IGARASHI, NAOAKI YOKOYAMA, XUENAN XUAN AND ORIEL THEKISOE (2019). A review of equine piroplasmiasis: epidemiology, vector ecology, risk factors, host immunity, diagnosis and control. Int. J. Environ. Res. Public Health. 2019, May 16, 16(10): 1736.
- A Literature Review of Equine Piroplasmiasis. APHIS, United States Department of Agriculture. Animal and Plant Health Inspection Service. 30 September 2010. Available from: https://www.aphis.usda.gov/animal_health/animal_diseases/piroplasmiasis/downloads/ep_literature_review_september_2010.pdf
- WISE, L. N., KAPPEMEYER, L. S., MEALEY, R. H., & KNOWLES, D. P. (2013). Review of equine piroplasmiasis. J. Vet. Intern. Med. 2013 Nov-Dec; 27(6):1334-1346.
- BELLOLI, C., CRESCENZO, G., LAI, O., CAROFIGLIO, V., MARANG, O., & ORMAS, P. (2002) Pharmacokinetics of imidocarb dipropionate in horses after intramuscular administration. Equine Vet. J. 2002 Sep; 34(6), 625-629.
- C.M. BUTLER, A.M. NIJHOF, J.H. VAN DER KOLK, O.B. DE HASETH, A. TAOUFIK, F. JONGEJAN, D.J. HOUWERS. (2008) Repeated high dose imidocarb dipropionate treatment did not eliminate *Babesia caballi* from naturally infected horses as determined by PCR-reverse line blot hybridization. Vet. Parasitol. 2008 Feb 14;151(2-4):320-2.

Article 12.7.6.

In response to a comment, the Code Commission proposed to delete 'of the genera *Dermacentor*, *Rhipicephalus*, *Hyalomma* and *Amblyomma*' as it considered it too detailed and superfluous. On the other hand, the Commission proposed to keep the latter part of the point as it considered it useful for Members.

Article 12.7.7.

The Code Commission proposed to replace 'been preventively treated' with 'received preventive treatment' for clarity.

Article 12.7.8.

The Code Commission proposed to add 'vessel' after 'vehicle' as it considered it necessary for completeness.

Article 12.7.9.

In point 5, in the third paragraph, in response to a comment to replace 'the number and types of traps' with 'surveillance methods', the Code Commission proposed to replace with 'collection methods' to allow the use of other collection methods other than traps.

In point 5, in the fifth paragraph, the Code Commission proposed to amend the text, to avoid using the term 'entomological surveillance' which might be confusing.

The revised Chapter 12.7. Equine piroplasmiasis is presented as **Annex 14** for comments and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU thanks the Code Commission and in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 14.

5.11. Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* (New Chapter 14.X.) and revision of Article 1.3.3.

Comments were received from Australia, Switzerland 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 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 noted that there were no recommendations for diagnostic tests for these pathogenic agents in the *Terrestrial Manual*. As this would impact the case definition and other measures to be recommended in the chapter, the Code Commission agreed not to progress this work until the Biological Standards Commission has progressed the work on a new chapter for the *Terrestrial Manual*.

At its February 2022 meeting, given 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.

In May 2022, the *Terrestrial Manual* Chapter 3.8.13. Theileriosis in sheep and goats (infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi*) was adopted.

Discussion

The Code Commission considered the comments received.

Article 1.3.3.

The Code Commission noted comments that supported the circulated text.

Article 14.X.1.

In response to a comment requesting clarification on whether 'occurrence of infection' referred just to active infection or to both active and previous infection, the Code Commission explained that, as defined in the Glossary, the term 'infection' means active infection, and that was the reason why point 3 stated that the detection of antibodies would be considered 'occurrence of infection with *Theileria*' only if the animal had epidemiological links to a suspected or confirmed case or if there is cause for suspicion of previous association with *Theileria*.

In points 1 and 2, the Code Commission agreed with a comment and amended the text to align with other chapters.

In point 2, the Code Commission agreed with a comment to delete 'antigen or', because there were no antigen tests described in the corresponding *Terrestrial Manual* chapter.

Article 14.X.2.

In point 6, the Code Commission proposed to add 'collected in accordance with the relevant chapters of the *Terrestrial Code*' for clarification.

Article 14.X.3.

In point 1(c), the Code Commission did not agree with a comment to delete the point and reiterated that if a country demonstrates the absence of competent vectors and the vector is essential for the transmission of the disease, the

country should be considered free from the disease without having to demonstrate the absence of cases. Nonetheless, the Commission noted that the Member pointed out that iatrogenic transmission was also a potential means of transmission of the disease, and requested the Member to provide scientific evidence to support a potential modification on this regard.

In point 3, the Code Commission did not agree with a comment to delete the point, and instead, proposed to delete point 2 as it was already covered in point 1 which states that the importation of sheep and goats is carried out in accordance with this chapter, i.e. Articles 14.X.4. and 14.X.5.

In the same point, the Code Commission agreed to delete 'or vaccinated' in response to comments that reference to vaccine was removed from Article 14.X.1. and no commercial vaccines were available for the disease, as described in the corresponding *Terrestrial Manual* chapter.

The revised Chapter 14.X. Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* and the revised Article 1.3.3. are presented as [Annex 15](#) and [Annex 16](#), respectively, for comments and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU thanks the Code Commission and in general supports this proposed new chapter and the amendment of Article 1.3.3. A comment is inserted in the text of Annex 15.

5.12. Middle East Respiratory Syndrome Coronavirus (MERS-CoV) (New Chapter X.X.)

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

Background

In September 2019, the Code Commission agreed to add the development of a disease-specific chapter for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) to its work programme, if the proposed inclusion of 'infection of dromedary camels with Middle East respiratory syndrome coronavirus' as a WOAHA listed disease in Chapter 1.3. was adopted, as well as a new chapter on this disease in the *Terrestrial Manual*.

Following the adoption of the abovementioned texts in May 2021, in its February 2022 meeting the Code Commission agreed to develop a new chapter for infection with MERS-CoV, but proposed to include only general provisions such as a definition of its occurrence. A new Chapter X.X. Infection with MERS-CoV was first circulated for comment in the Code Commission's February 2022 report.

Discussion

The Code Commission considered the comments received.

Article X.X.1.

The Code Commission amended the text to align it with the *Terrestrial Manual* and other chapters in the *Terrestrial Code*.

In response to a comment, the Code Commission agreed to replace 'human infections have a significant public health impact' with "it causes severe disease in humans" for alignment with the *Terrestrial Manual* and [the report of the ad hoc Group on Middle East Respiratory Syndrome Coronavirus \(January 2019\)](#).

The new Chapter X.X. Infection with Middle East respiratory syndrome coronavirus (MERS-CoV) is presented as [Annex 17](#) and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU thanks the Code Commission and in general supports this proposed new chapter. Comments are inserted in the text of Annex 17.

5.13. Infection with leishmania spp. (leishmaniosis) (New Chapter X.Y.)

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

Background

In September 2020, the Code Commission agreed to include the development of a new disease-specific chapter on Leishmaniosis in its work programme, pending the review of amendments that were being proposed to the corresponding chapter in the *Terrestrial Manual*. In February 2021, the Scientific Commission endorsed a case definition developed by subject matter experts, which has been placed on the WOAHP website to support Members' notification. A revised Chapter 3.1.11. Leishmaniosis of the *Terrestrial Manual* was adopted in 2021.

In February 2022, the Code Commission agreed to develop a new chapter for infection with *Leishmania spp.* (Leishmaniosis), including only a single article for general provisions, and the new Chapter X.Y. Infection with *Leishmania spp.* (Leishmaniosis) was first circulated for comment in the Code Commission's February 2022 report.

Discussion

The Code Commission considered the comments received and amended the text of the chapter for alignment with the *Terrestrial Manual* and other chapters in the *Terrestrial Code*.

In the first paragraph, the Commission replaced 'infection with *Leishmania spp.*' with 'Leishmaniosis' for consistency with other chapters that first describe the disease and then define the occurrence of infection. It also added 'protozoan' before 'parasites' to align with the *Terrestrial Manual* chapter.

In the same paragraph, the Commission agreed with comments to replace '*Phlebotomus* sandfly' with 'phlebotomine sandfly belonging to the genera *Phlebotomus* (Old World) or *Lutzomyia* (New World)', in line with the *Terrestrial Manual* chapter.

The new Chapter X.Y. Infection with *Leishmania spp.* (Leishmaniosis) is presented as [Annex 18](#) and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU thanks the Code Commission and in general supports most of the proposed changes to this chapter. However, important comments are inserted in the text of Annex 18.

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

Background

In 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 they would need to be amended.

Discussion

The Code Commission considered an analysis prepared by the Secretariat describing the use of the terms in the English version of the *Terrestrial Code*, noting that the terms 'foetal/foetus' were used in Chapters 4.10. and 7.5., as well as in the pathogen name, i.e. *Trichomonas foetus*, in Chapter 4.7. and Chapter 4.8.

The Commission agreed not to amend the pathogen name, *Trichomonas foetus*, noting that this is the scientific name for this pathogenic agent and agreed to replace 'foetal'/'foetus' with 'fetal'/'fetus', respectively, in Article 4.10.3. of Chapter 4.10. and to circulate this for comment. The Commission also acknowledged the need for amendments in Chapter 7.5. but noted that these would be addressed in the ongoing revision of that chapter (See Item 4.1.4. of this report).

The Commission reminded Members that this item refers only to the English version of the Code and that the proposed changes to these texts referred only to this specific terminology issue for consistency matters and did not intend to open the discussion of other aspects or parts of the texts.

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 19](#) for comments and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU supports the proposed changes to this article.

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

Background

In September 2020, as part of the discussion on Chapter 8.8., the Code Commission acknowledged comments requesting clarification of the term 'bovine' and agreed that this should be defined for the purposes of that chapter. Nonetheless, as the terms 'bovids' and 'bovines' were used with specific definitions for different disease-specific chapters and the term 'bovine' was used in several articles of Chapter 8.8, the Commission requested the Secretariat to propose a definition for the purposes of that chapter, in consultation with relevant experts as necessary.

In September 2021, the Code Commission agreed with a proposal of a joint Scientific Commission-Code Commission Taskforce, to replace 'bovines' with 'cattle' in Chapter 8.8, for consistency with Chapter 11.4. BSE and added specific references to water buffaloes in addition to cattle where applicable.

In February 2022, as part of the discussion on Theileriosis (Chapter 11.10.), the Code Commission noted a comment that water buffaloes and African buffaloes were also bovines. Acknowledging that there were some variations in the use of terms 'bovines', 'bovids' and 'cattle' in the *Terrestrial Code*, the Commission agreed to consider this issue in detail and requested the Secretariat to review the use of the terms throughout the Code to assess and prioritise the work needed to ensure consistency.

Discussion

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*, noting that these terms were widely used, and relevant references were found in the User's guide, Article 1.3.2., and Chapters 1.8, 1.10., 4.3., 4.7., 4.8., 4.12., 6.8., 6.11., 6.13., 7.2., 7.3., 7.4, 7.5., 7.6., 7.9., 7.11., 7.12., 8.2., 8.3., 8.4., 8.5., 8.7., 8.8., 8.11., 8.18., 11.1., 11.2., 11.3., 11.4., 11.5., 11.6., 11.7., 11.8., 11.9., 11.10., 11.11., and 14.7. and title of section 11; as well as in some of the texts currently being circulated.

- The Code Commission concluded that the term 'cattle' (used in the English version of the Code) was too vernacular, and its meaning was not precise in zoological terms and was not possible to be correctly translated into the other WOA official languages. The Commission thus agreed not to use the term 'cattle' anymore, and base its future use of terms following the taxonomical classification, as follows:
- 'Ruminant(s)' (in Spanish 'Rumiante(s)', in French 'Ruminant(s)'), meaning all members of the sub-order *Ruminantia*;
- '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*;
- 'Bovine(s)' (in Spanish 'Bóvino(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 'bovine' should be provided to specify the genus or species concerned.

The Code Commission agreed to include 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 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 the English version only and requested the Secretariat to assess the changes required to apply the agreed approach consistently in the French and Spanish versions and to report back at the next meeting.

The Code Commission agreed to progressively address the rest of the chapters when they would be under review. The Commission also acknowledged a lack of species-level definition in some chapters which had not been recently reviewed (e.g., Chapter 11.1., 11.2., 11.7.), and agreed that the clarification of species concerned should be sufficiently addressed, which will be important in terms of notification to WOA.

The Commission reminded Members that the proposed changes to these texts referred only to this specific terminology issue for consistency and did not intend to open the discussion of other aspects or parts of the texts.

The revised texts in the User's guide, Article 1.3.2. and the title of Section 11, are presented in [Annex 20](#) for comments and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU supports the proposed changes to the Code presented in Annex 20.

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

Background

At its February 2021 meeting, in the context of the development of the new chapter on official control programmes for listed and emerging diseases (Chapter 4.19), the 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 the work 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 with the Group to replace 'epizootic' with 'epidemic' throughout the chapter and requested the Secretariat to review the use of these terms in the *Terrestrial Code* and report back to the Commission at its next meeting.

Discussion

The Code Commission considered an analysis prepared by the Secretariat on the use of the terms 'enzootic' and 'epizootic', in the *Terrestrial Code* (2022 edition). The Commission noted that the terms are widely used in some other chapters, and also used as part of some disease names (i.e., infection with epizootic hemorrhagic disease virus, enzootic bovine leukosis, enzootic abortion of ewes).

Taking into consideration the above, the Commission agreed to use only the terms 'epidemic' and 'endemic' in the text of the *Terrestrial Code* chapters, but not to modify the disease names as these names are scientifically recognised, this may have practical implications and they are already used in the listed diseases and the *Terrestrial Manual*.

The Commission agreed to apply this change in the ongoing revision of Chapter 11.4., and to propose amendments to Chapter 4.19. (Article 4.19.1.) and 9.3. (Article 9.3.1.) to replace 'epizootic/enzootic' with 'epidemic/endemic'. The Commission noted that the change would also need to be applied in Chapters 5.5., 5.6, 5.7., 5.12., and 8.15., but agreed to address them as part of their future revision.

The Commission reminded Members that the proposed changes to these texts referred only to this specific terminology issue for consistency and did not intend to open the discussion on other aspects or parts of the texts.

The revised Article 4.19.1. and Article 9.3.1. are presented in [Annex 21](#) for comments and will be proposed for adoption at the 90th General Session in May 2023.

EU comment

The EU supports the proposed changes to the Code presented in Annex 21.

6. Texts circulated for comments

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

6.1. Revision of Chapter 4.6. 'Collection and processing of semen of animals'

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. At its September 2021 meeting, the Code Commission considered the work of the *ad hoc* Group and supported the WOAHS Secretariat's suggestion to engage an expert to undertake a technical review of the draft chapter developed by the *ad hoc* Group and to develop a revised draft aligned with the style used in the *Terrestrial Code*.

The WOAHS Secretariat informed the Commission that a call for tender, restricted to *ad hoc* Group members, was published in May 2022, and the tender was granted to one of the members, who undertook this work with the support of a Commission member.

Discussion

The Code Commission considered [the report of the *ad hoc* Group](#) together with the draft Chapter 4.6 developed by the assigned expert.

The Code Commission commended the work of the *ad hoc* Group and the expert, and acknowledged the difficulty to provide, in a single chapter, recommendations for the collection and processing of semen for a broad range of species given the practical differences in processes and facilities between species.

The Code Commission agreed to amend the title of Chapter 4.6. from 'General hygiene in semen collection and processing centres' to 'General hygiene in semen collection, processing and storage', and to change the Glossary definition for 'artificial insemination centre' to 'semen collection centre', to better align with the revised chapter. However, the Commission agreed to propose the change to the Glossary definition once the Commission has considered feedback from Members on the revised chapter. The Commission also made some additional amendments to improve readability and clarity.

The Code Commission noted that while the approach originally proposed by the *ad hoc* Group for the draft text was to provide general recommendations which are applicable to all species and additional species-specific recommendations for some species, the general epidemiological concepts of space, time, hygiene, and *biosecurity* practices should apply to all species. The Commission also agreed that the chapter should provide common principles applicable to the collection, processing, and storage of semen of bovine, ovine, caprine, porcine, equine, and cervid donor animals, and noted that if some standard practices in a country deviate from these recommendations, these should not be covered by the standards but rather specific conditions to be approved by each Veterinary Authority based on a risk analysis.

The Code Commission noted that the draft text included a reference to Chapter 4.7. while the current Chapter 4.7 only applies to bovine, porcine, and small ruminants, while the proposed draft also applies to equine and cervids. The Commission emphasised that this inconsistency will be addressed during the anticipated revision of Chapter 4.7.

The Code Commission agreed to circulate the revised Chapter 4.6. General hygiene in semen collection, processing and storage for comments, as a clean text given the extensive number of amendments.

The revised Chapter 4.6. General hygiene in semen collection, processing and storage is presented as [Annex 22](#), for comments.

EU comment

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

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

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 in light of the revision of some definitions in Chapter 6.9. Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals, which was adopted in 2018. The Commission had requested the advice of the WOAHA Working Group on Antimicrobial Resistance (AMR Working Group). The AMR Working Group considered this request at its 2019 meeting and recommended that a review of Chapter 6.10. not be undertaken until the work of the Codex Alimentarius Task Force on Antimicrobial Resistance had been progressed, in order to avoid inconsistencies.

At its February 2022 meeting, the Code Commission was informed that the revised Codex Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005) 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 a draft revised Chapter 6.10.

Discussion

The Code Commission was informed that a Subgroup of the AMR Working Group had met via video conference nine times between January and June 2022 to draft a revised chapter. The draft chapter and the report of the Subgroup meetings which documented the rationale for the proposed amendments were validated by the AMR Working Group at its August 2022 meeting. The Commission was also informed that the Subgroup took into account other relevant documents including the Codex Code of Practice CXC 61-2005 when drafting the revised chapter.

The Code Commission was also informed that, as requested, the AMR Working Group, at its next meeting in October 2022, will consider whether the other AMR related chapters (i.e., Chapters 6.7., 6.7., 6.9. and 6.11.) will need to be amended as a consequence of the proposed revisions of Chapter 6.10.

The Code Commission commended the AMR Working Group for its comprehensive work and very clear report and encouraged Members to read [the Working Group's August 2022 meeting report](#).

The Code Commission discussed the draft revised chapter together with the report of the Subgroup meetings. For the details of the rationale for amendments proposed by the Subgroup of the Working Group, the Commission encouraged Members to refer to [the Subgroup's report](#).

The Code Commission made some additional amendments to improve clarity and ensure alignment with other chapters of the *Terrestrial Code*, where relevant. The rationale for amendments made by the Code Commission is described below.

Article 6.10.1.

In the first paragraph, noting that the term 'veterinary medical use of antimicrobial agents' was defined in Chapter 6.9. Monitoring of the quantities and usage patterns of antimicrobial agents in food-producing animals, the Code Commission proposed to add 'for treatment, control and prevention of diseases' to clarify the scope of the chapter. The Commission also proposed that the definition for the term 'veterinary medical use of antimicrobial agents' be moved into the Glossary, and deleted from Chapter 6.9., once the chapter has been adopted.

In the same paragraph, the Code Commission discussed whether the term 'food and non-food producing animals' should be clarified and agreed that no change was needed to the draft text as it considered that this wording is clear as written regarding what animals are covered in this chapter. The Commission reminded Members that the term 'animal' was defined in Glossary of the *Terrestrial Code*.

In the second paragraph, the Code Commission proposed to replace 'food animal producers' with 'animal breeders, owners and keepers' throughout the chapter for clarity.

Article 6.10.3.

In point 2, in the ninth paragraph, the Code Commission proposed to replace 'consider expediting' with 'implement timely' for clarity.

Article 6.10.4.

In point 1(d), the Code Commission proposed to add 'and submit them' for clarity.

Article 6.10.6.

In point 1(d), the Code Commission proposed to add 'available' before 'diagnostic laboratory information' and delete 'where possible' for clarity.

In point 2, in the last paragraph, the Code Commission proposed to delete 'or to broaden the spectrum of activity' as it considered that 'to increase therapeutic effectiveness' was adequate and inclusive of this.

In point 4, the Code Commission proposed to delete the current point 4(b) as it considered that the proposed new point 4(b) addressed this.

Article 6.10.9.

The Code Commission agreed with the proposal from the Working Group to add a new Article 6.10.9. on Responsibilities of breeders, owners and keepers of non-food producing animals.

The revised Chapter 6.10. 'Responsible and prudent use of antimicrobial agents in veterinary medicine', is presented as [Annex 23](#), for comments.

EU comment

**The EU thanks the OIE and in general supports the proposed changes to this chapter.
Comments are inserted in the text of Annex 23.**

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

Background

The Code Commission considered a new proposal to include in its work programme the development of a new chapter on Infection with *Coxiella burnetii* (Q fever) in the *Terrestrial Code* based on a case definition developed by experts and endorsed by the Scientific Commission at its February 2022, that was placed on the WOAHP website to support Members notification.

The Code Commission had noted that there was currently no chapter in the *Terrestrial Code* for this disease and agreed to add this item to its work programme. The Commission reiterated its commitment to swiftly progress to have in the Code a chapter for each of the listed diseases, at least with a single article, to ensure Members have the adequate basis on WOAHP Standards to fulfil their notification obligations, as agreed with the Scientific Commission and WOAHP Headquarters.

Discussion

The Commission discussed the development of a new *Terrestrial Code* chapter for Q fever and considered the case definition that was endorsed by Scientific Commission, the experts' recommendations, opinions from Biological Standards Commission and *Terrestrial Manual* Chapter 3.1.17. Q fever.

The Code Commission drafted a new Chapter 8.X. Infection with *Coxiella burnetii* (Q fever) which has one single article for the general provisions, including the definition of its occurrence.

The Commission agreed that the name of the listed disease in Article 1.3.1, should be amended to 'Infection with *Coxiella burnetii* (Q fever)'. The Commission agreed to propose amendments to Article 1.3.1. closer to adoption as a consequence of the work on the disease-specific chapters. It also noted that once this new chapter is adopted, possibly with changes accompanying the commenting process, the case definition temporarily on the WOAHP website should be either aligned or removed.

The proposed new Chapter 8.X. Infection with *Coxiella burnetii* (Q fever) is presented as [Annex 24](#), for comments.

EU comment

The EU thanks the Code Commission and in general supports this proposed new chapter. A comment is inserted in the text of Annex 24.

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

Background

The Code Commission had 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 (see item 4.1.7. of this report).

The last amendment of Chapter 11.5. was adopted in 2014 (to include the OIE endorsed official control programme for CBPP which started in 2014). 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.

Discussion

The Code Commission reviewed the amendments proposed by the *ad hoc* Group on CBPP and by the Scientific Commission.

The Commission agreed with the proposed amendments and made some further amendments for harmonisation, clarity and consistency with other chapters.

The revised Chapter 11.5. 'Infection with *mycoplasma mycoides* susp. *Mycoides* SC (Contagious Bovine Pleuropneumonia)' is presented as [Annex 25](#) for comments.

EU comment

The EU in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 25.

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

Background

In 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) to be placed on the WOA website to support Members' notification and considered including the development of a disease-specific chapter for the *Terrestrial Code* on its work programme. 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 the work on 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 highlighted that if a change was to be proposed for either of the pathogenic agents or its hosts, it should be done through an assessment against the criteria in Chapter 1.2 of the *Code*. The Commission requested the assessments be undertaken before including these items in its work programme.

At its February 2022 meeting, Scientific Commission considered the opinion of the Code Commission and subsequently reviewed the text and endorsed a new case definition that was placed on the WOA website to facilitate notification by Members.

Discussion

The Code Commission discussed the development of a new *Terrestrial Code* chapter for BVD based on the amended case definition that was endorsed by the Scientific Commission and agreed to include this in its work programme.

The 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 on 'Infection with *Bovine Pestiviruses* (Bovine viral diarrhoea)' which has one single article for the general provisions, including the definition of its occurrence.

The Code Commission agreed that, following the proposed new chapter, the name of the listed disease in Article 1.3.2, should be amended to 'Infection with Bovine Pestiviruses (Bovine viral diarrhoea)'. The Commission agreed to propose amendments to Article 1.3.2. closer to adoption, as a consequence of the work on the disease-specific chapter. It also noted that once this new chapter is adopted, possibly with changes accompanying the commenting process, possibly with changes accompanying the commenting process, the case definition temporarily on the WOA website should be either aligned or removed.

The proposed new Chapter 11.X. Infection with Bovine Pestiviruses (Bovine viral diarrhoea) is presented as [Annex 26](#), for comments.

EU comment

The EU thanks the Code Commission but does not support this proposed new chapter as presented. Comments are inserted in the text of Annex 26.

6.6. African horse sickness (Chapter 12.1)

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 (see item 4.1.7. of this report).

At its February 2021 meeting, the Scientific Commission reviewed and endorsed the amendments proposed by the *ad hoc* Group on African horse sickness (December 2016 report). At its September 2021 meeting, the Scientific Commission finalised its discussion on one additional point on protection zone and agreed to refer to 'area' instead of 'zone' for clarity in Article 12.1.2.

Discussion

The Code Commission reviewed the amendments proposed by the *ad hoc* Group on 'Infection with African horse sickness virus' and by the Scientific Commission.

The Commission agreed with the proposed amendments and made some further amendments for harmonisation, clarity and consistency with other chapters.

The revised Chapter 12.1. Infection with African horse sickness virus is presented as [Annex 27](#), for comments.

EU comment

The EU in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 27.

6.7. Infection with Camelpox virus (New Chapter X.Z.)

Background

At its September 2020 meeting, the Code Commission agreed with a request from a Member to include the development of a new *Terrestrial Code* Chapter on Camelpox in their work programme, and requested the Secretariat to seek expert advice. The Code Commission also agreed with the Scientific Commission on the prioritisation of this disease for developing a case definition to support Members notification.

A new case definition of Camelpox was developed by subject matter experts and endorsed by the Scientific Commission at its February 2022 meeting, and was presented to the Code Commission for consideration for inclusion in the *Terrestrial Code*. A Chapter 3.5.1. Camelpox of the *Terrestrial Manual* was adopted in May 2021.

Discussion

The Code Commission discussed the development of a new *Terrestrial Code* chapter for Camelpox and considered the case definition that was endorsed by Scientific Commission, the experts' recommendations, opinions from Biological Standards Commission and the recently adopted Chapter in the *Terrestrial Manual*.

Based on these considerations, the Commission drafted a new Chapter X.Z. 'Infection with Camelpox virus' which has one single article for the general provisions, including the definition of its occurrence.

In the proposed point (2) of Article X.Z.1., unlike other chapters in the Code, the observation of characteristic orthopox virions in a sample from a susceptible animal was included, considering the specific fact that the virus is one of the biggest viruses and the shape of the virus is easily distinguishable from other viruses.

The Commission agreed that, following the proposed new chapter, the name of the listed disease in Article 1.3.9, should be amended to 'Infection with Camelpox virus'. The Commission agreed to propose amendments to Article 1.3.9. closer to adoption as a consequence of the work on the disease-specific chapter. The Commission noted that once this new chapter is adopted, possibly with changes accompanying the commenting process, the case definition temporarily on the WOAHP website should be either aligned or removed.

The Commission also acknowledged that this new chapter might need to be included in a new Section 16 on 'Other diseases and infections', together with the proposed new chapters for Infection with Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and infection with *Leishmania spp.* (Leishmaniasis), currently being circulated.

The proposed new Chapter X.Z. Infection with Camelpox virus is presented as [Annex 28](#), for comments.

EU comment

The EU thanks the Code Commission and in general supports this proposed new chapter. A comment is inserted in the text of Annex 28.

7. Updates on WOAHP initiatives relevant to the Code Commission

The Code Commission was updated on several WOAHP programmes and activities relevant to its work.

7.1. WOAHP Observatory

The Secretariat updated the Code Commission on the progress of the WOAHP Observatory since the last update at the February 2022 Commission meeting. The Secretariat reported on the key activities undertaken and confirmed

that the first WOAHS Observatory annual report is planned to be published in December 2022. Challenges faced in finding suitable information to assess the implementation of WOAHS standards were acknowledged. The Secretariat reported on a survey undertaken with Members in the context of the WOAHS Aquatic animal health strategy. The Secretariat also informed the Commission that the Observatory team was in the process of consolidation as part of a broader team dedicated to data integration. It also noted that the next steps would include the development of "thematic analysis" reports which would be focused on the implementation of standards for a given topic, for which the input of the Commission could be important and discussed possible ideas for the first case.

The Code Commission thanked the Secretariat for the information and highlighted that the WOAHS Observatory outputs would be a valuable source of information for the Commission and the Members to identify needs for the development and improvement of the *Terrestrial Code* standards and their applicability by Members. The Commission also highlighted that these outputs should also contribute to raising awareness and promoting Members' engagement in implementation of the WOAHS Standards.

Moreover, the Code Commission noted that the use and impact of WOAHS Standards for international trade was a recurrent topic raised by Members; however, little information is currently available on this matter. The Commission noted that it could be interesting to progressively explore how this could be further developed in support of Members.

The Code Commission reiterated its commitment to foster a continuous liaison with this WOAHS programme and requested the Secretariat to update the Commission on the progress and publication of the annual report to discuss further actions.

7.2. Global Burden of Animal Diseases (GBADs)

The Secretariat informed the Code Commission on the progress of the Global Burden of Animal Diseases programme to work on developing methodologies to assess the economic burden of animal diseases in a systematic manner including net loss of production, expenditure on preventing and controlling animal diseases and trade impacts. The Commission was briefed on the methodology development, initial outcomes from country case studies to test methods developed, recent publications, and activities of the first WOAHS Collaborating Centre of Animal Health.

The Code Commission reiterated its interest in the matter and highlighted the value that the outcomes of this programme could have as input to identify and prioritise possible future work for the Commission.

The Code Commission expressed its commitment to further liaison with this programme and highlighted that the outcomes of GBADs should be a valuable tool to facilitate its considerations on the need and value of developing relevant standards.

7.3. WOAHS Wildlife health framework

The Secretariat informed the Code Commission on the progress of the WOAHS Wildlife Health Framework. The Secretariat noted that wildlife health work at WOAHS was supported by the expertise of the Wildlife Working Group (WWG), a network of Collaborating Centres' experts around the world, the network of WOAHS wildlife focal points, and international partners, featuring complementary expertise and skills to better support WOAHS's work, and that additionally, several tools were also important to better address wildlife health, such as WOAHS international standards, the WAHIS notification system, and now a new WOAHS Wildlife Health Framework.

The Secretariat reported that the WOAHS Wildlife Health Framework aimed at protecting wildlife health with a focus on public health and conservation and that the first objective of this programme was to support Members to better prevent pathogens spillover at the wildlife/human/livestock/environment interface, and the second one focused on the surveillance and management of wildlife diseases.

The Secretariat reported that the activities were currently focusing on stock taking and needs assessments, while tools production and implementation was happening in parallel, especially at the regional and national levels. The Secretariat noted that several ongoing reviews were being undertaken through consultancies to assess how WOAHS tools currently take into account wildlife health and to identify opportunities to better integrate wildlife disease surveillance and health management. The Secretariat informed that their outcomes will be submitted to the WWG to provide recommendations, strategic guidance and key actions to take on and be proposed to the Specialist Commissions as relevant, to refine and adjust the current programme.

The Code Commission provided feedback on the role WOAHS standards could play and expressed its interest in the matter. The Commission noted that the outcomes of this work would be a critical input for the Commission to identify and prioritize possible future work, and to understand needs for further development of the *Terrestrial Code*. The Code Commission expressed its commitment to further liaison with this programme and agreed to include a specific work item in their work programme for which the scope will be further defined in future discussions, noting that the input and agreement of Members will be essential in standard-setting process.

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

7.4. 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. The work plan includes nine activities that address the four strategic 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 Secretariat updated the Commission on the status of implementation of the Strategy's work plan and highlighted that it included the development of e-learning modules on reptiles, pig production systems and killing for disease control purposes to be added on the WOAH training portal; that plans to reactivate the Regional Animal Welfare Strategies and Platforms in some WOAH Regions; and that the Fourth WOAH Global Animal Welfare Forum: 'Animal Welfare Economics' will be held as a virtual event on 12-13 October 2022.

7.5. Terrestrial Code data standardisation

7.5.1. Framework for *Terrestrial Code* standards

Background

At its February 2021 meeting, the Code Commission agreed with a proposal from the Secretariat to develop a framework for the development of disease-specific chapters of the *Terrestrial Code* that would define the structure and content of these chapters. The Commission agreed that this would serve as a useful guide to ensure a consistent approach when undertaking work on the development or revision of a chapter in terms of structure and content, also ensuring consideration of essential components to achieve complementarity and avoid discrepancies within and between different parts of the *Terrestrial Code*.

At its September 2021 meeting discussed a proposed draft and agreed with the proposed approach and requested the Secretariat to seek the opinion of the Scientific Commission and report back at its next meeting.

Discussion

The Secretariat informed the Code Commission that the project had been shared with the Scientific Commission for their input, which was going to discuss it at its September 2022 meeting.

The Commission highlighted that this will be a valuable WOAH internal resource, which should also guide experts involved in standards development to present the necessary rationale for their proposals in a consistent manner. The Commission noted that it could also provide valuable information to facilitate Member understanding and implementation of standards.

The Commission thanked the Secretariat for progressing with this work and requested the Secretariat to present a consolidated version for their upcoming meeting, incorporating some agreements reached by the Commission during their relevant discussions in this meeting.

The Code Commission noted that, once agreed, this framework should be applied to the development of new chapters and the revision of existing ones.

7.5.2. Commodities

Background

In its September 2021 meeting, the Commission agreed with a proposal from the Secretariat for a Standard Operating Procedure (SOP) to be applied internally when assessing commodities for inclusion in the lists of safe commodities in disease-specific chapters of the *Terrestrial Code*.

In its February 2022 meeting, the Code Commission agreed that the SOP should also cover the standardisation of names of commodities across the *Terrestrial Code* and agreed with the proposed SOP and requested to be informed if any points in the SOP require further amendments.

Discussion

The Secretariat informed the Code Commission that the SOP had been shared internally with all teams involved in standards setting and that work was being conducted to define the inventory of terminology currently used across the Code and to develop common reference names for future standards-setting work.

The Commission acknowledged that the work involved approximately more than 500 articles and that some heterogeneity had been observed across chapters.

The Commission thanked the Secretariat for progressing with this work and requested the Secretariat to present a consolidated version of the inventory for consideration by the Commission when available.

7.5.3. Codification

The Secretariat updated the Code Commission on the status of a WOAHA initiative to codify animal disease names, their causal agents and host species, which had been implemented in accordance with Strategic Objective two 'Data governance' of WOAHA 7th Strategic Plan.

The Code Commission was also briefed on several issues on the *Terrestrial Code* content that had been identified in the course of the codification work, such as discrepancies of listed disease names between Chapter 1.3. and disease-specific chapters (which was rectified by adopting revised Chapter 1.3. in May 2022), different terminologies to refer to host animals (e.g., bovid, Bovidae, bovine and cattle (see item 5.15 of this report)) and unclear host animals which are covered by each disease-specific chapter (e.g., whether wild animals are included is sometimes unclear).

The Code Commission emphasised the importance of the work and expressed its commitment to contributing to the WOAHA's initiative. The Commission explained that the identified issues had been or will be addressed in the ongoing works to develop case definitions and other relevant Code Commission's works.

The Commission requested that the Commission be kept informed of and involved with, as relevant, the progress of the work.

8. Updates on 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.

8.1. Update on Codex's works

The Secretariat updated the Code Commission on recent relevant developments in the Codex Alimentarius during the past year (from September 2021 to August 2022).

The Commission noted the adoption at the Codex Alimentarius Commission in November 2021 of revised Codex Guidelines for Design, Production, Issuance and Use of Generic Official Certificates (CXG 38-2001) which include Guidance on Paperless Use of Electronic Certificates and revised Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005). The Commission acknowledged that some provisions of draft Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine (see item 6.2 of this report) were aligned with the referred Codex Code of Practice and new Guidelines on integrated monitoring and surveillance of foodborne AMR (CXG 94-2021).

The Code Commission acknowledged that the Codex Committee on Food Hygiene (CCFH) had requested the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA) to collate the relevant scientific information on Salmonella and Campylobacter in chicken meat in preparation for an update of the existing Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat (CXG 78-2011) which includes references to the *Terrestrial Code* Chapters 6.5. and 6.6. The Commission noted that this may trigger a potential need to review the *Terrestrial Code* chapters, and requested that the Secretariat provide an update on the progress of this work in CCFH at its February 2023 meeting.

8.2. IATA Live Animal Regulation amendments

Background

Since 2006, WOAHA has been a member of the International Air Transport Association (IATA) Live Animal and Perishable Board (LAPB) and has been actively engaged.

In 2022, a Temporary Task Force under the LAPB was convened to discuss the revision of Chapter 8.1. of the IATA Live Animal Regulations and proposed to restructure some of its texts regarding tranquillization. It created a new subsection regarding sedation, tranquilization and use of psychoactive drugs in their chapter on 'Animal Welfare and Health Requirements'.

Given the importance of alignment between the IATA Live Animal Regulations (LAR) and in the *Terrestrial Code*, these IATA modifications could impact the recommendations on the use of tranquilizers in Article 7.4.7 of Chapter 7.4. 'Transport of animals by air' in the *Terrestrial Code*.

Discussion

The Code Commission noted the amendments being made in the IATA's LAR and recommended that no immediate change to Chapter 7.4. be proposed given that the amendments being proposed in IATA's LAR did not conflict with the current text in Chapter 7.4. The Commission agreed that minor amendments could be made to ensure better alignment and agreed that this would be considered during the future revision of Chapter 7.4.

.../Annexes

Annex 1. Adopted Agenda

MEETING OF THE WOAHP TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 13 to 22 September 2022

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: Paratuberculosis
 - 3.2. Biological Standards Commission
 - 3.3. Aquatic Animals Commission
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. Revision of Chapter 4.6. Collection and processing of semen of animals
 - 4.1.2. New chapter on biosecurity (Chapter 4.X.)
 - 4.1.3. Revision of Chapters 5.4. to 5.7.
 - 4.1.4. Revision of Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine
 - 4.1.5. New chapter on Animal welfare and laying hen production systems (Chapter 7.Z.)
 - 4.1.6. Revision of Chapter 7.6. Killing for disease control purposes
 - 4.1.7. New chapter on infection with *Trypanosoma evansi* (Chapter 8.X.)
 - 4.1.8. Harmonisation of official recognition of status by the WOAHP: contagious bovine pleuropneumonia (Chapter 11.5.), African horse sickness (Chapter 12.1.)
 - 4.1.9. New chapter on Camel pox
 - 4.1.10. Terminology
 - 4.1.10.1. Use of terms 'animal-based measures' and 'measurables'
 - 4.1.10.2. Use of terms 'enzootic', 'endemic', 'epizootic' and 'epidemic'
 - 4.2. **Items under consideration for inclusion in work programme**
 - 4.2.1. Surveillance of diseases of wildlife (from Wildlife Working Group)
 - 4.2.2. Infection with *Brucella abortus*, *B. melitensis* and *B. suis* (Chapter 8.4.)
 - 4.2.3. Infection with peste des petits ruminants virus (Chapter 14.7.)
 - 4.2.4. Melioidosis
 - 4.2.5. Bovine viral diarrhoea (Case definition)
 - 4.2.6. Terminology
 - 4.2.6.1. Use of terms 'bovid', 'bovidae', 'bovine' and 'cattle'
 - 4.2.6.2. Use of terms 'fetal', 'foetal', 'fetus' and 'foetus'
 - 4.2.6.3. Use of terms 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'
 - 4.3. **New proposals and requests for inclusion in work programme**
 - 4.3.1. Electronic certification - Proposal to revise Chapter 5.2.
 - 4.3.2. Request to revise Chapter 5.8.
 - 4.3.3. Request on Antiparasitic resistance
 - 4.3.4. Inclusion of the 'Five Domains' concept in Section 7
 - 4.3.5. Request to revise Chapter 8.10. Japanese encephalitis

- 4.3.6. Request to revise Chapter 12.11. Venezuelan equine encephalomyelitis
- 4.3.7. Avian mycoplasmosis – Chapter 10.5 (*Mycoplasma gallisepticum*, *M. synoviae*, *M. meleagridis* and *M. iowae*)
- 4.3.8. Q fever
- 4.4. **Prioritisation of items in work programme**
- 5. **Follow-up of chapters recently adopted**
- 5.1. Infection with *Theileria annulata*, *T. orientalis* and *T. parva* (Chapter 11.10.)
- 6. **Texts circulated for comments**
- 6.1. **In May 2022 General Session**
- 6.1.1. Bovine spongiform encephalopathy (Chapter 11.4.), Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy (Chapter 1.8.), Glossary A ('protein meal') and revision of the use of terms 'meat-and-bone meal' and 'greaves' throughout the Terrestrial Code
- 6.2. **In February 2022 meeting report**
- 6.2.1. Glossary definition for "Poultry"
- 6.2.2. Slaughter of animals (Chapter 7.5.) and Glossary definitions for 'death', 'distress', 'euthanasia', 'pain', 'slaughter', 'stunning' and 'suffering'.
- 6.2.3. Infection with rabies virus (Articles 8.14.6bis. and 8.14.7. of Chapter 8.14.)
- 6.2.4. Infection with Rift Valley fever virus (Chapter 8.15.)
- 6.2.5. Infection with Newcastle disease virus (Article 10.9.1.)
- 6.2.6. Contagious equine metritis (Chapter 12.2.)
- 6.2.7. Infection with equine influenza virus (Chapter 12.6.)
- 6.2.8. Equine piroplasmiasis (Chapter 12.7.)
- 6.2.9. New chapter on infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* (Chapter 14.X.) and revision of Article 1.3.3.
- 6.2.10. Middle East Respiratory Syndrome Coronavirus (MERS-CoV) (New Chapter X.X.)
- 6.2.11. Leishmaniasis (New Chapter X.Y.)
- 6.3. **Previously circulated**
- 6.3.1. Infection with foot and mouth disease virus (Chapter 8.8.)
- 7. **WOAH and HQ's initiatives relevant to TAHSC (Updates)**
- 7.1. WOAHObservatory
- 7.2. GBADs
- 7.3. WOAHO Wildlife health framework
- 7.4. WOAHO Global Animal welfare strategy
- 7.5. Terrestrial Code data standardisation
- 7.5.1. Framework for Terrestrial Code standards
- 7.5.2. Commodities
- 7.5.3. Codification
- 7.5.4. Code navigation tool
- 7.6. Standard operating procedure for determining whether a disease should be considered as emerging (revision of the SOP)
- 7.7. SOP for listing
- 7.8. WOAHO Rebranding
- 8. **Updates on works of other standard-setting bodies and international organisations**
- 8.1. Update on Codex's works
- 8.2. IATA Live Animal Regulation amendments (Impact in the Code)
- 9. **Meeting review**
- 10. **Date of next meeting**

Annex 2. List of Participants

MEETING OF THE WOAHP TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 13 to 22 September 2022

MEMBERS OF THE COMMISSION

Dr Etienne Bonbon
(President)
Senior Veterinary Advisor
Food and Agriculture Organization of
the United Nations,
Rome,
ITALY

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),
ESPAÑA

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

© World Organisation for Animal Health (WOAH), 2022

This document has been prepared by specialists convened by the World Organisation for Animal Health (WOAH). Pending adoption by the World Assembly of Delegates, the views expressed herein can only be construed as those of these specialists.

All WOAHP publications are protected by international copyright law. Extracts may be copied, reproduced, translated, adapted or published in journals, documents, books, electronic media and any other medium destined for the public, for information, educational or commercial purposes, provided prior written permission has been granted by the WOAHP.

The designations and denominations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the WOAHP concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers and boundaries.

The views expressed in signed articles are solely the responsibility of the authors. The mention of specific companies or products of manufacturers, whether or not these have been patented, does not imply that these have been endorsed or recommended by the WOAHP in preference to others of a similar nature that are not mentioned.

UNOFFICIAL VERSION

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

EU comment

The EU commends the Code Commission for its continuous efforts to prioritise its heavy work programme, in coordination with other specialist commissions as relevant. We appreciate the opportunities for members to regularly comment on the work programme and thank the Code Commission for having taken into consideration comments submitted previously (especially re. work on Chapter 6.10. *Responsible and prudent use of antimicrobial agents in veterinary medicine*; to propose case definitions developed by SCAD for inclusion in the Code instead of them being published on WOAH's website; and to look into the inconsistencies between the Code and the Manual re. avian mycoplasmosis pathogens). We fully support the revised work programme and its prioritisation.

In particular, we support work to revise Chapter 5.8. *International transfer and Laboratory containment of animal pathogenic agents*, noting for example that Article 5.8.3. is especially outdated as the Manual no longer refers to classification of pathogens in four risk categories. Close coordination of this work with the Biological Standards Commission will be essential.

Finally, the EU requests an urgent revision of Chapter 14.19. *Sheep pox and goat pox*. Indeed, that chapter has not been revised since it was first adopted in 1986. It lacks a case definition and contains only few recommendations for safe trade in commodities, and is thus in dire need of an update. The urgency is linked to recent outbreaks in areas where the disease had not been present for decades, and the challenges encountered linked to the lack of recommendations for certain commodities such as milk and meat.

Chapter	Issues	Summary of the work	Status - September 2022		Priority order *
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	
General	Wildlife Health	Overarching consideration on how wildlife animal health is addressed in the Terrestrial Code	preliminary discussions	Noted in Sep 2022 TAHSC report	3
	Five domains concept	Impact assessment for the inclusion of the concept in the Terrestrial Code	Preparatory work	Noted in Sep 2022 TAHSC report	3

Use of terms	Use of terms: disease / infection / infestation	Review use of the terms across the Code for consistency	Preparatory work	Refer to Feb 2020 TAHSC report	2
	Use of terms: animal health status	Review use of the terms across the Code for consistency	Preparatory work	Refer to Feb 2020 TAHSC report	3
	Use of terms: animal-based measures / measurables	Review use of the terms across the Code for consistency Develop a policy for their use	Preparatory work	Refer to Feb 2021 TAHSC report	2
	Use of terms: enzootic / endemic / epizootic / epidemic	To consider replacing 'enzootic' with 'endemic' and 'epizootic' with 'epidemic' throughout the Code	Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report (Sep 2022/1)	1
	Use of terms: notify / notifiable disease / report / reportable disease	Review use of the terms across the Code for consistency. Develop a policy for their use	Preparatory work	Refer to Feb 2019 TAHSC report	2
	Use of terms: Competent Authority / Veterinary Authority / Veterinary Services	Review use of the terms across the Code for consistency	Preparatory work	Noted in Sep 2022 TAHSC report	2
	Use of terms: fetal / foetal / fetus / foetus	Review use of the terms across the Code for consistency	Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report (Sep 2022/1)	1
	Use of terms: bovid / bovidae / bovine / cattle	Review use of the terms across the Code for consistency Develop a policy for their use	Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report (Sep 2022/1)	1
User's guide	Revision of the Users' guide (standing item)	Amendments related to use of terms: Competent Authority / Veterinary Authority / Veterinary Services and bovid / bovidae / bovine / cattle	Standing item Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report (Sep 2022/1)	1
Glossary	'Death', 'euthanasia', 'slaughter' and 'stunning'	In-depth revision in relation to work on Ch 7.5-7.6	Expert consultation	Noted in Sep 2022 TAHSC report (Sep 2019/3)	2

	'Poultry'	Revise to exclude populations of pet birds for breeding or selling from the definition.	Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report (Feb 2022/2)	1
	New definition for 'protein meal'	Develop the new definition as a result of discussion on revision of Ch 11.4.	Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report (Feb 2021/4)	1
	New definitions for 'distress', 'pain' and 'suffering'	Develop the new definitions as a result of discussion on revision of Ch 7.5. (to remove them from Ch 7.8.)	Expert consultation	Noted in Sep 2022 TAHSC report (Sep 2019/2)	2
	New definitions for 'animal products', 'product of animal origin' and 'animal by-product'	Review use of the terms across the Code for consistency. Develop a policy for their use and draft definitions.	Preparatory work	Refer to Feb 2020 TAHSC report	3
	New definition for 'swill'	Review use of the term across the Code. Develop a policy for its use and consider developing a definition.	Preparatory work	Refer to Sep 2021 TAHSC report	1
	Use of terms 'meat-and-bone meal' and 'greaves'	Review use of the term 'meat-and-bone meal' across the Code and consider replacing the term with 'protein meal' after adoption of new definition	Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report (Sep 2022/1)	1
		Review use of the term 'greaves' across the Code and consider replacing the term with 'protein meal' after adoption of new definition	Preparatory work	Noted in Sep 2022 TAHSC report	2
Section 1					
1.3.	Listing of Infection with <i>T. lestoquardi</i> , <i>T. luwenshuni</i> and <i>T. uilenbergi</i> (Article 1.3.3.)	Consider listing based on the conclusion that the disease meets the criteria for listing	Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report (Feb 2022/2)	2

1.6.	Procedures for official recognition of animal health status, endorsement of an official control programme, and publication of a self-declaration of animal health status, by the OIE	Partial revision to improve clarity on the ability for Members to hold pathogenic agents within laboratories without affecting their animal health status	Expert consultation	Noted in Sep 2022 TAHSC report	3
1.8.	Application for official recognition by the OIE of free status for bovine spongiform encephalopathy	Full revision of chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report (Sep 2019/6)	1
Section 4					
4.4.	Zoning and compartmentalisation	Partial revision to define a time limit for containment zones	Preparatory work	Refer to Sep 2021 TAHSC report	1
4.6.	Collection and processing of semen of animals	Comprehensive revision of chapter	Circulated for comments	Noted in Sep 2022 TAHSC report (Sep 2022/1)	1
4.7.	Collection and processing of bovine, small ruminant and porcine semen	Comprehensive revision of chapter	Preparatory work	Pending progress of the work on Ch 4.6.	2
4.8.	Collection and processing of <i>in vivo</i> derived embryos from livestock and equids	Partial revision - to include new text addressing animal welfare requirements for embryo collection - to reclassify the category for Bluetongue	Not started	Pending progress of the work on Ch 4.6. and Ch 4.7.	3
4.9.	Collection and processing of oocytes and <i>in vitro</i> produced embryos from livestock and horses	Partial revision (Art. 4.9.5.) to include provisions regarding risk mitigation measures for BVD	Not started	Pending progress of the work on Ch 4.6. and Ch 4.7.	3
4.13.	Disposal of dead animals	Consider including all potentially contaminated wastes/products/fomites	Preparatory work	Refer to Feb 2022 TAHSC report	2
4.14.	General recommendations on disinfection and disinsection	Comprehensive revision of chapter	Preparatory work	Refer to Feb 2022 TAHSC report	2
4.X.	New chapter on biosecurity	Develop a new chapter	Preparatory work	Noted in Sep 2022 TAHSC report	1

Section 5					
General	Revision of Section 5 Trade measures, import/export procedures and veterinary certification (especially Chs 5.4. to 5.7.)	Comprehensive revision of Chs 5.4 to 5.7.	Expert consultation	Noted in Sep 2022 TAHSC report	1
5.2.	Certification procedures	Partial revision to review provisions on electronic certification	Expert consultation	Noted in Sep 2022 TAHSC report	3
5.11.	Model veterinary certificate for international movement of dogs, cats and ferrets originating from countries considered infected with rabies	Consequential revision due to revision of Ch 8.14.	Preparatory work	Pending progress of the work on Ch 8.14.	3
5.12.	Model passport for international movement of competition horses	Update the relevant chapters on equine diseases to take into account proposals made by the AHG on HHP Horses Veterinary Certificates	Preparatory work	Pending progress of the works on Chs on horse diseases	3
Section 6					
6.2.	The role of the Veterinary Services in food safety systems	Review the chapter based on the revised Glossary definitions for 'CA', 'VA' and 'VS'	Preparatory work	Noted in Sep 2022 TAHSC report	3
6.3.	Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection	Revision to avoid duplication with Ch 6.2., to simplify and to refer to relevant Codex GLs more	Not started	-	3
6.10.	Responsible and prudent use of antimicrobial agents in veterinary medicine	Comprehensive revision of chapter	Circulated for comments	Noted in Sep 2022 TAHSC report (Sep 2022/1)	1

6.12.	Zoonoses transmissible from non-human primates	Consider possible inclusion of SARS-CoV-2 in this chapter, possible inclusion of Macacine Herpesvirus 1 and the revision of test schedule and animal species to be tested for tuberculosis (Origin Member requests)	Not started	Noted in Feb 2022 TAHSC report	3
Section 7					
General	Transport of animals by land, sea and air (Chs 7.2., 7.3. and 7.4.)	Comprehensive revision of chapters	Preparatory work	Noted in Feb 2022 TAHSC report	3
7.5.	Slaughter of animals	Comprehensive revision of chapter	Expert consultation	Noted in Sep 2022 TAHSC report (Feb 2021/2)	1
7.6.	Killing of animals for disease control purposes	Comprehensive revision of chapter	Preparatory work	Refer to Sep 2022 TAHSC report	2
7.X.	New chapter on animal welfare and laying hen production systems	Develop a new chapter	Consultation	Noted in Feb 2022 TAHSC report	2
Section 8					
8.8.	Infection with foot and mouth disease virus	Comprehensive revision of chapter (including harmonisation of chapters with official status recognition)	Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report (Sep 2015/4)	1
8.10.	Japanese encephalitis	Comprehensive revision of chapter (related to works on Chs 12.4. and 12.11.)	Preparatory work	Noted in Sep 2022 TAHSC report	3
8.11.	Infection with <i>Mycobacterium tuberculosis</i> complex	Partial revision - to add recommendations for camelids and goats - to clarify point 1(b) of Article 8.11.4.	Not started	Noted in Feb 2022 TAHSC report	3
8.13.	Paratuberculosis	Consider amendments to ensure alignment with recently revised Manual chapter	Not started	Refer to Sep 2020 TAHSC report	4

8.14.	Infection with rabies virus	Partial revision - to amend the provisions for the importation of vaccinated dogs from infected countries or zones - to add provisions for the implementation of a rabies vaccination programme for dogs	Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report (Sep 2020/3)	1
		Partial revision - to add recommendations on wildlife-mediated rabies	Preparatory work	Noted in Sep 2022 TAHSC report	3
8.15.	Infection with Rift Valley fever virus	Comprehensive revision of chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report (Feb 2019/5)	1
8.X.	New Chapter on Infection with <i>Coxiella burnetii</i> (Q fever)	Develop a new chapter	Circulated for comments	Noted in Sep 2022 TAHSC report (Sep 2022/1)	2
8.Y.	New Chapter on Surra	Develop a new chapter	Preparatory work	Noted in Sep 2022 TAHSC report	2
Section 10					
10.3.	Avian infectious laryngotracheitis	Consider amendments to ensure alignment with recently revised Manual chapter	Not started	Refer to Sep 2020 TAHSC report	4
10.5.	Infection with <i>Mycoplasma gallisepticum</i> (Avian mycoplasmosis)	Full update of the chapter (content and structure) based on the recent update of the Manual Chapter. Consider inclusion of <i>M. synoviae</i> into a single chapter (and listed disease).	Preparatory work	Noted in Sep 2022 TAHSC report	3
10.9.	Infection with Newcastle disease virus	Remove the definition of poultry	Circulated for comments	Noted in Sep 2022 TAHSC report	1

			(proposed for adoption in May 2023)	(Feb 2022/2)	
		Revision to align with recent revision of Ch 10.4.	Not started	Refer to Feb 2022 TAHSC report	3
Section 11					
11.4.	Bovine spongiform encephalopathy	Comprehensive revision of chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report and Sep 2022 SCAD report (Sep 2019/6)	1
11.5.	Infection with <i>Mycoplasma mycoides</i> subsp. <i>mycoides</i> SC (Contagious bovine pleuropneumonia)	Harmonisation of chapters with official status recognition	Circulated for comments	Noted in Sep 2022 TAHSC report (Sep 2022/1)	2
11.11.	Trichomonosis	Comprehensive revision of chapter	Expert consultation	Refer to Feb 2022 TAHSC report (Sep 2020/2)	3
11.X.	New Chapter on Infection with bovine pestivirus (bovine viral diarrhoea)	Develop a new chapter	Circulated for comments	Noted in Sep 2022 TAHSC report (Sep 2022/1)	2
Section 12					
12.1.	African horse sickness	Harmonisation of chapters with official status recognition Proposals from AHG on AHS and SCAD	Circulated for comments	Noted in Sep 2022 TAHSC report (Sep 2022/1)	2
12.2.	Contagious equine metritis	Comprehensive revision of chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report (Sep 2020/3)	1
12.3.	Dourine	Comprehensive revision of chapter	Expert consultation	Refer to Feb 2019 TAHSC report and SCAD Sept 2021	2

12.4.	Equine encephalomyelitis (Eastern and Western)	Comprehensive revision of chapter (related to works on Chs 8.10. and 12.11.)	Not started	Pending ongoing work on case definition	3
12.6.	Infection with equine influenza virus	Partial revision - to add a case definition - to revise Article 12.6.6 based on the outcomes of work to evaluate equine influenza vaccination protocols prior to shipment of horses coordinated by an OIE Reference Laboratory - to consider the consequential amendments to the chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report (Feb 2019/5)	1
12.7.	Equine piroplasmiasis	Comprehensive revision of chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Sep 2022 TAHSC report (Sep 2020/3)	1
12.11.	Venezuelan equine encephalomyelitis	Comprehensive revision of chapter (related to works on Chs 8.10. and 12.4.)	Not started	Noted in Sep 2022 TAHSC report	3
Section 13					
13.2.	Rabbit haemorrhagic disease	Partial revision - to add a case definition - to add a new article on recovery of free status - to revise other articles, as appropriate	Not started	Noted in Feb 2022 TAHSC report	3
Section 14					
14.8.	Scrapie	Comprehensive revision of chapter	Not started	Noted in Feb 2022 TAHSC report	3
14.X.	New Chapter on infection with <i>Theileria</i> in small ruminants	Develop a new chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2022 TAHSC report (Sep 2017/3)	1
Section 15					

15.3.	Infection with porcine reproductive and respiratory syndrome virus (Article 15.3.9.)	Partial revision to address a concern that the testing regime in relation to semen collection centres is not sufficient to prevent the introduction of the virus through semen from countries that are not free from PRRS	Not started	Refer to Feb 2018 TAHSC report	4
Others					
X.	New Chapter on Crimean Congo haemorrhagic fever	Develop a new chapter	Preparatory work	Noted in Feb 2022 TAHSC report Pending ongoing work on case definition	2
X.X.	New Chapter on infection with Middle East respiratory syndrome coronavirus	Develop a new chapter following listing and Manual chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2022 TAHSC report (Feb 2022/2)	1
X.Y.	New Chapter on infection with <i>Leishmania</i> spp. (Leishmaniosis)	Develop a new chapter following Manual chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2022 TAHSC report (Feb 2022/2)	1
X.Z.	New Chapter on Camel pox	Develop a new chapter	Circulated for comments	Noted in Sep 2022 TAHSC report (Sep 2022/1)	2

* Description of priority order	
1	- active work for the TAHSC - to be put forward for next meeting agenda
2	- active work for the TAHSC - to be included in next meeting agenda if time allows, depending on other progress
3	- not immediate work for the TAHSC - needs to progress before consideration for next meeting agenda
4	- not active - not to be immediately started

List of abbreviations	
AHG	<i>Ad hoc</i> Group
BSC	Biological Standards Commission
Ch	Chapter
HQ	OIE Headquarters
SCAD	Scientific Commission for Animal Diseases
TAHSC	Terrestrial Animal Health Standard Commission

OFFICIAL VERSION

TERMINOLOGY: USE OF THE TERMS
‘COMPETENT AUTHORITY’, ‘VETERINARY AUTHORITY’,
‘VETERINARY SERVICES’

USER'S GUIDE

EU comment

The EU supports the proposed change to the User's guide.

[...]

C. Specific issues

[...]

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.

[...]

GLOSSARY

EU comment

The EU supports the proposed changes to the Glossary.

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.

POULTRY

means all birds reared or kept in captivity for the production of any commercial animal products or for breeding for this purpose, fighting cocks used for any purpose, and all birds used for restocking supplies of game or for breeding for this purpose, until they are released from captivity.

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

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

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.

CHAPTER 8.8.

INFECTION WITH
FOOT AND MOUTH DISEASE VIRUS**EU comment**

The EU thanks the Code Commission and in general supports most of the proposed changes to this chapter. However, important comments are inserted in the text below.

In addition, since this chapter is proposed for adoption in May 2023, it would be most relevant to adopt in parallel the Chapter 1.11. Application for official recognition by the OIE of free status for foot and mouth disease. Indeed, various changes proposed in Chapter 8.8. will have major consequences in the Chapter 1.11.

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 families *Suidae* and the subfamilies *bovinae*, *caprinae* and *cervidae* ~~Cervidae~~, the subfamilies *bovinae* and *caprinae* of the family *Bovidae*, order *Artiodactyla*, and *Camelus bactrianus* with FMDV (hereafter 'susceptible animals').

EU comment

The EU notes the changes proposed in point 2 above go in the right direction, in particular as regards clarity. However, it still means a significant narrowing down of the list of species in the definition of FMD compared to the current text. Indeed, certain species should continue to be included (e.g. subfamily *Antilopinae*) as depending on the local circumstances and practices their epidemiological role may be significant. The EU therefore does not support point 2 above as presented.

2bis) For the purposes of this chapter, 'cattle' a 'bovine' means an animal 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 5.15. of the Code Commission report). This is not appropriate and should not be justified with prior use of the term cattle, which was never well defined in the first place.

Furthermore, in some articles of this chapter, further species are added in addition to bovine 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.

We would thus prefer a broader definition of bovine in point 2 bis.

- 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

EU comment

The EU does not support the addition of “and identified as such” in point a) above, as it is superfluous. Agent identification is implicitly part of “FMDV has been isolated”.

Indeed, identification of the agent via specific laboratory diagnostic methods is an inherent part of virus isolation, as indicated and described in the recently adopted corresponding Manual chapter.

The combination of “pathogenic agent” + “isolation” is a well-established practice in the case definitions of disease specific chapters and should be maintained consistently throughout the Code.

- b) ~~viral~~ antigen or viral ribonucleic 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 **outbreak case** of FMD, or giving cause for suspicion of previous association or contact with FMDV; or
- c) antibodies to structural (SP) or non-structural proteins (NSP) of FMDV, that are not a consequence of *vaccination*, have been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed **outbreak case** of FMD, or giving cause for suspicion of previous association or contact with FMDV.

EU comment

The EU fully supports the changes proposed in points b) and c) above, that are very important for clarity. We would only suggest to also replace the word “identified” with “detected” in point c) above, for consistency with point b) and other chapters of the Code currently being revised (this change should in general be made in all case definitions of chapters currently being revised).

Furthermore, the EU suggests swapping the order of “suspected” and “confirmed” in points b) and c) above (for them to read “or epidemiologically linked to a confirmed or suspected case of FMD”), for consistency with other chapters currently being revised (e.g. CEM, EIV, RVF, Theileria).

- 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 the OIE 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 which transmission of FMDV has been proven 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.~~
- 87) 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 status of the exporting country or zone:

- 1) UHT milk and derivatives thereof;
- 2) heat-treated meat products in hermetically sealed container with a F₀ 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;

EU comment

In order to support point 3 above, the EU requests 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. For example, is the Veterinary Authority requested to provide detailed habitat maps for each wild and feral susceptible animal species?

- 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 would like to reiterate its previous comment and elaborate on the rationale provided in the September 2022 meeting report of the Code Commission.

The EU 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 additional costs related to increased complexity of surveillance to be supported by the importing country.

It agrees with the comment of the Code Commission, namely that “these provisions aimed at providing recommendations for the safe movement of animals, and that importing countries had to implement them based on risk analysis”. This statement is one of the building principles of the SPS Agreement, however it should be applied when deviating from WOAHS standards; given the increased level of risk when importing vaccinated animals, this should not be the starting point of a WOAHS standard.

For more clarity, the following points can be summarised as follows:

- a) the recommendation to accept vaccinated animals into an officially free country or zone where vaccination is not practised in the WOAHS standard puts the burden on the importing country to carry out a risk assessment to justify not adhering to the WOAHS standard, because of the increased costs in surveillance involved. This not acceptable, especially considering the constantly growing requirements for maintenance of the WOAHS official free status;**
- b) there would be significant additional burden (administrative, diagnostic and logistical) on the importing country or zone to maintain its official free status for FMD towards WOAHS, for little apparent benefit. In addition, the introduction of vaccinated animals would also have an impact for exports as this would put additional requirements for livestock management and surveillance in order to justify its mixed FMD health status (i.e. both populations of non-vaccinated and vaccinated animals exist in the same country or zone);**
- c) the fact that additional risk mitigating measures would be needed (i.e. differentiated surveillance schemes) recognises, *de facto*, that this practice increases the risk compared to the current procedure. The EU does not support this increase of risk.**

The EU therefore reiterates its comment and asks that WOAHS standards do not allow the importation of vaccinated animals into a country or zone officially free of FMD where vaccination is not practised.

- 5) ~~4)~~ measures to prevent the introduction of the infection have been in place: in particular, the importations or movements of commodities into the country or zone have been carried out in accordance with this chapter and other

relevant chapters of the *Terrestrial Code*. Introduction of vaccinated animals have only been carried out in accordance with Articles 8.8.11. or 8.8.11bis; 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 animals introduced for direct slaughter in accordance with Articles 8.8.8., 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. For 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 the OIE in accordance with the requirements in Chapter 1.1.

A country or zone free from FMD may maintain its free status despite an incursion of potentially infected African buffaloes provided that the surveillance programme substantiates the absence of transmission of FMDV.

Provided the conditions of points 1 to 4.3 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 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 4.4.3.6. 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 the OIE.

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;

- e) ~~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;~~
 - e) ~~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 the OIE 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

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 the OIE as such, wishes to change its status to FMD free country or zone free from FMD where vaccination is not practised, it should notify the OIE in advance of the intended date of cessation of vaccination and apply for the new status within 24 months of the cessation. The status of this country or zone remains unchanged until compliance with Article 8.8.2. is approved by the OIE. If the dossier application for the new status is not provided within 24 months of the cessation or the compliance is not approved by the OIE, then the status of the country or zone as being free with vaccination 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.

EU comment

For reasons of clarity and consistency, the EU suggests amending the paragraph above as follows:

“... then the status of the country or zone as being free from FMD where vaccination is practised with vaccination will be 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 the OIE as such, wishes to change its status to country or zone free from FMD where vaccination is practised, it should provide the OIE with an application and a plan following the structure of the Questionnaire of Article 1.6.6., indicating the intended date of beginning of vaccination. The status as country or zone free from FMD where vaccination is not practised of this country or zone remains unchanged until the application and plan are approved by the OIE. As soon as recognised free 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.

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 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 4.34. and 4.45. should be followed. Susceptible animals in the FMD free compartment should be separated from any other susceptible animals by the effective application of an effective biosecurity plan management system.

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;~~
 - ab) no evidence of infection with FMDV has been found ~~detected~~ occurred during the past 12 months;
 - eb) vaccination against FMD is prohibited;
 - ec) no animal vaccinated against FMD within the past 12 months is in the compartment;
 - ed) animals, semen, embryos and animal products may only enter the compartment in accordance with relevant articles in this chapter;
 - fe) documented evidence shows that surveillance in accordance with Articles 8.8.40. to 8.8.42. is in operation;
 - gf) an animal identification and traceability system in accordance with Chapters 4.21. and 4.32. 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 4.34. and 4.45. 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;~~
 - ab) no evidence of ~~infection with infection~~ or transmission of FMDV has ~~been found~~ occurred during the past 12 months;
 - be) 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;
 - cd) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;
 - de) 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;
 - ef) an *animal identification* and *traceability* system in accordance with Chapters 4.12. and 4.23. 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(c), 2(e) and 2(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 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 the OIE, ~~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 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 the OIE.

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, 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 while the free status of the rest of the country or zone is not affected. If 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 the OIE. 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 the OIE.

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 the OIE, in addition to the requirements of Article 4.4.7. in support of the application, documented evidence that:

- 1) on suspicion, a strict standstill has been imposed on the suspected establishments and in the country or zone animal movement control has been imposed and effective controls on the movement of other commodities mentioned in this chapter are in place;
- 2) on confirmation, an additional standstill of susceptible animals has been imposed in the entire containment zone and the movement controls described in point 1 have been reinforced;
- 3) the definitive boundaries of the containment zone have been established after an epidemiological investigation (trace-back, trace forward) has demonstrated that the outbreaks are epidemiologically related and limited in number and geographic distribution;
- 4) investigations into the likely source of the outbreaks have been carried out;
- 5) a stamping-out policy, with or without the use of emergency vaccination, has been applied;
- 6) no new cases have been found in the containment zone within a minimum of two incubation periods as defined in Article 8.8.1. after the application of a stamping-out policy to the last detected case;
- 7) the susceptible domestic and captive wild animal populations within the containment zone are clearly identified as belonging to the containment zone;

- 48) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in place in the *containment zone* and in the rest of the country or zone;
- 59) measures that prevent the spread of FMDV to the rest of the country or zone, taking into consideration physical and geographical barriers, are in place.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of the these areas outside the *containment zone* may be reinstated irrespective of the provisions of Article 8.8.7., once the *containment zone* has been approved by the OIE as complying with points 1 to 59 above. ~~Commodities from susceptible animals for international trade should be identified as to their origin, either from inside or outside the *containment zone*.~~

In the event of recurrence of *infection* with FMDV in unvaccinated animals or FMDV transmission of FMDV in vaccinated animals in the *containment zone*, established in accordance with point 4(a) of Article 4.4.7., the approval of the *containment zone* is withdrawn and the FMD status of the whole country or zone is suspended until the relevant requirements of Article 8.8.7. are fulfilled.

In the event of occurrence of *infection* with FMDV in unvaccinated animals or transmission of FMDV in vaccinated animals in the outer zone of a *containment zone* established in accordance with point 4(ab) of Article 4.4.7., the approval of the *containment zone* is withdrawn and the status of the whole country or zone is suspended until the relevant requirements of Article 8.8.7. are fulfilled.

The recovery of the FMD free status of the *containment zone* should be achieved within 12-18-24 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 1.116-6., has been accepted by the OIE.

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 1.116.6, has been accepted by the OIE.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.8.3. applies.

- 3) When a case of infection with FMDV 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 Articles 8.8.40. as appropriate; or
 - b) 12 months after the detection of the last *case* where a *stamping-out policy* is not applied, but where emergency *vaccination* and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins 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 the OIE.

Where 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 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 *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the infected zone;
- 6) *vehicles* and the *slaughterhouse/abattoir* ~~should be~~ are subjected to thorough cleansing and *disinfection* immediately after use.

The animals should have been subjected to ante- and post-mortem inspection within 24 hours before and after *slaughter* with no evidence of FMD, and the *meat* derived from them treated in accordance with point 2 of Article 8.8.22. or Article 8.8.23. Other products obtained from the animals and any products coming into contact with them should be treated in accordance with Articles 8.8.31. to 8.8.38. in order to destroy any FMDV potentially present.

Article 8.8.9.

Direct transfer of FMD susceptible animals from a containment zone for slaughter in a free zone (whether vaccination is practised or not)

~~In order not to jeopardise the status of a free zone, FMD susceptible animals should only leave the containment zone if transported directly to for slaughter in the nearest designated *slaughterhouse/abattoir* under the following conditions:~~

- 1) ~~the containment zone has been officially established in accordance with the requirements in Article 8.8.6.;~~
- 2) ~~the animals should be are transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;~~
- 3) ~~such an *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the *containment zone*;~~
- 4) ~~*vehicles* and the *slaughterhouse/abattoir* should be are subjected to thorough cleansing and *disinfection* immediately after use.~~

~~The animals should have been subjected to ante- and post-mortem inspection within 24 hours before and after *slaughter* with no evidence of FMD and the *meat* derived from them treated in accordance with point 2 of Article 8.8.22. or Article 8.8.23. Other products obtained from the animals and any products coming into contact with them should be treated in accordance with Articles 8.8.31. to 8.8.38. in order to destroy any FMDV potentially present.~~

Article 8.8.9bis.

Direct transfer of FMD vaccinated animals from a free zone free from FMD where vaccination is practised or not for slaughter in a free zone where vaccination is not practised

EU comment

With reference to the EU comment on Article 8.8.2. above, the EU suggests clarifying in the sentence above that this relates to transfer of animals within the same country, and not to an importation (i.e. international trade), by inserting the words “within a country” after “Direct transfer”.

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

The EU queries what is meant by “domestic”, and whether that term is defined. Indeed, that term may give rise to problems of interpretation, which is why it is no longer used in EU legislation. And it is not clear whether the term “ruminants” includes camels.

This comment is valid also for Articles 8.8.12.

Furthermore, we note that Article 8.8.21. refers to “ruminants and pigs”; does this mean that wild ruminants and pigs are included in the scope?

Finally, Article 8.8.22ter. refers to “domestic small ruminants”, which should preferably also be defined to avoid possible confusion.

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.

EU comment

Same as in point 5, the words “place of shipment” in point 6 above should be italicised, in order to refer to the glossary definition.

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) 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) 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 23(a) and 23(b) above;
- 5) 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;

65) 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 4.56. and 4.67.;
 - 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~~ 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 4.56. and 4.67.;
 - 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

EU comment

Reference is made to the EU comment on Article 8.8.11. above, in relation to the term “ruminants and pigs”.

For fresh meat and meat products of ruminants and pigs

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

- 1) have been kept in the ~~FMD free~~ country or zone or compartment free from FMD where *vaccination* is practised, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections ~~for FMD~~ with favourable results;
- 3) for ruminants the head, including the pharynx, tongue and associated lymph nodes, has been excluded from the shipment.

Article 8.8.22.

Recommendations for importation 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 cattle ~~cattle~~ 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 cattle~~ **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 6.23., 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 6.23., 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 small ruminants (excluding feet, head and viscera) from FMD infected countries or zones where an official control programme exists

EU comment

Reference is made to the EU comment on Article 8.8.11. above, in relation to the term “domestic small ruminants”.

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 (other than those 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~~

EU comment

The EU suggests deleting the words “for use in animal feeding or”, as it does not look exempted from risks to trade milk from vaccinated animals to be used as feed.

~~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 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 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 from FMD-free countries or zones or compartments free from FMD, where whether vaccination either is practised or is not practised

EU comment

In line with the change proposed in Article 8.8.37, the EU suggests replacing the word “wildlife” with “animals” in Article 8.8.29. and 8.8.30. Indeed, skins and trophies of domestic animals are commonly produced and would not require any different treatment.

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 from ~~FMD-infected~~ countries or zones infected with FMDV

For skins and trophies derived from FMD susceptible wildlife

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of FMDV in accordance with the procedures in Article 8.8.37.

Article 8.8.31.

Procedures for the inactivation of FMDV in meat and meat products

For the inactivation of FMDV present in *meat* and *meat products*, one of the following procedures should be used:

1. Canning

Meat and *meat products* are subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate FMDV.

2. Thorough cooking

Meat, previously deboned and defatted, and *meat products* are subjected to a heat treatment that results in a core temperature of at least 70°C for a minimum of 30 minutes.

After cooking, they should be packed and handled in such a way they are not exposed to a source of FMDV.

3. Drying after salting

When *rigor mortis* is complete, the *meat* is deboned, treated with salt (NaCl) and 'completely dried'. It should not deteriorate at ambient temperature.

'Completely dried' is defined as a moisture protein ratio that is not greater than 2.25:1 or a water activity (Aw) that is not greater than 0.85.

Article 8.8.31bis.

Procedures for the inactivation of FMDV in swill

For the inactivation of FMDV in swill, one of the following procedures should be used:

- 1) the swill is maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or
- 2) the swill is maintained at a temperature of at least 121°C for at least ten minutes at an absolute pressure of 3 bar; or
- 3) the swill is subjected to an equivalent treatment that has been demonstrated to inactivate FMDV.

Article 8.8.32.

Procedures for the inactivation of FMDV in wool and hair

For the inactivation of FMDV present in wool and hair for industrial use, one of the following procedures should be used:

- 1) for wool, industrial washing, which consists of the immersion ~~of the wool~~ in a series of baths of water, soap and sodium hydroxide (~~soda~~ NaOH) or potassium hydroxide (~~potash~~ KOH);

- 2) chemical depilation by means of slaked lime or sodium sulphide;
- 3) fumigation with formaldehyde in a hermetically sealed chamber for at least 24 hours;
- 4) for wool, industrial scouring which consists of the immersion of ~~wool~~ in a water-soluble detergent held at 60-70°C;
- 5) for wool, storage of ~~wool~~ at 4°C for four months, 18°C for four weeks or 37°C for eight days.

Article 8.8.33.

Procedures for the inactivation of FMDV in bristles

For the inactivation of FMDV present in bristles for industrial use, one of the following procedures should be used:

- 1) boiling for at least one hour; or
- 2) immersion for at least 24 hours in a 1% aqueous solution of formaldehyde.

Article 8.8.34.

Procedures for the inactivation of FMDV in raw hides and skins

For the inactivation of FMDV present in raw hides and skins for industrial use, the following procedure should be used: treatment for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na₂CO₃).

Article 8.8.35.

Procedures for the inactivation of FMDV in milk ~~and cream for human consumption~~

For the inactivation of FMDV present in ~~milk and cream for human consumption~~, one of the following procedures should be used:

- ~~1) a process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]); or~~
- ~~2) if the milk has a pH less than 7.0, a process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]); or~~
- ~~3) if the milk has a pH of 7.0 or greater, the HTST process applied twice.~~

~~Article 8.8.36.~~

~~Procedures for the inactivation of FMDV in milk for animal consumption~~

~~For the inactivation of FMDV present in milk for animal consumption, one of the following procedures should be used:~~

- ~~1) the HTST process applied twice; or~~
- ~~2) HTST combined with another physical treatment, e.g., maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with desiccation; or~~
- ~~3) UHT combined with another physical treatment referred to in point 2 above.~~

Article 8.8.37.

Procedures for the inactivation of FMDV in skins and trophies from susceptible wildlife 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 (Na₂CO₃) 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 (Na₂CO₃).

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% Na₂HPO₄ and 2.8% Na₃PO₄ (weight/weight/weight), either dry or as a saturated brine (a_w< 0.80), and kept at a temperature of greater than 12°C during this entire period.

Article 8.8.39.

OIE endorsed official control programme for FMD

~~The overall objective of an OIE endorsed official control programme for FMD is for countries to progressively improve the situation and eventually attain FMD free status. The official control programme should be applicable to the entire country even if certain measures are directed towards defined subpopulations only.~~

~~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 the OIE, 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 outbreaks;
 - 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;
 - e) 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;
 - e) 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 an OIE 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 the OIE of their *official control programme* for FMD, in accordance with Article 8.8.39. *Surveillance* aimed at identifying disease and FMDV infection with, or transmission of, FMDV should cover domestic and, where appropriate, *wildlife* species as indicated in point 2 of Article 8.8.1.

1. Early detection

A *surveillance* system in accordance with Chapter 1.4. should be the responsibility of the *Veterinary Authority* and should provide an *early warning system* to report suspected *cases* throughout the entire production, marketing and processing chain. A procedure should be in place for the rapid collection and transport of samples to a *laboratory* for FMD diagnosis. This requires that sampling kits and other equipment be available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to seek assistance from a team with expertise in FMD diagnosis and control.

2. Demonstration of freedom

The impact and epidemiology of FMD widely differ in different regions of the world and therefore it is inappropriate to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from FMD in the country, *zone* or *compartment* at an acceptable level of confidence should be adapted to the local situation. For example, the approach to demonstrating freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMDV should differ significantly from an approach designed to demonstrate freedom from FMD in a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*.

Surveillance for FMD should be in the form of a continuing programme. Programmes to demonstrate no evidence of *infection with FMDV* and transmission of FMDV should be carefully designed and implemented to avoid producing results that are insufficient to be accepted by the OIE or trading partners, or being excessively costly and logistically complicated.

The strategy and design of the *surveillance* programme will depend on the historical epidemiological circumstances including whether ~~or not~~ *vaccination* has been used practised or not.

A Member Country wishing to substantiate FMD freedom where *vaccination* is not practised should demonstrate no evidence of *infection with FMDV 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 *populations*. Within vaccinated *populations*, 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. OIE endorsed official control programme

Surveillance strategies employed in support of an OIE endorsed *official control programme* should demonstrate evidence of the effectiveness of any *vaccination* used and of the ability to rapidly detect all FMD *outbreaks*.

Therefore, considerable latitude is available to Member Countries to design and implement *surveillance* to establish that the whole territory or part of it is free from *FMDV infection with*, and transmission of FMDV and to understand the epidemiology of FMD as part of the *official control programme*.

The Member Country should submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors, including the role of *wildlife*, if appropriate, are identified and managed. This should include provision of scientifically based supporting data.

4. Surveillance strategies

The strategy employed to establish the prevalence of *infection with FMDV* or to substantiate freedom from *FMDV infection with*, or transmission of FMDV may be based on randomised or targeted clinical investigation or sampling at an acceptable level of statistical confidence, as described in Articles 1.4.4. and 1.4.5. If an increased likelihood of *infection* in particular localities or species can be identified, targeted sampling may be appropriate. Clinical inspection may be targeted at particular species likely to exhibit clear clinical signs (e.g., bovines cattle cattle 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 positives ~~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 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 practised, 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. Hunting, capture and non-invasive sampling and observation methods can 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 an OIE Reference Laboratory.

Virological *surveillance* aims to:

- a) confirm clinically suspected *cases*;
- b) follow up positive serological results;
- c) characterise isolates for epidemiological studies and vaccine matching;
- d) monitor *populations* 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 *populations*, ~~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 for optimal sensitivity one should select an antigen or virus closely related to the field strain expected.

~~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 cattle cattle 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 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~~ 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

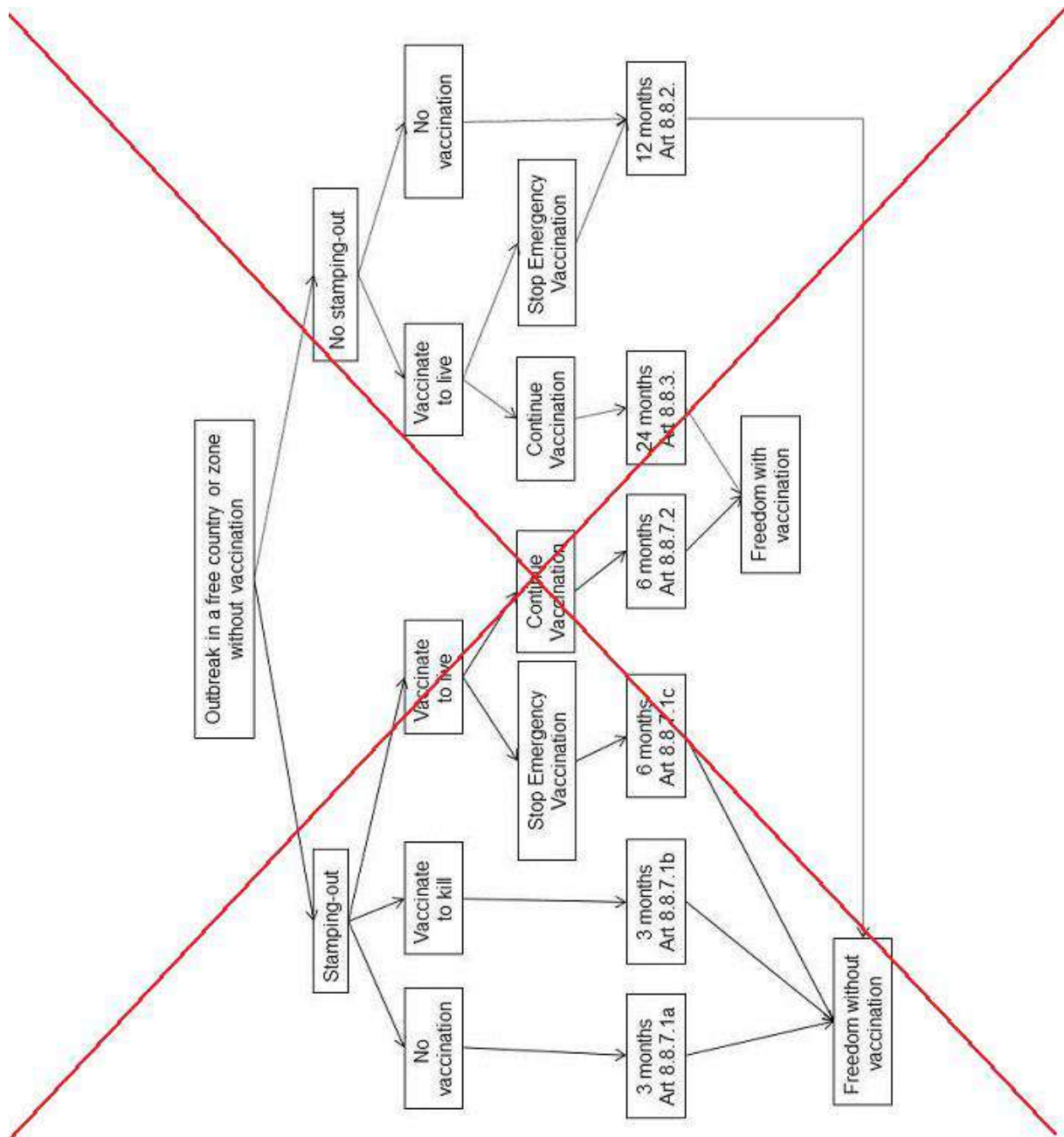
If transmission is demonstrated, an *outbreak* is declared.

~~It is difficult to determine~~ 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.

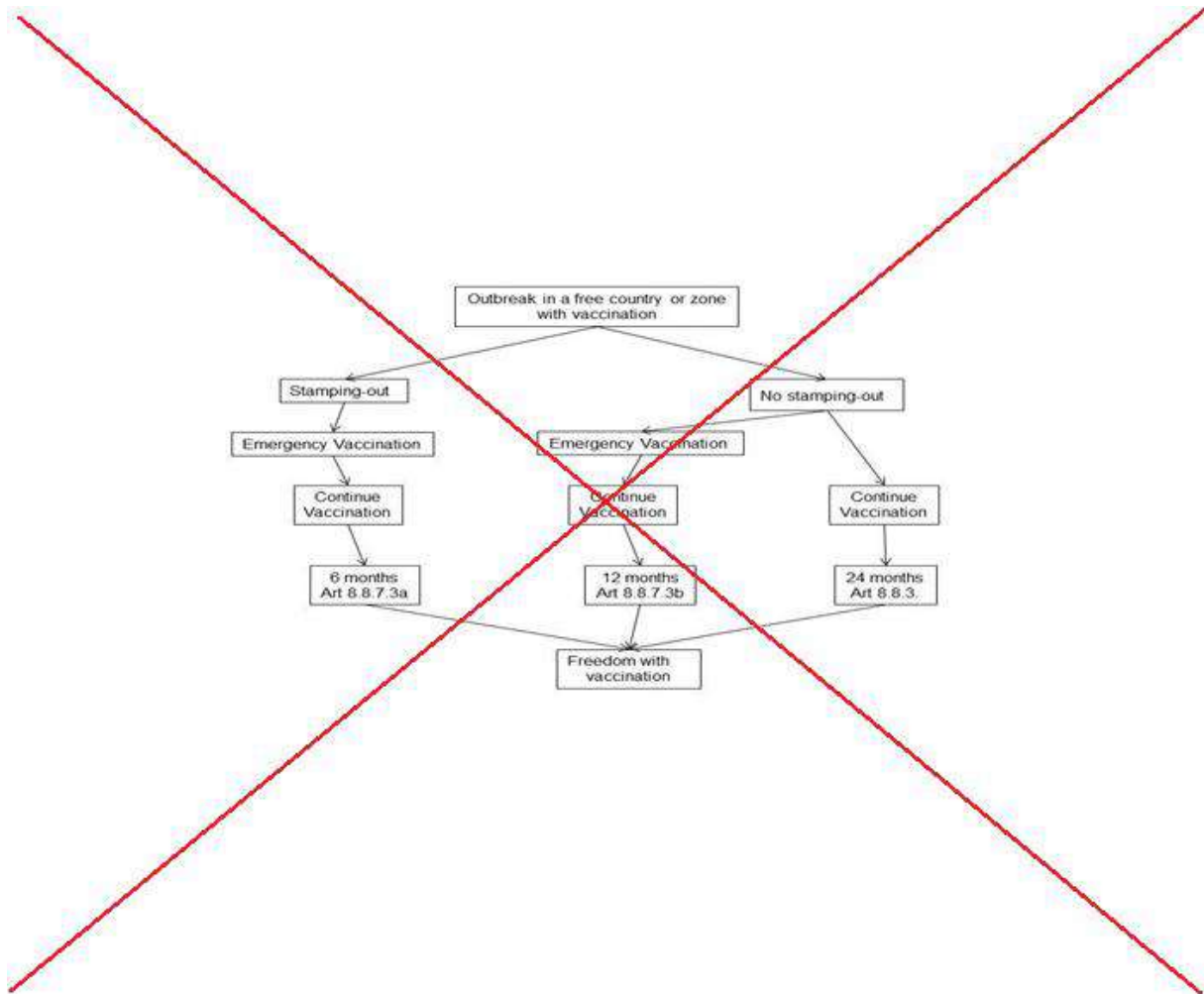
Abbreviations and acronyms:	
ELISA	Enzyme-linked immunosorbent assay
VNT	Virus neutralisation test
NSP	Nonstructural protein(s) of foot and mouth disease virus (FMDV)
3ABC	NSP antibody test
SP	Structural protein of foot and mouth disease virus

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



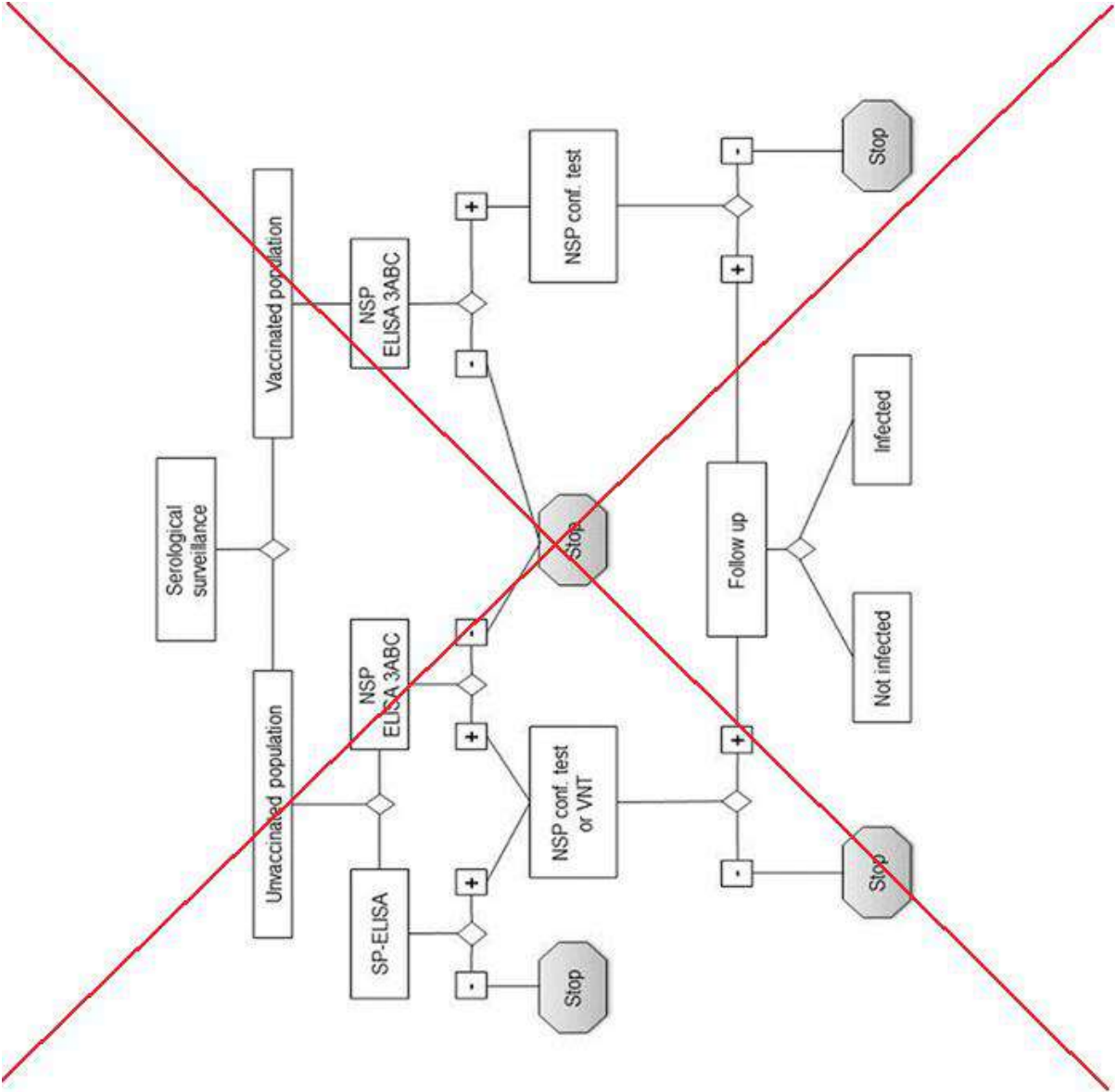
Waiting periods are minima depending upon outcome of surveillance specified in respective articles. If there are multiple waiting periods because of different control measures, the longest applies.

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



UNCG

CHAPTER 8.14.

INFECTION WITH RABIES VIRUS

EU comment

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

However, the EU considers that it cannot support the proposed changes to this chapter as presented.

Taking into account its specific context and in order to remain consistent with the risk assessment carried out by the European Food Safety Authority (https://www.efsa.europa.eu/sites/default/files/2022-05/efs2_7350.pdf), the EU can only continue to oppose the changes proposed by WOAAH in Article 8.14.6bis, to reduce the waiting period after the antibody titration test and prior to the international movement of dogs, from the current three months to 30 days, even though it is well aware of the provisions offered to members wishing to apply more stringent sanitary measures.

[...]

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:

Annex Z (contd)

- 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 interrupt the rabies virus transmission cycle.
- b) Vaccination campaigns should be conducted recurrently (usually annually). More regular 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 should be provided to dog owners as proof of vaccination.
 - c) Vaccination coverage should be monitored at the smallest administrative level possible.
-

CHAPTER 8.15.

INFECTION WITH RIFT VALLEY FEVER VIRUS

EU comment

The EU thanks the Code Commission and in general supports the proposed changes to this chapter. Comments are inserted in the text below.

Article 8.15.1.

General provisions

- 1) The aim of this chapter is to mitigate the animal and public health risks posed by Rift Valley fever (RVF) and to prevent its international spread.
- 2) For the purposes of this chapter:
 - a) 'epizootic/epidemic area' means a part of a country or zone in which an epizootic/epidemic of RVF is occurring, and which does not correspond to the definition of zone;
 - b) 'epizootic/epidemic of RVF' means a sudden and unexpected change in the distribution or increase in incidence of, or morbidity or mortality of RVF;
 - c) 'inter-epizootic/epidemic 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.
- ~~3~~2) 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* and susceptible animals with Rift Valley fever virus ~~Rift Valley fever virus~~ (RVFV).
- ~~4~~3) The following defines the occurrence of *infection* with RVFV:
 - a) RVFV, excluding vaccine strains, has been isolated and identified as such from a sample from a ~~ruminant~~ susceptible animal; or
 - b) antigen or ribonucleic acid specific to RVFV, excluding vaccine strains, has been identified in a sample from a ~~ruminant~~ susceptible animal epidemiologically linked with epidemiological links 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 to RVFV antigens which are not the consequence of *vaccination*, have been identified in a sample from a ~~ruminant~~ susceptible animal with either epidemiological links 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.

EU comment

The EU suggests replacing the word “identified” with “detected” both in points b) and c) above, for consistency with the corresponding draft Manual chapter and other chapters of the Code currently being revised.

Furthermore, taking into account the comments of the Code Commission under Item 5.5. of its September 2022 meeting report, namely that ‘infection in humans that has been acquired in a different geographical area would not be linked to infection in animals’ and to ensure alignment with the wording of point 2(b) of Article 8.15.3 and of Article 8.15.11. below, the words “to a human infected with RVFV” in points 4(b) and 4(c) of

Article 8.15.1. above could be replaced with “to an indigenous infection of a human infected 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, ~~epizootic epidemics~~ of RVF may occur following favourable climatic, and other environmental conditions and availability of susceptible ~~host animal~~ and competent *vector* populations. ~~Epizootic Epidemics~~ are separated by inter-~~epizootic epidemic~~ periods. The transition from an inter-epizootic epidemic period to an epizootic epidemic complies with point 1)(-de) of Article 1.1.3. in terms of *notification*.
- 6) For the purposes of this chapter:
- 'area' means a part of a country that experiences epizootics and inter-epizootic periods, but which does not correspond to the definition of *zone*;
 - '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;
 - '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;
 - ruminants include dromedary camels.
- 7) The historical distribution of RVF has been parts of the African continent, Madagascar, some other Indian Ocean Islands and the south-western Arabian Peninsula. However, ~~vectors, environmental and climatic factors, land-use dynamics, and animal movements may modify the temporal and spatial distribution of the *infection*.~~
- 78) When authorising 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*.
- 89) 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 health~~ status of the ruminant susceptible animal population of the *exporting country or zone*:

- hides and skins;
- wool and fibre;
- extruded dry pet food;
- 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:

- it meets the requirements for historical freedom in ~~point 1 a)~~ of Article 1.4.6.; or
- 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.

Strategies to protect from vector attacks during transport

Strategies to protect animals from *vector* attacks during transport should take into account the local ecology and potential insecticide resistance of the vectors, ~~and potential~~ Risk management measures include:

- 1) treating animals and vehicles/vessels with insect repellents and insecticides prior to and during transportation;
- 2) *loading*, transporting and *unloading* animals at times of low *vector* activity;
- 3) ensuring vehicles/vessels do not stop en route ~~during dawn or dusk, or overnight,~~ unless the animals are held behind insect-proof netting protected from vector attacks;

EU comment

The EU notes that, according to the ‘Report of the virtual meeting of the OIE ad hoc Group on Rift Valley Fever 14-18 June 2021’, the sentence ‘during dawn or dusk’ was to be removed from point 3) in Article 8.15.5. and replaced with ‘in epizootic areas’.

However, ‘in epizootic areas’ has not been added to point 3) in Article 8.15.5.

In case the Code Commission decides to add it, it should be written ‘in *epidemic areas*’ to harmonise the text with the rest of the chapter.

- 4) using historical and current information to identify lower risk ports and transport routes.

Article 8.15.7.

Recommendations for importation of susceptible animals from countries or zones free from RVF

For ruminants susceptible animals

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

1) were kept in a country or *zone* free from RVF since birth or for at least 14 days prior to shipment;

AND

2) either:

- a) were vaccinated at least 14 days prior to leaving the free country or *zone*; or
- b) did not transit through an epizooticepidemic area experiencing an epizootic during transportation to the *place of shipment*; ~~or~~
- c) ~~were protected from vector attacks when transiting through an epizootic area experiencing an epizootic.~~

Article 8.15.87.

Recommendations for importation of susceptible animals from countries or zones infected with RVFV during the inter-epizootic period

For ruminants susceptible animals

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

- 1) showed no clinical signs of RVF on the day of shipment;
- 2) met one of the following conditions:
 - a) were vaccinated against RVF at least 14 days prior to shipment ~~with a modified live virus vaccine~~; or
 - b) were held for at least 14 days prior to shipment in a *vector-protected quarantine station*, which is located in an area of demonstrated low *vector* activity. During this period the animals showed no clinical sign of RVF;

AND

3) either:

- a) did not 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 8.15.1098.

Recommendations for importation of semen and *in vivo* derived embryos of susceptible animals from countries or zones ~~not free from~~ infected with RVFV

For semen and *in vivo* derived embryos of ruminants susceptible animals

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

- 1) showed no clinical signs of RVF within the period from 14 days prior to and 14 days following collection of the semen or embryos;

AND

- 2) either:
 - a) were vaccinated against RVF at least 14 days prior to collection; or
 - b) were subjected to a serological test demonstrated to be seropositive on the day of collection, with positive result; or
 - c) were subjected to a serological test on two occasions with negative results on the day of collection and 14 days after collection testing of paired samples has demonstrated that seroconversion did not occur within 14 days of between semen or embryo collection and 14 days after.

Article 8.15.1109.

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:
 - 1a) ruminants which susceptible animals that showed no clinical signs of RVF within 24 hours before *slaughter*;
 - 2b) ruminants which susceptible animals that were slaughtered in an approved *slaughterhouse/abattoir* and were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3. with favourable results;
 - 3c) carcasses which that were submitted to maturation at a temperature above 2°C for a minimum period of 24 hours following *slaughter*;
- 2) the necessary precautions were taken to avoid contact of the products 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 8.15.12110.

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 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 mosquito 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 RVE, 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 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 and the decision-making process for the prevention and control of RVF.

CHAPTER 10.9.

INFECTION WITH NEWCASTLE DISEASE VIRUS

Article 10.9.1.

EU comment

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

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) This chapter deals with NDV *infection of poultry* as defined in point 2 above in the presence or absence of clinical signs.
- 5) 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) 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) 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*.

[...]

CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

EU comment

The EU thanks the Code Commission for the latest version of the revised Chapter 11.4. on bovine spongiform encephalopathy and for having reintroduced paragraphs a) and b) on the feed ban in point 1 of Article 11.4.3., as requested in the EU comments provided in May 2022.

The EU requests the Code Commission to address the following comments and suggestions.

The EU can accept that for the purpose of the Code the occurrence of a case of BSE is restricted to C-type BSE, as laid down in point 3 of Article 11.4.1. However, the EU considers that the addition of the word “classical” in front of the expression “BSE agents” has introduced some confusion. The EU is of the opinion that whenever related to recycling, all BSE agents should 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. and as acknowledged in the expression “risk of BSE agents being recycled within the bovine population” which is used throughout the chapter. Drafting suggestions are proposed in the text below where necessary.

The EU considers that the proposed modification of Article 11.4.10. on the recommendation for importation of meat and meat products from a country with negligible or controlled risk is unacceptable, as it introduces a fundamental flaw in the logic of the draft chapter, while significantly reducing the difference of safety insurance level provided by the controlled BSE risk status on the one hand and negligible BSE risk status on the other hand. Only the commodities derived from animals born after the date from which the risk of BSE agents being recycled within the bovine population has been demonstrated to be negligible should be exempted from the mitigation measures currently applicable. The same reasoning applies to Article 11.4.13. concerning the recommendations for importation of blood and blood products derived from cattle.

The EU does not support the addition of the new point 2) in Article 11.4.17. on the procedures for reduction of BSE infectivity in bovine protein meal, as no condition is laid down to frame the demonstration of efficacy of alternative procedures. As proposed, this additional option presents serious potential risks, particularly when linked to the recently added point 2) of Article 11.4.12. on the recommendations for importation of bovine protein meal from a country posing a negligible BSE risk.

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 BSE) and atypical strains (H- and L-type BSE). 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 cattle-a bovine have 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 there is no evidence that it plays a significant role in the epidemiology of BSE.

EU comment

There is no question about the fact that atypical BSE also has a potential for recycling, as actually acknowledged in the expression “risk of BSE agents being recycled within the bovine population”, which is used throughout the chapter. The real issue is about the risk. The EU therefore suggests that the last sentence is clarified and reads as follows:

“A bovine has been experimentally infected by the oral route with a low molecular weight type of atypical BSE (L-type BSE) and the potential risk for of recycling of atypical BSE cannot can therefore not be ruled out, but even though 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) The occurrence of a BSE case of BSE is defined by the immunohistochemical (IHC) or immunochemical detection of C-type BSE PrP^{BSE}PrP^{Sc} in brain tissue of a bovid bovine of the species *Bos taurus* or *Bos indicus*, with 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) —, ‘Cattle bovine’ 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) 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 the OIE of risk status for bovine spongiform encephalopathy” that evaluates the likelihood risk of BSE agents 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) Cattle bovines;
- ii) Ruminant-derived protein meal/protein meal;
- iii) Feed (except packaged and labelled pet food not intended for pets) that contains ruminant-derived protein meal/protein meal;
- iv) Fertilizers that contain ruminant-derived protein meal/protein meal;
- v) Any other commodity that either is or could be contaminated by commodities listed in Article 11.4.14.

b) Exposure assessment

~~An~~The exposure assessment evaluates the likelihood of cattle bovines being exposed to classical BSE agents during the preceding eight years, either through imported *commodities* or as a result of the presence of classical BSE agents ~~in~~ within the indigenous cattle bovine population of the country, zone or compartment.

EU comment

In line with the general comment on the use of the expressions “the classical BSE agent” and “BSE agents”, and considering that the exposure assessment includes rendering and feeding practices which have a direct link to recycling, the EU suggests that the sentence reads as follows:

“The exposure assessment evaluates the likelihood of bovines being exposed to classical BSE agents during the preceding eight years, either through imported *commodities* or as a result of the presence of classical BSE agents within the indigenous 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;
 - ≡ 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

The consequence assessment evaluates the likelihood of cattle bovines becoming infected with following exposure to the classical BSE agents 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:

EU comment

In line with the general comment on the use of the expressions “the classical BSE agent” and “BSE agents”, and considering that the consequence assessment is about “the likely extent and duration of any subsequent recycling and amplification within the bovine population”, the EU suggests that the sentence above reads as follows:

“The consequence assessment evaluates the likelihood of bovines becoming infected following exposure to the classical BSE agents together with the likely extent and duration of any subsequent recycling and amplification within the 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-ovine** 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 classical~~ BSE agents ~~have been being~~ recycled ~~in within the **cattle-ovine** 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-ovine** population has been negligible.

EU comment

In line with the general comment on the use of the expressions “the classical BSE agent” and “BSE agents”, and considering that the risk estimation results from the exposure and consequence assessments and is about the risk of BSE agents being recycled within the bovine population”, the EU suggests that the sentence reads as follows:

“The risk estimation combines the results and conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk of ~~classical~~ BSE agents being recycled within the bovine population, and to determine the date from which the risk of BSE agents being recycled within the bovine population has been negligible.”

2) ~~the~~ The ongoing implementation of a *surveillance* programme for ~~classical~~-BSE in the **cattle-ovine** 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.**

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-ovine** population are met for ~~at least~~ at least the preceding eight years:

1) A *risk assessment* as described in Article 11.4.2. that has identified all potential risk factors associated with the **occurrence of BSE, 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 BSE agents being recycled ~~in within~~ the **cattle-ovine** 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 11.4.2018. 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-ovine 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-ovine population has continued to be negligible.
- 4) Any cases of BSE or 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 the OIE in accordance with Chapter 1.1.

~~Article 11.4.3bis.~~

Recovery of negligible BSE risk status

~~When Should an indigenous case of classical BSE is reported in an animal born within the preceding eight years occur in a country or zone recognised as having posing a negligible BSE risk for BSE, the status, of the negligible BSE risk status country or zone is suspended and the recommendations for controlled BSE risk status apply, pending. The status may be recovered when the outcome of subsequent investigations confirming confirms that 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 the OIE 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

Should an indigenous case of classical BSE in an 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 the OIE 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 the OIE, the provisions of Article 11.4.3. or Article 11.4.4. apply.

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 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 is demonstrated as having that the cattle-bovines selected for export have not 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 is demonstrated as having that the~~ cattle-bovines selected for export have not 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 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 population has been demonstrated to be negligible;

OR

- 4) the fresh meat and meat products:

- a) derived from cattle not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, 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 and/or or from the vertebral column from of cattle over 30 months of age.

EU comment

The EU considers that the proposed modification of this article is not acceptable, as it introduces a fundamental flaw in the logic of the draft chapter, while significantly reducing the difference of safety insurance level provided by the controlled BSE risk status on the one hand and negligible BSE risk status on the other hand. When it comes to importation from a country with controlled risk, and in line with the provision of point 1.b) of Article 11.4.14., only the commodities derived from animals born after the date from which the risk of BSE agents being recycled within the bovine population has been demonstrated to be negligible should be exempted from the mitigation measures applicable to a country with undetermined risk. The same reasoning applies to Article 11.4.13.

Article 11.4.10. must therefore be reinstated in its previous form with the reintroduction of the deleted paragraphs from “AND EITHER: ...” to “...30 months of age”.

Article 11.4.11.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing an undetermined BSE risk

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

- 1) the cattle-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 been fed ~~protein meal~~ protein meal derived from ruminants;
- 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;
 - bb) 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;
- 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/or 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.~~ came from a country, zone or compartment posing a negligible BSE risk;

2) were 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-ovine 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 bovinecattle (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

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 are were identified through an animal identification system and 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 population has been demonstrated to be negligible;

EU comment

Following the same reasoning as for Article 11.4.10., the EU considers that the proposed modification of the point 2 of this article is not acceptable.

Article 11.4.10. must therefore be reinstated in its previous form with the reintroduction of the deleted part “after the date ... to be negligible”.

OR

23) 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

4) 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:

a1) 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, food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices or any other product containing proteins prepared using commodities listed in points 1) a) or 1) b) above of this article, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk, should not be traded.
 - 3) CattleBovine-derived protein meal/protein meal, or any commodities containing such products, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk, should not be traded.

~~These points do not apply to cattle in a country or zone with a controlled BSE risk when they are born during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.~~

Article 11.4.15.

Recommendations for importation of tallow (other than as defined in Article 11.4.1bis.) 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) ~~The~~ raw material should be reduced to a maximum particle size of 50 mm before heating-;
- 2) ~~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.

EU comment

The EU does not support the addition of the new point 2) in this article, as no condition is laid down to frame the demonstration of efficacy of alternative procedures. As proposed, this additional option presents serious potential risks, particularly when linked to the recently added point 2) of Article 11.4.12. on the recommendations for importation of bovine protein meal from a country posing a negligible BSE risk.

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) 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, 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 be 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 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 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. other common causes of recumbency has have been ruled out);
- d) those found dead (fallen stock), with an appropriate supporting clinical history (i.e. other common causes of death has have been ruled out).

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 identification and reporting of potential candidate animals 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.
-

DRAFT CHAPTER 1.8.

APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE
OF RISK STATUS FOR BOVINE SPONGIFORM
ENCEPHALOPATHY**EU comment**

The EU thanks the Code Commission for the latest version of the draft Chapter 1.8. and invites it to reconsider certain expressions to clarify the fact that, whenever related to recycling, all BSE agents should be considered and not only the classical BSE agent, since the risk of recycling of atypical BSE clearly exists as stated in point 1 of Article 11.4.1. and as acknowledged in the expression “risk of BSE agents being recycled within the bovine population” which is used throughout the Chapter 11.4.

The EU therefore suggests replacing the terms “classical BSE agents” or “the BSE agent” by the terms “BSE agents” in Articles 1.8.1. and 1.8.5. of this chapter when reference is made to the risk of recycling of BSE infectivity via rendering or feeding practices.

The EU also suggests inserting a reference to atypical BSE in point 3 of the Article 1.8.6. of this Chapter to acknowledge the fact that atypical BSE, although not compulsory reportable to WOAHP, should be adequately monitored and discriminated from classical BSE as explicitly mentioned in point 2 of Article 11.4.18. of Chapter 11.4.

Drafting suggestions are proposed in the text below where necessary.

Article 1.8.1.

Guidelines

In accordance with Article 11.4.2., the bovine spongiform encephalopathy (BSE) risk of the cattle (*Bos indicus* and *Bos taurus*) population of a country or zone is determined on the basis of a risk assessment that evaluates the risk of **classical** BSE agents (**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**.

EU comment

In line with the general comment when reference is made to the risk of recycling, the EU suggests that the sentence reads as follows:

“In accordance with Article 11.4.2., the bovine spongiform encephalopathy (BSE) risk of a country or zone is determined on the basis of a risk assessment that evaluates the risk of ~~classical~~ BSE agents being recycled within the bovine 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.”

In this chapter, “BSE” refers to both classical and atypical forms, unless specified otherwise.

For the purposes of this chapter, ‘BSE case’ means the occurrence of classical BSE, as 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 OIE Member Countries in support of their application for official recognition of BSE risk status in accordance with Chapter 11.4. of the *Terrestrial Code*. The structure of the dossier should follow guidelines provided in the “Standard Operating Procedure for official recognition of disease status and for the endorsement of national official control programmes of Member Countries” (available on the OIE website).

Each element of the core document of the dossier provided to the OIE, should be clearly and concisely addressed, with an explanation, where relevant, of how each one complies with the provisions of the *Terrestrial Code* for the BSE risk status for which the Member is applying. The rationale leading to the conclusions reached for each section needs to be clearly explained and, as appropriate, figures, tables and maps should be provided. The core document of the dossier should include the following sections:

- The history of occurrence and management of BSE cases in the country or zone (Article 1.8.2.)
- Legislation (Article 1.8.3.)
- Veterinary system (Article 1.8.4.)
- BSE risk assessment (Article 1.8.5.)
- BSE surveillance (Article 1.8.6.).

The terminology defined in the *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in the dossier. The dossier and all of its annexes should be provided in one of the OIE official languages.

Article 1.8.2.

History of occurrence and management of BSE cases in the country or zone

Describe the history of occurrence and management of BSE cases by providing the following documentary evidence:

- 1) If a case of BSE 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) OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway, and highlight the results relevant to BSE.
- 3) Describe how the *Veterinary Services* supervise, control, enforce and monitor all BSE-related activities.
- 4) Provide a description of the involvement and the participation of industry; producers, farmers, herdsmen, 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 Authorities.

Article 1.8.5.

BSE risk assessment

1-) Entry assessment

As described in Article 11.4.2., an entry assessment evaluates the likelihood that the classical BSE agent has been introduced into the country or *zone* through the importation of *commodities*.

For the purposes of undertaking an entry assessment, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.).

The *commodities* to be considered in the entry assessment are:

- Cattle bovines;
- Ruminant-derived protein meal/protein meal;
- Feed (not intended for pet except packaged and labelled pet food) that contains ruminant-derived protein meal/protein meal;
- Fertilizers that contain ruminant-derived protein meal/protein meal;
- Any other commodity that either is or could be contaminated by commodities listed in Article 11.4.14., e.g. over 30 months old cattle carcass or half carcass from which the spinal cord and vertebral column were not removed, originating from a country, zone or compartment posing a controlled or undetermined BSE risk.

- 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

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 agents 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*.

EU comment

In line with the general comment and considering that the exposure assessment includes rendering and feeding practices which have a direct link to recycling, the EU suggests that the sentence reads as follows:

“As described in Article 11.4.2., an exposure assessment evaluates the likelihood of bovines being exposed to ~~the classical~~ BSE agents either through imported *commodities* or as a result of the presence of ~~classical~~ BSE agents within the indigenous 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., 11.4.9, 11.4.10., 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-

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-ovine 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-ovine population to the classical BSE agents, given the ongoing livestock industry practices in a country or *zone*.

EU comment

In line with the general comment and considering that the livestock industry practices include rendering and feeding practices which have a direct link to recycling, the EU suggests that the second sentence reads as follows:

“The intention here is to evaluate the likelihood and extent of exposure of the bovine population to the classical BSE agents, given the ongoing livestock industry practices in a country or *zone*.”

- i) Demographics of the cattle-ovine population and production and farming systems:-

Describe the composition of the cattle-ovine population and how the cattle-ovine industry is structured in the country or *zone*, considering the types of production systems, including all that apply, such as dairy, beef rearing, feedlot, fattening and beef finishing, and the farming systems, such as intensive, extensive, semi-intensive, transhumant, pastoral, 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 fertilizers containing ruminant-derived ~~protein meal~~ protein meal, composted materials derived from fallen stock (i.e. cattle-ovines 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 are applied to land where cattle-ovines graze or where forage is harvested for feeding to cattle-ovines. Where such fertilizers or composted materials are used, provide information on the extent and frequency of use.

Describe, for mixed-species farms that include ruminants, the number and size of such farms and whether or not there are any practices in place to ensure that ruminants are not likely to be fed with *feed* meant for non-ruminant species or that ruminant *feed* is not likely to be cross-contaminated with *feed* intended for non-ruminants that may contain rendered products of ruminant origin.

- iii) Slaughtering and waste management practices:-

Describe the practices for fallen stock, including cattle-ovines 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-ovines 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.

EU comment

In line with the general comment and considering that rendering practices have a direct link to recycling, the EU suggests that the sentence reads as follows:

“The intention here is to evaluate the likelihood and extent of exposure of the bovine population to ~~classical~~ BSE agents, given the ongoing livestock industry practices in a country or zone.”

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 Authorities*.

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.

EU comment

In line with the general comment and considering that rendered products have a direct link to recycling, the EU suggests that the sentence reads as follows:

“Where rendered products are used as ingredients in the production of animal *feed* the exposure of bovines to classical BSE agents may arise as a result of the use of rendered products containing materials of ruminant origin as ingredients in bovine *feed* or as a result of 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 Authorities.

- 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 classical or atypical BSE agents during the preceding eight years negligible or non-negligible?

EU comment

In line with the general comment and considering that rendered products have a direct link to recycling, the EU suggests that the sentence reads as follows:

“Given the livestock industry practices described above, is the likelihood that the bovine population has been exposed to classical BSE agents 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-

For those countries that have reported classical BSE cases in indigenous cattle-bovines, it is apparent that their historic livestock industry practices did not prevent the recycling of the 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.

EU comment:

In line with the general comments when reference is made to the risk of recycling, the EU suggests that the first sentence reads as follows:

“For those countries that have reported BSE cases in indigenous bovines, it is apparent that their historic livestock industry practices did not prevent the recycling of the BSE agents within their bovine populations.”

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-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-compliances) such as recalls, destruction and monetary penalties.

Provide information on the ongoing results of the official inspection programme for each of the preceding eight years, using tables as appropriate:

- planned *versus* actual delivery inspections at rendering facilities, *feed* mills, farms, etc., with an explanation of any significant variance-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-compliances) that were likely to have led to cattle-bovines being exposed to *feed* contaminated with ruminant material (excluding those listed in Article 11.4.1bis) 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 classical or atypical BSE negligible or non-negligible?

EU comment

In line with the general comment and considering that the exposure assessment includes rendering and feeding practices which have a direct link to recycling, the EU suggests that the sentence reads as follows:

“Given the evaluation of BSE-specific risk mitigation measures and their enforcement as described above, is the likelihood that, during the preceding eight years, the bovine population has been exposed to classical BSE agents negligible or non-negligible?”

- Clearly and concisely describe the rationale leading to the conclusion reached.
- Where the likelihood estimate is negligible, proceed to *Section 4) Risk estimation*.
- Where the likelihood estimate is non-negligible, proceed to *Section 3) Consequence assessment*.

3-) Consequence assessment

~~While uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated feed, it is reasonable to assume for the purposes of a consequence assessment, that the likelihood of cattle becoming infected would be similar to 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 agents (classical or atypical) together with the likely extent and duration of any subsequent recycling and amplification.

EU comment

In line with the general comment and considering that the exposure assessment includes rendering and feeding practices which have a direct link to recycling, the EU suggests that the sentence reads as follows:

“As described in Article 11.4.2., a consequence assessment evaluates the likelihood of bovines becoming infected following exposure to ~~the classical~~ BSE agents 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 classical BSE agents, to initiate a cycle of BSE infectivity within a cattle bovine population the following series of events would need to unfold:

EU comment

In line with the general comment and considering that the exposure assessment includes rendering and feeding practices which have a direct link to recycling, the EU suggests that the sentence reads as follows:

“Considering that, for all practical purposes, oral exposure to contaminated *feed* is the principal, if not the only route of transmission of ~~classical~~ BSE agents, to initiate a cycle of BSE infectivity within a 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 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 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 agents within a cattle bovine population:

EU comment

In line with the general comment when reference is made to the risk of recycling, the EU suggests that this sentence reads as follows:

“Factors to consider when evaluating the likely extent of recycling of the classical BSE agents within a 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 BSE agents at less than 12 months of age and destined to enter the breeding *herd* are much more likely to become infected and survive long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically. If these materials were rendered and subsequently contaminated cattle 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 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 agents ~~in~~ within the **cattle-ovine** population where an infraction (non-compliance) has occurred that may have led to *feed* being ~~cross-~~contaminated, it is important to consider the impact of both the livestock industry practices and the ongoing measures under a *feed* ban. Even if an infraction that arose several years ago led to susceptible young animals becoming infected, in evaluating the likelihood of recycling in future years, consideration would need to be given to the effectiveness of the *feed* ban in subsequent years or whether or not any changes to livestock industry practices may have influenced the exposure risk.

EU comment

In line with the general comment when reference is made to the risk of recycling, the EU suggests that the first sentence reads as follows:

“When evaluating the potential for the recycling of ~~the classical~~ BSE agents within the bovine population where an infraction (non-compliance) has occurred that may have led to feed being contaminated, it is important to consider the impact of both the livestock industry practices and the ongoing measures under a feed ban.”

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-ovine** population has been exposed to the **classical** BSE agents, what is the likelihood that they have been recycled within the **cattle-ovine** population during the preceding eight years?

EU comment

In line with the general comment when reference is made to the risk of recycling, the EU suggests that the sentence reads as follows:

“Where the outcome of the evaluation of livestock industry practices or the evaluation of BSE-specific mitigation measures, that include the nature and scope of the *feed* ban and its enforcement, has concluded that there was a non-negligible likelihood that the bovine population has been exposed to ~~the classical~~ BSE agents, what is the likelihood that they have been recycled within the bovine population during the preceding eight years?”

Clearly describe the rationale leading to the conclusions reached.

4-) Risk estimation

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~~ **classical** BSE agents ~~have been being~~ recycled ~~in~~ within the **cattle-ovine** population ~~through the feeding of ruminant-derived protein meal.~~

EU comment:

In line with the general comment on the use of the expression “classical BSE agents” when reference is made to the risk of recycling, the EU suggests that this sentence reads as follows:

“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 of classical BSE agents being recycled within the bovine population.”

- 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 for date 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.~~

EU comment

In line with the general comment on the use of the expression “classical BSE agents” when reference is made to the risk of recycling, the EU suggests that the first sentence reads as follows:

“Indicate the date from which it can be considered that the risk of classical BSE agents being recycled within the bovine population has been negligible.”

Article 1.8.6.

BSE surveillance

Article 11.4.18. describes the criteria that underpin a credible *surveillance* programme, together with an overview of the range and progression of clinical signs that cattle-*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 official languages of the OIE may also be provided, where they exist).
- e) Provide details on how the effectiveness of the awareness and training programmes is evaluated.
- f) Provide details of any contingency or preparedness plan for BSE.

2-) 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 "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 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 ~~laboratory~~ laboratories in the country or ~~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)?

EU comment

In line with the general comment on the need to adequately monitor and discriminate classical BSE from atypical BSE, the EU suggest that the first paragraph reads as follows:

“Describe the diagnostic protocol and tests used for processing samples for BSE and how they may have evolved over time, indicating: the primary test used; 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 (e.g. primary positive result followed by a secondary negative result); tests undertaken in case of positive result to discriminate classical BSE from atypical BSE and their results.”

- 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		

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 identification number	Age (in months) at <u>the time of reporting first detection</u>	Type of production system (dairy, beef, mixed, etc.)	Description of observed clinical signs	Clinical presentation (A, B, C or D)	Final diagnosis (if BSE, specify the strain)	For a BSE case, indicate the origin (indigenous or imported; if imported, indicate the country of birth)

Article 1.8.7.

Recovery Maintenance of BSE risk status

Following the occurrence of an indigenous case of **classical** BSE in an **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 comment**

The EU thanks the Code Commission and in general supports the proposed changes to this chapter. Comments are inserted in the text below.

As a general comment, the EU queries whether the 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

EU comment

The EU maintains that the words “and identified [as such]” are superfluous and should be deleted, in line with current established practice in the Code.

- 2) **nucleic acid specific to *T. equigenitalis* has been identified in a sample from a horse; or**

- 3) **antigen or genetic material antigen** specific to *T. equigenitalis* has been identified 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*;

EU comment

The EU suggests replacing the word “identified” with “detected” both in points 2 and 3 above, for consistency with other chapters currently being revised.

- 3) ~~genetic material specific to *T. equigenitalis* has been identified in a sample from a male horse.~~

For the purposes of the *Terrestrial Code*:

- due to long-term persistence of *T. equigenitalis* in horses, the *infective period* shall be lifelong;
- the *incubation period* in mares shall be 14 days.

Standards for diagnostic tests ~~and vaccines~~ are described in the *Terrestrial Manual*.

For the purposes of this chapter, a temporary importation refers to the introduction of a horse into a country or *zone*, ~~for competition or cultural events excluding breeding~~, for a defined period of time, not exceeding 90 days, during which the *risk* of transmission of the *infection* is mitigated through specific measures under the supervision of the *Veterinary Authority*. Temporary imported horses are re-exported at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or *zone*, should be defined in advance.

When authorising 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~~ 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*, an ~~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. 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. Horses must have not been treated with antibiotics nor subjected to antiseptic washing of genital mucous membrane for at least 21 days before the sampling;

EU comment

In point c) above, for reasons of consistency with point 3 b) of Article 12.2.6. and point 2 b ii) of Article 12.2.4 below, please amend the last sentence as follows:

“Horses ~~must~~ have not been treated with antibiotics nor subjected to antiseptic washing of genital mucous membranes for at least 21 days before the prior to sampling,”

Furthermore, we note that the corresponding Manual chapter, in terms of timing of swabbing after testing, recommends the following:

“Swabbing for *T. equigenitalis*, therefore, should not recommence until at least 7 days (systemic treatment) or 21 days (local treatment) following treatment.”

We therefore query whether it would be appropriate to further amend the sentence above (and the corresponding ones in other relevant articles of this chapter), as follows:

“Horses have not been treated with antibiotics for at least 7 days prior to sampling, nor were they subjected to antiseptic washing of genital mucous membranes for at least 21 days prior to sampling;”

- d) stored semen was subjected to a test for detection of genetic material of ~~to detect~~ *T. equigenitalis* with negative results, carried out on an aliquot of the stored semen.

EU comment

The EU queries whether point d) above is necessary. Indeed, if all horses in the herd have been tested, testing of stored semen does not seem necessary.

In addition, we query what is meant by ‘stored semen’? Does it cover fresh, chilled and frozen semen, or only frozen semen? Normally fresh semen is not stored but dispatched as soon as possible after its collection. Therefore, we assume that ‘stored semen’ does not include fresh semen and we query why only stored semen (and not fresh semen) would need to be tested. We also wonder about establishments which do not store semen (e.g. only collect and send away / sell fresh semen), would these be exempted from that testing (which would be a big advantage in terms of burden compared to those storing semen), or would they not be able to gain the free status at all?

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 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) 21 days after the last removal or the last treatment of an infected horse, all horses have been subjected to a *T. equigenitalis* test, with negative results, on three occasions, within a 12-day period with an interval of no less than three days ~~apart~~ between ~~each~~ tests;

EU comment

In point b) above, please amend the text as follows (editorial, and for consistency with other parts of the chapter):

“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* tests, with negative results, on three occasions, within a 12-day period with an interval of no less than three days between tests;”.

- c) 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 of *T. equigenitalis* with negative results in accordance with Article 12.2.8., carried out on an aliquot of the stored semen;

EU comment

Again, the EU queries why point c) above would only apply to stored semen, and not to semen from infected horses sent away, sold or destroyed right after collection.

In addition, it is not clear what is to be done with semen that tests positive, or with semen from an infected horse that tests negative (should the latter be used, or discarded?).

Some clarification would be appreciated.

- d) the introduction of horses and their germplasm into the establishment~~herd~~ is carried out in accordance with the import~~ation~~ 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 an 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 an 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, on three occasions, within a 12-day period, with an interval of no less than three days apart~~between~~ each tests, being the last test being carried out within the 30 days prior to shipment. Horses ~~must not have~~ not been treated with antibiotics for at least 21 days prior to sampling and have not been mated after sampling.

EU comment

For reasons of clarity and consistency with other articles of this chapter, the EU suggests keeping the reference to *T. equigenitalis* in point c) above, instead of referring to “the agent” (i.e. “subjected to tests for the detection of ~~the agent~~ *T. equigenitalis*, with negative results, ...).

Furthermore, for consistency with other articles of this chapter, the last sentence should be amended as follows:

“Horses have not been treated with antibiotics nor subjected to antiseptic washing of genital mucous membranes for at least 21 days prior to sampling and have not been mated after sampling.”.

Article 12.2.5.

Recommendations for temporary importation of horses

When importing on a temporary basis horses that do not comply with recommendations in Article 12.2.4. for purposes different 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, used 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

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 an 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 an 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 *T. equigenitalis* identification tests, with negative results, on three occasions, within a 12-day period with an interval of no less than three days apart between each tests, being the last test 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 days prior to sampling and have not been mated after sampling;

EU comment

For reasons of consistency, please amend point b) above as follows:

“Horses have not been treated with antibiotics nor subjected to antiseptic washing of genital mucous membranes for at least 21 days prior to sampling and have not been mated after sampling.”

OR

- 4) aliquots of fresh semen were subjected to culture and a test for detection of genetic material ~~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 semen corresponding to the ~~earliest oldest~~ and the most recent collection were subjected to culture and a test for detection of genetic material for *T. equigenitalis* with negative results.

EU comment

The EU queries whether the term “frozen semen” in point 5 above has the same meaning as “stored semen”, used in previous articles of this chapter. Or is “stored semen” a more general term, that includes fresh, chilled or frozen semen?

Should “stored semen” indeed be the same as “frozen semen”, the same term should preferably be used consistently across the chapter (with preference for “frozen semen”).

Article 12.2.7.

Recommendations for importation of oocytes or embryos of horses

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

- 1) the oocytes and embryos were collected, processed and stored in *approved* centres following the general provisions in accordance with Chapters 4.9. and 4.10.;
- 2) the donor mare showed no clinical signs of *infection* with *T. equigenitalis* on the day of collection;

AND

for the importation of embryos:

- 3) the semen used for embryo production complied with Chapters 4.6. and 4.7.

Article 12.2.8.

Surveillance

- 1) General principles of surveillance

Surveillance for *infection* with *T. equigenitalis* is relevant for *establishments* seeking to achieve and demonstrate freedom from *infection*, as well as 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;~~
- e) 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 bacteriological and molecular tests, as asymptomatic carriers play an important role in the maintenance and transmission of the *infection*.

EU comment

For clarity reasons, the paragraph above should be amended as follows:

“However, clinical *surveillance* should be complemented by ~~bacteriological and molecular tests~~ culture for *T. equigenitalis* and molecular 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 comment

The EU thanks the Code Commission and in general supports the proposed changes to this chapter. Comments are inserted in the text below.

Article 12.6.1.

General provisions

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an *infection* of domestic and *captive 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

EU comment

The EU does not support the addition of “and identified as such” in point 1 above, as it is superfluous. Agent identification is implicitly part of “EIV, [...], has been isolated”.

Indeed, identification of the agent via specific laboratory diagnostic methods is an inherent part of virus isolation. The combination of “pathogenic agent” + “isolation” is a well-established practice in the case definitions of disease specific chapters and should be maintained consistently throughout the Code.

- 2) ribonucleic 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 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 not the consequence of *vaccination*, have been detected in paired samples from a domestic or *captive wild* equid showing clinical signs or pathological lesions consistent with suggestive of 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 ~~24~~ 10 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~~ health status of the ~~equine animal~~ population of the *exporting country, zone or compartment*:

- 1) equine semen;

EU comment

As part of the ongoing revision of Chapter 4.6., it is foreseen to include horses in the scope of that chapter. The EU therefore suggests, as soon as the revised Chapter 4.6. is adopted, to include a reference to that chapter in point 1 above (e.g. “equine semen collected, processed and stored in accordance with Chapter 4.6.;”).

- 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~~ 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, providing that surveillance in accordance with Chapter 1.4. 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 days; in the case of a vaccinated domestic equid, information on its *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 days and showed no clinical sign of EI during isolation nor on the day of shipment; and

AND

3b) 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:

ai) between 14 and 90 days before shipment either with either a primary course or a booster; or

bii) 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, cCountries 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:

1i) came from an EI free country, zone or compartment free from EI, in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid horses, information on its their vaccination status should be included in the veterinary certificate;

OR

2ii) showed no clinical sign of EI in any premises in which the domestic equids horses had been resident for the 21 days prior to shipment nor on the day of shipment; and

EU comment

Both in points i) and ii) above, “21 days” should be replaced with “10 days”, in line with the other parts of this chapter.

3iii) 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 comment

The EU thanks the Code Commission and in general supports the proposed changes to this chapter. Comments are inserted in the text below.

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 *T. equi* or *B. caballi* has been identified 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 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*.~~

EU comment

For reasons of consistency with other chapters in the Code and with the corresponding Manual chapter, the EU suggests replacing the word “identified” with “detected” in both points 2 and 3 above.

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 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*;

EU comment

As part of the ongoing revision of Chapter 4.6., it is foreseen to include horses in the scope of that chapter. The EU therefore suggests, as soon as the revised Chapter 4.6. is adopted, to further revise point 6 above, by including a reference to that specific chapter (e.g. “semen collected, processed and stored in accordance with Chapter 4.6.;”).

- 7) sterile filtered horse serum;
- 8) embryos collected, processed and stored in accordance with Chapters 4.9. and 4.10.

Article 12.7.3.

Country or zone free from infection with *T. equi* and *B. caballi*

- 1) Historical freedom as described in Chapter 1.4. does not apply to infection with *T. equi* and *B. caballi*.
- 2) A country or a zone may be considered free from infection with *T. equi* and *B. caballi* when:
 - a) infection with *T. equi* and infection with *B. caballi* have been notifiable diseases in the entire country for at least the past 10 years and, in the country or zone:

EITHER:

- i) there has been no case of infection with *T. equi* and no case of infection with *B. caballi* during the past six years; and
- ii) a surveillance programme performed in accordance with Article 12.7.9. has demonstrated no evidence of infection with *T. equi* and no evidence of infection with *B. caballi* in the past six years 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) importations 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 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:

EU comment

In point b) above, in the second sentence, temporary importation should refer to horses only, not equids.

- c) a country or zone free from infection with *T. equi* and *B. caballi* adjacent to an infected country or zone should include a high-risk area in which continuous serological, agent and vector surveillance is conducted in accordance with Article 12.7.9.

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 12.7.25.

Recommendations for the importation of equines-equids

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

- 1) the animals showed no clinical signs equine piroplasmosis of infection with *T. equi* or *B. caballi* on the day of shipment, and
- 2) EITHER:
 - a) the animals were kept in a country or zone free from infection with *T. equi* and *B. caballi* since birth;

OR

 - 2) were subjected to diagnostic tests for equine piroplasmosis (*Theileriaequi* and *Babesia caballi*) with negative results during the 30 days prior to shipment;
 - b) i) were subjected to a serological or agent identification 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 12.7.36.

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 on a temporary basis does not comply with the recommendations in Article 12.7.5., Veterinary Authorities of importing countries should:

~~1-~~

1) require that:

- a) ~~the horses are the animals~~ 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) 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) equid 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

Under the direct supervision of the Veterinary Authority:

- 1) equids are kept in tick-protected facilities and transported in protected ~~vehicles-vehicles/vessels~~ according to Article 12.7.8.;
- 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

The establishment or facility should be approved by the Veterinary Authority and the means of protection should at least comprise the following:

- 1) measures to limit or eliminate habitats for competent tick vectors should be implemented for an appropriate time and over an appropriate distance in the vicinity of the area where equids are kept;

- 2) the facility and immediate surroundings of the stables and exercise or competition areas should be treated with an effective acaricide before the arrival of equids;
- 3) when transporting animals 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 owners, riders and workers who have day-to-day contact with equids, as well as veterinary paraprofessionals and diagnosticians, who should report promptly any suspicion of infection with *T. equi* and any suspicion of infection with *B. caballi* to the Veterinary Authority.

Under the responsibility of the Veterinary Authority, Member Countries should have in place:

- ≡ a formal and ongoing system for detecting and investigating cases;
- ≡ a procedure for the rapid collection and transport of samples from suspected cases of infection with *T. equi* or *B. caballi* to a laboratory for diagnosis;
- ≡ a system for recording, managing and analysing diagnostic and surveillance data.

2) Clinical surveillance

Clinical surveillance aims at detecting clinical signs by close physical examination of equids.

3) Serological and agent surveillance

An active programme of surveillance of equids to detect evidence of infection with *T. equi* and evidence of infection with *B. caballi* by serological or agent identification 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 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, animal-based surveillance strategies are preferred to detect *T. equi* or *B. caballi* transmission than entomological surveillance.

CHAPTER 14.X.

INFECTION WITH *THEILERIA LESTOQUARDI*,
T. LUWENSHUNI AND *T. UILENBERGI***EU comment**

The EU thanks the Code Commission and in general supports this proposed new chapter. A comment is inserted in the text below.

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*), 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 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

EU comment

For reasons of consistency with other chapters in the Code and with the corresponding Manual chapter, the EU suggests replacing the word “identified” with “detected” in point 2 above.

- 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~~ 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) 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 *establishment* 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 entry and at least 25 days after entry into 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 (Na₂CO₃); 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.

CHAPTER 1.3.
DISEASES, INFECTIONS AND INFESTATIONS
LISTED BY THE OIE

EU comment

The EU supports the proposed changes to this chapter.

[...]

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.

[...]

CHAPTER X.X.

INFECTION WITH MIDDLE EAST RESPIRATORY
SYNDROME CORONAVIRUS**EU comment**

The EU thanks the Code Commission and in general supports this proposed new chapter. Comments are inserted in the text below.

Article X.X.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 bear 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 causes severe disease in humans.

EU comment

The EU suggests amending the sentence above as follows:

“[...] it can causes severe disease in humans.”

Indeed, while it is acknowledged that MERS-CoV infection in humans can cause severe disease, this is not the case for all infected humans. According to the WHO fact sheet ([https://www.who.int/news-room/fact-sheets/detail/middle-east-respiratory-syndrome-coronavirus-\(mers-cov\)](https://www.who.int/news-room/fact-sheets/detail/middle-east-respiratory-syndrome-coronavirus-(mers-cov))), “The clinical spectrum of MERS-CoV infection ranges from no symptoms (asymptomatic) or mild respiratory symptoms to severe acute respiratory disease and death.”

As an alternative, the wording of the corresponding Manual chapter could also be used here (i.e. to replace “severe disease” with “significant mortality and morbidity”).

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

EU comment

The EU does not support the addition of “and identified as such” in point 1) above, as it is superfluous. Agent identification is implicitly part of “MERS-CoV has been isolated”.

Indeed, identification of the agent via specific laboratory diagnostic methods is an inherent part of virus isolation, as indicated and described in the recently adopted corresponding Manual chapter.

The combination of “pathogenic agent” + “isolation” is a well-established practice in the case definitions of disease specific chapters and should be maintained consistently throughout the Code.

- 2) ribonucleic acid specific to MERS-CoV has been ~~identified~~ detected in a samples from a dromedary camel showing clinical signs or pathological lesions suggestive of MERS-CoV or epidemiologically linked to a ~~suspected or confirmed~~ or suspected case of 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*.

UNOFFICIAL VERSION

CHAPTER X.Y.

INFECTION WITH *LEISHMANIA* SPP. (LEISHMANIOSIS)**EU comment**

The EU thanks the Code Commission and in general supports this proposed new chapter. A comment is inserted in the text below.

Article X.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 by **protozoan** parasites of the **genus *Leishmania***, family *Trypanosomatidae*, order *Kinetoplastida*.

EU comment

The EU queries why “infection with *Leishmania* spp.” is replaced with “leishmaniosis” in the sentence above. Indeed, “leishmaniosis” is not otherwise used in the text of this chapter.

Furthermore, as the definition is for the purposes of the *Terrestrial Code*, we would suggest also amending Article 1.3.9. for consistency (i.e. listing “Infection with *Leishmania* spp.” instead of “Leishmaniosis”).

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** samples from a dog or a cat; or
- 2) nucleic acid specific to *Leishmania* spp. has been detected in a sample from a dog or a cat 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 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*.

TERMINOLOGY: USE OF THE TERMS 'FETAL', 'FOETAL', 'FETUS' AND 'FOETUS'

EU comment

The EU supports the proposed changes to this 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.

TERMINOLOGY: USE OF THE TERMS 'BOVID', 'BOVIDAE', 'BOVINE' AND 'CATTLE'

EU comment
The EU supports the proposed changes to the Code presented in this annex.

USER'S GUIDE

[...]

B. Terrestrial Code content

[...]

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 each relate to the host species of the pathogenic agent: multiple species or single species of Apidae, Aves, ~~Bovidae~~ Bovinae, Equidae, Leporidae, Caprinae and Suidae. Some chapters include specific measures to prevent and control the infections of global concern. Although the OIE aims to include a chapter for each OIE listed disease, not all OIE 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.

[...]

Article 1.3.2.

The following are included within the category of ~~cattle~~ bovine diseases and *infections*:

[...]

SECTION 11. ~~BOVIDAE~~ BOVINAE

TERMINOLOGY: USE OF THE TERMS 'ENZOOTIC', 'ENDEMIC', 'EPIZOOTIC' AND 'EPIDEMIC'

EU comment

The EU supports the proposed changes to the Code presented in this annex.

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*.

CHAPTER 4.6.

GENERAL HYGIENE IN SEMEN COLLECTION,
PROCESSING AND STORAGE**EU comment**

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

Article 4.6.1.

EU comment

As a general comment on the structure of this article, the EU notes that the numbering is such that a reference to specific sections of this article will be difficult (i.e. there are three different sets of points, numbered 1 to 3, 1 to 5, and 1 to 4, without any numbering of e.g. paragraphs that would make referencing these points easier and clearer).

General provisions

The objective of this chapter is to provide recommendations that will reduce the likelihood of introduction and spread of *listed diseases* and contamination of fresh, chilled, or frozen semen of various species of donor animals with potentially pathogenic agents in a *semen collection centre*.

This chapter provides recommendations on:

- 1) procedures for the collection, processing, and storage of semen of bovine, ovine, caprine, porcine, equine, and cervid donor animals;
- 2) *biosecurity* measures for the operation of *semen collection centres*;
- 3) conditions applicable to the management and housing of semen donor animals and teasers.

This chapter provides a comprehensive framework for processes that can be applied to reduce the likelihood of transmission of *listed diseases* in semen. *Veterinary Services* play a key role in identifying, assessing, and managing disease *risk* posed by the collection, processing, and storage of semen from various species of donor animals in a *semen collection centre* and establishing appropriate measures to minimize this risk. The *Veterinary Authority* should provide the regulatory standards and/or oversight to ensure that the recommendations in this chapter, as appropriate, are complied with.

EU comment

For reasons of clarity, at the end of the first sentence of the paragraph above, please replace “in semen” with “through semen”.

Although this chapter is focused on reducing the probability of transmitting *listed diseases* through international trade of semen, the recommendations in this chapter may also be appropriately applied when semen is collected, processed, and stored for domestic distribution.

Recommendations on animal welfare are applicable to the animals kept within the *semen collection centre*, in accordance with relevant articles in Chapter 7.1. of the *Terrestrial Code*.

Recommendations regarding specific animal health requirements for donor animals to provide assurance of the absence of selected *listed diseases*, infections and infestations are found in Chapter 4.7. and other relevant disease-specific chapters.

EU comment

Please delete the word “other” at the end of the paragraph above, as Chapter 4.7. is not a disease-specific chapter.

For the purposes of the *Terrestrial Code*, the *semen collection centre* is comprised of:

- 1) animal accommodation facilities;
- 2) semen collection facilities;
- 3) semen processing facilities, including mobile laboratories;

EU comment

In the point above, it is mentioned that a semen collection centre is comprised of, amongst others, semen processing facilities, including mobile laboratories. We suggest replacing a term “mobile laboratories” with “mobile processing units”.

- 4) semen storage facilities;
- 5) administration offices.

The listed facilities may be on one location or consist of single or multiple facility entities on several locations.

For the purposes of this chapter,

- 1) ‘biosecure’ refers to the state of a place or facility, in which *biosecurity* is effectively implemented;
- 2) ‘resident facility’ means a biosecure accommodation facility where donor and teaser animals are kept for the purpose of semen collection;

EU comment

In the second point 1 of this article above, it is mentioned that a semen collection centre is comprised of, amongst others, animal accommodation facilities where donor animals are kept.

The third point 2 of this article above defines “resident facility”, which seems to be equal to, or part of, the animal accommodation facility. However this is unclear. Also the “pre-entry isolation facility” (defined in the third point 3 of this article below) could be part of the animal accommodation facility. Indeed, the definition of both of these terms include the words “accommodation facility”.

The EU would therefore suggest clarifying this, either in the definition of animal accommodation facilities in the second point 1 of this article, e.g. by adding the words (“which comprises one or more resident facilities and pre-entry isolation facilities”), or by inserting the word “animal” before “accommodation facility” in both the definitions of “resident facility” and “pre-entry isolation facility”. It could also be explained in Article 6.4.3.

- 3) ‘pre-entry isolation facility’ means a biosecure accommodation facility where donor and teaser animals are subjected to testing prior to entering the resident facility;

EU comment

In relation to the point above, “pre-entry isolation facility” and rules related to it should not be required for equine semen donors, and probably for cervids as well, because of different semen collection regimes for those species. This should be clarified, either in the definition above, or in Article 4.6.3. below.

- 4) 'germplasm storage tank' means a sealable canister for storage and transport of semen, embryos or oocytes.

Article 4.6.2.

General conditions applicable to semen collection centres

The *semen collection centre* should be approved by the *Veterinary Authority*.

For that purpose, the *Veterinary Services* should conduct regular audits of *biosecurity plans*, protocols, procedures and records on the health of the animals in the *semen collection centre* and on the hygienic production, storage and dispatch of semen, at least annually, and request appropriate corrective actions, if needed.

Each facility in the *semen collection centre* should be under the direct supervision of a *veterinarian* who is responsible for ensuring that the health, welfare, and *biosecurity* in the facilities under his/her supervision are implemented, and all documentation is kept current.

EU comment

The sentence above needs redrafting, as it is not clear what is meant by “the health, welfare, [...] in the facilities [...] are implemented”.

Animal identification, animal traceability, and movement registration should be in accordance with Chapter 4.2. and Chapter 4.3.

The *semen collection centre* should implement and document processes that ensure identification and traceability of semen from collection to processing and storage and final dispatch from the semen storage facility. Fresh, chilled, or frozen semen products stored and/or dispatched from the semen storage facility should be identified in accordance with the national regulation to allow accurate and transparent identification of the donor animal, where the semen was collected and/or processed, and when it was collected.

Donor and teaser animals should be maintained in animal accommodation facilities separate from animals not associated with the *semen collection centre* or maintained in separate animal accommodation facilities that may have a different *animal health status*.

EU comment

The second part of the sentence above is unclear – is the intended meaning that animals of different animal health status should be kept in separate animal accommodation facilities? If that is the case, we suggest redrafting as follows:

“[...] or . In case groups of donor and teaser animals with different animal health status are present in the semen collection centre, they should be maintained in separate animal accommodation facilities that may have a different animal health status.”

Biosecurity plans should be developed for the *semen collection centre* in accordance with a *risk analysis* and should at a minimum address the following for each facility:

- 1) Personnel on the *semen collection centre* should be technically competent and apply high standards of personal hygiene, to prevent the introduction of pathogenic agents. Personnel should receive regular training and demonstrate competency of skills applicable to the *semen collection centre* and covering his/her specific responsibilities at the centre, which are documented.

EU comment

We suggest replacing “his/her” with “their” (gender neutral, non-binary).

- 2) In general, only donor and teaser animals of the same species should be permitted to the *semen collection centre*. All donor and teaser animals should meet the animal health status as determined by the *semen collection centre* and comply with the regulations set out by the *Veterinary Authority*. If other animals are needed on the *semen collection centre*, such as dogs for herding purposes, these should be kept on the *semen collection centre* and not transferred from one establishment to another and measures to prevent their contacts with *wildlife* should be implemented. Other species may be resident on the *semen collection centre*, provided that appropriate pre-entry tests have been conducted

and *biosecurity* is in place to ensure they meet the animal health status as determined by the *semen collection centre* prior to entry. These animals should be kept in separate biosecure animal accommodation facilities that are physically separate from animals associated with semen production.

- 3) Natural mating should be avoided at least four weeks prior to entry into the pre-entry isolation facility and avoided after entry into the animal accommodation facility or semen collection facility.

EU comment

It is not clear what is meant by “avoided” in point 3 above, and what the measures / consequences of natural mating would be.

However, the EU would prefer that natural mating is not allowed during at least 30 days before semen collection.

- 4) Measures should be in place to prevent the entry of *wildlife* susceptible to pathogenic agents transmissible to the animals in the *semen collection centre*.

EU comment

The EU suggests inserting the words “and feral animals” after “wildlife”, as e.g. cats or pigeons should also be kept out.

- 5) The entry of visitors to any part of the *semen collection centre* where *biosecurity* is required should only be allowed if authorised and controlled. Appropriate protective clothing and footwear only for use within the *semen collection centre* facilities should be provided. Footbaths should be provided, where necessary, and regularly cleaned. Records should be kept of all visitors that enter the *semen collection centre*.

EU comment

For clarity, we suggest inserting the words “by the veterinarian responsible for the centre” after “authorised and controlled”.

- 6) Appropriate *disinfection* of work areas and equipment should be implemented and documented regularly by trained and competent staff.
- 7) **Control measures should be in place to minimise the entry of insects and rodents.**

EU comment

Point 7 above seems partly redundant with point 4 (as regards rodents). Both should preferably be merged into one.

Reference is made here to the second to last paragraph of Article 6.4.3., which uses the terms “wildlife or pests”.

- 8) *Vehicles* for the transport of animals, *feed*, and waste and manure removal should be used in a manner which minimises health risks to animals in the *semen collection centre*.

Article 4.6.3.

Recommendations applicable to animal accommodation facilities

Animal accommodation facilities should be designed so that cleaning and *disinfection* measures are easy and efficient to implement. Individual and group housing pens should be kept clean and the bedding renewed as often as necessary to ensure it is dry and clean.

EU comment

Please replace “are easy and efficient to implement” with “can be implemented easily and efficiently” (clarity and style).

The animal accommodation facilities should include dedicated areas for *feed* storage, for manure storage, bedding storage, and for the isolation of any sick animals. Animal accommodation facilities should be species-specific, where relevant.

EU comment

The last sentence of the paragraph above seems to contradict the principles of point 2 of Article 4.6.2., and should thus be deleted.

There should be a separate pre-entry isolation facility that is managed as a separate biosecure facility for holding animals that are required to complete testing and isolation prior to entry to the resident facility. Procedures for animal identification, blood sampling and vaccination of animals within the *semen collection centre* should be conducted in accordance with relevant recommendations in the *Terrestrial Code*. In the instance where the *Veterinary Authority* has determined that pre-entry isolation facility is not required, pre-entry conditions to enter the resident facility or semen collection facility should be included in the *biosecurity plan* of the *semen collection centre*.

The decision to house animals indoors or outdoors will be determined by the *semen collection centre* in accordance with the *biosecurity plan*. Donor animals and teasers that are housed outdoors or allowed access outdoors, should be accommodated to minimise *vector* attacks and adequately protected from adverse weather conditions. Donor animals and teasers that are housed indoors, should be accommodated to allow for adequate ventilation and proper footing and bedding.

All donor and teaser animal accommodations should be adapted to the needs of the species of donor being collected. Watering and feeding systems should be constructed so that it provides minimum contact between donor animals and can be easily cleaned.

Bedding should be clean and dry, soft, easy to spread and remove. Bedding should be removed regularly and replaced, following thorough cleaning and *disinfection* of relevant surfaces.

Feed and bedding material should be kept in a dry place and stored in a manner to prevent access by *wildlife* or pests and stored in conditions that are well monitored.

Manure, litter, and bedding material should be disposed of in such a way as to prevent the transmission of diseases and be in compliance with all relevant health and environmental legislation.

EU comment

The last part of the sentence above (“and be in compliance with all relevant health and environmental legislation”), while certainly correct, goes beyond the remit of this Code chapter and should thus be deleted.

Article 4.6.4.

Recommendations applicable to semen collection and semen collection facilities

The semen collection facility can be co-located with the resident facility and share *biosecurity* to accommodate the same designated *animal health status* of the resident facility. If the semen collection facility is co-located with a resident facility, the semen collection facility should not be used to collect other donor animals not housed in the resident facility. If the semen collection facility is a separate facility, *biosecurity* should be in place to allow only animals of the same *animal health status* to be permitted entry into that facility.

Donors and teaser animals should be kept and prepared in a way to facilitate the hygienic collection of semen. Donor animals should be dry and clean when arriving in the semen collection area.

Donor animals should be collected in the semen collection facility and not collected in the resident facility.

EU comment

For reasons of clarity, in the sentence above please replace the words “Donor animals” with the word “Semen”.

Personnel and visitors should be provided with protective clothing and footwear for use only at the semen collection facilities and worn at all times.

Equipment used for the animals should be dedicated to the semen collection facility or disinfected before being introduced to the centre. All other equipment and tools brought on to the premises should be examined and *disinfected*, if necessary, to minimise the introduction of pathogenic agents.

EU comment

In the first sentence of the paragraph above, for reasons of clarity the EU suggests adding the words “, if not new,” before “disinfected before being”.

Furthermore, in the same sentence, we suggest replacing the word “centre” with the words “semen collection facility”.

Finally, the meaning of the word “premises” in the second sentence of the paragraph above is unclear; this should preferably be specified further (semen collection facility?).

The semen collection facility and associated equipment should allow for effective cleaning and *disinfection*, where applicable.

The floor of the mounting area should be clean and provide safe footing. When rubber mats are used, they should be cleaned after each collection.

Preputial orifices of donor animals should be clean and free of excessive hair or wool to avoid contamination of the semen. Hair or wool at the preputial orifice should be regularly trimmed as needed but not completely removed to avoid excessive irritation of the preputial mucosa while urinating.

Hair or wool on the hindquarters of teaser animals should be kept short to avoid contamination during the collection process. A teaser animal should have its hindquarters thoroughly cleaned before each collection session. A plastic apron can be used to cover the hindquarters of the teaser animal, but the apron should be replaced with a clean apron or thoroughly cleaned and *disinfected* between donor animals.

A dummy mount, if used, should be made of a material that is easy to clean and disinfect and should be thoroughly cleaned after each collection. Disposable plastic covers may be used.

When used, the artificial vagina should be cleaned completely after each collection. It should be dismantled, washed, rinsed, dried, and protected from dust. The inside of the body of the device and the cone should be *disinfected* before re-assembly using *disinfection* procedures approved by the *Veterinary Authority*.

Lubricant used in the artificial vagina should be new and the equipment used to spread the lubricant should be clean and free of dust.

The artificial vagina should be handled in a manner to prevent dirt and debris from entering.

When successive ejaculates are being collected from the same donor, a new artificial vagina should be used for each collection to prevent any contamination. The artificial vagina should also be changed when the animal has inserted its penis without ejaculating.

All semen should be collected into a sterile receptacle, either disposable or sterilised by autoclaving or heating and kept clean prior to use.

After semen collection, the receptacle should be left attached to the cone within its sleeve or sheath until it has been removed from the collection area to the laboratory.

EU comment

For reasons of clarity, the EU suggests amending the sentence above as follows:

“After semen collection, the receptacle should be left attached to the cone within its sleeve or sheath until it has been removed from the semen collection facility area and transferred to the semen processing facility laboratory.”

During collection, the technician should wear disposable gloves and change them between donor animals.

Article 4.6.5.

General principles applicable to semen processing and semen processing facilities

The semen processing facility should be physically separated from other semen collection facilities and may include separate areas for the preparation and cleaning of artificial vaginas, semen evaluation and processing, semen pre-storage and storage.

EU comment

The word “other” in the sentence above is confusing and should be deleted (for the sentence to read: “The semen processing facility should be physically separated from ~~other~~ the semen collection facilities and [...])”.

Furthermore, it is not clear why storage is included at the end of the sentence. Indeed, according to Article 4.6.1. and 4.6.6., semen storage facilities are separate from semen collection facilities.

The semen processing facility should be constructed with materials that permit effective cleaning and *disinfection*, in accordance with Chapter 4.14.

Entry to the facility should be restricted to authorised personnel only.

Protective clothing for use only in the semen processing facility should be provided and worn at all times.

The facility and its equipment should be regularly cleaned and well maintained. Work surfaces for semen evaluation and processing should be regularly cleaned and disinfected.

Only semen from the same species and from donors with the same *animal health status* should be processed at the same time. Semen from donors with a different *animal health status* or from different species may be processed consecutively if appropriate hygienic measures in accordance with the *biosecurity plan* have been implemented.

Semen should be collected in a manner that ensures accurate identification and traceability of collecting tubes from the time of semen collection until storage.

EU comment

For reasons of clarity and consistency with the title of this article, please insert the words “and processed” after “collected” in the sentence above.

All containers and instruments used for the collection, processing, preservation or freezing of semen should be single-use or be cleaned and disinfected or sterilised before use, depending on the manufacturer’s instructions.

The receptacle containing freshly collected semen should be stoppered or covered in a way to prevent contamination as soon as possible after collection, until processing. During processing, containers containing the semen should be stoppered or covered during times when diluent or other components are not being added.

EU comment

For clarity, the EU suggests replacing the word “stoppered” with the word “closed” in the paragraph above. Indeed, depending on the type of receptacle, a different method for closing would be used instead of a stopper.

This comment is valid also for point 5 of Article 4.6.5.

Equipment used for gender-sorting of sperm should be clean and disinfected between ejaculates in accordance with the recommendations of the manufacturer. Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from animals of the same *animal health status*.

Recommendations regarding the use of diluents for processing semen:

- 1) Buffer solutions used in diluents prepared on the premises should be sterilised by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additives, or antibiotics.

- 2) In the case of ready-to-use commercial extenders, the manufacturer's recommendations should be followed.
- 3) If the constituents of a diluent are supplied in commercially available powder form, the water used should have been distilled or demineralised, sterilised (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.

EU comment

For clarity, the EU suggests inserting the words “for preparing the semen diluent” after “water used” in point 3 above.

- 4) Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product should be free from pathogenic agents or sterilised; milk heat-treated at 92°C for 3–5 minutes, eggs from SPF flocks when available. When egg yolk is used, it should be separated from the egg white using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination. Commercial powdered skim milk for human consumption may be used. Other additives should be sterilised before use.
- 5) Diluent should be stored according to manufacturer's instructions. Storage vessels should be stoppered.
- 6) Antibiotics may be added to the diluent to minimise the growth of bacterial contaminants or control specific venereal pathogens that may be present in semen.

Article 4.6.6.

General principles applicable to semen storage and storage facilities

Semen storage facilities and germplasm storage tanks should allow for easy cleaning and *disinfection*.

The manufacturer's instructions for the safe *disinfection* of germplasm storage tanks should be complied with.

Movement of germplasm storage tanks from one semen storage facility to another should be completed under controlled conditions subject to the *biosecurity plan* of the *semen collection centre*.

Access to the semen storage facility should be restricted to authorised personnel.

Accurate records should be maintained that identify semen being transferred in, stored, and transferred out of the semen storage facility.

Only new liquid nitrogen should be used to fill or top up germplasm storage tanks.

CHAPTER 6.10.

RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL
AGENTS
IN VETERINARY MEDICINE

EU comment

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

Comments are inserted in the text below.

Article 6.10.1.

Purpose and scope

This document provides guidance for the responsible and prudent use of *antimicrobial agents* in veterinary medicine for treatment, control and prevention of diseases in food and non-food producing animals, with the aim of protecting both *animal* and human health as well as minimising and containing antimicrobial resistance risks in the relevant animal the environment, as part of a One Health approach.

EU comment

For reasons of readability, the EU proposes to add a hyphen (–) after the word food, so that the first sentence would read as follows: “[...]control and prevention of diseases in food– and non-food–producing animals, [...]”

It defines the respective responsibilities of the *Competent Authority* and stakeholders such as the veterinary pharmaceutical industry, *veterinarians*, *animal feed* manufacturers, distributors, and food–animal producers–breeders, owners and keepers, who are involved in any or all of the following activities: the authorization regulatory approval, production, control, importation, exportation, sales, advertising, distribution and use of *veterinary medicinal products (VMPs)* containing *antimicrobial agents*.

EU comment**The EU proposes:**

- **to replace “Competent Authority” by “Competent Authority(ies)” in the paragraph above.**
This change is proposed to reflect the fact that, in some countries, there may be more than one Competent Authority in charge of the issues discussed in this Chapter. For this reason and to ensure that the One Health approach can be implemented to its full potential, we propose to include the possibility that several Competent Authorities may be involved. Such a possibility is foreseen under Codex document CXC 61-2005.
- **to amend the last part of the paragraph above, for reasons of clarity, as follows: “[...] regulatory approval, production, control, importation, exportation, sales, advertising, distribution and use of veterinary medicinal products containing antimicrobial agents,**

including premixes, powders and solutions intended for oral administration.”

Responsible and prudent use is determined by taking into account the specifications detailed in the relevant regulatory approval marketing authorization and their implementation when *antimicrobial agents* are administered to *animals* and is part of good veterinary and ~~good agricultural~~ *animal* husbandry practices. All measures to prevent infectious *animal* diseases contribute to a decreased need of using *antimicrobial agents* in *animals*, thus reducing the risk for development of antimicrobial resistance.

Activities associated with the responsible and prudent use of *antimicrobial agents* should involve all relevant stakeholders.

Coordination of these activities at the national or regional level is recommended and may support the implementation of targeted actions by the stakeholders involved and enable clear and transparent communications.

Article 6.10.2.

Objectives of responsible and prudent use

Responsible and prudent veterinary medical use of *antimicrobial agents* includes implementing ~~practical measures and recommendations~~ intended to improve *animal* health and *animal welfare* while preventing or reducing the selection, emergence and spread of antimicrobial-resistant bacteria and resistance determinants in *animals*, humans and the relevant *animal* environment; in *animals* and humans. Such measures include:

EU comment

The EU proposes to amend the paragraph above, as follows: “[...] while preventing or reducing the selection, emergence and spread of antimicrobial-resistant bacteria micro-organisms [...]”

This change is proposed to reflect the fact that prudent and responsible use of antimicrobials does not only consist of prudent and responsible use of antibiotics to fight antibiotic-resistance bacteria, but more broadly to fight antimicrobial-resistant micro-organisms (including viruses, fungi or protozoa for example with antivirals, antifungals and antiprotozoals).

- 1) ensuring the responsible and prudent ~~rational~~ use of *antimicrobial agents* in *animals* with the purpose of optimising both their effectiveness ~~efficacy~~ and safety in *animals*;

EU comment

For reasons of clarity, the EU suggests to amend the paragraph above, as follows: “1) ensuring the responsible and prudent use of antimicrobial agents with the purpose of optimizing preserving both their effectiveness and safety in animals;” “

- 2) complying with the ethical obligation and economic need to keep *animals* in good health;
- 3) preventing or reducing ~~the~~ transfer of resistant micro-organisms or resistance determinants within *animal* populations, between *animals*, humans, and the relevant *animal* environment ~~the environment and between *animals* and humans;~~

- 4) contributing to the maintenance of the effectiveness ~~efficacy and usefulness~~ of antimicrobial agents used in animal and human medicine;

EU comment

For reasons of consistency throughout the text, the EU suggests to amend the paragraph above, as follows: “4) contributing to the maintenance of the effectiveness of antimicrobial agents used in animal veterinary and human medicine;”

- 5) protecting consumer health by ensuring the safety of food of *animal* origin with respect to residues of antimicrobial agents.

Article 6.10.3.

Responsibilities of the Competent Authority

1. National Action Plan

The Competent Authority should design and oversee the implementation of the relevant part of their National Action Plan. The Competent Authority in cooperation with animal health, plant health, and public health professionals should adopt a One Health approach to promote the responsible and prudent use of antimicrobial agents as an element of a national strategy to minimise and contain antimicrobial resistance. Furthermore, the Competent Authority should allocate budgetary resources for the design and implementation of the relevant part of their National Action Plan including communication strategies. The Competent Authority should also conduct regular monitoring and evaluation of the National Action Plan. National Action Plans should incorporate best management practices, including disease prevention and control measures, biosecurity policies and development of animal health programmes to reduce the burden of animal disease thereby reducing the need for antimicrobial use. As part of National Action Plans for antimicrobial resistance, the Competent Authority should ensure that surveillance for antimicrobial use and antimicrobial resistance in the animal health sector are in place and should work closely together with human, plant and environmental sectors on the harmonisation, analysis and integration of surveillance across sectors.

National Action Plans should include recommendations to relevant professional organisations as appropriate to develop evidence-based, species or sector-specific antimicrobial use guidelines.

EU comment

In order to allow countries to decide which organisations are best suited to develop the guidelines described and in order to be more inclusive, the EU proposes to delete the word ‘professional’ in the sentence above, as follows: “National Action Plans should include recommendations to relevant ~~professional~~ organisations as appropriate to develop evidence-based, species or sector-specific antimicrobial use guidelines.”. As an example, it may be appropriate in some countries that such guidelines be drafted jointly for example by academia, authorities and professional organisations.

12. Regulatory approval~~Marketing authorisation~~

~~All Member Countries should combat the unauthorised manufacture, compounding, importation, advertisement, trade, distribution, storage and use of unlicensed, adulterated and counterfeit products, including bulk active ingredients, through appropriate regulatory controls and other measures.~~

The *Competent Authority* is responsible for granting relevant regulatory approval ~~marketing authorisation~~ which should be done in accordance with the provisions of the *Terrestrial Code*. The *Competent Authority* ~~it~~ has a significant role in specifying the terms of this ~~authorisation~~ approval and in providing the appropriate information to *veterinarians* and all other relevant stakeholders.

The *Competent Authority* should establish and implement efficient statutory registration procedures that evaluate the quality, safety and efficacy and proposed post-marketing surveillance programmes for *VMP-veterinary medicinal products* containing *antimicrobial agents*. According to Article 3.2.2., the *Competent Authority* should be free from any commercial, financial, hierarchical, political or other pressures which might influence ~~affect~~ its judgement or decisions.

Member Countries lacking the necessary resources to implement an efficient registration procedure for *VMP-veterinary medicinal products* containing *antimicrobial agents*, and which are importing them, should undertake the following measures:

- a) evaluate the effectiveness ~~efficacy~~ of administrative controls on the import of these *VMP-veterinary medicinal products*;
- b) evaluate the validity of the registration procedures of the exporting and/or manufacturing country as appropriate;
- c) develop the necessary technical co-operation with an ~~experienced relevant authorities~~ *Competent Authority* to check the quality of imported *VMP-veterinary medicinal products* as well as the validity of the recommended conditions of use.

The *Competent Authorities* of *importing countries* should request the pharmaceutical industry to provide quality certificates prepared by the *Competent Authority* of the exporting or ~~and~~ manufacturing country as appropriate.

Regulatory approval ~~Marketing authorisation~~ is granted on the basis of the data submitted by a ~~the~~ pharmaceutical company ~~industry or other~~ applicant and only if the criteria of quality, safety, quality and efficacy are met.

~~Member countries~~ The *Competent Authority* ~~are~~ is encouraged to apply or require the use of the existing guidelines established by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

An evaluation of the ~~potential~~ risks and benefits to both *animals* and humans resulting from the use of *antimicrobial agents* in ~~with particular focus on use in food-producing animals~~, should be carried out. The evaluation may ~~should~~ focus on each individual *antimicrobial agent* and the findings from one agent should not be generalised to the antimicrobial class to which the particular active ingredient belongs. Guidance on use ~~usage~~ should be provided for all target species, route of administration, dosage regimens, (dose, dosing interval and duration of the treatment), and withdrawal period as relevant ~~and different durations of treatment that are proposed~~.

The *Competent Authority* should ~~expedite~~ implement timely the regulatory approval process for new *antimicrobial agents* in order to address ~~a~~ specific needs for the treatment of *animal diseases* and should take into account recommendations included in the OIE List of Antimicrobials of Veterinary Importance.

EU comment

The EU proposes to add a paragraph under section 2. as follows: “Antimicrobial agents should not be granted regulatory approval for the purposes of growth promotion or yield increase.”.

It is recognised on the international policy stage and in international guidance documents, including in Codex document CXC 61-2005, that responsible and prudent use of antimicrobial agents does not include use for growth promotion.

23. Quality control of antimicrobial agents and VMP-veterinary medicinal products containing antimicrobial agents

The Competent Authority should make sure that the quality of the veterinary medicinal products was determined by the applicant in accordance with national and international guidance to ensure that:

Quality controls should be performed:

- a) the specifications of antimicrobial agents in compliance with the provisions of good manufacturing practices;
- b) ~~to ensure that analysis specifications of antimicrobial agents~~ used as active ingredients comply with the provisions of registration documentations (such as monographs) approved by the relevant *Competent Authority*;
- eb) ~~to ensure that~~ the quality of *antimicrobial agents* in the marketed dosage forms is maintained until the expiry date, established under the recommended storage conditions;
- ec) ~~to ensure~~ the stability and compatibility of *antimicrobial agents* when mixed with feed or drinking water;
- ed) ~~to ensure that~~ all *antimicrobial agents* and the VMP-veterinary medicinal products containing them are manufactured to the appropriate quality and in compliance with the provisions of good manufacturing practices ~~purity in order to guarantee their safety and efficacy.~~

34. Assessment of therapeutic efficacy

The Competent Authority should conduct an assessment of the therapeutic efficacy based on data provided in the relevant regulatory approval application submitted by the applicant to enable marketing.

EU comment

The EU suggests to delete the word ‘therapeutic’ from the title of section 4. and its following sentence, as its inclusion does not bring added value and may generate confusion. The revised text would read as follows:

“4. Assessment of ~~therapeutic~~ efficacy.

The Competent Authority should conduct an assessment of the ~~therapeutic efficacy~~ based on data provided in the relevant regulatory approval application submitted by the applicant to enable marketing:”

- a) Preclinical trials
 - i) Preclinical trials should:
 - establish the spectrum of activity of *antimicrobial agents* against relevant pathogenic agents and non-pathogenic agents (commensals);
 - assess the capacity of the *antimicrobial agents* to select for resistance *in vitro* and *in vivo*, taking into consideration intrinsically resistant and pre-existing resistant strains and strains with acquired resistance;
 - establish an appropriate dosage regimen (~~dose, dosing interval and duration of the treatment~~) and route of administration necessary to ensure the therapeutic efficacy of the *antimicrobial agents* and limit the selection of antimicrobial resistance. Pharmacokinetic and pharmacodynamic data and models can assist in this appraisal. Such data together with clinical data could be used by independent experts to establish clinical breakpoints per animal species, antimicrobial agent and pathogen combination.
 - ii) The activity of *antimicrobial agents* towards the targeted microorganism should be established by

pharmacodynamics investigations. The following characteristics ~~criteria~~ should be taken into account:

- spectrum of activity and mode of action;
- minimum inhibitory and bactericidal concentrations against recent isolates;
- time-kill kinetics when appropriate;
- time- or concentration-dependent activity or co-dependency;
- activity at the site of *infection*.

iii) The dosage regimens allowing maintenance of effective antimicrobial concentrations ~~levels~~ should be established by pharmacokinetics investigation. ~~The following criteria~~ and should be taken into account:

- ~~bio-availability in accordance with the route of administration~~;
- absorption, distribution, of the antimicrobial agents in the treated animal and concentration at the site of infection, metabolism and elimination;
- ~~metabolism~~;
- ~~excretion routes~~;
- any potential routes of administration proposed by the applicant.

Any proposed use of combinations of *antimicrobial agents* should be scientifically supported.

b) Clinical trials

Clinical trials in the target *animal* species should be performed to confirm the validity of the claimed therapeutic indications and dosage regimens established during the preclinical phase. The following criteria should be taken into account:

- diversity of the clinical cases encountered when performing multi-centre trials;
- compliance of protocols with good clinical practice;
- eligibility of studied clinical cases, based on appropriate criteria of clinical and bacteriological diagnoses;
- parameters for qualitatively and quantitatively assessing the efficacy of the treatment.

45. Assessment of the potential of antimicrobial agents to select for resistance

Other studies may be requested in support of the assessment of the potential of *antimicrobial agents* to select for resistance. The applicant for regulatory approval ~~The party applying for market authorisation~~ should, where possible, supply data derived in target *animal* species under the intended conditions of use.

For this assessment the following may be considered:

- a) the concentration of either active *antimicrobial agents* ~~or and, where appropriate, active~~ metabolites in the gut of the *animal* (where the majority of ~~potential foodborne~~ pathogenic and commensal bacteria agents reside) at the defined dosage level;
- b) the antimicrobial activity of the antimicrobial agents and metabolites in the intestinal environment;

b~~c~~) the pathway for the human exposure to antimicrobial resistant microorganisms and antimicrobial residues in the environment;

EU comment

The EU proposes for the sake of completeness to amend paragraph c) above, as follows: “c) the pathway for human exposure to antimicrobial resistant microorganisms, antimicrobial resistance determinants and antimicrobial residues in the environment.”

e~~d~~) the presence of and potential degree for co-resistance and cross-resistance;

e~~e~~) the intrinsic and pre-existing, baseline level of resistance in the pathogenic agents, commensal and food-borne bacteria of human health relevance concern in both animals and humans.

6. Establishment of clinical breakpoints

In order to interpret the result of a susceptibility test, there is a need for clinical breakpoints for each bacteria-antimicrobial-animal species combination. Those clinical breakpoints should be established by independent experts.

EU comment

The EU proposes:

- **for reasons of accuracy, to amend the paragraph above, as follows: “~~In order to interpret the result of a susceptibility test, there is a need for~~ The Competent Authority should support the development of clinical breakpoints for each bacteria-antimicrobial-animal species combination. Those clinical breakpoints should be established by independent experts.”**

Indeed, it may not be the Competent Authority itself that actually develops the breakpoints, but the work of independent experts can be supported in various ways.

- **for reasons of clarity and coherence, to move point 6. on the ‘Establishment of clinical breakpoints’, including the amended paragraph above, to after point 12. on ‘Control of advertising’ and before point 13. on ‘Training related to the use of antimicrobial agents and antimicrobial resistance’.**

Indeed, this paragraph would be better placed outside of the flow of points that are part of the regulatory approval process.

57. Establishment of acceptable daily intake (ADI), maximum residue limit (MRL) and withdrawal periods in food-producing animals

a) When setting the ADI and MRL for an *antimicrobial agent*, the safety evaluation should also include the potential microbiological biological-effects on the intestinal flora-microbiome of humans to derive ADI.

b) The establishment of an ADI for each *antimicrobial agent*, and an MRL for each *animal-derived food*, should be undertaken before a ~~VMP-veterinary medicinal product~~ containing it is granted ~~marketing authorization-regulatory approval.~~

- c) For all ~~VMP~~veterinary medicinal products containing antimicrobial agents for use in food-producing animals, withdrawal periods should be established for each *animal* species in order to ensure compliance with the MRLs, taking into account:
- the MRLs established for the *antimicrobial agent* in the target *animal* edible tissues;
 - the composition of the product and the pharmaceutical form;
 - the dosage regimen;
 - the route of administration.
- d) The applicant should describe methods for regulatory testing of residues in food based on the established marker residues.

~~68.~~ Assessment Protection of the impact on the relevant animal environment

An assessment of the impact of the proposed antimicrobial use on risks to the relevant environment should be conducted in accordance with national or international guidelines.

The Competent Authority should consider the results of an antimicrobial resistance environmental risk assessment. For both food and non-food producing animals the following risk factors should be taken into consideration as appropriate: reuse of wastewater for irrigation, use of manure, other waste-based fertilizers for soil fertilization, transfer of antimicrobial resistant genes or bacteria in veterinary practice. When a significant antimicrobial resistance risk is determined the need for monitoring and proportionate risk management measures should be discussed.

EU comment

For reasons of clarity and to present the text in a more logical order, the EU suggests to move point 8. on ‘Assessment of the impact on the relevant animal environment’ to after current point 5. on ‘Assessment of the potential of antimicrobial agents to select for resistance’.

~~79.~~ Establishment of a summary of product characteristics or equivalent for each ~~VMP~~veterinary medicinal product containing antimicrobial agents

~~The summary of product characteristics contains~~The Competent Authority should ensure that the Summary of Product Characteristics (SPC) or equivalent, the package insert and labelling includes the information necessary for the appropriate use of ~~VMP~~veterinary medicinal products containing antimicrobial agents, and constitutes the official reference for their labelling and package insert. This The SPC or equivalent summary should contain the following items as appropriate:

- a) name of the veterinary medicinal product;
- ~~a)~~ active ingredient and class;
- c) pharmaceutical form;
- d) quantitative composition;
- ~~b)~~ pharmacological properties;
- ef) any potential adverse effects;

- eg) target *animal* species and, as appropriate, age or production category;
- eh) therapeutic indications;
- fi) target micro-organisms;
- gj) dosage regimen and route of administration;
- hk) withdrawal periods;
- il) incompatibilities and interactions;
- jm) storage conditions and shelf-life;
- kn) operator safety;
- lo) particular precautions before use;
- p) precautions for the protection of the environment;
- q) use during pregnancy, lactation or lay;
- mr) particular precautions for the proper disposal of unused ~~un-used~~ or expired products;
- ns) information on conditions of use relevant to the potential for selection of resistance;
- et) ~~C~~ontraindications.

9.10. Post-marketing antimicrobial resistance surveillance

The Competent Authority should assess ~~the~~ information collected through existing pharmacovigilance and surveillance programmes, including reporting of lack of response efficacy, and any other relevant scientific data. These information sources should form part of the comprehensive strategy to detect and minimise antimicrobial resistance. In addition to this, the following should be considered:

- a) General epidemiological surveillance

The *surveillance* of *animal* microorganisms resistant to *antimicrobial agents* is essential. The Competent Authority ~~relevant authorities~~ should implement a programme in accordance with Chapter 1.4.

EU comment

The EU suggests:

- **for the sake of completeness, to amend the paragraph above as follows: “[...]. The Competent Authority should implement a programme in accordance with Chapter 1.4 and Chapter 6.8.”**
- **for reasons of clarity, to move the point a) ‘General epidemiological surveillance’, including the amended text above, to a point of its own, right before current point 14. on ‘Monitoring of antimicrobial use’.
General epidemiological surveillance is not part of post-marketing surveillance, it is an activity unrelated to specific products. This is clear from**

Chapter 6.8.

- b) Specific surveillance

Specific surveillance to assess the impact of the use of a specific ~~antimicrobial agent~~ veterinary medicinal product may be implemented after the granting of the relevant regulatory approval ~~marketing authorisation~~. The *surveillance* programme should evaluate not only resistance in target animal pathogens ~~pathogenic agents~~, but also in foodborne and other relevant zoonotic pathogens ~~pathogenic agents~~, and commensals if relevant and possible. This will also contribute to general epidemiological *surveillance* of antimicrobial resistance.

911. Distribution ~~Supply and administration of the antimicrobial agents or VMP~~ veterinary medicinal products containing antimicrobial agents

~~The relevant authorities~~ The Competent Authority should ensure that all the *antimicrobial agents* and *veterinary medicinal products* containing *antimicrobial agents* used in *animals* including through feed and water are:

- a) ~~prescribed by a veterinarian or other suitably trained person authorised to prescribe VMP containing antimicrobial agents in accordance with the national legislation and under the supervision of a veterinarian;~~
- ba) supplied only through licensed or authorised distribution systems;
- b) not illegal, substandard, falsified medicines or unapproved formulations and that these are prevented from entering distribution systems;
- c) prescribed by a veterinarian or other suitably trained person authorised to prescribe veterinary medicinal products containing antimicrobial agents in accordance with the national legislation;
- ed) administered to animals by a veterinarian or under the supervision of a veterinarian, or by other authorised suitably trained persons, animal breeder, owners or keepers as appropriate.

The Competent Authority should encourage the availability of authorised products on the market and in collaboration with the pharmaceutical industry follow-up any potential drug shortages.

~~The relevant authorities~~ The Competent Authority should develop effective procedures for the safe collection and disposal or destruction of unused or expired ~~VMPs~~ veterinary medicinal products containing *antimicrobial agents*. Their labels should have appropriate instructions for disposal and destruction.

1012. Control of advertising

All advertising of *antimicrobial agents* should be compatible with the principles of responsible and prudent use and should be controlled by codes of advertising standards. ~~The relevant authorities~~ The Competent Authority ~~must ensure that the advertising of these products:~~

- a) ~~complies with the regulatory approval~~ marketing authorisation granted, in particular regarding the content of the summary of product characteristics or equivalent;
- b) ~~is restricted to a veterinarian or other suitably trained person authorised to prescribe VMP~~ veterinary medicinal products containing *antimicrobial agents* in accordance with the national legislation ~~and under the supervision of a veterinarian.~~

EU comment

The EU fully agrees on the need to control advertising and that advertising should be subject to certain conditions. Persons qualified to prescribe or supply

veterinary medicinal products can properly evaluate the information available in advertising, because of their knowledge, training and experience in animal health.

For this reason, the EU proposes to amend the paragraph above, as follows: “b) is restricted to a veterinarian, ~~or to other suitably trained person authorised to prescribe veterinary medicinal products containing antimicrobial agents, or to persons permitted to supply veterinary medicinal products~~ in accordance with national legislation.”

11.13. Training related to the use ~~on the usage~~ of antimicrobial agents and antimicrobial resistance

The *Competent Authority* should take a key role in promoting training for responsible and prudent use of antimicrobials and on antimicrobial resistance. The target audiences for t~~he training on the usage-use of *antimicrobial agents* should include all the relevant stakeholders and organisations, such as the ~~*Competent Authority*~~, pharmaceutical industry, veterinary schools and paraprofessional education establishments, research institutes, veterinary professional and paraprofessional organisations and other approved users such as food *animal* owners and manufacturers of medicated *animal feed*. ~~The~~ This training may should focus on preserving the effectiveness of *antimicrobial agents* and include:~~

EU comment

For reasons of clarity and consistency, the EU suggests:

- **to replace ‘food animal owners’ by ‘food-producing animal owners’ and amend the paragraph above as follows: “[...]The target audiences for the training [...] and other approved users such as food-producing animal owners [...]”.**
- **to also amend the paragraph above as follows: “[...]The training may include, as appropriate for the audience targeted:”**

- a) ~~information on disease prevention, management and mitigation strategies;~~
- ba) ~~the ability of *antimicrobial agents* to select for resistant microorganisms in *animals* and the relative importance of that resistance to public and *animal* health and the environment;~~
- eb) ~~the need to observe responsible and prudent use principles recommendations for the use of *antimicrobial agents* in *animal* husbandry in agreement with the provisions of the marketing authorisations regulatory approval, national and international guidelines and recommendations from the OIE List of Antimicrobial Agents of Veterinary Importance~~
- ec) ~~information on the appropriate storage conditions before and during use and proper disposal of unused or expired VMP *veterinary medicinal products*;~~
- e) ~~record-keeping;~~
- d) training in new methodologies for molecular detection of resistance, understanding methods and results of antimicrobial susceptibility testing and molecular analysis;

EU comment

The EU proposes to amend the paragraph above, as follows: “d) training in new methodologies for molecular detection of resistance, understanding methods and results of antimicrobial susceptibility testing, target pathogen identification and molecular analysis.”

The EU believes that target pathogen identification is an essential step in the process of fighting antimicrobial resistance and should therefore be part of the training proposed.

- e) interpretation of relevant risk assessment outputs of antimicrobial resistance derived from the use of *veterinary medicinal products* containing *antimicrobial agents* in *animals* and how to use these outputs to inform the development of *risk communication* and *risk management* strategies;
- f) the collection and reporting of antimicrobial resistance and antimicrobial use data to the *Competent Authority* to complement existing national and international surveillance programmes;
- g) information on disease prevention, management and mitigation strategies that can contribute to reducing the need to use *antimicrobial agents* in *animals*.

14. Monitoring of antimicrobial use

The *Competent Authority* should collate antimicrobial use in a harmonised manner to improve the understanding of the extent and trends of antimicrobial use and antimicrobial resistance in *animal* populations at national level and identify areas for further research. The data collected on antimicrobial use at country level should:

EU comment

The EU suggests for reasons of clarity to amend the paragraph above, as follows: “In accordance with Chapter 6.9, tThe Competent Authority should collate [...]”.

- a) give an indication of the trends in the use of *antimicrobial agents* in *animals* over time and potential associations with antimicrobial resistance in *animals*;
- b) help in the interpretation of antimicrobial resistance *surveillance* data and assist in responding to problems of antimicrobial resistance in a precise and targeted way;
- c) assist in *risk management* to evaluate the effectiveness of efforts and mitigation strategies;
- d) inform *risk communication* strategies.

The *Competent Authority* should provide the antimicrobial use data to the ‘Animal Antimicrobial Use Global database of the World Organisation for Animal Health’ on a yearly basis.

1215. Knowledge gaps and rResearch

The *Competent Authority* relevant authorities should encourage coordination of public- and industry-funded research, in the following areas but not limited to: for example on methods to identify and mitigate the public health risks associated with specific *antimicrobial agent* uses, or on the ecology of antimicrobial resistance.

- a) improve the knowledge about the mechanisms of action, pharmacokinetics and pharmacodynamics of *antimicrobial*

agents to optimize the dosage regimens for veterinary medical use and their effectiveness;

- b) improve the knowledge about the mechanisms of transmission, selection, co-selection, emergence and dissemination of resistance determinants and resistant microorganisms in *animal* populations and along the food chain;

EU comment

For reasons of consistency, the EU proposes to amend the paragraph above as follows: “[...] and resistant microorganisms in animal populations, between animals, humans, and the relevant animal environment, including and along the food chain;”

- c) develop practical models for applying the concept of *risk analysis* to assess the *animal* and public health concerns linked to the development of antimicrobial resistance in *animals* and *animal-derived* foods;
- d) further develop protocols to predict, during the authorization process, the impact of the proposed use of the *antimicrobial agents in animals* on the rate and extent of antimicrobial resistance development and spread to *animals*, humans, plants and the environment, following a One Health approach;

EU comment

For reasons of consistency, the EU suggests to amend the paragraph above, as follows: “[...] to predict, during the ~~authorization~~ regulatory approval process, the impact [...]’.

- e) assess the primary drivers leading to use of *antimicrobial agents in animals*, and the effectiveness of different interventions to change behaviour and reduce the need to use *antimicrobial agents in animals*;
- f) develop safe and effective alternatives to *antimicrobial agents*, new *antimicrobial agents*, rapid diagnostics, and vaccines for infectious diseases to reduce the need for antimicrobial use in *animals*;
- g) improve knowledge on the role of the environment on the persistence of *antimicrobial agents*, and the emergence, transfer and persistence of antimicrobial resistance determinants and resistant microorganisms resulting from antimicrobial use in *animals*.

Article 6.10.4.

Responsibilities of the veterinary pharmaceutical industry with regards to ~~VMP~~ veterinary medicinal products containing antimicrobial agents

1. Regulatory approval~~Marketing authorisation~~

The veterinary pharmaceutical industry has responsibilities to:

- a) ~~Supply~~ provide all the information requested by the national *Competent Authority* as specified in Article 6.10.3;
- b) guarantee the quality of this information in compliance with the provisions of good manufacturing, laboratory and clinical practices;
- c) implement and regularly report on a pharmacovigilance programme and on request, *specific surveillance* for bacterial

susceptibility and resistance data:-

- d) isolate and identify bacteria, and collect relevant data and submit them to the *Competent Authority*. The data will enable independent experts to establish clinical breakpoints for use in the laboratory to guide antimicrobial therapy.

EU comment

The EU proposes that point d) is further elaborated. It is rather vague and unclear which bacteria are being referred to, which data is needed and how the data will be analysed, by whom and for which purpose.

2. Marketing and export

For the marketing and export of ~~VMP~~veterinary medicinal products containing *antimicrobial agents*:

- a) only licensed and officially approved ~~VMP~~veterinary medicinal products containing *antimicrobial agents* should be sold and supplied, and then only through ~~licensed~~/authorised distribution systems;
- b) the pharmaceutical industry should provide quality certificates prepared by the *Competent Authority* of the exporting or ~~and~~ manufacturing countries to the *importing country*;
- c) the pharmaceutical industry should endeavour to guarantee the availability of authorised products and cooperate with the *Competent Authority* to forecast and avoid any drug shortage;
- ed) the *Competent Authority* national regulatory authority should be provided with the information necessary to evaluate the amount of *antimicrobial agents* marketed.

3. Advertising

The veterinary pharmaceutical industry should respect principles of responsible and prudent use and should comply with established codes of advertising ~~practices~~standards, including to:

- a) distribute information in compliance with the provisions of the granted ~~authorization~~ approval;
- b) not advertise ~~VMP~~veterinary medicinal products containing *antimicrobial agents* directly to the food ~~animal-producer breeder, owner and keeper~~.

4. Training

The veterinary pharmaceutical industry should participate in training programmes as defined in point ~~131~~ of Article 6.10.3.

5. Research

The veterinary pharmaceutical industry should contribute to research as defined in point ~~125~~ of Article 6.10.3.

Article 6.10.5.

Responsibilities of wholesale and retail distributors

- 1) Distributors of ~~VMP~~ containing *antimicrobial agents* should only distribute *veterinary medicinal products* containing *antimicrobial agents* ~~de se~~ on the prescription of a *veterinarian* or other suitably trained person authorised to prescribe

~~VMP-veterinary medicinal products~~ containing *antimicrobial agents* in accordance with the national legislation ~~and under the supervision of a veterinarian~~. All products should be appropriately labelled.

- 2) The recommendations on the responsible and prudent use of ~~VMP-veterinary medicinal products~~ containing *antimicrobial agents* should be reinforced by retail distributors who should keep for an appropriate period detailed records of:
- a) date of supply;
 - b) name of prescriber;

EU comment

The EU proposes that point b) is complemented with ‘contact details’, as follows: “b) name and contact details of prescriber”.

- a) name of user;

EU comment

The EU proposes that point c) is further clarified. Is the term ‘user’ referring to the ‘animal breeders, owners and keepers’, or to the ‘recipient’ (buyer)?

- d) name of product;
 - e) batch number;
 - f) expiration date;
 - g) quantity supplied;
 - h) copy of prescription;
 - i) other information as required by national legislation.
- 3) Distributors should also be involved in training programmes on the responsible and prudent use of ~~VMP-veterinary medicinal products~~ containing *antimicrobial agents*, as defined in point ~~131~~ of Article 6.10.3.

Article 6.10.6.

Responsibilities of veterinarians

The *veterinarian's* responsibility is to promote public health, antimicrobial stewardship, *animal health* and *animal welfare*, including detection, diagnosis-identification, prevention and treatment of *animal diseases*. The promotion of sound *animal husbandry* methods, hygiene procedures, *biosecurity* and *vaccination* strategies can help to minimise the need for antimicrobial use in ~~food-producing animals~~.

EU comment

For reasons of clarity and completeness, the EU proposes that the first sentence of the paragraph above is rephrased as follows: “The veterinarian’s responsibility is to promote public health, antimicrobial stewardship, animal health and animal welfare, as well as

public health, by promoting antimicrobial stewardship, including through detection, diagnosis, prevention, control and treatment of animal diseases”.

The veterinarians should only prescribe antimicrobial agents for animals under their care. The veterinarian should consider non-antimicrobial options or alternatives to antimicrobials before prescribing antimicrobial agents.

EU comment

To avoid creating confusion through redundancies, the EU proposes to amend the paragraph above, as follows: “[...] The veterinarian should consider non-antimicrobial options or alternatives to antimicrobials before prescribing antimicrobial agents.”

Some of the responsibilities described in this article may be applicable to veterinary paraprofessionals or other suitably trained persons according to the national legislation.

1. Use of antimicrobial agents Pre-requisites for using antimicrobial agents

The responsibilities of veterinarians are to obtain a detailed history and carry out a proper clinical examination of the animal(s) and then, taking appropriate samples for further testing as necessary. If the provisional or definitive diagnosis is a microbial infection, then the veterinarian should:

- a) administer, or prescribe, dispense or administer antimicrobial agents only when necessary and taking into consideration the OIE list of antimicrobial agents of veterinary importance to treat, control or prevent infectious diseases in animals;
- b) avoid using antimicrobial agents routinely to compensate for inadequate animal husbandry practices;

EU comment

The EU believes this point should be made stronger and therefore proposes to amend the paragraph above, as follows: “b) avoid using not use antimicrobial agents routinely to compensate for inadequate animal husbandry practices;”

- c) take into consideration the OIE List of Antimicrobial Agents of Veterinary Importance and follow science-based species or sector-specific antimicrobial use guidelines for responsible and prudent use when available and follow the principles of antimicrobial stewardship;
- ~~bd)~~ make an appropriate choice of antimicrobial agent based on clinical experience and available diagnostic laboratory information (pathogenic agent isolation, identification and ~~antibiogram~~ antimicrobial susceptibility testing) where possible;
- ee) provide a detailed treatment protocol, including precautions and withdrawal ~~period-times~~ (if applicable), especially when prescribing extra-label or off-label use;
- f) appropriate supportive therapy, which may, for example, include fluid therapy, segregation from other animals, administration of anti-inflammatory or analgesic agents.

EU comment

For reasons of clarity, the EU proposes to amend the paragraph above, as follows: “provide appropriate supportive therapy, as appropriate, which may, for example, include [...]”.

2. Choosing antimicrobial agents

a- The effectiveness ~~expected efficacy~~ of the treatment is based on:

EU comment

For reasons of clarity, the EU proposes to amend the paragraph above, as follows: “a) ~~The effectiveness of the treatment is~~ Veterinarians should choose antimicrobial agents that are effective or likely to be effective based on elements, such as: [...]”

- ia) the clinical experience of the *veterinarians*, their diagnostic insight and therapeutic judgement;
- ib) diagnostic laboratory information (pathogenic agent isolation, identification and ~~antibiogram~~ antimicrobial susceptibility testing);
- ic) pharmacodynamics properties of the selected antimicrobial agent, including the activity towards the pathogenic agents involved;
- id) the appropriate dosage regimen and route of administration;
- ie) pharmacokinetics and tissue distribution to ensure that the selected therapeutic agent is effective at the site of *infection*;
- if) the epidemiological history ~~relevant to of the animal or animals being treated~~ rearing unit, particularly in relation to the antimicrobial resistance profiles of the pathogens ~~pathogenic agents~~ involved.

Should a first-line antimicrobial treatment fail or should the disease recur, an investigation ~~a second line treatment~~ should be undertaken based on the results of diagnostic tests. ~~In the absence of such results, an appropriate antimicrobial agent belonging to a different class or sub-class should be used to reassess the circumstances including reviewing the diagnosis and then formulate and implement a new treatment plan, which may or may not include another antimicrobial agent.~~

~~In emergencies~~ In particular situations, a *veterinarian* may treat *animals* empirically, before ~~without recourse to~~ an accurate diagnosis and antimicrobial susceptibility testing results are available, to prevent the development of clinical disease and for reasons of *animal welfare*.

- b- ~~Use of combinations of antimicrobial agents should be scientifically supported. Combinations of antimicrobial agents may be used for their synergistic effect to increase therapeutic effectiveness efficacy or to broaden the spectrum of activity, but only when scientifically supported.~~

EU comment

To avoid confusion, the EU suggests to amend the paragraph above as follows: “[...] but only when scientifically supported and when needed.”

3. Appropriate use of the selected VMP-veterinary medicinal product containing antimicrobial agents chosen

The A-prescription of a for VMP-veterinary medicinal product containing *antimicrobial agents* should indicate precisely the dosage regimen, the withdrawal period where applicable, and when considering group treatments, the total amount of VMP-veterinary medicinal products containing *antimicrobial agents* to be provided, which will depend ~~depending~~ on the dosage, duration of treatment, and the number of *animals* to be treated.

When prescribing, dispensing or administering a *veterinary medicinal product* containing *antimicrobial agents* intended for veterinary medical use to an individual or a group of *animals* to treat, control or prevent infectious disease as defined in Chapter 6.9, the *veterinarian* should give specific consideration to their categorisation in the OIE List of Antimicrobial Agents of Veterinary Importance as well as to the WHO List of Critically Important Antimicrobials. Preference should be given to the least important *antimicrobial agent* as categorised by WHO that is appropriate for use.

EU comment

For reasons of clarity, the EU suggests:

- to amend the paragraph above as follows: “When prescribing, dispensing or administering [...], as well as to the WHO List of Critically Important Antimicrobials for Human Medicine, and relevant national lists. Preference should be given to the least important antimicrobial agent as categorised by WHO or relevant national categorisation that is appropriate for use.”
- to move the amended paragraph above to point 2. Indeed this paragraph is paramount in choosing the relevant antimicrobials and would therefore be better placed under corresponding point 2.

EU comment

The EU proposes to add here the following sentence: “Prudent and responsible use of antimicrobial agents in animals does not include their use for the purposes of growth promotion or yield increase.”

It is recognised on the international policy stage and in international guidance documents, including in Codex document CXC 61-2005, that responsible and prudent use of antimicrobial agents does not include use for growth promotion.

The *veterinarian* should ensure that instructions for the administration of the product are clearly explained and understood by the food *animal* breeder, owner or keeper.

The extra-label or off-label use of a VMP-veterinary medicinal product containing *antimicrobial agents* may be permitted in certain appropriate circumstances and should be in agreement with the national legislation in force including the withdrawal periods ~~to be used~~, as applicable. It is the *veterinarian's* responsibility to define the conditions of responsible and prudent use in such a case including the dosage regimen, the route of administration and the withdrawal period.

The use of compounded VMP-veterinary medicinal products containing *antimicrobial agents* and extra-label or off-label use of registered VMP-veterinary medicinal products containing *antimicrobial agents* should be limited to circumstances where

an appropriate registered product is not available and should take into account recommendations provided in the OIE List of Antimicrobial Agents of Veterinary Importance.

EU comment

The EU suggests to amend the last two paragraphs of point 3. as follows:

“The extra-label or off-label use of a veterinary medicinal product and the use of compounded veterinary medicinal products containing antimicrobial agents may be permitted in certain appropriate circumstances and should be in agreement with the national legislation in force including the withdrawal periods to be used, as applicable. It is the veterinarian's responsibility to define the conditions of responsible and prudent use in such a case including the dosage regimen, the route of administration and the withdrawal period. The use of compounded veterinary medicinal products containing antimicrobial agents and extra-label or off-label use of registered veterinary medicinal products containing antimicrobial agents should be limited to circumstances where an appropriate registered product is not available and should take into account recommendations provided in the OIE List of Antimicrobial Agents of Veterinary Importance. and should be in agreement with the national legislation in force, including the withdrawal period as applicable. It is the veterinarian's responsibility to define the conditions of responsible and prudent use in such cases, in line with national legislation.”

4. Recording of data

Records of ~~VMP~~ veterinary medicinal products containing *antimicrobial agents* should be kept in conformity with the national legislation. ~~Information~~ Records should include the following, as appropriate:

- a) name of the veterinary medicinal products;
- ab) quantities of VMP used per animal species in animals or supplied to each establishment or animal breeder, owner or keeper;
- b) a list of all VMP supplied to each food-producing animal holding;
- c) route of administration;
- d) animal species;
- e) number of animals treated;
- f) clinical condition treated;
- eg) treatment schedules including animal identification and withdrawal period;
- eh) antimicrobial susceptibility data;
- e) comments concerning the response of animals to treatment;
- fi) the investigation of adverse reactions associated with ~~to~~ antimicrobial treatment, including lack of response due to possible antimicrobial resistance. Suspected adverse reactions should be reported to the appropriate Competent Authority regulatory authorities.

Veterinarians should also periodically review farm records on the use of ~~VMP~~ veterinary medicinal products containing *antimicrobial agents* to ensure compliance with their directions or prescriptions and use these records to evaluate the ~~effectiveness~~ efficacy of treatments.

5. Labelling

All ~~VMP~~ veterinary medicinal products supplied by a *veterinarian* should be labelled in accordance with the national legislation.

6. Training and continued professional development

Veterinary professional and paraprofessional organisations should participate in the training programmes as defined in point 134) of Article 6.10.3. It is recommended that veterinary professional and paraprofessional organisations develop for their members species-specific clinical practice recommendations on the responsible and prudent use of ~~VMP~~ veterinary medicinal products containing *antimicrobial agents*.

Article 6.10.87.

Responsibilities of animal feed manufacturers

1. **The manufacturing and supply of medicated feed containing antimicrobial agents to farmers keeping food-producing animals** by *animal feed* manufacturers should be allowed only on the prescription of a *veterinarian*. Alternatively, such medicated *feed* may be prescribed by other suitably trained persons authorised to prescribe ~~VMP~~ veterinary medicinal products containing *antimicrobial agents* in accordance with the national legislation ~~and under the supervision of a veterinarian~~. *Animal feed* manufacturers preparing medicated *feed* should do so following rules put in place by the *Competent Authority* in accordance with the national legislation. All medicated *feed* and medicated premixes should be appropriately labelled.
2. Keep detailed records for medicated feed and premixes for a suitable period of time according to national legislation.
- ~~2.~~ The regulations and recommendations on the responsible and prudent use of VMP containing *antimicrobial agents* should be reinforced by *animal feed* manufacturers who should keep detailed records.
3. Use only approved sources of pharmaceutical products ~~medications~~: *Animal feed* manufacturers preparing medicated *feed* should ensure that only approved sources of medications are added to *feed* at a level, and for a species and purpose as permitted by the medicated drug-premix label or a veterinary prescription.
4. Ensure appropriate labelling with product identification, direction for use and withdrawal time: *animal feed* manufacturers preparing medicated *feed* should ensure that medicated *animal feed* are labelled with the appropriate information (e.g., level of medication, approved claim, target intended-species, directions for use, warning, cautions) ~~so as to ensure effective and safe use by the producer.~~
5. Implement appropriate production practices to prevent contamination of other *feed*: *animal feed* manufacturers preparing medicated *feed* should implement good manufacturing ~~appropriate production practices~~ to avoid unnecessary carry over and unsafe cross contamination of unmedicated *feed*.
6. Feed manufacturers should participate in training programmes as defined in point 13 of Article 6.10.3.

Article 6.10.78.

Responsibilities of food animal ~~producers~~ breeders, owners and keepers

1. Food ~~animal producers~~ breeders, owners and keepers, with the assistance and guidance of a *veterinarian*, are responsible for implementing *animal health* and *animal welfare* programmes, including biosecurity and good husbandry practices on their farms in order to reduce the need for the use of antimicrobial agents in animals, and to promote animal health and

food safety.

EU comment

For reasons of consistency, the EU proposes to amend the title and paragraph above as follows:

“Responsibilities of ~~food animal~~ breeders, owners and keepers of food-producing animals”

“1. ~~Food animal b~~Breeders, owners and keepers of food-producing animals, [...]”

2. Food *animal producers* breeders, owners and keepers should:

- a) draw up a health plan with the attending *veterinarian* that outlines preventive measures (e.g., feedlot health plans, mastitis control plans, endo- and ectoparasite control, *vaccination* programmes and other biosecurity measures);

EU comment

For reasons of clarity, the EU suggests to amend the title and paragraph above as follows: “a) draw up a health plan with the attending veterinarian that outlines preventive measures (e.g., feedlot health plans, mastitis control plans, endo- and ectoparasite control, vaccination programmes and ~~other~~ biosecurity measures);”

- b) address on-farm biosecurity measures and take hygiene precautions as appropriate;

EU comment

To reinforce the notion that this paragraph intends to promote action, the EU suggests to amend the text of paragraph above as follows: “b) address implement on-farm biosecurity measures and good hygiene practices as appropriate”

- ec) isolate sick *animals*, when appropriate, to avoid the transfer of pathogenic agents;
- d) dispose of dead or dying *animals* promptly under conditions approved by the relevant authorities;
- e) ~~address on-farm biosecurity measures and take basic hygiene precautions as appropriate;~~
- be) use *veterinary medicinal products* VMP containing *antimicrobial agents* only on the prescription and under the supervision of a *veterinarian*, *veterinary paraprofessional* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agents* in accordance with the national legislation ~~and under the supervision of a *veterinarian*;~~
- ef) use *veterinary medicinal products* VMP containing *antimicrobial agents* in accordance with product label instructions, including storage conditions, and ~~or~~ the instructions of the ~~attending prescribing~~ *veterinarian*;

EU comment

The EU suggests that the paragraph above is complemented to allow for extra-label or off-label use of antimicrobials, as provided in Article 6.10.6. point 3 and therefore to amend the paragraph above, as follows: “f) use veterinary medicinal products containing antimicrobial agents in accordance with product label instructions, including storage conditions, and the instructions of the prescribing veterinarian; extra-label or off -label use of veterinary medicinal products containing antimicrobial agents should be in line with the relevant national legislation and the instructions of the prescribing veterinarian;”

- fg) comply with ~~and record~~ the recommended withdrawal periods to ensure that residue levels in *animal*-derived food do not present a *risk* for the consumer;
- gh) use ~~VMP~~ veterinary medicinal products containing *antimicrobial agents* within the expiry date and dispose of unused and expired surplus ~~VMP~~ veterinary medicinal products containing *antimicrobial agents* under conditions safe for the environment according to the SPC or equivalent, or relevant national legislation;
- i) ensure that only medicated premixes containing *antimicrobial agents* from authorised sources are added to feed at a dose and duration appropriate for the target *animal species* and purpose of use as permitted by the medicated premix label or a veterinary prescription when preparing medicated *feed on-farm*;
- hj) maintain all the laboratory records of bacteriological and susceptibility tests; these data should be made available to the *veterinarian* responsible for treating the *animals*;

EU comment

In order to align with Codex document CXC 61-2005 and acknowledge the fact that it is frequently the veterinarian who maintains such records, the EU suggests that the paragraph above is amended, as follows: “j) maintain, or have their veterinarian maintain, all the laboratory records of bacteriological and susceptibility tests; these data should be made available to the veterinarian responsible for treating the animals;”

- ik) keep adequate records of all ~~VMP~~ veterinary medicinal products containing *antimicrobial agents* used, including the following:
 - i) name of the product and active substance, batch number and expiry date;
 - ii) name of prescriber and the supplier;
 - iii) date of administration;
 - iv) identification of the *animal* or group of *animals*, and the number of *animals* to which the *antimicrobial agent* was administered;
 - v) clinical conditions treated;
 - vi) ~~dose~~ dose regimen;

- vii) withdrawal periods including the end-date of the withdrawal periods;
- viii) results of laboratory tests;
- ix) effectiveness of therapy;
- x) suspected adverse events;

EU comment

Under point k):

- **The animal breeders, owners, keepers of food-producing animals are requested to keep an extensive record. The EU proposes to reduce the amount of information recorded to the essential elements needed, in order to simplify the implementation at farm level, while also aligning with Codex document CXC 61-2005;**
- **For reasons of consistency of wording with Codex document CXC 61-2005, the EU also suggests that under point v), ‘clinical conditions treated’ is replaced by ‘disease treated’;**
- **For reasons of clarity, the EU proposes to make more explicit possible elements covered by the expression ‘dose regimen’;**

so that the text would be amended as follows:

“k) keep adequate records of all veterinary medicinal products containing antimicrobial agents used, including the following:

- i) name of the product and active substance, and batch number ~~and expiry date~~;**
- ii) name and contact details of prescriber and the supplier;**
- iii) date of administration;**
- iv) identification of the animal or group of animals, and the number of animals to which the antimicrobial agent was administered;**
- v) ~~clinical conditions treated;~~ disease treated;**
- vi) dose regimen (including dose, frequency and duration of treatment);**
- vii) withdrawal periods including the end-date of the withdrawal periods;**
- ~~viii) results of laboratory tests;~~**
- ~~ix) effectiveness of therapy;~~**
- ~~x) suspected adverse events;”~~**

ij) inform the responsible *veterinarian* of recurrent disease problems.

3. Training

Food ~~animal producers~~ breeders, owners and keepers should participate in the training programmes as defined in in point 134 of Article 6.10.3.

It is recommended that food ~~animal producer~~ organisations work in cooperation with the veterinary professional organisations to implement existing guidelines for the responsible and prudent use of ~~VMP~~ veterinary medicinal products containing *antimicrobial agents*.

Article 6.10.9.

Responsibilities of breeders, owners and keepers of non-food producing animals

Animal breeders, owners and keepers, with the assistance and guidance of a *veterinarian*, are responsible for the health and welfare of their *animals* and should:

- 1) implement the wellness plans and preventative health plans recommended by their *veterinarian*;
- 2) strictly follow their *veterinarian's* recommendations and ensure that if any, the administration of *veterinary medicinal products* containing *antimicrobial agents* follows the veterinary prescription;
- 3) avoid administering over the counter, leftover and expired human and *animal antimicrobials agents* to their *animals*;

EU comment

The EU wishes to propose a stronger wording to discourage the use of leftover and expired antimicrobial agents and proposes to amend the paragraph above by splitting it in two different paragraphs, as follows: “3) avoid administering over the counter ~~leftover and expired human and animal~~ veterinary antimicrobials agents to their animals; 4) not administer leftover and expired human and veterinary antimicrobials agents to their animals;”

- 4) inform their *veterinarian* or *veterinary paraprofessional* of the administration of any additional medicinal products than those prescribed by the *veterinarian* during the consultation;
- 5) inform their *veterinarian* of any observed lack of response or other adverse effect.

CHAPTER 8.X.

INFECTION WITH *COXIELLA BURNETII* (Q FEVER)**EU comment**

The EU thanks the Code Commission and in general supports this proposed new chapter. A comment is inserted in the text below.

Article 8.X.1.

General provisions

Various animal species and humans can be affected by Q fever. For the purposes of the *Terrestrial Code*, Q fever is defined as an *infection* of domestic and *captive wild* ruminants, dogs, and cats (hereafter 'susceptible animal') with *Coxiella burnetii*.

The following defines the occurrence of *infection* with *C. burnetii*:

- 1) *C. burnetii* has been isolated and identified as such in a sample from a susceptible animal; or
- 2) nucleic acid specific to *C. burnetii* has been detected in a sample from a susceptible animal that is epidemiologically linked to a confirmed or suspected *case*; or
- 3) antibodies specific to *C. burnetii*, that are not the consequence of *vaccination*, have been detected in a sample from a susceptible animal that is epidemiologically linked to a confirmed or suspected *case*.

EU comment

The EU suggests including reference to clinical signs, in both points 2 and 3 above, as in other chapters of the Code.

Indeed, according to the corresponding Manual chapter, and depending on the species, clinical signs can be observed in animals (mainly abortions).

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

CHAPTER 11.5.

**INFECTION WITH *MYCOPLASMA*
MYCOIDES SUBSP. *MYCOIDES* SC
(CONTAGIOUS BOVINE PLEUROPNEUMONIA)**

EU comment

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

Article 11.5.1.

General provisions

1) For the purposes of this chapter, susceptible *animals* means domestic bovines (*Bos indicus*, *B. taurus*, *B. grunniens* and *Bubalus bubalis*).

EU comment

The EU queries why the list of susceptible animals in point 1 above is restricted to domestic bovines, while the recommendations in some of the articles below relate to bovines (no distinction between domestic and wild). We would suggest deleting the word “domestic” in the point above, and throughout the chapter.

2a) For the purposes of the *Terrestrial Code*, the incubation period for contagious bovine pleuropneumonia (CBPP) shall be six months.

For the purpose of this chapter, is defined as an *animal infected of susceptible animals* with *Mycoplasma mycoides* subspecies *mycoides* SC (*Mmm*SC), and freedom from CBPP means freedom from *Mmm*SC infection.

For the purpose of this chapter, susceptible *animals* include bovids (*Bos indicus*, *B. taurus* and *B. grunniens*) and water buffaloes (*Bubalus bubalis*).

3) For the purposes of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by *Mmm*SC, but also with the presence of *infection* with *Mmm*SC in the absence of clinical signs.

4) The following defines the occurrence of *infection with Mmm*SC *infection*:

1a) *Mmm*SC has been isolated and identified as such in from an *animal*, embryos, oocytes or semen a *sample from a susceptible animal*; or

2b) *Mmm* deoxyribonucleic acid has been detected in a sample from a susceptible animal showing pathological lesions consistent with an *infection with Mmm*SC, and epidemiological links to a confirmed case.

c) antibodies specific to *Mmm*SC antigens, which are not the consequence of vaccination, have been detected in a sample from a susceptible animal showing pathological lesions consistent with an *infection with Mmm*SC, and epidemiological links to a confirmed case or *Mmm*SC deoxyribonucleic acid have been identified in one or more animals showing pathological lesions consistent with *infection with Mmm*SC with or without clinical signs, and epidemiological links to a confirmed outbreak of CBPP in susceptible animals.

EU comment

The EU queries why clinical signs and suspected cases are not referred to in both points b) and c) above, as is the case in most case definitions. Indeed, we note that point 4 of Article 11.5.13. makes reference to clinical surveillance, while point 5 of that article refers to suspected cases.

5) The purposes of the *Terrestrial Code*, the incubation period shall be six months.

When authorising import or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 11.5.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the CBPP status of the domestic bovids and water buffalo population of the *exporting country, zone or compartment*.

6) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 11.5.2.

Safe commodities

When authorising the importation or transit of the following *commodities*, *Veterinary Authorities* should not require any CBPP-related conditions, regardless of the CBPP status of the domestic bovids bovine and water buffalo population of the *exporting country, zone or compartment*:

- 1) *milk and milk products*;
- 2) *hides and skins*;
- 3) *meat and meat products* (excluding lung).

Article 11.5.3.

Country or zone free from CBPP free country or zone

A country or zone may be considered free from CBPP 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 24 months:

- 1) there has been no case of infection with *Mmm*;
- 2) the *Veterinary Authority* has current knowledge of, and authority over, all herds of susceptible animals;
- 3) appropriate surveillance has been implemented in accordance with:
 - a) Article 1.4.6. where historical freedom can be demonstrated; or
 - b) Articles 11.5.13. and 11.5.14. where historical freedom cannot be demonstrated;
- 4) measures to prevent the introduction of the *infection* have been in place: in particular, the importations or movements of bovine *commodities* into the country or zone have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*;
- 5) no vaccination or treatment against CBPP has been carried out;
- 6) no animal vaccinated or treated against CBPP have been introduced since the cessation of vaccination.

EU comment

The EU queries why in point 6 above, the time limit for not having introduced vaccinated animals is “since the cessation of vaccination”. This assumes that at some point in the past, animals were vaccinated in that country or zone, which may not be the case. The EU therefore suggests adding “or for at least the past 24 months”. Alternatively, the sentence could end with “[...] have been introduced”, as the chapeau sentence already refers to “for at least the past 24 months”.

To qualify for inclusion in the existing list of CBPP free countries and zones, a Member Country should:

- 1) have a record of regular and prompt animal disease reporting;

2) send a declaration to the OIE stating that:

- a) there has been no outbreak of CBPP during the past 24 months;
- b) no evidence of CBPP infection has been found during the past 24 months;
- c) no vaccination against CBPP has been carried out during the past 24 months;

and supply documented evidence that surveillance for CBPP in accordance with this chapter is in operation and that regulatory measures for the prevention and control of CBPP have been implemented;

3) not have imported since the cessation of vaccination any animals vaccinated against CBPP.

The country or zone will be included in the list of countries or zones free from CBPP in accordance with Chapter 1.6. only after the submitted evidence 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. that the information in points 2 a), 2 b), 2 c) and 3 above be re-submitted annually and Documented evidence should be resubmitted annually for points 1 to 4 above. Any changes in the epidemiological situation or other significant events should be reported notified to the OIE in accordance with the requirements in Chapter 1.1.

Article 11.5.46.

Compartment free from CBPP free compartment

The bilateral recognition of a CBPP free compartment should follow the principles laid down in this chapter and in Chapters 4.3. and 4.4.

A compartment free from CBPP can be established in any country or zone. In defining such a compartment the principles of Chapters 4.4. and 4.5. should be followed. Susceptible animals in the compartment should be separated from any other susceptible animals by the effective application of a biosecurity plan.

A Member Country wishing to establish a compartment free from CBPP 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 CBPP in place in accordance with Articles 11.5.13. and 11.5.14. that allows knowledge of the prevalence, distribution and characteristics of CBPP in the country or zone;

2) declare for the free compartment that:

- a) there has been no case of CBPP during the past 24 months;
- b) no infection with Mmm has been detected during the past 24 months;
- c) vaccination against CBPP is prohibited;
- d) no animal vaccinated or treated against CBPP within the past 24 months is in the compartment;
- e) animals, semen and embryos may only enter the compartment in accordance with relevant articles in this chapter;
- f) documented evidence shows that surveillance in accordance with Articles 11.5.13. and 11.5.14. is in operation;
- g) an animal identification and traceability system in accordance with Chapters 4.1. and 4.2. is in place;

3) describe in detail:

- a) the animal subpopulation in the compartment;
- b) the biosecurity plan to mitigate the risks identified by the surveillance carried out in accordance with point 1 notably to prevent the aerosol transmission of CBPP.

The compartment should be approved by the Veterinary Authority.

Article 11.5.5.

Country of zone infected with Mmm CBPP infected country or zone

A country or zone shall be considered as infected with Mmm when the requirements for acceptance as a CBPP free country or zone free from CBPP are not fulfilled, a country or zone shall be considered as infected.

Article 11.5.5bis.

Establishment of a containment zone within a country or zone previously free from CBPP

In the event of outbreaks of CBPP within a country or zone previously free from CBPP, including within a protection zone, a containment zone, which includes all epidemiologically linked outbreaks, can be established, in accordance with Article 4.4.7., to minimise the impact on the rest of the country or zone.

EU comment

The EU suggests replacing the word “can” with “may” in the paragraph above, for clarity and consistency with Article 4.4.7. and with the corresponding provision in other disease-specific chapters (e.g. FMD).

For this to be achieved and for the Member Country to take full advantage of this process, the Veterinary Authority should submit as soon as possible to the OIE, in addition to the requirements of Article 4.4.7., in support of the application, documented evidence that:

- 1) on suspicion, a strict standstill has been imposed on the suspected establishments and in the country or zone animal movement control has been imposed and effective controls on the movement of other relevant commodities are in place;
- 2) on confirmation, an additional standstill of susceptible animals has been imposed in the entire containment zone and the movement controls described in point 1 have been reinforced;
- 3) investigations into the likely source of the outbreaks have been carried out;
- 4) a slaughter policy, with or without the use of emergency vaccination, has been applied;
- 5) surveillance in accordance with Articles 11.5.13. and 11.5.14. is in place in the containment zone and in the rest of the country or zone;
- 6) measures that prevent the spread of CBPP 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 may be reinstated irrespective of the provisions of Article 11.5.4., once the containment zone has been approved by the OIE as complying with Article 4.4.7. and points 1 to 6 above.

In the event of recurrence of infection with Mmm 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 CBPP status of the whole country or zone is suspended until the relevant requirements of Article 11.5.4. are fulfilled.

In the event of occurrence of infection with Mmm in the outer zone of a containment zone established in accordance with point 4(b) of Article 4.4.7., the approval of the containment zone is withdrawn and the status of the whole country or zone is suspended until the relevant requirements of Article 11.5.4. are fulfilled.

The recovery of the CBPP free status of the containment zone should follow the provisions of Article 11.5.4.

Article 11.5.64.

Recovery of free status

Should an outbreak of CBPP occur in a previously free country or zone, its status may be recovered when surveillance in accordance with Articles 11.5.13. and 11.5.14. has been carried out with negative results, and 12 months after:

- 1) the disinfection of the last affected establishment, provided that a slaughter policy without vaccination has been implemented, or
- 2) the disinfection of the last affected establishment and the slaughter of all vaccinated animals, provided that a slaughter policy with emergency vaccination and slaughter of vaccinated animals has been implemented.

When a CBPP outbreak occurs in a CBPP free country or zone, one of the following waiting periods is required to regain the status of CBPP free country or zone:

EU comment

There is an issue with this article – there are duplications of text, and it seems the sentence above is not newly added (it corresponds to the current text in this article).

- 1) 12 months after the last case where a stamping-out policy and serological surveillance and strict movement control are applied in accordance with this chapter;
- 2) if vaccination was used, 12 months after the slaughter of the last vaccinated animal.
- 1) 12 months after the slaughter of the last case where a slaughter policy, without emergency vaccination, and surveillance are applied in accordance with Articles 11.5.13. and 11.5.14.; or
- 2) 12 months after the slaughter of the last case and of all vaccinated animals, whichever occurred last, where a slaughter policy, emergency vaccination and surveillance in accordance with Articles 11.5.13. and 11.5.14. are applied.

The country or zone will regain the status of CBPP free country or zone only after the submitted evidence, based on the provisions of Chapter 1.10., has been accepted by the OIE.

Where a ~~stamping-out~~ slaughter policy is not practised, the above waiting periods do not apply but Article 11.5.3. applies.

Article 11.5.7.

Recommendations for importation of susceptible animals from CBPP-free countries, ~~or zones,~~ or compartments free from CBPP free compartments

For domestic bovids and water buffaloes

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

- 1) showed no clinical sign of CBPP on the day of shipment;
- 2) were kept in a CBPP free country, zone or compartment since birth or for at least the past six months.

Article 11.5.8.

Recommendations for importation of susceptible animals from CBPP-infected countries or zones infected with Mmm for immediate slaughter

For domestic bovids and water buffaloes for slaughter

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

- 1) showed no clinical sign of CBPP on the day of shipment;
- 2) originate from an establishment in which surveillance in accordance with Articles 11.5.13. and 11.5.14. demonstrates that where no case of CBPP had occurred was officially reported for during the past six months; and

- 3) are transported directly under the supervision of the Veterinary Authority in a vehicle/vessel, which was subjected to disinfection before loading, directly from the establishment of origin to the slaughterhouse/abattoir in sealed vehicles without coming into contact with other susceptible animals.

EU comment

For clarity and consistency with the title of the article, the EU suggests inserting the words “for immediate slaughter” after “slaughterhouse/abattoir” in point 3 above.

Article 11.5.9.

Recommendations for importation of bovine semen from CBPP free countries, or zones, or compartments free from CBPP free compartments

For bovine semen

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

- 1) the donor animals:
 - a) showed no clinical sign of CBPP on the day of collection of the semen;
 - b) were kept in a CBPP free country, *zone* or *compartment* since birth or for at least the past six months;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.

Article 11.5.10.

Recommendations for importation of bovine semen from CBPP infected countries or zones infected with Mmm

For bovine semen

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

- 1) the donor animals:
 - a) showed no clinical sign of CBPP on the day of collection of the semen;
 - b) were subjected to the complement fixation a serological test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;
 - c) were isolated from other domestic bovids and water buffaloes susceptible animals from the day of the first the complement fixation serological test until collection;
 - d) were kept since birth, or for the past six months, in an *establishment* in which surveillance in accordance with Articles 11.5.13. and 11.5.14. demonstrates that where no case of CBPP was reported had occurred during that period, and that the establishment was not situated in a CBPP infected zone;
 - e) AND EITHER:
 - i) have not been vaccinated against CBPP;
 - OR
 - ii) were vaccinated using a vaccine complying with the standards described in the Terrestrial Manual not more than four months prior to collection; in this case, the condition laid down in point b) above is not required;
- 2) the semen:
 - a) was collected, processed and stored in accordance with Chapters 4.56. and 4.67.;

- b) was subjected to a test for the identification of the agent.

Article 11.5.11.

Recommendations for importation of in vivo derived or in vitro produced oocytes or embryos of susceptible animals from CBPP free countries, or zones, or compartments free from CBPP free compartments

~~For in vivo derived or in vitro produced oocytes or embryos of domestic bovids and water buffaloes~~

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

- 1) the donor animals:
 - a) showed no clinical sign of CBPP on the day of collection of the oocytes or embryos;
 - b) were kept in a CBPP free country, zone or compartment since birth or for at least the past six months;
- 2) the oocytes were fertilised with semen meeting the conditions of Articles 11.5.9. or 11.5.10.;
- 3) the oocytes or embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.

Article 11.5.12.

Recommendations for importation of in vivo derived or in vitro produced oocytes or embryos of susceptible animals from CBPP infected countries or zones infected with Mmm

~~For in vivo derived or in vitro produced oocytes or embryos of domestic bovids and water buffaloes~~

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

- 1) the donor animals:
 - a) showed no clinical sign of CBPP on the day of collection of the embryos or oocytes;
 - b) were subjected to the complement fixation a serological test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;
 - c) were isolated from other domestic bovids and water buffaloes from the day of the first the complement fixation serological test until collection;

EU comment

For consistency with the title of the chapter, the EU suggests replacing “domestic bovids and water buffaloes” in point c) above with “susceptible animals”.

- d) were kept since birth, or for the past six months, in an *establishment* in which surveillance in accordance with Articles 11.5.13. and 11.5.14. demonstrates that where no case of CBPP was reported had occurred during that period, and that the establishment was not situated in a CBPP infected zone;
- e) AND EITHER:
 - i) have not been vaccinated against CBPP;OR
 - ii) were vaccinated using a vaccine complying with the standards described in the Terrestrial Manual not more than four months prior to collection; in this case, the condition laid down in point b) above is not required;
- 2) the oocytes were fertilised with semen meeting the conditions of Articles 11.5.9. and or 11.5.10.;

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

Article 11.5.13.

Introduction to surveillance General principles of surveillance

Articles 11.5.13. ~~to and~~ 11.5.17.14. define the principles and provide a guide for the *surveillance* of CBPP in accordance with Chapter 1.4. notably point 2(h) of Article 1.4.3. concerning quality assurance applicable to Member Countries seeking establishment of freedom from CBPP. Guidance is provided for Member Countries seeking reestablishment, maintenance or recovery of freedom from CBPP for at the entire country, or for a zone, following an outbreak or compartment level or seeking endorsement by the OIE of their official control programme for CBPP, in accordance with Article 11.5.13. *Surveillance* aims at identifying infection in susceptible species as indicated in Article 11.5.1.

1. Early detection

A surveillance system for early detection should be in place in accordance with Chapter 1.4. under the responsibility of the Veterinary Authority.

2. Demonstration of freedom

The impact and epidemiology of CBPP differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from CBPP at an acceptable level of confidence should be adapted to the local situation. It is incumbent upon the applicant Member Country to submit a dossier to the OIE in support of its application that not only explains the epidemiology of CBPP in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically-based supporting data. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that the absence of CBPP infection is assured at an acceptable level of confidence.

Surveillance for CBPP should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from CBPP infection.

A Member Country wishing to substantiate freedom from CBPP should demonstrate absence of infection with Mmm in susceptible populations.

~~Article 11.7.14.~~

General conditions and methods for surveillance

3. OIE endorsed official control programme

Surveillance strategies employed in support of an OIE endorsed official control programme should demonstrate evidence of the effectiveness of any control strategy used and of the ability to rapidly detect all outbreaks of CBPP outbreaks.

Considerable latitude exists for Member Countries to design and implement surveillance to establish that the whole country or a zone is free from CBPP and to understand the epidemiology of CBPP as part of the official control programme.

The Member Country should submit a dossier to the OIE in support of its application that explains the epidemiology of CBPP in the region concerned and demonstrates how all the risk factors are identified and managed. This should include provision of scientifically based supporting data.

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.

The entire investigative process should be documented within the surveillance system in accordance with Chapter 1.4. should be under the responsibility of the Veterinary Authority. A procedure should be in place for the rapid collection and transport of samples from suspect cases of CBPP to a laboratory for CBPP diagnoses.

2) The CBPP surveillance programme should:

- a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers (such as community animal health workers) who have day to day contact with livestock, meat inspectors as well as laboratory diagnosticians, should report promptly any suspicion of CBPP. They should be integrated directly or indirectly (e.g. through private veterinarians or veterinary para-professionals) into the surveillance system. All suspect cases of CBPP should be investigated immediately. Where suspicion cannot be resolved by the epidemiological and clinical investigation, samples should be taken and submitted to a laboratory. This requires that sampling kits information should be substantiated, and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in CBPP diagnosis and control;
- b) implement, when relevant, regular and frequent clinical inspection and testing of high risk groups of animals, such as those adjacent to a CBPP infected country or zone (for example, areas of transhumant production systems);
- c) take into consideration additional factors such as animal movement, different production systems, geographical and socio-economic factors that may influence the risk of disease occurrence.

An effective surveillance system will periodically identify suspicious cases that require follow up and investigation to confirm or exclude that the cause of the condition is CBPP. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from CBPP infection should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand still orders, etc.) should be collated in the final report.

Article 11.7.15.

4. Surveillance strategies

1. Introduction

The target population for surveillance aimed at identifying disease and infection should cover all the susceptible species (*Bos taurus*, *B. indicus*, *B. grunniens* and *Bubalus bubalis*) within the country or zone.

Given the limitations of the diagnostic tools available, the interpretation of serological surveillance results should be at the herd level rather than at the individual animal level.

Randomised surveillance may not be the preferred approach given the epidemiology of the disease (usually uneven distribution and potential for occult foci of infection in small populations) and the limited sensitivity and specificity of currently available tests. Targeted Risk-based surveillance (e.g. based on the increased likelihood of infection in particular localities or species, focusing on slaughter findings, and active clinical surveillance) may be the most appropriate strategy. The applicant Member Country should justify the surveillance strategy chosen as adequate to detect the presence of CBPP infection in accordance with Chapter 1.4. and the epidemiological situation.

Targeted Risk-based surveillance may involve testing of the entire target subpopulation or a sample from it. In the latter case the sampling strategy should incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing should be large enough to detect infection if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant Member Country should justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular should be clearly based on the prevailing or historical epidemiological situation.

Regular and frequent clinical inspection and testing of high-risk groups of animals, such as those adjacent to a country or zone infected with *Mmm* (for example, areas of transhumant production systems) should be implemented when relevant.

Additional factors such as animal movement, different production systems, geographical and socio-economic factors that may influence the risk of disease introduction and occurrence should be taken into consideration.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated.

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 an *infection* with *Mmm*. 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 measures applied to the animals concerned during the investigation.

Irrespective of the surveillance system employed, the design should anticipate the occurrence of false positive laboratory results/reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether or not they are indicative of *infection* or not. This should involve follow-up with supplementary tests, clinical and follow-up investigation and post-mortem examination in to collect diagnostic material from the original sampling epidemiological unit as well as and herds which may be epidemiologically linked to it.

Laboratory results should be examined in the context of the epidemiological situation.

Article 11.5.14.

Methods of surveillance

1. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs of CBPP in a *herd* by close physical examination of susceptible *animals*. Clinical inspection is an important component of CBPP *surveillance* contributing to reach the desired level of confidence of detection of disease if a sufficiently large number of clinically susceptible *animals* is examined.

Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of CBPP suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing and post-mortem examination may contribute to confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced.

2. Pathological surveillance

Systematic pathological *surveillance* for CBPP is the most effective approach and should be conducted at slaughterhouses/abattoirs and other slaughter facilities. Suspect pathological findings should be confirmed by agent identification. Training courses for slaughter personnel and meat inspectors are highly recommended.

4. Serological 3. Laboratory testing

Serological *surveillance* is not the preferred strategy for CBPP. However, in the framework of epidemiological investigations, serological testing may be used.

The limitations of available serological tests for CBPP make the interpretation of results difficult and useful only at the *herd* level. Positive findings should be followed up by clinical and pathological investigations and agent identification.

Clustering of seropositive reactions should be expected in CBPP *infections* and is usually accompanied by clinical signs. As clustering may signal field strain *infection*, the investigation of all instances should be incorporated in the *surveillance* strategy.

Following the identification of a CBPP infected *herd*, contact *herds* should be tested serologically. Repeated testing may be necessary to reach an acceptable level of confidence in *herd* classification.

5. Agent surveillance

Agent *surveillance* should be conducted to follow-up and confirm or exclude infection with *Mmm* suspect cases. Isolates should be typed to confirm *Mmm*SC.

Article 11.5.16.

Countries or zones applying for recognition of freedom from CBPP

In addition to the general conditions described in this chapter, a Member Country applying for recognition of CBPP freedom for the country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme depend on the prevailing epidemiological circumstances and should be planned and implemented in accordance with general conditions and methods in this chapter, to demonstrate absence of CBPP *infection*, during the preceding 24 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of CBPP *infection*.

Article 11.5.17.

Countries or zones re-applying for recognition of freedom from CBPP following an outbreak

In addition to the general conditions described in this chapter, a Member Country re-applying for recognition of country or *zone* freedom from CBPP should show evidence of an active *surveillance* programme for CBPP, following the recommendations of this chapter.

Two strategies are recognised by the OIE in a programme to eradicate CBPP *infection* following an *outbreak*:

- 1) *slaughter* of all clinically affected and in contact susceptible animals;
- 2) *vaccination* used without subsequent *slaughter* of vaccinated animals.

The time periods before which an application can be made for re-instatement of freedom from CBPP depends on which of these alternatives is followed. The time periods are prescribed in Article 11.5.4.

Article 11.5.15-18.

OIE endorsed official control programme for CBPP

The overall objective of an OIE endorsed *official control programme* for CBPP is for Member Countries to progressively improve their situation and eventually attain CBPP free status. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined subpopulations.

A Member Country^{ies} may, on a voluntary basis, apply for endorsement of their/its *official control programme* for CBPP in accordance with Chapter 1.6. when they have it has implemented measures in accordance with this article.

For an *official control programme* for CBPP to be endorsed by the OIE, the Member Country should provide a detailed *official control programme* for the control and eventual eradication of CBPP in the country or *zone*. This document should address and provide documented evidence on the following:

- 1) epidemiology:
 - a) the detailed epidemiological situation of CBPP 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) CBPP *surveillance* in place, in accordance with Chapter 1.4. and Articles 11.5.13. and 11.5.14.
 - b) diagnostic capability and procedures, including regular submission of samples to a laboratory that performs diagnostic testing and further characterisation of strains in accordance with the *Terrestrial Manual* including procedures to isolate and identify *Mmm*;
- 3) vaccination (if practised as part of the *official control programme* for CBPP):
 - a) *vaccination* is in accordance with Chapter 4.18. and compulsory in the target *population*;
 - 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 and description of the vaccine licensing procedures in place;
 - vii) 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 CBPP *outbreaks*;
 - 5) an emergency preparedness plan and an emergency response plan to be implemented in case of CBPP *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 *Veterinary Services* to control CBPP; this evidence can be provided by countries following the OIE PVS Pathway;
 - 3) submit a detailed plan of the programme to control and eventually eradicate CBPP in the country or zone including:
 - a) the timeline;
 - b) the performance indicators for assessing the efficacy of the control measures to be implemented;
 - e) submit documentation indicating that the *official control programme* for CBPP has been implemented and is applicable to the entire territory;
 - 4) submit a dossier on the epidemiology of CBPP in the country describing the following:
 - a) the general epidemiology in the country highlighting the current knowledge and gaps;
 - b) the measures to prevent introduction of *infection*, the rapid detection of, and response to, all CBPP *outbreaks* in order to reduce the incidence of CBPP *outbreaks* and to eliminate CBPP in at least one *zone* in the country;
 - e) the main livestock production systems and movement patterns of CBPP susceptible animals and their products within and into the country;
 - 5) submit evidence that CBPP *surveillance* is in place,
 - a) taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter;
 - b) have diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains in accordance with the *Terrestrial Manual* including procedures to isolate and identify *M. mycoides* subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC;
 - 6) where *vaccination* is practised as a part of the *official control programme* for CBPP, 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;
 - iii) technical specification of the vaccines used and description of the licensing procedures in place;
 - iv) the proposed timeline and strategy for the cessation of *vaccination*;
- 7) provide an emergency preparedness and contingency response plan to be implemented in case of CBPP *outbreaks*.

The Member Country's *official control programme* for CBPP will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE.

The country will be included in the list of countries having an OIE endorsed *official control programme* for CBPP 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 of CBPP that cannot be addressed by the programme.
-

CHAPTER 11.X.

INFECTION WITH BOVINE PESTIVIRUSES
(BOVINE VIRAL DIARRHOEA)**EU comment**

The EU thanks the Code Commission but does not support this proposed new chapter as presented. Comments are inserted in the text below.

Article 11.X.1.

General provisions

For the purposes of the *Terrestrial Code*, bovine viral diarrhoea is defined as an *infection* of bovines (*Bos taurus*, *Bos indicus* and *Bubalus bubalis*) (hereafter 'susceptible animals') with bovine viral diarrhoea virus type 1 (pestivirus A), type 2 (pestivirus B), and type 3 (pestivirus H) (hereinafter 'bovine pestiviruses').

EU comment

The EU does not support the proposed definition of the term “bovines” in the paragraph above. Indeed, it is not clear why it does not include all species of the genus *Bos*, and also the genus *Bubalus* and *Bison* (as indicated for the term “bovines” under Item 5.15. of the Code Commission report), which would be more appropriate. We therefore suggest referring to bovines only, or to add *Bos*, *Bubalus* and *Bison* spp. in parenthesis after “bovines”.

The following defines the occurrence of *infection* with bovine pestiviruses:

- 1) bovine pestivirus, excluding vaccine strains, has been isolated and identified as such in a sample from a susceptible animal; or

EU comment

The EU does not support including the words “and identified as such” in point a) above, as they are superfluous. Agent identification is implicitly part of “bovine pestivirus [...] has been isolated”.

Indeed, identification of the agent via specific laboratory diagnostic methods is an inherent part of virus isolation, as indicated and described in the recently adopted corresponding Manual chapter.

The combination of “pathogenic agent” + “isolation” is a well-established practice in the case definitions of disease specific chapters and should be maintained consistently throughout the Code.

- 2) antigen or ribonucleic acid specific to bovine pestivirus, excluding vaccine strains, has been detected in a sample from a susceptible animal.

EU comment

The EU does not support point 2 above as presented. Indeed, antigen or ribonucleic acid detection alone would have the same effect as virus isolation (no difference to point 1). This is neither appropriate nor in line with other case definitions in the Code. We therefore suggest amending point 2 above as follows:

“antigen or ribonucleic acid specific to bovine pestivirus, excluding vaccine strains, has been detected in a sample from a susceptible animal showing clinical signs consistent with bovine viral diarrhoea, or epidemiologically linked to a confirmed or suspected case of bovine viral diarrhoea.”

Furthermore, for consistency with other case definitions in the Code, the EU suggests adding a point 3, as follows:

“3) antibodies to bovine pestiviruses, that are not a consequence of vaccination, have been detected in a sample from a susceptible animal showing clinical signs consistent with bovine viral diarrhoea, or epidemiologically linked to a confirmed or suspected case of bovine viral diarrhoea.”

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

UNOFFICIAL VERSION

CHAPTER 12.1.
INFECTION WITH
AFRICAN HORSE SICKNESS VIRUS

EU comment

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

Article 12.1.1.

General provisions

For the purposes of the *Terrestrial Code*, African horse sickness (AHS) is defined as an *infection* of equids with African horse sickness virus (AHSV).

The following defines **the occurrence of** an *infection* with AHSV:

- 1) AHSV has been isolated and identified **as such in a sample** from an equid **or a product derived from that equid**; or

EU comment

The EU suggests deleting the words “and identified as such” in point 1) above, as they are superfluous. Agent identification is implicitly part of “AHSV has been isolated”.

Indeed, identification of the agent via specific laboratory diagnostic methods is an inherent part of virus isolation.

The combination of “pathogenic agent” + “isolation” is a well-established practice in the case definitions of disease specific chapters and should be maintained consistently throughout the Code.

- 2) **antigen or** ribonucleic acid specific to AHSV has been identified in **a sample** from an equid showing clinical signs **or pathological lesions** consistent with AHS, or epidemiologically linked to a **confirmed or** suspected **or confirmed** case; or

EU comment

For reasons of consistency with other chapters currently being revised or adopted recently, the EU suggests replacing the word “identified” with “detected” in point 2 above.

- 3) **serological evidence of active infection with AHSV by detection of** seroconversion with production of antibodies against **structural or nonstructural proteins of** AHSV that are not a consequence of *vaccination* **have has been identified detected in a sample from** an equid that either shows clinical signs **or pathological lesions** consistent with AHS, or is epidemiologically linked to a **confirmed or** suspected **or confirmed** case.

EU comment

The EU suggests deleting the words “seroconversion with production of” in point 3) above, as they are superfluous and not adapted to the proposed deletion of the first part of the sentence. Referring just to “antibodies” would be in line with other case definitions in the Code. And strictly speaking, detection of seroconversion would require paired samples (not possible with just one sample).

For the purposes of the *Terrestrial Code*, the *infective period* for AHS is 40 days for **domestic** horses. **Although critical information is lacking for some species, this chapter applies to all equidae.**

EU comment

The EU queries what the infective period is for AHS in equids other than horses. Can the isolation time before dispatch for equids other than horses be the same as for horses? This would be relevant also for the recommendations on semen, oocytes and embryos.

All countries or zones adjacent to a country or zone not having free status should determine their AHSV status from an ongoing surveillance programme. Throughout the chapter, surveillance is in all cases understood as being conducted as described in Articles 12.1.11. to 12.1.13.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 12.1.2.

AHS free country or zone free from AHS

1) A country or zone may be considered free from AHS 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: infection with AHSV is notifiable in the whole country, systematic vaccination is prohibited, importation of equids and their semen, oocytes or embryos are carried out in accordance with this chapter, and either:

1) for at least the past 24 months:

a) the Veterinary Authority has current knowledge of, and authority over, all domestic and captive wild equids in the country or zone;

b) the Veterinary Authority has current knowledge of the distribution, habitat and indication of disease occurrence through passive surveillance of wild and feral equids in the country or zone;

c) either:

i) there has been no case of infection with AHSV and the country or zone is not adjacent to an infected country or zone; or

ii) a surveillance programme has demonstrated no evidence of *Culicoides* in accordance with Chapter 1.5:

EU comment

The EU queries whether point c) above means that, when a country or zone is not adjacent to an infected country or zone, there is no need to demonstrate through a surveillance programme that there was no evidence of AHSV in the country or zone for the past two years, as long as surveillance demonstrates no evidence of *Culicoides*. This would be a significant change compared to the current chapter.

d) appropriate surveillance has been implemented in accordance with:

i) Article 1.4.6. where historical freedom can be demonstrated; or

ii) Articles 12.1.11. to 12.1.13. where historical freedom cannot be demonstrated;

e) if adjacent to an infected country or zone, include an area in which surveillance is conducted in accordance with Articles 12.1.11. to 12.1.13.;

f) 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*;

2) no systematic vaccination against AHS has been carried out for at least the past 12 months.

- a) historical freedom as described in Chapter 1.4. has demonstrated no evidence of AHSV in the country or zone; or
 - b) the country or zone has not reported any case of AHS for at least two years and is not adjacent to an infected country or zone; or
 - c) a surveillance programme has demonstrated no evidence of AHSV in the country or zone for at least two years; or
 - d) the country or zone has not reported any case of AHS for at least 40 days and a surveillance programme has demonstrated no evidence of *Culicoides* for at least two years in the country or zone.
- 2) An AHS free country or zone which is adjacent to an infected country or zone should include a zone in which surveillance is conducted in accordance with Articles 12.1.11. to 12.1.13., as relevant.
- 3) An AHS free country or zone will not lose its free status through the importation of seropositive or vaccinated equids and their semen, oocytes or embryos from infected countries or zones, provided these imports are carried out in accordance with this chapter.
- 4) To qualify for inclusion in the list of AHS free countries or zones, a Member Country should:
- a) have a record of regular and prompt animal disease reporting;
 - b) send a declaration to the OIE stating:
 - i) the section under point 1) on which the application is based;
 - ii) no routine vaccination against AHS has been carried out during the past year in the country or zone;
 - iii) equids are imported in accordance with this chapter;
 - c) supply documented evidence that:
 - i) surveillance in accordance with Articles 12.1.11. to 12.1.13. is applied, unless historically free in accordance with Article 1.4.6.;
 - ii) regulatory measures for the early detection, prevention and control of infection with AHSV have been implemented.
- 5) The Member Country will be included in the list only after the submitted evidence has been accepted by the OIE.

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

Retention on the list requires annual reconfirmation of compliance with all points above and relevant provisions under point 4 of Article 1.4.6. that the information in points 4 b) ii) and iii) and 4 c) above be annually re-submitted and Documented evidence should be resubmitted annually for point 1 above. Any changes in the epidemiological situation or other significant events should be reported notified to the OIE in accordance with the requirements in Chapter 1.1., and in particular, formally state that:

EU comment

The EU queries why annual reconfirmation will not require confirmation of point 2 above (i.e. that there was no systematic vaccination). Does that mean that vaccination may be taken up in a country or zone with official status, with no consequence for maintenance of the status?

- a) there has been no outbreak of AHS during the past year in the country or zone;
- b) no evidence of infection with AHSV has been found during the past year in the country or zone.

Article 12.1.3.

AHS-infected country or zone infected with AHSV

A country or zone shall be considered as infected with AHSV. For the purposes of this chapter, an AHS-infected country or zone is one that does not fulfil when the requirements for acceptance as a country or zone free from AHS are not fulfilled to qualify as AHS-free.

Article 12.1.4.

Establishment of a containment zone within an AHS-free country or zone previously free from AHS

In the event of limited outbreaks of AHS within an AHS-free country or zone previously free from AHS, including within a protection zone, a single containment zone, which includes all epidemiologically linked outbreaks, can be established, in accordance with Article 4.4.7, for the purpose of to minimising the impact on the entire rest of the country or zone. Such a zone should include all cases and can be established within a protection zone.

EU comment

The EU suggests replacing the word “can” with “may” in the paragraph above, for clarity and consistency with Article 4.4.7. and with the corresponding provision in other disease-specific chapters (e.g. FMD).

For this to be achieved and for the Member Country to take full advantage of this process, the Veterinary Authority should provide submit as soon as possible to the OIE, in addition to the requirements of Article 4.4.7., in support of the application, documented evidence that:

- 1) the outbreaks have been contained are limited based on the following factors:
 - a) immediately on suspicion, a rapid response has been implemented, including notification-reporting, standstill of movements of equids and effective controls of the movements of equine commodities has been made;
 - b) standstill of movements of equids has been imposed, and effective controls on the movement of equids and their products specified in this chapter are in place;

EU comment

The EU suggests inserting the words “on confirmation,” before “standstill” in point b) above, for clarity and to distinguish from the provisions of point a). Reference is made to the wording of the corresponding article in the chapter on FMD (Article 8.8.6.).

In addition, for consistency with point a), the words “equids and their products” could be replaced with “equine commodities” in point b) above.

- e) epidemiological investigation (trace-back, trace-forward) has been completed;
- cd) the infection has been confirmed and notified in accordance with Chapter 1.1;

EU comment

Point c) above could be moved up, before point b). Alternatively, points b) and c) could be merged into one point.

- de) investigations on into the likely source of the outbreak have been carried out;

EU comment

Given deletion of point c), the word “epidemiological” could be inserted in point d) above, before “investigations”.

- f) all cases have been shown to be epidemiologically linked;
- eg) no new cases have been found in the *containment zone* within a minimum of two *infective periods* as defined in Article 12.1.1.;
- 2) the equids within the *containment zone* are clearly identifiable as belonging to the *containment zone*;
- 2) increased passive and targeted *surveillance* in accordance with Articles 12.1.11. to 12.1.13. in the rest of the country or *zone* has not detected any evidence of *infection*;
- 3) animal health measures are in place to effectively prevent the spread of AHSV *infection* to the rest of the country or *zone*, taking into consideration the establishment of a *protection zone* within the *containment zone*, the seasonal *vector* conditions and existing physical, geographical and ecological barriers;
- 4) ongoing *surveillance* in accordance with Articles 12.1.11. to 12.1.13. is in place in the *containment zone*.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established in accordance with points 1) to 5) above. The free status of the areas outside the *containment zone* may be reinstated irrespective of Article 12.1.5. once the *containment zone* has been approved is recognised by the OIE as complying with points 1 to 4 above.

In the event of the recurrence of AHSV *infection* with AHSV 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 AHS status of the whole country or *zone* is suspended until the relevant requirements of Article 12.1.5. are fulfilled.

In the event of occurrence of *infection* with AHSV in the outer zone of a *containment zone* established in accordance with point 4(b) of Article 4.4.7., the approval of the *containment zone* is withdrawn and the status of the whole country or *zone* is suspended until the relevant requirements of Article 12.1.5. are fulfilled.

The recovery of the AHS free status of the *containment zone* should follow Article 12.1.5.

Article 12.1.5.

Recovery of free status

To regain free status when an AHS *outbreak* occurs in a country or *zone* previously free, Article 12.1.2. applies, irrespective of whether emergency *vaccination* has been applied or not.

Should an outbreak of AHS occur in a previously free country or *zone*, its status may be recovered in accordance with Article 12.1.2., irrespective of whether emergency *vaccination* has been applied or not.

The AHS free status of the country or *zone* will be reinstated only after the submitted evidence has been accepted by the OIE.

Article 12.1.6.

Recommendations for importation from AHS free countries or zones

For equids

EU comment

The EU suggests incorporating the words “For equids” into the title of the article, for clarity and consistency with other chapters currently being revised.

This comment is valid also for Article 12.1.7. below.

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

- 1) showed no clinical sign of AHS on the day of shipment;

- 2) have not been vaccinated against AHS within the last 40 days;
- 3) were kept in an AHS free country or *zone* since birth or for at least 40 days prior to shipment;
- 4) either:
 - a) did not transit through an infected *zone* during transportation to the *place of shipment*; or
 - b) were protected from *Culicoides* attacks at all times when transiting through an infected *zone*.

Article 12.1.7.

Recommendations for importation from AHS infected countries or zones

For equids

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

- 1) showed no clinical sign of AHS on the day of shipment;
- 2) have not been vaccinated against AHS within the last 40 days;
- 3) were held in isolation in a *vector-protected establishment*:
 - a) for a period of at least 28 days and a serological test to detect antibodies against the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the *vector-protected establishment*; or
 - b) for a period of at least 40 days and serological tests to detect antibodies against AHSV were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after introduction into the *vector-protected establishment*; or
 - c) for a period of at least 14 days and an agent identification test for the identification of the agent was carried out with a negative result on a blood sample collected not less than 14 days after introduction into the *vector-protected establishment*; or
 - d) for a period of at least 40 days and were vaccinated, at least 40 days before shipment, against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 12.1.12. and 12.1.13., and were identified in the accompanying certification as having been vaccinated;
- 4) were protected from *Culicoides* attacks at all times during transportation (including transportation to and at the *place of shipment*).

Article 12.1.8.

Recommendations for the importation of equine semen

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

- 1) showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;
- 2) had not been immunised vaccinated against AHS with a live attenuated vaccine within 40 days prior to the day of collection;
- 3) were either:

- a) kept in an AHS free country or zone for at least 40 days before commencement of, and during collection of the semen; or
- b) kept in an AHS free *vector-protected artificial insemination centre* throughout the collection period, and subjected to either:

EU comment

Once Chapter 4.6. that is currently under revision will be adopted, the term “artificial insemination centre” in point b) above should be replaced with “semen collection centre”.

- i) a serological test to detect antibodies against the AHSV group, carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of semen; or
- ii) **agent identification** tests **for the identification of the agent** carried out with negative results on blood samples collected at commencement and conclusion of, and at least every seven days, during semen collection for this consignment.

EU comment

Once Chapter 4.6. that is currently under revision will be adopted, the following point 4 should be added:

4) the semen was collected, processed and stored in accordance with Chapter 4.6.

Article 12.1.9.

Recommendations for the importation of *in vivo* derived equine oocytes or embryos

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

- 1) the donor animals:
 - a) showed no clinical sign of AHS on the day of collection of the oocytes or embryos and for the following 40 days;
 - b) had not been **immunised vaccinated** against AHS with a live attenuated vaccine within 40 days prior to the day of collection;
 - c) were either:
 - i) kept in an AHS free country or *zone* for at least 40 days before commencement of, and during collection of the oocytes or embryos, or
 - ii) kept in an AHS free *vector-protected collection centre* throughout the collection period, and subjected to either:
 - a serological test to detect antibodies against the AHSV group carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of oocytes or embryos; or
 - **agent identification** tests **for the identification of the agent** carried out with negative results on blood samples collected at commencement and conclusion of, and at least every seven days during oocytes or embryos collection for this consignment;
- 2) the embryos were collected, processed and stored in accordance with Chapters 4.8. and 4.10., as relevant;
- 3) the semen used to fertilise the oocytes complies at least with the requirements in Article 12.1.8.

Protecting animals from *Culicoides* attacks

1. Vector-protected establishment or facility

The *establishment* or facility should be approved by the *Veterinary Authority* and the means of protection should at least comprise the following:

- a) appropriate physical barriers at entry and exit points, for example double-door entry-exit system;
- b) openings of the building are *vector* screened with mesh of appropriate gauge impregnated regularly with an approved insecticide in accordance with the instructions of the manufacturer;
- c) *vector surveillance* and control within and around the building;
- d) measures to limit or eliminate breeding sites for *vectors* in vicinity of the *establishment* or facility;
- e) Standard Operating Procedure, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of equids to the place of *loading*.

2. During transportation

When transporting equids through AHS infected countries or *zones*, *Veterinary Authorities* should require strategies to protect animals from *Culicoides* attacks during transport, taking into account the local ecology of the *vector*.

a) Transport by road

Potential *risk management* strategies include a combination of:

- i) treating animals with chemical repellents prior to and during transportation, in sanitized *vehicles* treated with appropriate residual contact insecticide;
- ii) *loading*, transporting and *unloading* animals at times of low *vector* activity (i.e. bright sunshine and low temperature);
- iii) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the *animals* are held behind insect proof netting;
- iv) darkening the interior of the *vehicle*, for example by covering the roof or sides of *vehicles* with shade cloth;
- v) surveillance for *vectors* at common stopping and offloading points to gain information on seasonal variations;
- vi) using historical, ongoing or modelling information on AHS to identify low risk ports and transport routes.

b) Transport by air

Prior to *loading* the equids, the crates, *containers* or jet stalls are sprayed with an insecticide approved in the country of dispatch.

Crates, *containers* or jet stalls in which equids are being transported and the cargo hold of the aircraft should be sprayed with an approved insecticide when the doors have been closed and prior to take off. All possible insect harbourage should be treated. The spray containers should be retained for inspection on arrival.

In addition, during any stopover in countries or *zones* not free from AHS, prior to the opening of any aircraft door and until all doors are closed, netting of appropriate gauge impregnated with an approved insecticide should be placed over all crates, *containers* or jet stalls.

Article 12.1.11.

Introduction to surveillance

Articles 12.1.11. to 12.1.13. define the principles and provide guidance on *surveillance* for AHS, complementary to Chapter 1.4. and, for *vectors*, complementary to Chapter 1.5.

AHS is a *vector-borne infection* transmitted by a limited number of species of *Culicoides* insects. Unlike the related bluetongue virus, AHSV is so far geographically restricted to sub Saharan Africa with periodic excursions into North Africa, southwest Europe, the Middle-East and adjacent regions of Asia. An important component of AHSV epidemiology is vectorial capacity which provides a measure of disease *risk* that incorporates *vector* competence, abundance, seasonal incidence, biting rates, survival rates and the extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context.

According to this chapter, a Member Country demonstrating freedom from *infection* with AHSV for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented in accordance with general conditions and methods described in this chapter. This requires the support of a *laboratory* able to undertake identification of *infection* with AHSV through the virus detection and antibody tests.

Susceptible *captive wild, feral* and *wild* equine populations should be included in the *surveillance* programme.

The purpose of *surveillance* is to determine if a country or *zone* is free from AHS. *Surveillance* deals not only with the occurrence of clinical signs caused by AHSV, but also with evidence of *infection* with AHSV in the absence of clinical signs.

Article 12.1.12.

General conditions and methods for surveillance

- 1) A *surveillance* system should be under the responsibility of the *Veterinary Authority*. In particular the following should be in place:
 - a) a formal and ongoing system for detecting and investigating *outbreaks* of disease;
 - b) a procedure for the rapid collection and transport of samples from suspected cases of AHS to a *laboratory* for diagnosis;
 - c) a system for recording, managing and analysing diagnostic, epidemiological and *surveillance* data.
- 2) In a free country or *zone*, the *surveillance* programme for AHS should include an *early warning system* for reporting suspected cases. Persons who have regular contact with equids, as well as diagnosticians, should report promptly any suspicion of AHS to the *Veterinary Authority*. An effective *surveillance* system will periodically identify suspected cases that require follow-up and investigation to confirm or exclude that the cause of the condition is AHS. The rate at which such suspected cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected cases of AHS should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment be available to those responsible for *surveillance*.
- 3) In a free country or zone bordering an infected country or zone, surveillance based upon geography, climate, history of infection and other relevant factors should be carried out over an appropriate distance of at least 100 kilometres from the border with the infected country or zone; lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of AHSV.

EU comment

In point 3 above, the EU suggests replacing the word “bordering” with “adjacent to”, for clarity and consistency with other relevant articles in the Code (e.g. the proposed new text in Article 12.1.13. below).

Furthermore, the words “based upon” should be replaced with “taking into account” (clarity).

4) In an AHS infected country or *zone*, random or targeted serological and virological *surveillance*, appropriate to the epidemiological situation, should be conducted in accordance with Chapter 1.4.

Article 12.1.13.

Surveillance strategies

The target population for *surveillance* aimed at identification of disease or *infection* should cover susceptible equids within the country or *zone*. Active and passive *surveillance* for *infection* with AHSV should be ongoing. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate to the epidemiological situation.

A Member Country should justify the *surveillance* strategy chosen as appropriate to detect the presence of *infection* with AHSV in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. horses). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. donkeys).

In vaccinated populations serological and virological *surveillance* is necessary to detect the AHSV types circulating to ensure that all circulating types are included in the *vaccination* programme.

Serological or virological *surveillance* is also needed to detect subclinical *infections* in free countries or *zones* adjacent to countries or *zones* in which live attenuated AHS vaccines are used.

For random surveys, the design of the sampling strategy should incorporate epidemiologically appropriate design prevalence. The sample size selected for testing should be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size, expected prevalence and diagnostic sensitivity of the tests determine the level of confidence in the results of the survey. The Member Country should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence, in particular, should be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination* or *infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles for *surveillance* for disease or *infection* are technically well defined. *Surveillance* programmes to prove the absence of AHSV *infection* or transmission, should be carefully designed to avoid producing results that are insufficiently reliable to be accepted by the OIE for official recognition of status. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

1. Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of AHS in equids particularly during a newly introduced *infection*. In horses, clinical signs may include pyrexia, oedema, hyperaemia of mucous membranes and dyspnoea.

Suspected cases detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

2. Serological surveillance

Serological *surveillance* of equine populations is an important tool to confirm absence of AHSV transmission in a country or *zone*. The species tested should reflect the local epidemiology of *infection* with AHSV, and the equine species available. Management variables that may reduce the likelihood of *infection*, such as the use of insecticides and animal housing, should be taken into account when selecting equids to be included in the *surveillance* system.

Samples should be examined for antibodies against AHSV. Positive AHSV antibody tests results can have four possible causes:

- a) natural *infection* with AHSV;
- b) *vaccination* against AHS;
- c) maternal antibodies;
- d) lack of specificity of the test.

Sera collected for other purposes may be used for AHSV *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of *infection* with AHSV should not be compromised.

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

Serological *surveillance* in a free *zone* should target those areas that are at highest risk of AHSV transmission, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of AHSV, either random or targeted sampling is suitable to select *herds* or animals for testing.

Serological *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 over a distance of at least 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of AHSV. An AHS free country or *zone* may be protected from an adjacent infected country or *zone* by a *protection zone*.

Serological *surveillance* in infected *zones* will identify changes in the boundary of the *zone*, and can also be used to identify the AHSV types circulating. In view of the epidemiology of *infection* with AHSV, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis of AHSV from a proportion of infected animals is beneficial in terms of providing information on serotype and genetic characteristics of the viruses concerned.

Virological *surveillance* can be conducted:

- a) to identify virus transmission in at risk populations;
- b) to confirm clinically suspected cases;
- c) to follow up positive serological results;
- d) to better characterise the genotype of circulating virus in a country or *zone*.

4. Sentinel animals

Sentinel animals are a form of targeted *surveillance* with a prospective study design. They comprise groups of unexposed equids that have not been vaccinated and are managed at fixed locations and observed and tested regularly to detect new *infections* with AHSV.

The primary purpose of a sentinel equid programme is to detect *infections* with AHSV occurring at a particular place, for instance sentinel groups may be located on the boundaries of infected *zones* to detect changes in distribution of AHSV. In addition, sentinel equid programmes allow the timing and dynamics of *infections* to be observed.

A sentinel equid programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of AHSV in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting AHSV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid confounding factors sentinel groups should comprise animals selected to be of similar age and susceptibility to *infection* with AHSV. The only feature distinguishing groups of sentinels should be their geographical location. Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling should reflect the equine species used and the reason for choosing the sampling site. In endemic areas virus isolation will allow monitoring of the serotypes and genotypes of AHSV circulating during each time period. The borders between infected and non-infected areas can be defined by serological detection of *infection*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that *infections* with AHSV are not occurring unobserved. Here sampling prior to and after the possible period of transmission is sufficient.

Definitive information on AHSV circulating in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required sentinels should be sampled at sufficiently frequent intervals to ensure that some samples are collected during the period of viraemia.

5. Vector surveillance

AHSV is transmitted between equine hosts by species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential *vector* species accurately although many such species are closely related and difficult to differentiate with certainty.

Vector surveillance is aimed at demonstrating the absence of *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 continued absence of *vectors*.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local *vector* species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to equids.

Vector surveillance should be based on scientific sampling techniques. The choice of the number and types of traps to be used in *vector surveillance* and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of *vector surveillance* sites at the same locations as sentinel animals is advisable.

The use of a *vector surveillance* system to detect the presence of circulating viruses is not recommended as a routine procedure as the typically low *vector infection* rates mean that such detections can be rare. Animal-based *surveillance* strategies are preferred to detect virus transmission.

CHAPTER X.Z.

INFECTION WITH CAMELPOX VIRUS

EU comment

The EU thanks the Code Commission and in general supports this proposed new chapter. A comment is inserted in the text below.

Article X.Z.1.

General provisions

For the purposes of the *Terrestrial Code*, *infection* with camelpox virus is defined as an *infection* of dromedary and bactrian camels (hereafter 'susceptible animals') with camelpox virus of genus *Orthopoxvirus*, family *Poxviridae*.

The following defines the occurrence of *infection* with camelpox virus:

- 1) camelpox virus has been isolated and identified as such in a sample from a susceptible animal; or

EU comment

The EU does not support the words “and identified as such” in point 1) above, as it is superfluous. Agent identification is implicitly part of “camelpox virus has been isolated”.

Indeed, identification of the agent via specific laboratory diagnostic methods is an inherent part of virus isolation, as indicated and described in the recently adopted corresponding Manual chapter.

The combination of “pathogenic agent” + “isolation” is a well-established practice in the case definitions of disease specific chapters and should be maintained consistently throughout the Code.

- 2) characteristic orthopox virions have been observed in a sample from a susceptible animal showing clinical signs suggestive of *infection* with camelpox virus or epidemiologically linked to a confirmed or suspected case; or
- 3) antigen or nucleic acid specific to camelpox virus has been detected in a sample from a susceptible animal showing clinical signs suggestive of *infection* with camelpox virus or epidemiologically linked to a confirmed or suspected case; or
- 4) antibodies specific to camelpox virus, that are not the consequence of *vaccination*, have been detected in a sample from a susceptible animal showing clinical signs suggestive of *infection* with camelpox virus or epidemiologically linked to a confirmed or suspected case.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.