WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

ANNEX 1

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September 2021

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

Virtual meeting, 7–16 & 23 September 2021

EU comment

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

A number of general comments on this report of the September 2021 meeting of the Code Commission are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report.

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

The OIE Terrestrial Animal Health Standards Commission (the Code Commission) held its meeting electronically from 7 to 16, and 23 September 2021. The list of participants is attached as **Annex 1**.

The Code Commission thanked the following Members and partner organisations for providing comments on its February 2021 report: Argentina, Australia, Brazil, Burkina Faso, Cameroon, Canada, China (People's Republic of), Japan, New Zealand, Norway, Singapore, South Africa, Thailand, the United Kingdom (UK), the United States of America (USA), Members of the OIE Asia, Far East and Oceania Region, the African Union Interafrican Bureau for Animal Resources (AU-IBAR) on behalf of African Member Countries of the OIE, Members of the OIE Americas Region, the Comité Veterinario Permanente del Cono Sur (CVP) on behalf of Argentina, Bolivia, Brazil, Chile, Paraguay and Uruguay, the Member States of European Union (EU), the International Coalition for Farm Animal Welfare (ICFAW), and the World Renderers Organization (WRO).

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

Amendments to new or revised text of the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) are presented in the usual manner by '<u>double underline</u>' and '~~strikethrough~~', and the texts are annexed to this report. In previously circulated texts, new amendments proposed at this meeting are highlighted with a coloured background to distinguish them from those proposed previously.

The Code Commission encouraged Members to refer to previous reports for longstanding issues. The Commission also draws the attention of Members to where the Scientific Commission for Animal Diseases (the Scientific Commission), the Biological Standards Commission (the Laboratories 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 relevant report of these expert groups and Members are encouraged to review these reports together with the report of the Code Commission. These reports are available on the OIE website.

Members should note that texts in **Part A (Annexes 4 to 18)** of this report are circulated for Member comments and will be proposed for adoption at the 89th General Session in May 2022. **Part B (Annex 19)** are texts circulated for Member comments only.

All comments on relevant texts in **Part A** and **Part B** must reach OIE Headquarters **by 27 December 2021** for them to be considered by the Code Commission at its February 2022 meeting. Comments received after the due date will not be submitted to the Code Commission for its consideration. In addition, the Code Commission would like to highlight that comments should be submitted through the OIE Delegate of Member Countries or organisations which the OIE has a Cooperative Agreement with.

All comments should be sent to the OIE Standards Department at **TCC.Secretariat@oie.int** no later than **27 December 2021**.

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

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1. Welcome from the Deputy Director General

Dr Matthew Stone, OIE Deputy Director General International Standards and Science (DDG ISS), welcomed the Code Commission and congratulated members on their election. Dr Stone together with Dr Gillian Mylrea, Head of the Standards Department, conducted an induction session at the start of the meeting. This was the final session of the Specialist Commission induction programme that had been implemented as part of the Performance Management System. In previous months induction sessions had been conducted for new Commission members, Presidents and all Commission members and Secretariats to meet each other and share information relevant to this new term.

During this induction session, Dr Stone presented for the consideration of members a discussion on managing the workload, roles and responsibilities, process innovation, and the performance management system.

Dr Stone recalled that the February 2021 Commission reports had been produced in two parts, A (texts for adoption) and B (texts for comments and information) to ensure early publication of texts that were to be proposed for adoption ahead of the virtual General Session. He noted that the OIE will continue with this approach in 2022. Dr Stone also recalled that Pre-General Session webinars hosted by Commission members to explain the standards being proposed for adoption were well received and will be repeated in future. Dr Stone also encouraged Commission members to conduct webinars in their respective regions for Delegates and relevant Focal Points after the September meeting to explain decisions made. He acknowledged that these webinars would also provide a good way for members to build their networks.

Dr Stone recalled that the proposed new Chapter 7.Z. Animal welfare and laying hen production systems had not been adopted during the 2021 General Session and noted that a number of Members and partner organisations had submitted comments in response to this outcome. Dr Stone indicated that the OIE was exploring a number of different options to find ways to address this very important topic. He indicated that the OIE would discuss possible options with the Code Commission at its February 2022 meeting.

The members of the Code Commission thanked Dr Stone for this informative presentation. With respect to the laying hens draft chapter, the Commission noted that the decision of the Assembly is part of the standard-setting process and that the Commission will support the OIE to find an approach that meets Member's expectations.

The members of the Code Commission thanked Dr Stone and acknowledged the excellent support provided to them by the OIE Secretariat.

Dr Mylrea facilitated a short session on agreed ways of working in which members discussed expectations around behaviour and how they would like to work as a group in the coming three years. The President of the Code Commission also shared with the members his expectations for the new term.

2. Meeting with the Director General

Dr Monique Eloit, the OIE Director General, met the Code Commission on 14 September 2021 and congratulated the new and re-elected members of the Commission. Dr Eloit provided an update on progress in the implementation of the 7th OIE Strategic Plan and highlighted one example of new work that will be undertaken to assess the OIE science system including OIE Reference Centres and expertise in OIE *ad hoc* Groups, Working Groups, and how the OIE can ensure the best use of these networks of experts. Dr Eloit also acknowledged the large workload of the Commission and highlighted that prioritisation of its work programme is critical during this coming period and highlighted that quality of the work is more important than quantity.

The members of the Code Commission congratulated Dr Eloit for her election for a second term as OIE Director General and expressed the commitment of the Commission to support the achievement of OIE objectives, and specially concurred with favouring quality over quantity in the work programme. Dr Bonbon highlighted some key areas of work that would be prioritised for this new term, notably the need to review some key chapters in Section 5 of the *Terrestrial Code*.

3. Adoption of agenda

The proposed agenda was discussed and adopted, taking into consideration the priorities of the work programme and time availability. It is presented in **Annex 2**.

Due to time constraints, the Code Commission did not discuss agenda items 5.1.7. Infection with Mycobacterium tuberculosis complex (Chapter 8.11.); 5.1.8. Infection with equine influenza virus (Chapter 12.6.); 5.1.11. Harmonisation of official recognition of status by the OIE: contagious bovine pleuropneumonia (Chapter 11.5.); 5.1.12. Mers Cov; 5.1.13. Leishmaniosis; 5.1.14.2. Use of terms 'epizootics/epidemics', 'enzootic/endemic' and 'pandemic'; 5.1.15. Pet food as safe commodities; 5.1.16. Honey – definitions and provisions on importation; and 7.2.6. Contagious equine metritis (Chapter 12.2.). The Commission agreed to postpone these items until a future meeting.

4. Cooperation with other Specialist Commissions

4.1. Scientific Commission for Animal Diseases

The OIE Secretariat updated the Code Commission on relevant ongoing activities of the Scientific Commission. The Scientific Commission, at its September 2021 meeting, will consider a number of topics relevant to the Code Commission's work programme, and will provide its opinions on a number of points regarding Chapter 8.14. Infection with rabies virus; Chapter 8.15. Infection with Rift Valley fever virus; Chapter 12.7. Equine piroplasmosis; and Chapter 8.X. and Chapter 12.3. on Surra and dourine. The Code Commission, at its February 2022 meeting, will consider the opinion of the Scientific Commission together with other pending issues, in order to progress work on the revision of these chapters.

The Code Commission was provided with an update on the progress of the work to develop case definitions to support notification being conducted by the Scientific Commission. In response to this update, the Code Commission recognised the value of this work and reminded Members that in order to support notification, newly developed case definitions of listed diseases would be published on the OIE Website if they do not conflict with existing OIE Standards. These case definitions would then be considered for inclusion in the relevant disease-specific chapter of the *Terrestrial Code* according to the prioritisation of the Code Commission's work programme and the standard-setting process.

The Code Commission acknowledged the rationale provided in the Scientific Commission's February 2021 report that chronic wasting disease does not meet the criteria for listing, specifically for point 2 of Article 1.2.2. of Chapter 1.2. Criteria for the inclusion of diseases, infections and infestations in the OIE list. The Commission also noted that the Scientific Commission will consider the expert consultation reports and the opinion of the Laboratories Commission on assessments undertaken for paratuberculosis and West Nile virus in accordance with Chapter 1.2.

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 contributions is noted under the relevant agenda items of this report and encouraged Members to read this report together with the September 2021 Scientific Commission report.

4.2. Biological Standards Commission

The OIE Secretariat provided an update to the Code Commission on relevant activities of the Laboratories Commission, including recently adopted chapters and those under review in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *Terrestrial Manual*).

The Code Commission considered and discussed the following items relevant to its work programme in relation to work being undertaken by the Laboratories Commission:

- Infection with *Theileria* in small ruminants (Chapter 14.X.): the Code Commission was informed that the Laboratories Commission will be considering a new draft c at its September 2021 meeting. The Code Commission agreed it will recommence work on the *Terrestrial Code* draft Chapter 14.X. once the revised *Terrestrial Manual* chapter has been adopted.

- The change of taxonomic name for 'Newcastle disease virus': as reported in the Laboratories Commission's September 2020 report, the Laboratories Commission had proposed to change the name of avian paramyxovirus serotype 1 (APMV-1) to avian orthoavulavirus 1 (AOAV-1) in Chapter 3.3.14. of the *Terrestrial Manual*. However, the Laboratories Commission, at its February 2021 meeting, agreed not to propose this change in the revised draft chapter for adoption after considering several Member comments. To ensure alignment with the corresponding Chapter 10.9. Infection with Newcastle disease virus in the *Terrestrial Code*, the Code Commission agreed to not make any changes in the current text and to remove this item from its work programme.

4.3. Aquatic Animals Health Standards Commission

The Code Commission and the Aquatic Animals Health Standards Commission (Aquatic Animals Commission) continued to work together to coordinate their respective work on the revision of the glossary definitions for Competent Authority, Veterinary Authority and Veterinary Services in the *Terrestrial Code* with the Glossary definitions for Competent Authority, Veterinary Authority and Aquatic Animal Health Services in the OIE *Aquatic Animal Health Code* (the *Aquatic Code*), noting the importance of ensuring alignment of these definitions, except where differences could be well justified (see item 6.1. of this report for more details).

As part of the discussion of the next steps for the revision of Section 4 of the *Terrestrial Code*, the OIE Secretariat provided the Code Commission with a summary report of relevant work completed or planned by the Aquatic Animals Commission. The Code Commission appreciated this information and acknowledged that some of the work of the Aquatic Animals Commission would be helpful for its work given that many of the topics addressed in Section 4 are relevant for both the aquatic and terrestrial domains (refer to item 5.1.1. of this report for more details).

The Code Commission also discussed the need for a review of some chapters in Section 5 and the importance of coordinating this work with parallel work being considered by the Aquatic Animals Commission (refer to item 5.1.3. of this report for more details).

The Code Commission discussed with the OIE Secretariat the need to establish a robust exchange mechanism between the two Commissions for a closer follow up of relevant items in their respective work programmes.

5. Code Commission's work programme

Comments were received from the EU.

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

5.1. Ongoing priority topics

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 as below.

5.1.1. Revision of Section 4 Disease prevention and control

Background

The Code Commission had agreed to develop a number of new chapters and to revise some existing chapters of Section 4. Disease prevention and control. To date, a new Chapter 4.18. Vaccination was adopted in 2018, and a revised Chapter 4.4. Zoning and compartmentalisation and a new Chapter 4.19. Official control programmes for listed and emerging diseases were adopted in 2021. Work 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 is in progress.

Discussion

The OIE Secretariat presented a summary of the current status of the revision of Section 4, including comments received previously. Taking this into account, the Code Commission reviewed Section 4 and agreed that in addition to the ongoing work to revise Chapters 4.6. and 4.7., high priority should also be given to the revision of Chapter 4.13. Disposal of dead animals and Chapter 4.14. General recommendations on disinfection and disinsection as well as to the development of a new chapter on biosecurity.

The Code Commission made the following comments regarding the scope of the chapters:

a) Revision of Chapter 4.13. Disposal of dead animals

The Code Commission considered that this chapter should not be limited to dead animals but also address all potentially contaminated wastes/products/fomites.

b) Revision of Chapter 4.14. General recommendations on disinfection and disinsection

The Code Commission had included the revision of Chapter 4.14. in its work programme since February 2017, acknowledging that the chapter needed revision to address disinfection in more detail. The Commission noted that a new Chapter 4.1. Disinfection of

aquaculture establishments and equipment of the *Aquatic Code* was adopted in 2016 and could provide some guidance for the revision of Chapter 4.14. of the *Terrestrial Code*.

The Code Commission noted that Chapter 4.14. is cross-referenced in many parts of the *Terrestrial Code*, including the Glossary definition for 'stamping-out policy' and a range of articles on recovery of free status in disease-specific chapters. The Commission also acknowledged that it had received a comment to amend the Glossary definition for 'disinfection' to allow 'fallowing' to be covered as a disinfection method and noted that the need to revise relevant Glossary definitions would be considered in this work.

c) Development of a new chapter on biosecurity

The development of a new chapter on biosecurity was first included in the Code Commission's work programme in September 2017, acknowledging that biosecurity is fundamental to disease prevention and control and should be addressed in the *Terrestrial Code*. The Commission also noted that a new chapter on biosecurity for aquaculture establishments in the *Aquatic Code* was adopted in 2021 and this could provide some guidance for this new chapter.

The Code Commission also noted that some chapters in the *Terrestrial Code* and some guidelines developed by other organisations provide some specific recommendations on components of biosecurity to be covered in the new chapter. Moreover, the Commission explained that its work on a definition for swill would be addressed as part of this work (refer to the February 2021 Commission report for more details).

The Code Commission also reminded that it was in the process of revising the use of the word 'biosecurity' across the *Terrestrial Code*, and therefore that work would also be related to the development of this new chapter.

The Code Commission requested the OIE Secretariat to prepare terms of reference for these revisions and development, including scope, expertise needed and tentative timeframe, and to report back at its next meeting.

5.1.2. Work of the *ad hoc* Group on the Revision of *Terrestrial Code* chapters regarding the 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 reflected 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 these chapters.

The first meeting of the *ad hoc* Group took place virtually between November–December 2020. The *ad hoc* Group agreed to work on Chapter 4.6. first before starting work on Chapter 4.7. and proposed a revised structure for Chapter 4.6. At its February 2021 meeting, the Code Commission endorsed the work of the *ad hoc* Group and provided further guidance on the holdings and species to be covered in the chapter.

Update

The *ad hoc* Group met for the second time between May–July 2021 and further developed draft text for Chapter 4.6.

The Code Commission reviewed the *ad hoc* Group's report and commended the *ad hoc* Group for its work. The Commission supported the *ad hoc* Group's recommendation to consult species-specific experts for further information regarding entry protocols, accommodation conditions and general hygiene that should be applied during the collection of semen, notably for equids and cervids.

The Code Commission supported the proposal of the OIE Secretariat to continue the review of Chapter 4.6. by engaging an expert who will work closely with the Secretariat and a representative of the Commission to further develop the draft text prepared by the *ad hoc* Group, also taking into consideration the advice of the Commission, and to incorporate recommendations from species-specific experts. The Commission agreed that the revised draft text should then be presented to the *ad hoc* Group for comment before being presented to the Commission at a future meeting.

The Code Commission encouraged Members to read the report of the OIE *ad hoc* Group on the Revision of *Terrestrial Code* chapters regarding the collection and processing of semen of animals available on the OIE Website (https://www.oie.int/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/).

5.1.3. Revision of Section 5 Trade measures, import/export procedures and veterinary certification

Background

The Code Commission included the review of Section 5 of the *Terrestrial Code* on Trade measures, import/export procedures and veterinary certification in its work programme in September 2017, acknowledging that some of the chapters have not been updated for some time and may not be adequate to support Members in managing the risks of introduction of diseases through the importation of commodities.

Discussion

The OIE Secretariat presented to the Code Commission a summary of previous discussions, including comments received previously from Members. Taking this into account, the Commission reviewed the current content of Section 5 and agreed that a revision of Chapters 5.4. to 5.7. should be given priority.

The Code Commission highlighted that the revision of these four chapters (Chapters 5.4., 5.5., 5.6. and 5.7.) should address the entire process of international trade, including measures at origin, in transit, and on arrival. The Commission noted that both live animals and animal products would be addressed.

Recognising that Section 5 of the *Terrestrial Code* and *Aquatic Code* have many similarities in content and structure and that overarching principles should continue to be aligned between the two *Codes*, the Code Commission requested that this work be done in close collaboration with the Aquatic Animals Commission.

The Secretariat informed the Code Commission that the Codex had proposed draft guidance on paperless use of electronic certificates, which will be considered for adoption at Step 5 by the 44th Codex Alimentarius Commission (2021) and that the OIE is currently considering its future work on this topic. The Commission noted the importance of e-certification and agreed that e-veterinary certification should also be taken into consideration as part of the review of Section 5.

The Code Commission also discussed other related topics which could be considered during this revision such as risks posed by illegal or informal cross-border trade of commercial and non-commercial animal products, including products delivered via postal or courier services. It also noted that the pathway of waste from international air and seaports could also be considered as part of the revision of relevant chapters (this would also be linked with the new chapter to be developed on biosecurity).

The Code Commission proposed that the OIE Secretariat develop the scope of this work and terms of reference including expertise needed and tentative timeframe, which the Commission will consider at its next meeting.

5.1.4. 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 as well as 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, adopted in 2018, that could have an impact on Chapter 6.10. The Commission had requested the advice of the OIE Working Group on Antimicrobial Resistance. The Working Group considered this request at its 2019 meeting and recommended that amendments to Chapter 6.10. not be undertaken until work of the Codex Alimentarius Task Force on Antimicrobial Resistance (TFAMR) had progressed, in order to avoid duplication and inconsistencies.

At its February 2021 meeting, the Code Commission was informed that the Codex Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005) had been adopted at Step 5 at the Codex Alimentarius Commission meeting in November 2020. Noting the progress being made by Codex, the Commission asked that the Working Group provide their views on the review of Chapter 6.10., including expanding the scope of the chapter to non-food producing animals, identifying the main areas of the chapter that would benefit from an update, and the best way to progress this work.

Update

The Code Commission was informed that the report of the 43rd Session of the Codex Alimentarius Commission (CAC43) noted that following a procedural schedule to finalise the work to revise the Codex Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (after a further round of comments (at Step 6), and finalisation by the TFAMR (at Step 7, in October 2021), the text would be proposed for adoption at Step 8 at the CAC44 to be held in November 2021.

The Code Commission was informed that the Working Group, at its April 2021 meeting, had considered the Commission's request and identified the main areas that it considered should be updated. The Working Group highlighted that given the current chapter is not limited to food producing animals, some additional references to companion animals, such as responsibilities of owners of companion animals, could be considered for inclusion. The Working Group also noted that the addition of elements relating to the environment, although important in the context of AMR, may be outside of the scope of this chapter which is included in Section 6 Veterinary Public Health of the *Terrestrial Code*.

The Code Commission agreed that it would be beneficial to consider explicitly expanding the scope of Chapter 6.10. to companion and leisure animals, and considered that the addition of elements relating to the environment was within the scope of this chapter given that the circulation of antimicrobial agents from veterinary medicinal products and AMR bacteria from animals in the environment may impact animal and public health.

The Code Commission proposed for the Working Group to be asked to review and revise Chapter 6.10. and also to consider whether the other AMR chapters (Chapters 6.7., 6.8., 6.9., and 6.11.) would need to be amended as a consequence of the revision of Chapter 6.10.

The Code Commission commended the Working Group for its advice and willingness to revise the chapter and encouraged Members to refer to the Working Group's April 2021 report that presents details about its considerations.

5.1.5. Revision of animal welfare chapters on transport of animals by land, sea and air (Chapters 7.2., 7.3. and 7.4.)

The OIE Secretariat presented a proposal to the Code Commission for the revision of the three chapters on animal transport to address gaps in the current scientific knowledge, to reduce duplication and inconsistencies and to improve syntax and layout.

The Code Commission agreed that it was important to review these chapters to ensure they reflect current scientific approaches, in particular the use of animal-based measures to help animal welfare assessment and acknowledged that this would be a large piece of work. The Commission requested the OIE Secretariat to review the current chapters to determine what articles would need reviewing and the extent of work required to address these issues. The Commission asked the Secretariat to present an analysis at its February 2022 meeting so it could discuss how to prioritise this work amongst other items on its work programme.

5.1.6. Slaughter of animals (Chapter 7.5.)

Background

In February 2018, the Code Commission agreed to revise Chapter 7.5. Slaughter of animals and Chapter 7.6. Killing of animals for disease control purposes and requested that an *ad hoc* Group be convened to undertake this work. The *ad hoc* Group met in person and virtually on several occasions since February 2018 to undertake a comprehensive review, starting with Chapter 7.5. The *ad hoc* Group considered Member comments received on a new proposed structure and on articles related to free-moving animals arriving at the slaughterhouse that were circulated for comments in the Commission's September 2019 report. In 2020, the *ad hoc* Group was reconvened to finalise the new draft articles related to animals arriving at the slaughterhouse in containers. A revised draft chapter was circulated for comments in the Commission's February 2021 report.

Discussion

The Code Commission reviewed comments and requested that the *ad hoc* Group be reconvened to consider these and amend the draft chapter, as appropriate. The Commission also requested that the *ad hoc* Group:

- review the layout and structure of the two categories: 'free moving animals' and 'animal arriving in containers' and discuss an alternative approach to avoid duplication and improve readability;
- discuss options to include information on specific parameters to use for the different stunning methods recommended in the chapter;
- discuss the feasibility to include references to documents from other international organisations.

The Commission requested an update at its February 2022 meeting.

5.1.7. Scrapie (Chapter 14.8.)

Background

Given that a revision of Chapter 14.8. Scrapie has been on the Code Commission's work programme for many years, the Code Commission, at its February 2021 meeting, requested the OIE Secretariat to collate all pending issues and to report back to the Commission at this meeting so it could consider a way forward.

Update

The OIE Secretariat presented a summary of previous discussions of the Code Commission and the Scientific Commission on this chapter, including Member comments received since 2011 when the most recent update of this chapter was last adopted.

The Code Commission acknowledged that the Members' requests covered a broad range of issues, including testing for genetic resistance to scrapie as valid methods for ensuring safe trade, provisions for surveillance to demonstrate freedom, and requests to review the articles on trade of sheep/goats, semen, embryos, milk, among others.

The OIE Secretariat informed the Code Commission that the revision of Chapter 3.8.11. on 'Scrapie' in the *Terrestrial Manual* had been included in the Laboratories Commission list for review in its 2021/2022 review cycle and that the Laboratories Commission would consider a draft revised chapter at its September 2021 meeting.

The Code Commission noted that the main pending issue was the assessment of scrapie against the listing criteria in accordance with Chapter 1.2., as reported in the September 2014 report of the Scientific Commission. The Code Commission agreed that this assessment should be considered before starting any work on Chapter 14.8. in the *Terrestrial Code*.

In line with the Standard Operating Procedure for listing decisions for pathogenic agents of terrestrial animals, the Code Commission requested that the assessment of the pathogenic agent against the criteria for inclusion in the OIE List be presented to the OIE DDG ISS for consideration.

5.1.8. Framework for *Terrestrial Code* standards

The OIE Secretariat updated the Code Commission on the progress of the work to develop a framework for the development of disease-specific chapters of the *Terrestrial Code* discussed at its February 2021 meeting. The Commission agreed to continue to work with the OIE Secretariat to progress this work and to review progress at its next meeting.

5.1.9. Safe commodities Standard Operating Procedure

Following a discussion at the Code Commission's February 2021 meeting, the OIE Secretariat presented a draft 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*. The Code Commission agreed with the proposed approach and requested the OIE Secretariat to apply the draft SOP when assessing some of the safe commodities being proposed for inclusion in the Code to check that it is fit for purpose. The Commission requested that the Secretariat report back to its next meeting whether the draft SOP requires any further edits.

5.2. Follow-up of recently adopted chapters

The Code Commission discussed specific issues raised in the context of the 88th General Session on a number of texts that were adopted at that General Session. The Commission considered the need and added value of introducing new amendments to recently adopted texts.

The Code Commission reminded Members that all texts adopted at the 88th General Session had undergone an extensive commenting and review process, where Members had several opportunities to comment and propose modifications, including those of an editorial nature. Given this process, the Commission agreed that reopening recently adopted texts immediately after adoption should be exceptional and be limited to critical issues. The Commission considered some additional comments on the following chapters which had been adopted at the 88th General Session:

- *Introduction to recommendations on Veterinary Services (Chapter 3.1.) and Quality of Veterinary Services (Chapter 3.2.)*

  The Code Commission followed up on a comment discussed at its February 2021 meeting that was raised again during the 88th General Session on the need to develop a definition for 'One Health' in the context of the *Terrestrial Code* (refer to item 6.2. of this report).

- *Veterinary legislation (Chapter 3.4.)*

  The Code Commission considered and agreed with a comment to amend the wording of point (b) of Article 3.4.11. for clarity (refer to item 6.3. of this report). Concerning a comment requesting to include a specific reference to storage of veterinary medicinal products in the same point, the Commission agreed that it was unnecessary as storage was necessarily a part of other processes such as manufacture, wholesale and retail.

- *Containment zone (Article 4.4.7.)*

  The Code Commission agreed with a comment to consider amending the text of Article 4.4.7. to clarify that a time limit should be defined for a containment zone. The Code Commission referred to a similar proposal by the Scientific Commission that had been discussed at the Code Commission's February 2021 meeting. The Code Commission discussed possible ways to address this request and shared a proposed amended text with the Scientific Commission for its consideration.

- *Official control programmes for listed and emerging diseases (Chapter 4.19.)*

  The Code Commission considered a request to amend the second paragraph of Article 4.19.1. to note that 'official control programmes' should be continually reviewed. The Commission agreed with the importance of systematic review but did not agree to amend the text noting that this point was already covered in the last paragraph of this article and also in Article 4.19.13.

  The Code Commission noted several comments of an editorial nature and agreed that as none were critical to the understanding of the text and that these adopted texts had been circulated for comment on several occasion, no amendments would be made.

- *Infection with Trypanosoma brucei, T. congolense, T. simiae and T. vivax (Chapter 8.18.)*

  In response to a request to include rendered products such as tallow and meat-and-bone meal as safe commodities in Article 8.18.2. given that there is no scientific evidence that these products are not safe for trade, the Code Commission first clarified that this apparent absence of evidence does not constitute evidence that these products are safe and an assessment against the criteria in Chapter 2.2. should be conducted. In addition, the Commission proposed that 'protein meal' be assessed as a safe commodity if its proposal to replace 'meat-and-bone meal' with 'protein meal' in the Glossary (refer to item 6.8. of this report) is adopted.

  In response to a request for specific data on genera of species of competent vectors for disease-specific chapters of vector-borne diseases, such as Chapter 8.18., the Code Commission reminded Members that it had provided an explanation to a similar comment in its February 2021 report that it was not always possible to provide a detailed list of competent vectors for every disease and that such a list could even vary by region. The Code Commission highlighted that competency of vectors for OIE listed diseases, infections and infestations are regularly considered by the Scientific Commission and Laboratories Commission. The Code Commission also noted that the Scientific Commission had acknowledged inconsistencies in the requirements for disease freedom for some vector-borne disease chapters, including demonstrating the absence of competent vectors. The Code Commission noted that this issue would be considered when new chapters are developed or reviewed.

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

  In response to comments on the appropriate geographical radius where no apiary has been subject to any restrictions associated with the occurrence of infestation with *A. tumida*, the Code Commission clarified that Article 9.4.5. describes the measures for the safe trade of live bees and points 2 and 3 address bees originating from countries or zones not free from *A. tumida.* These provisions should not be interpreted as requirements for a country or zone to be considered free from *A. tumida*. The recommended 50-km radius was deemed sufficient not as a standalone risk mitigation measure, but in conjunction with systems operating in the exporting country related to its animal health management and implementation of sanitary measures, including surveillance, movement restrictions and disease control measures.

- *Infection with high pathogenicity avian influenza viruses (Chapter 10.4.)*

  The Code Commission considered a request to review point 3 of Article 10.4.1. regarding the occurrence of specific low pathogenicity avian influenza (LPAI) subtypes with zoonotic potential. The Commission noted that this issue had been extensively discussed during the revision of the chapter and that the *ad hoc* Group had clearly explained that it was not possible to identify or predict the potential zoonotic behaviour of avian influenza viruses, and that the zoonotic strains of LPAI had been addressed by adding to the OIE list a new entity: 'Infection of domestic and captive wild birds with low pathogenicity avian influenza viruses having proven natural transmission to humans associated with severe consequences'. The Commission agreed not to amend this point.

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

  The Code Commission noted the recent publication of the 'FAO/OIE Guidelines for the Control and Prevention of Peste des Petits Ruminants (PPR) in Wildlife Populations (2021)', aimed at supporting countries in the development and implementation of PPR eradication programmes, including facilitating the integration of the wildlife sector into the national strategic plan.

  In light of this publication, the Code Commission requested the OIE Secretariat to assess, in coordination with the Scientific and Laboratories Commissions, whether additional changes pertaining to wildlife, including incorporating wildlife into the case definition in the chapter, should be considered for Chapter 14.7. The Commission agreed that it would consider a comment to specify the precise reference for Article 1.4.6. regarding historical freedom in Article 14.7.3.when the chapter is next reviewed.

- *Infection with classical swine fever (Chapter 15.2.)*

  The Code Commission noted a comment concerning point 6 of Article 15.2.3. regarding the use of vaccination in a country or zone claiming historical freedom, and the lack of specific recommendations on surveillance of vaccinated populations in the chapter. The Commission explained that as there were currently no means to distinguish between vaccinated and infected pigs in accordance with the *Terrestrial Manual*, point 6 may only be satisfied by countries or zones that do not carry out vaccination. The Commission agreed to not modify this chapter at this time and clarified that provisions on surveillance of vaccinated populations would be developed when a reliable means of DIVA is included in the *Terrestrial Manual*.

5.3. New proposals / requests

5.3.1. Request from OIE Working Group on Wildlife: Surveillance of disease of wildlife

The OIE Secretariat provided the Code Commission with an update regarding the Working Group on Wildlife's proposal to develop a new chapter in the *Terrestrial Code* on surveillance of disease of wildlife (as reported in its December 2020 report), which linked with the OIE Wildlife Health Framework and the OIE 7th Strategic Plan. The Commission was also provided with a brief analysis on the current recommendations on wildlife disease surveillance in the *Terrestrial Code*.

The Code Commission acknowledged the request and discussed how this request could be considered in the context of the *Terrestrial Code*. The Commission noted that wildlife is currently covered in chapters describing, among others, surveillance system requirements (notably Chapter 1.4. Animal Health Surveillance), and therefore a new chapter dedicated to surveillance of wildlife health could result in duplication or inconsistencies. The Commission acknowledged that wildlife is dealt with as part of the epidemiology of listed or emerging diseases, with a focus on managing the impact on relevant domestic animal populations or humans, and recognised that some specificities of wildlife as such could be better taken into consideration in the current Chapter 1.4. and potentially in related horizontal and disease-specific chapters. The Commission also noted that, by definition and as described in Article 1.4.1., surveillance is paired with 'action' objectives, and that surveillance in wildlife should also have such objectives and be included in the logic of the *Terrestrial Code*. The Commission acknowledged that work on the User's guide may also be needed. The Commission concluded its discussion and advised the OIE Secretariat to take into consideration these points together with the health management expectations for the better scoping of this proposed work.

The Code Commission highlighted the importance of this topic and reiterated its willingness to work with the Working Group on Wildlife in the scoping of a chapter for the *Terrestrial Code*. However, before its inclusion in the Commission's work programme, it requested the Working Group on Wildlife to further discuss the purpose and work with the OIE Secretariat to assess any impacts on existing *Terrestrial Code* chapters. The Commission highlighted that this topic and proposal should also be discussed with the other Specialist Commissions and encouraged Members to comment on this work.

5.4. Prioritisation of items in the Code Commission's work programme

Based on a number of considerations and the progress of different topics made during this meeting (see items 5., 6. and 7. of this report) as well as in coordination with other Specialist Commissions (see item 4. of this report), the Code Commission updated its work programme and discussed the prioritisation of ongoing and future work.

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

EU comment

The EU thanks the OIE for having taken into consideration comments submitted previously and in general supports the revised work programme of the Code Commission and its prioritisation. Specific comments are inserted in Annex 3.

6. Texts for comments and proposed for adoption in May 2022

The Code Commission agreed to propose the following texts for adoption in May 2022, pending its consideration of comments received on these proposals.

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

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

Background

In September 2018, the Code Commission agreed to revise the Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' in the *Terrestrial Code* following Member requests and feedback from the *ad hoc* Group on Veterinary Services (2018 report). The revised definitions were circulated for comments in the Commission's September 2018 report. The *ad hoc* Group on Veterinary Services considered comments received and proposed additional amendments. Given the importance of ensuring alignment of these definitions in the *Aquatic Code* and *Terrestrial Code*, where relevant, the Code Commission and the Aquatic Animals Commission agreed to work together on this matter. Revised definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' in the *Terrestrial Code* and 'Competent Authority', 'Veterinary Authority' and 'Aquatic Animal Health Services' in the *Aquatic Code* were circulated for comments in the September 2020 reports of the Code Commission and the Aquatic Animals Commission, respectively.

In preparation for the September 2021 meetings, the Presidents of the Code Commission and the Aquatic Animals Commission met to review all comments received and to consider if additional amendments were needed whilst also considering the importance of aligning these definitions, where relevant. They acknowledged that the comments received indicated some confusion amongst Members as to the intended meaning and use of these terms and that the September 2020 Commission reports did not provide sufficient information about the rationale for the proposed amendments. The Presidents agreed that the proposed definitions did not need significant changes and they proposed to provide a more detailed explanation of the rationale for the proposed amendments, as well as some more detailed information on the use of these terms in each *Code* in the two September 2021 Commission reports.

At the September 2021 meeting, each President informed its respective Commission about these discussions and sought input and agreement from Commission members.

Discussion

The Code Commission considered the comments received on its September 2020 report as well as the feedback from the President regarding the coordination with the Aquatic Animals Commission. The Code Commission agreed that the proposed amended definitions did not need further substantial edits and the September 2021 meeting report should include a more detailed explanation on the purpose and current use of these definitions, as well as a clearer explanation of the proposed changes.

The text presented below reflects the opinion of both Commissions and is presented in the September 2021 reports of the Aquatic Animals Commission and Code Commission to ensure a shared understanding in the context of both *Codes*.

General consideration on Glossary definitions

The objective of the Glossaries in the *Aquatic* and *Terrestrial Codes* is to provide definitions of key terms that require precise interpretation for the purpose of their use in the *Codes*. These definitions might deviate from those provided by common dictionary definitions. It is desirable to pursue harmonisation where possible to assist interpretation by users of both *Codes* because Glossary terms should be used consistently throughout all chapters.

The Glossary definitions are expected to be concise and should not contain unnecessary descriptive detail or further elaborations beyond what is necessary to define the term. Further descriptive detail or explanation that may be necessary for the implementation of a standard are provided within the contents of the relevant chapters.

Purpose of the definitions of 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'/'Aquatic Animal Health Services'

The purpose of these terms in the *Codes* is to differentiate responsibilities for implementation of the OIE standards. It is important to note that the definitions apply only for the purposes of each of the *Codes* and are not intended to dictate the administrative structure, or the naming of governmental authorities, within a Member Country. To achieve this purpose, the definitions must be applicable to the diversity of administrative arrangements among Members and must be sufficiently precise to provide clarity on the responsibilities for the implementation of the standards by relevant governmental authorities or public or private services.

Current application of these definitions

The *Terrestrial Code* uses the three terms extensively ('Competent Authority', 'Veterinary Authority' and 'Veterinary Services') across its different sections. The Code Commission considers that these terms are generally applied correctly in the *Terrestrial Code*, as explained above, and in line with the relevant horizontal recommendations in Section 3, Veterinary Services, notably Chapter 3.4. Veterinary legislation. However, the use of the terms will be reviewed once the revised definitions have been adopted.

The *Aquatic Code* currently uses the terms 'Competent Authority' and 'Aquatic Animal Health Services' but uses 'Veterinary Authority' only in certain Glossary definitions and in Section 5, Trade measures, importation/exportation procedures and health certification. This approach was previously adopted (i.e. 'Competent Authority' in place of 'Veterinary Authority') because governmental responsibilities for aquatic animal health and welfare are not necessarily the responsibility of a veterinary governmental authority/agency. The Aquatic Animals Commission is aware that there are currently some inconsistent and incorrect uses of the terms within the *Aquatic Code*. Proposals to address these issues will be made and proposed for comments once the revised definitions have been adopted.

Proposed changes to the definitions of 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' / 'Aquatic Animal Health Services'

A decision was made to revise these definitions because many users found they lacked clarity, which led to contradicting interpretations among Members, with significant discrepancies in the understanding of the terms. It is important to note that the changes proposed to the definitions are not intended to change their meaning or application, only to bring clarity.

Some cross-references between the *Codes* within these definitions have been removed because they are irrelevant (e.g. references to the *Aquatic Code* within definitions in the *Terrestrial Code*).

a) Competent Authority

The proposed wording recognises that, in many countries, more than one governmental authority

is responsible for implementing standards of the *Terrestrial* or *Aquatic Codes*. The term *Competent Authority* is intended to apply to any governmental authority with some responsibility for the implementation of some OIE standards.

Key changes to the definitions include:

– 'responsibility… for implementation' was deemed simpler, clearer language than the current reference to 'competence for ensuring implementation';

– 'in the whole or part of the territory' reflects that under some administrative arrangements government authorities may have responsibility for certain standards over the whole territory of a country, or just over a part of it, e.g. provincial or state authorities;

– 'certain standards' reflects that governmental authorities may have responsibility for a clearly defined area of standards. Responsibility for implementation of other standards of the *Codes* would be part of the mandate of different Competent Authorities within the same country.

These revisions are consistent with Article 3.4.5. on Competent Authorities of the *Terrestrial Code*. There is no equivalent chapter on Veterinary Legislation within the *Aquatic Code*.

b) Veterinary Authority

The level of detail in the existing definition was deemed unnecessary, and the definition was simplified to make it clearer. This term distinguishes the role of the *Veterinary Authority* as a single Competent Authority that has responsibility for communicating with the OIE and an overarching responsibility for implementation of OIE standards. Examples of the differentiated role for the Veterinary Authority include disease notification requirements or demonstrating compliance with international standards for international trade or for disease free status.

The Aquatic Animals Commission agreed that it was necessary to include reference to coordinating the implementation of standards 'by Competent Authorities' in the Glossary definition of 'Veterinary Authority' for the purpose of the *Aquatic Code*. These words add clarity given that 'Competent Authority' is the primary term used within the *Aquatic* Code (refer to the section 'current application of the definitions' above) and also reflects the fact that the Veterinary Authority itself may not always be the Competent Authority with responsibility for the implementation of the standards of the *Aquatic Code*. The Code Commission did not consider this to be necessary in the definition for Veterinary Authority in the *Terrestrial Code*.

Key changes to the definitions include:

– 'comprising veterinarians, other professionals and paraprofessionals' was removed as these words do not define the term and do not distinguish it from other governmental authorities;

– 'primary responsibility' was included to distinguish the Veterinary Authority from other Competent Authorities;

– 'having the responsibility and competence for ensuring or supervising the implementation' was changed to 'having the primary responsibility … for coordinating the implementation' as this is more concise and direct language and reflects the fact that some standards may not be under the direct responsibility or competence of the Veterinary Authority;

– 'implementation of the standards of' was included to replace 'animal health and welfare measures, international veterinary certification and other standards of' as the latter includes unnecessary detail.

c) Veterinary Services/Aquatic Animal Health Services

This term covers a broad range of actors that are involved in the implementation of OIE standards and are not necessarily part of governmental authorities or regulatory agencies. This may be the case for standards that involve a complex chain of responsibilities to be appropriately

implemented. The definition has been reduced substantially to the key defining elements.

This term does not refer to a defined governmental structure but to a combination of individuals and organisations, public and private, which cannot be individually listed in the definition.

Key changes to the definitions include:

- The word 'individuals' was added to ensure that private veterinarians, aquatic animal health professionals, veterinary paraprofessionals and others, would be covered under the definition when appropriate.
- The terms 'Private sector organisations, aquatic animal health professionals, veterinarians, veterinary paraprofessionals or aquatic animal health professionals' were removed as these were considered unnecessary, and could exclude other relevant actors.
- "that implement animal health and welfare measures and other standards and recommendations' was changed to 'that perform activities to implement standards*"*, to better differentiate from the more specific role of responsible government authorities, which are covered by the terms Competent Authority and Veterinary Authority.
- 'implement standards of the *Aquatic Code/Terrestrial Code'* was included to replace '*animal* health and welfare measures and other standards and recommendations in the OIE *Terrestrial Code* and the OIE *Aquatic Code',* as the latter includes unnecessary detail.
- The current reference to the Veterinary Authority within the definition of Veterinary Services was not considered necessary, as the definition for Veterinary Authority is sufficiently clear, and was removed.
- "Private sector organisations, veterinarians, veterinary paraprofessionals or aquatic animal health professionals are normally accredited or approved by the Veterinary Authority to deliver the delegated functions" was deleted to keep the definition simple and to the point, and as these elements are described in the relevant chapters of Section 3 of the *Codes*.

The revised Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' are presented in **Annex 4** for Member comments and are proposed for adoption at the 89th General Session in May 2022.

EU comment

The EU supports the proposed changes to the Glossary definitions of 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'.

6.2. Introduction to Recommendations on Veterinary Services (Article 3.1.1.) and Quality of Veterinary Services (Articles 3.2.3. and 3.2.9.)

Background

A new Chapter 3.1. Introduction to Recommendations on Veterinary Services and a revised Chapter 3.2. Quality of Veterinary Services were adopted at the 88th General Session in May 2021.

At its February 2021 meeting, in response to comments, the Code Commission had agreed to consider the development of a definition for 'One Health' to ensure a shared understanding of the concept of 'One Health' in the context of the *Terrestrial Code*, and had requested the OIE Secretariat to consider the possibility of developing a definition of 'One Health' in collaboration with the Tripartite and other relevant partners. Similar comments were also raised during the 88th General Session in May 2021.

Discussion

Article 3.1.1.

The Code Commission highlighted that 'One Health' is not exclusively the domain of the OIE, and therefore, any definition should be developed in collaboration with the Tripartite and other relevant partners.

The Code Commission noted that the term 'One Health' is only used in Section 3 and not in a specific meaning for the purposes of the *Terrestrial Code*. Therefore, the Commission agreed that the development of a Glossary definition was not appropriate. Nonetheless, the Commission agreed to include some text that explained the meaning of the 'One Health Approach' on the first instance where the term was used. To this end, the Commission proposed to add 'involving all relevant sectors and disciplines across the human-animal-environment interface' at the end of the first paragraph, noting that this text was aligned with the definition used in the Tripartite Zoonoses Guide.

Articles 3.2.3.

In considering the amendment in Article 3.1.1., the Code Commission reviewed other articles of the chapter where the term 'One Health approach' was used, and agreed to add 'relevant' before governmental authorities in the second paragraph of Article 3.2.3.

Article 3.2.9.

In point 1(b), the Code Commission agreed with a comment to add a specific reference to the storage of veterinary medicinal products.

The revised Article 3.1.1. and Articles 3.2.3. and 3.2.9. are presented as **Annexes 5 and 6** for Member comments and are proposed for adoption at the 89th General Session in May 2022.

EU comment

The EU supports the proposed changes to these chapters.

6.3. Veterinary legislation (Articles 3.4.5. and 3.4.11.)

Background

A revised Chapter 3.4. Veterinary Legislation was adopted at the 88th General Session in May 2021. The chapter had undergone a thorough review and had been circulated five times for comments.

At this meeting, the Code Commission considered comments received in the context of the 88th General Session, and also introduced changes as a consequence of the revision of the use of the term 'sanitary measures' across the *Terrestrial Code*.

Discussion

Article 3.4.5.

In point 1(d), the Code Commission proposed to replace 'sanitary measures' with 'measures and procedures' it considered that the context did not match with the Glossary definition for 'sanitary measures'. The Commission noted that as the text was recently adopted, comments on this article would only be considered if referred to this specific amendment.

Article 3.4.11.

In point 1(b), the Code Commission agreed to delete the terms 'safe and effective', noting that these terms which had been introduced in the version circulated in the Commission February 2021 report and adopted, did not make sense in the context of the paragraph. The Commission noted that safety and efficacy should be addressed in the regulation of all the steps mentioned (i.e. authorisation, importation, manufacture, wholesale, retail, usage of, commerce in, and disposal) and not be referred to independently. The Commission also noted that 'safety and effectiveness' are covered in the Glossary definition for 'veterinary medicinal product'.

The revised Article 3.4.5. and 3.4.11. of Chapter 3.4. Veterinary legislation are presented as **Annex 7** for comments and is proposed for adoption at the 89th General Session in May 2022.

EU comment

The EU supports the proposed changes to this chapter.

6.4. Zoonoses transmissible from non-human primates (Chapter 6.12.)

Comments were received from Burkina Faso, Cameroon, Singapore, the USA, the AU-IBAR and the EU.

Background

In February 2019, in response to a request from the European Association of Zoos and Aquaria (EAZA), the Scientific Commission had requested the Working Group on Wildlife to conduct a review of the potential transmission of hepatitis B from gibbons to humans. In its March 2020 meeting report, the Working Group on Wildlife had concluded that hepatitis B was a disease of humans, as the *Hepadnaviridae* strains affecting humans are different from those affecting non-human primates. Moreover, current diagnostic techniques have made it possible to differentiate the different hepatitis B virus strains circulating in humans and non-human primates.

At its February 2021 meeting, the Code Commission considered the Scientific Commission's proposal to amend this chapter to reflect that hepatitis B is a disease of humans and agreed to revise Articles 6.12.4., 6.12.6. and 6.12.7. The revised articles were circulated for comments in the Code Commission's February 2021 report.

Discussion

The Code Commission was informed that the corresponding Chapter 3.10.10. Zoonoses transmissible from non-human primates in the *Terrestrial Manual* had been revised to reflect that hepatitis B is a disease of humans, not a zoonotic disease, and adopted in May 2021.

The Code Commission reiterated that, as noted in its February 2021 report, the scope of these proposed amendments was only to address this issue and that the chapter was not open for wider comments. In line with this decision, the Commission agreed not to address other comments.

The Code Commission considered relevant comments and agreed that no additional amendments were needed.

Article 6.12.7.

In point 5, the Code Commission did not agree with a comment to reinstate 'hepatitis B' and reiterated that the Working Group on Wildlife (March 2020) had concluded that hepatitis B was a disease of humans, as the *Hepadnaviridae* strains affecting humans are different from those affecting non-human primates. It also reiterated that current diagnostic techniques have made it possible to differentiate the different hepatitis B virus strains circulating in humans and non-human primates.

The revised Articles 6.12.4., 6.12.6. and 6.12.7. of Chapter 6.12. Zoonoses transmissible from non-human primates are presented as **Annex 8** for Member comments and are proposed for adoption at the 89th General Session in May 2022.

EU comment

The EU supports the proposed changes to this chapter.

6.5. Stray dog population control (Dog population management) (Chapter 7.7.)

Background

In September 2018, the Code Commission agreed to revise Chapter 7.7. Stray dog population control to ensure it was aligned with the OIE Global Strategy to end human death due to dog-mediated rabies by 2030.

The *ad hoc* Group on the Revision of Chapter 7.7. Stray dog population control was reconvened for a third time in 2021 via video conference to address comments on the revised draft chapter circulated in the Code Commission's September 2020 report.

Discussion

The Code Commission considered the *ad hoc* Group's report, including the revised draft Chapter 7.7., and commended its members for its comprehensive work.

The Code Commission reminded Members that the *ad hoc* Group report detailed the rationale for proposed amendments and responses to comments. The Commission encouraged Members to refer to the *ad hoc* Group's report when considering the proposed revised chapter presented in Annex 9. The June 2021 *ad hoc* Group report on the Revision of Chapter 7.7. Stray dog population control is available

on the OIE Website (https://www.oie.int/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/).

In addition, the Code Commission made the following additional amendments.

Definitions

The Code Commission noted the *ad hoc* Group's proposal to replace the current definition of 'stray dog' with 'free-roaming dog' in the Glossary. The Commission agreed with the Group's proposed definition which considers all categories of dogs under the scope of the revised chapter.

Article 7.7.1.

The Code Commission agreed to add a reference to Chapter 7.1. in the last sentence of this article as it deemed important to consider the concepts described in that chapter when developing dog population management (DPM).

Article 7.7.2.

The Code Commission decided to move the definitions section from Article 7.7.4., to Article 7.7.2., to align with the format used in other chapters of the *Terrestrial Code*.

Article 7.7.5.

In the fifth indent, the Code Commission moved 'traffic accident' in front of 'zoonotic diseases' to improve readability and consistency.

Article 7.7.7.

In the second sentence of point 1, the Code Commission deleted the word 'level', when referring to the action plan, as it considered it unnecessary as such plans should be developed at the highest level possible.

Article 7.7.8.

In the subtitle, the Code Commission decided to include the term 'actors' to cover other participants that may have a role in the development of DPM programmes.

Article 7.7.9.

In the sixth indent, the Code Commission decided to modify the text to clarify that licencing is for 'veterinarians' and not for the practice of veterinary medicine.

Article 7.7.11.

In the first paragraph, the Code Commission agreed to modify the first sentence to indicate that there is a need for assessment and planning at the initial stage of the development of a DPM programme.

Article 7.7.12.

In the first paragraph, the Code Commission agreed to modify the first sentence to indicate that there is a need for monitoring and evaluation at the later stages of the development of a DPM programme.

Article 7.7.15.

In the last sentence of the last paragraph, the Code Commission replaced the wording proposed by the *ad hoc* Group from 'sales from the street' to 'unregulated sales' to improve clarity.

Article 7.7.20.

In the third paragraph, the Code Commission added a reference to Chapter 7.1. Introduction to the recommendations for animal welfare to highlight the need to ensure that the welfare of dogs is taken into consideration when they are transported.

In the last sentence of the last paragraph, the Code Commission did not agree with the *ad hoc* Group's proposal, in response to a comment, to replace the term 'should' with 'must', noting that the use of the term 'should' is in line with the language used in the *Terrestrial Code*.

Article 7.7.21.

In the first sentence of the first paragraph, the Code Commission deleted the term 'Veterinary Services' as provider of veterinary care, noting that other actors may provide this care.

Article 7.7.23.

In the first sentence, the Code Commission replaced the word 'prevalence' with 'occurrence', because prevalence is a defined term in the Glossary used in relation to diseases.

Article 7.7.26.

In the first paragraph, the Code Commission discussed the recommendation of the *ad hoc* Group to include a reference to the term 'five-welfare needs', in particular the ones related to the conditions that dogs may be subjected to in premises keeping dogs. The Commission agreed to delete this reference given that there is no reference to these needs in the *Terrestrial Code*, noting that the text includes a description of these needs.

The revised Glossary definition of 'Stray dogs' is presented in **Annex 4** for Member comments.

EU comment

The EU in general supports the proposed changes to the Glossary definition of 'Stray dogs'. One comment is inserted in the text of Annex 4.

The revised Chapter 7.7. Stray Dog population control is presented as **Annex 9** for Member comments and is proposed for adoption at the 89th General Session in May 2022.

EU comment

The EU thanks the OIE for having taken into consideration comments submitted previously. We welcome and in general support the revision of Chapter 7.7. Specific comments are inserted in the text of Annex 9.

6.6. Infection with rinderpest virus (Chapter 8.16.)

Comments were received from Cameroon, Burkina Faso, New Zealand, Thailand, the AU-IBAR and the EU.

Background

A thorough review of Chapter 8.16. Infection with rinderpest virus was undertaken by the *ad hoc* Group on Rinderpest (March 2020 report), in response to Member requests and to better clarify the definitions of 'case' and 'suspected case', the reporting obligations of Members, and the inclusion of measures that should be implemented if there is a re-emergence of rinderpest virus.

The Code Commission had agreed with the Scientific Commission and OIE Secretariat that in this post-eradication era, the priority should be the maintenance of global freedom from rinderpest and its prompt recovery in case of re-emergence, and consequently, the structure of the chapter and trade provisions should be revised to ensure they are aligned with this objective. The revised chapter was circulated for comments for the second time in the Commission's February 2021 report.

Discussion

Article 8.16.1.

In the first paragraph of point 1, the Code Commission further considered a comment discussed at its previous meeting regarding a request to add a footnote referring to the OIE resolution that noted that the manipulation of existing RPV-containing material is forbidden unless authorised by the FAO and OIE. The OIE Secretariat informed the Code Commission that OIE resolutions are not referenced in the *Terrestrial Code.* The Commission agreed that given that OIE resolutions have been adopted by the World Assembly, there was no need to provide a cross-reference to the original resolution. The Commission agreed that given this article includes text that addresses key aspects of what was stated in the resolution, a specific reference to the resolution should not be included. The Commission also amended some text in this paragraph to improve clarity.

In point 2(b), the Code Commission did not agree with a comment to add 'and the finding has been confirmed at an OIE reference laboratory' after 'identified' in point (i), and after 'animal' in point (ii), and explained that this point is to define what a case is. The way a case should be confirmed is described in Article 8.16.3.

In point 2(b)(iii), the Code Commission did not agree with a comment to delete 'that are not a consequence of *vaccination*' after 'antibodies'. The Commission noted that vaccination had been globally banned since 2008, and therefore, some previously vaccinated animals could be still alive. It also reminded Members of the rationale presented in its February 2021 report that this information may be relevant in the event of re-emergence of rinderpest if emergency vaccination is used.

In response to comments to better differentiate the definition of a 'suspected case' from a 'potential case', the Code Commission noted that the identification of potential cases was based on the exclusion of other possible causes of 'stomatitis-enteritis syndrome' by epidemiological or clinical investigations only, while if other diseases had been ruled out by laboratory investigations, it should be considered a 'suspected case'. The Commission agreed to amend the text to improve clarity in point 2(c)(i), to replace 'or' by 'and' before 'laboratory investigation'; and, in point 3(b), to add 'clinical or' before 'epidemiological considerations', and delete 'appropriate laboratory' before investigation.

Article 8.16.2.

In point 2(a), the Code Commission agreed to delete 'which have been submitted to the usual chemical and mechanical processes in use in the tanning industry' at the end of the point, for consistency with the general approach used for 'safe commodities' in the *Terrestrial Code*, noting that Chapter 2.2. Criteria applied by the OIE for assessing the safety of commodities states that for commodities that meet the criteria "it is expected that processing or treatment (i) uses standardised protocols".

Article 8.16.3.

In the first sentence of the first paragraph, the Code Commission agreed to delete 'infection' after 'rinderpest' and to replace 'rinderpest absence' with 'absence of infection with RPV' for consistency with other text of the chapter.

In the third sentence of the first paragraph, the Code Commission did not agree with a comment to delete 'potential' before 'cases' as it considered it was needed for clarity.

Article 8.16.4.

In the first sentence, the Code Commission did not agree with a comment to amend the text to avoid redundancy, as it considered that 'annual report' referred to the scope of the report, while 'submitted every year' referred to the frequency of submission, which would not necessarily be the same.

Article 8.16.5.

In the first sentence, the Code Commission agreed to replace 'notified' by 'reported' for consistency with the Glossary definitions and use of this term in other parts of the *Terrestrial Code* where 'reporting'

refers to communication to the Veterinary Authority at country level and 'notification' refers to the action performed by Veterinary Authorities to the OIE.

In the first two paragraphs, the Code Commission discussed the feedback from the OIE Secretariat on its query, from February 2021, regarding the legal obligation for the notification of suspected cases of rinderpest. The Commission agreed that, based on the notification obligations stated in Chapter 1.2. and in the OIE Basic Texts, the text as written provided sufficient grounds to establish a disease-specific requirement for mandatory notification of suspected cases for this disease. The Commission requested that the OIE Secretariat consider mechanisms to ensure this is feasible through OIE-WAHIS.

In the fourth paragraph of point 2, the Code Commission did not agree with a comment to replace 'may' by 'should' for consistency with the changes proposed in Article 8.16.8. The Commission noted that the selection of the disease control measures is the prerogative of Members and clarified that the use of 'should' in the context of Article 8.16.8. refers to the compliance with OIE standards in the case that a country chooses to establish a containment zone.

Article 8.16.6.

In the first paragraph, in response to a comment proposing a timeframe for the submission of the risk assessment to the OIE, the Code Commission agreed with the Scientific Commission on the importance of having a short time limit for risk assessment showing that all potential pathways for introduction are adequately managed and that all OIE Members should be asked to provide such assessment to be evaluated and approved by the OIE. Nevertheless, it considered that no amendment was needed in the text and this timeframe would be decided by the OIE if and when rinderpest reemerges.

In the same paragraph, the Code Commission did not agree with a comment requesting to amend the text to clarify how and when the free status of a country would be reinstated if suspended, as it considered the text sufficiently clear for the purposes of the *Terrestrial Code*.

The Code Commission agreed that the details for processes such as those discussed in the paragraphs above were outside the scope of the *Terrestrial Code* and should not be included in the chapter. The Commission requested the OIE Secretariat to consider the development of the appropriate processes and guidance as part of the OIE Official Status recognition system.

Article 8.16.9.

In the first paragraph, the Code Commission did not agree with a comment to replace 'free from rinderpest' by 'free from infection with RPV'. The Commission explained that the text is the current convention for the *Terrestrial Code*, and 'rinderpest' is defined in the first article of the chapter.

In the second paragraph, the Code Commission did not agree with a comment to reinstate 'rinderpest' before 'free status', as it considered this unnecessary and referred Members to the rationale provided in its February 2021 report in support of this deletion.

Article 8.16.11.

In point 2, the Code Commission noted a comment regarding the use of the term 'potential case', and agreed that due to the changes introduced on Article. 8.16.1., no further amendments were needed.

Article 8.16.12.

In the title of the article, the Code Commission agreed with a comment to delete 'rinderpest' before 'susceptible animals', as these were already defined in Article 8.16.1.

Article 8.16.13.

The Code Commission did not agree with a comment to replace 'not free from' by 'infected with', and reiterated the rationale presented in its February 2021 report, that countries whose free status have been suspended in accordance with the first paragraph of Article 8.16.6. are covered by this article.

The revised Chapter 8.16. Infection with rinderpest virus is presented as **Annex 10** for Member comments and is proposed for adoption at the 89th General Session in May 2022.

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 10.

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

Background

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

At its September 2020 meeting, the Code Commission noted that work had commenced to update the corresponding chapters of the *Terrestrial Manual*, and requested the OIE Secretariat to prepare amended versions of Chapters 8.5. and 15.4. of the *Terrestrial Code*, taking into consideration the changes included in the *Terrestrial Manual*, and in consultation with relevant experts.

A revised Chapter 3.10.3. on 'Cysticercosis (including infection with *Taenia solium*)' of the *Terrestrial Manual* was adopted in May 2021, and a revised Chapter 3.1.6. on 'Echinococcosis' (infection with *Echinococcus granulosus* and with *E. multilocularis*) has been developed and is intended to be presented for adoption in 2022.

Update

The Code Commission reviewed proposed amendments to Chapter 8.5. Infection with *Echinococcus granulosus* and Chapter 15.4. Infection with *Taenia solium* (Porcine cysticercosis) to reflect the latest modifications included or proposed in the *Terrestrial Manual*., prepared through an electronic consultation with some members of the *ad hoc* Group on Porcine Cysticercosis who had developed the revised draft chapter in 2015.

The Code Commission also reviewed each chapter and agreed that the text was still relevant and did not need updating except to address the use of vaccination. The Commission agreed to introduce specific provisions to include vaccines as prevention or control tools and to ensure any amendments were aligned with changes in the *Terrestrial Manual* chapters.

Regarding Chapter 15.4., the Code Commission noted that the sections on meat inspection had been removed from the *Terrestrial Manual* as they were not considered relevant for the *Terrestrial Manual*. The Commission considered the text removed from the *Terrestrial Manual* and agreed that no further amendment was needed in Chapter 15.4. of the *Terrestrial Code*.

The revised Chapter 8.5. Infection with *Echinococcus granulosus* and Chapter 15.4. Infection with *Taenia solium* (Porcine cysticercosis) are presented as **Annex 11** and **Annex 12,** respectively, for Member comments and are proposed for adoption at the 89th General Session in May 2022.

EU comment

The EU in general supports the proposed changes to these chapters. Comments are inserted in the text of Annexes 11 and 12.

6.8. Bovine spongiform encephalopathy (Chapter 11.4.), Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy (Chapter 1.8.) and Glossary definition for 'protein meal'

Background

In February 2018, following preliminary work and scientific exchanges, the Code Commission and the Scientific Commission agreed to an in-depth review of Chapter 11.4. Bovine spongiform encephalopathy (BSE). The OIE convened three different *ad hoc* Groups between July 2018 and March

2019: i) an *ad hoc* Group on BSE risk assessment, which met twice, ii) an *ad hoc* Group on BSE surveillance, which met once, and iii) a joint *ad hoc* Group on BSE risk assessment and surveillance, which met once. The Code Commission, at its September 2019 meeting, reviewed the four *ad hoc* Group reports and the opinion of the Scientific Commission regarding the draft revised chapter and circulated a revised draft Chapter 11.4. for comments.

In February 2020, the Code Commission considered comments received on the revised draft Chapter 11.4. and requested that the joint *ad hoc* Group on BSE risk assessment and surveillance be reconvened to address comments of a technical nature. In June 2020, the joint *ad hoc* Group was convened to address relevant comments and was also requested 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.

In September 2020, the Code Commission reviewed the joint *ad hoc* Group report and the revised draft Chapters 11.4. and 1.8. and made some additional amendments and circulated the revised chapters for comments in its September 2020 report. In February 2021, the Commission considered comments received and amended the chapters, as appropriate, and circulated the revised chapters for a third round of comments.

In preparation for the September 2021 meetings, some 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 a common understanding of the main concerns raised by Members, the decisions made on the revised chapters and their impact on the official status recognition, as well as on the adapted procedures that will be required. During this meeting, it was agreed that each Commission would address the issues relevant to its meeting and document discussions in their respective reports.

Discussion

a) **Chapter 11.4. Bovine spongiform encephalopathy**

Comments were received from Argentina, Australia, Brazil, Burkina Faso, Cameroon, Canada, China (People's Rep. of), Japan, New Zealand, the USA, Members of the OIE Asia, Far East and Oceania Region, the AU-IBAR, the CVP, the EU, and the WRO.

General comments

The Code Commission noted concerns raised by some Members that the proposed concept that two subpopulations (the cattle population born before the date from which the risk of BSE agents being recycled has been negligible and the cattle population born after that date) would be differentiated within a country or zone recognised as either negligible or controlled BSE risk, and the proposal that the recommendations for importation from 'negligible BSE risk' and 'controlled BSE risk' be merged would increase the administrative burden to the OIE and its Members for official status recognition and create more onerous steps for certification. The Commission . highlighted that currently used export certificates contain often stricter provisions than those recommended in the *Terrestrial Code*, and often included the age or birthdate of live cattle, and sometimes a maximum age of cattle from which meat is derived, without clear risk mitigation justification; in this regard, the respect by importing countries of the proposed certificates would be a great improvement in terms of trade facilitation. The Commission also noted that for Members having negligible BSE risk status, the cattle population born before the date from which the risk of BSE agents being recycled has been negligible has become extremely small and the impact on trade would not be as significant than presented by the Members. Moreover, the Commission, based on previous considerations and on the *ad hoc* group reports, reminded Members that official status recognition for BSE has always been considered a risk status and not a freedom status, and therefore the concept that different cattle populations and commodities derived from these animals present different risks is not new, rather it is inherent in the OIE's approach to BSE risk management already applied to official status recognition.

In response to concerns that the revised BSE provisions may impact Members who currently have a recognised BSE risk status, the Code Commission reminded Members that the potential impact had been discussed in previous *ad hoc* Group and Scientific Commission reports. In addition, the Code Commission explained that it would be discussed further at the September 2021 meeting of

the Scientific Commission. The Code Commission encouraged Members to refer to the September 2021 report of the Scientific Commission for outcomes of its discussion.

The Code Commission considered the text 'period when the risk of BSE agents being recycled within the cattle population has been demonstrated to be negligible' and agreed that the use of the term 'period' was not clear. The Commission agreed that 'date' (of effective implementation of BSE risk mitigation measures) would be a more appropriate term considering that a period should have a start and end date, the latter being not the case. Accordingly, the Commission proposed to change 'period' to 'date' throughout Chapter 11.4. as well as in Chapter 1.8., as appropriate. The Code Commission also noted that the Scientific Commission would consider at its September 2021 meeting how to define the date for each Member which has an official BSE risk status and how to communicate this to all Members, and encouraged Members to refer to the report of the meeting.

In response to a comment that the level of surveillance considered appropriate to maintain a negligible risk status is unclear, the Code Commission reminded Members that the rationale for removing the point-based BSE surveillance has been provided in previous *ad hoc* Group, Code Commission and Scientific Commission reports. The Code Commission encouraged Members to refer to the June 2020 report of the *ad hoc* Group on BSE risk assessment and surveillance for relevant information.

The Code Commission agreed with a comment to change 'foetal' to 'fetal' as this reflected current usage in scientific literature. The Commission noted that this term as well as 'foetus' are used in other chapters of the *Terrestrial Code* and should also be amended accordingly. The Commission requested that the OIE Secretariat review the use of these terms in the *Terrestrial Code* in order to determine where they need to be amended and to report back to the Commission at its next meeting.

Article 11.4.1.

In point 1, the Code Commission agreed with a comment to move the fourth sentence 'Oral exposure to contaminated *feed* is the main route of transmission of classical BSE.' to after the second sentence as it considered the proposed order (description on classical BSE and then description on atypical BSE) improved clarity.

In the same point, the Code Commission did not agree with a comment to amend the last sentence to reflect that the risk of atypical BSE agent being recycled in a cattle population is negligible and reminded Members that the joint *ad hoc* Group on BSE risk assessment and surveillance had concluded that atypical BSE is considered capable of being recycled in a cattle population if cattle are exposed to contaminated feed. The Commission encouraged Members to refer to the relevant information provided in the March 2019 report of the *ad hoc* Group on BSE risk assessment and surveillance.

In point 3(b), the Code Commission agreed with a comment to replace 'PrP^{BSE}' with 'PrP^{Sc}' in order to align with the corresponding Chapter 3.4.5. in the *Terrestrial Manual*.

In point 4(b), the Code Commission agreed with a comment to delete 'blood and blood products' from the exclusion from the definition for 'protein meal', as it considered that blood is a tissue and is included in the definition of meat. The Commission explained that blood and blood products that went through the rendering process are included in the proposed definition for 'protein meal' and hence are considered in the entry and exposure assessments described in Article 11.4.2.

Article 11.4.1bis.

In point 7, the Code Commission did not agree with a comment to delete 'foetal blood' and reiterated its decision to add 'foetal blood' to the list of safe commodities was based on the rationale provided by BSE experts, i.e. i) blood *per se* is considered free of BSE infectivity; ii) even if prions were present in blood due to slaughter practices the placental barrier of bovines would make BSE maternal transmission unlikely; and iii) it is unlikely that cross contamination with potentially infected tissues from a cow occurs during foetal blood collection. The Commission encouraged Members to refer to the June 2020 report of the joint *ad hoc* Group on BSE risk assessment and surveillance where the rationale is reported in more detail.

Article 11.4.2.

In the first paragraph, the Code Commission noted comments that 'Due to its etiological and epidemiological features' was unnecessary as these features are common to the determination of risk for any disease, and considered that official recognition for BSE considers a risk status and not a freedom status as is the case for other diseases for which the OIE grants official recognition of status, and because of this specificity, this phrase should be kept. However, the Commission proposed to add 'specific' before 'etiological' for clarity.

In point 1(a)(iii), in response to a comment to delete '(not intended for pets)', the Code Commission proposed to replace it with '(except packaged and labelled pet food)' as it considered that although appropriately packaged and labelled pet food does not need to be taken into consideration, pet food in bulk or raw materials for pet food should be considered in the entry assessment, and the risk of feeding to cattle should be assessed in the subsequent exposure assessment. The Commission proposed a similar amendment in Article 1.8.5.

In point 1(b)(i), under the first indent, the Code Commission agreed with a comment to add 'and farming' after 'production' to ensure alignment with point 2(a)(i) of the revised Article 1.8.5.

In point 1(d), the Code Commission agreed with comments to delete 'through the feeding of ruminant-derived protein meal, with indigenous cases arising', and explained that given the feeding of ruminant-derived protein meal is the principal transmission pathway of BSE agents, the exposure assessment described in the point 1(b) focuses on this pathway; however, the risk estimation described in point 1(d) is a standalone result that combines the conclusions from points 1(a), 1(b) and 1(c). Additionally, the Commission reiterated that the risk for each Member would be assessed, as appropriate, by the *ad hoc* Group on the Evaluation of BSE risk status of Members. This amendment was also made in point 4 of Article 1.8.5.

In the same point, in response to a proposal noted in the June 2021 *ad hoc* Group report on the revision of BSE standards and its impact on the official status recognition and a comment received previously, the Code Commission agreed to add 'and to determine the date from which the risk of BSE agents being recycled within the cattle population has been negligible' at the end of the point. The Commission confirmed that this would be the result of the risk estimation, and noted that the addition will ensure alignment with point 4(d) of the revised draft Article 1.8.5.

Article 11.4.3.

In the first paragraph, the Code Commission did not agree with a comment to reinstate 'compartment' and reminded Members that the OIE grants official status for countries and zones only, and not for compartments. The Commission noted that it had proposed a new Article 11.4.4bis. for a compartment with negligible or controlled BSE risk. The Commission noted that this response also applied to a similar comment submitted for Article 11.4.4.

In the same paragraph, the Code Commission agreed with a comment to reinstate 'at least' as it considered the deletion had caused confusion. The Commission reiterated that a Member applying for official recognition of a negligible BSE risk status for a country or zone, may be able to demonstrate that the risk of BSE agents being recycled in the cattle population has been negligible for eight years or more and, in that case, the Member should demonstrate compliance with all four steps of the risk assessment as described in this article for the years that it wished to consider.

In point 1, the Code Commission did not agree with a comment to reinstate the deleted point 1(a) 'Protein meal derived from ruminants has not been fed to ruminants', as it was not needed here, since it was covered by the preceding article. It explained that as described in point 1 of Article 11.4.1., oral exposure to contaminated feed is the main route of transmission of classical BSE and therefore the exposure assessment described in point 1(b) of Article 11.4.2. considers the impact of both 'livestock industry practices preventing cattle from being fed ruminant-derived protein meal' and 'specific risk mitigation measures preventing cattle from being fed ruminant-derived protein meal'. The Commission noted that Members need to demonstrate that any assessed risks have been properly mitigated in order to obtain official BSE risk status, and that would imply the prevention of feeding ruminants with ruminant-derived protein meal. The Commission reminded Members that the dossier for each Member would be assessed by the *ad hoc* Group on the Evaluation of BSE risk status of Members. The Commission noted that this response also applies to a similar comment submitted for Article 1.8.5.

In points 3(b)(i) and 3(i)(ii), the Code Commission considered a comment seeking clarification of these requirements and proposed amended text to align with its new proposal to refer a 'date' rather than a 'period' (see General comments section above).

In point 3(b)(ii), the Code Commission agreed with a request for stricter requirements in the case of the occurrence of indigenous case of classical BSE in an animal younger than eight years, and added 'any identified source of *infection* has been mitigated and' after 'confirmed that'. The Commission considered that the occurrence of an indigenous case of classical BSE born after the date from which the risk of BSE agents being recycled within the cattle population has been negligible does not necessarily reflect a breakdown of effective control measures but rather may be due to isolated pockets of residual infectivity in a complex network of rendering, feed production, distribution and storage (refer to the June 2020 report of the *ad hoc* Group on BSE risk assessment and surveillance for a more detailed rationale). The Commission emphasised that it is essential that the source be properly investigated, and any identified issues be rectified.

In point 4, in response to a comment to add provisions to manage the risk associated with cohort animals, the Code Commission reiterated that the complete destruction of all cohort animals would not provide a significant gain in risk reduction, as long as measures including a feed ban and the removal and destruction of tissues listed in Article 11.4.14. had been continuously and effectively implemented, and an effective surveillance system for the detection and investigation of cases was in place. The Commission reminded Members to refer to the July 2018 report of the *ad hoc* Group on BSE risk assessment for more details.

In the same point, the Code Commission did not agree with a comment to add 'to ensure that the distal ileum, skull, brain, eyes, vertebral column and spinal cord of the case does not enter the animal feed chain' as it considered that the text was clear as presented and that specifying the risk materials was not needed given that any case of BSE should be disposed of in a biosecure manner.

Article 11.4.3bis.

In the first paragraph, the Code Commission agreed with a comment to add 'any identified source of *infection* has been mitigated and' based on the rationale provided above (see point 3(b)(ii) of Article 11.4.3.).

Article 11.4.4.

In the first paragraph, the Code Commission did not agree with a comment to replace 'at least one of these conditions has not been met for the preceding eight years' with 'the mandatory eight-year time frame has not yet been met', as it considered the text clear as written. The Commission explained that a controlled BSE risk status is a step towards the negligible BSE risk status, and that the BSE risk of a country or zone can be considered to be controlled provided all of the conditions described in points 1 to 4 of Article 11.4.3. have been met, but at least one of these conditions has not been met for the preceding eight years. Once all the conditions have been met for eight years or more, the BSE risk of a country or zone can be considered negligible.

Article 11.4.5.

In the text of the article, the Code Commission agreed with a comment to delete 'compartment', as it considered that by definition, a compartment is a subpopulation with a specific animal health status.

Deleted Article 11.4.6.

The Code Commission did not agree with comments to reinstate the deleted Article 11.4.6. The Commission reiterated that two subpopulations (cattle population born before the date from which the risk of BSE agents being recycled has been negligible and cattle population born after that date) are differentiated within a country or zone recognised as negligible or controlled BSE risk and therefore to merge Article 11.4.6. with Article 11.4.7. is appropriate.

Article 11.4.7.

In point 2, the Code Commission agreed with comments to replace ‘the country’ with ‘a country’ noting that the intention of this provision was not that the exported cattle must be born in the exporting country.

In the same point, the Code Commission proposed to add ‘and kept’ after ‘born’ in response to a comment that pointed out a possibility that the cattle was kept and exposed to protein meal in a country that was different than a country where the cattle was born. The Commission noted that this rationale also applies to similar comments received for Articles 11.4.10., 11.4.12. and 11.4.13.

Article 11.4.8.

In the title of the article, the Code Commission proposed to delete ‘compartment’ based on the rationale provided above (see Article 11.4.5).

Deleted Article 11.4.9.

The Code Commission did not agree with comments to reinstate the deleted Article 11.4.9. based on the rationale provided above (see General comments).

Article 11.4.10.

In point 1, the Code Commission did not agree with a comment to move ‘the cattle from which the *fresh meat* and *meat products* were derived’ to the end of the chapeau paragraph, because the subject of point 4 is ‘the fresh meat and meat products’ not the cattle.

In point 1, the Code Commission proposed to delete ‘came from a country, *zone* or *compartment* posing a negligible or controlled BSE risk and’ as it considered this text to be redundant.

Article 11.4.12.

In point 2, the Code Commission did not agree with comments to delete the whole or latter part of this point as it considered the point relevant and feasible. The Commission explained that for most Members who already have a negligible BSE risk status, the cattle population born before the date from which the risk of BSE agents being recycled has been negligible has become extremely small. The Commission encouraged Members to refer to the Commission’s February 2021 report for more details.

The Code Commission did not agree with a comment to amend points 1 and 2 and add a new third point to demonstrate animals have not been fed protein meal derived from ruminants, as it considered the recommendation sufficient as written and explained that the third proposed requirement would not provide any added value as the recommendation for importation of protein meal, which is different from the recommendation for importation of cattle described in Article 11.4.7.

In response to a comment to align this article with other similar articles, the Code Commission proposed to delete point 1 and to rephrase point 2. It also reiterated that in accordance with this chapter, only Members with negligible BSE risk can export cattle-derived protein meal.

Article 11.4.13.

In the title, the Code Commission did not agree with a comment to delete ‘(except foetal blood)’ based on the same rationale provided above (see Article 11.4.1bis.).

In point 1 and point 2, the Code Commission did not agree with comments to revert to original texts based on a similar rationale provided above (see General comments).

The Code Commission did not agree with a comment to delete points 1 and 2, as it considered the points are relevant and ensure the safe trade of blood and blood products. It encouraged Members to refer to the March 2019 report of the *ad hoc* Group on BSE risk assessment and surveillance for more details on the development of this article.

The Code Commission proposed to merge points 1 and 2 to ensure alignment with the proposal for Article 11.4.12.

Article 11.4.14.

In point 1, the Code Commission did not agree with a comment to add 'and tonsils' after 'Distal ileum' and reminded Members that the March 2019 report of the *ad hoc* Group on BSE risk assessment and surveillance had concluded that the reference to tonsils should be removed.

In the same point, the Code Commission did not agree with a comment to add 'or death' after 'slaughter' as it considered this was implied, and that only those tissues from slaughtered animals should be traded.

In point 1(b), the Code Commission did not agree with comments to delete 'or a negligible BSE risk' based on the rationale provided above (see General comments).

In point 2, in response to a comment that the commodities are already noted in point 1 and thus are redundant, the Code Commission explained that point 1 and point 2 refer to different products; point 1 is for ingredients of final products such as feed and fertilisers and point 2 is for the final products.

Article 11.4.16bis.

In point 3, in response to a comment to clarify the parameters for temperature, time and pressure to safely produce tallow derivatives, the Code Commission informed Members that the *ad hoc* Group on the Revision of BSE standards and its impact on the official status recognition, had considered this comment at its meeting in June 2021. The Commission noted that the *ad hoc* Group had stated that they could not specify any particular parameters because there is a wide variation in the conditions under which these products are commercially produced, based on evidence available in the literature. The *ad hoc* Group agreed to maintain the text as it is, given the absence of no new scientific evidence. The Commission agreed with the position of the *ad hoc* Group.

In the same point, the Code Commission did not agree with a comment to replace the text with 'have been submitted in a system (as filtration, centrifugation or decantation or others) that guarantees maximum level of tallow's insoluble impurities of 0.15%' as it considered that although the proposed procedure is scientifically valid in terms of mitigating the BSE risk, Members do not need to specifically certify it as a BSE risk mitigation measure, since the final products are safe commodities as described in point 5 of Article 11.4.1bis.

The Code Commission agreed with a proposal to move Article 11.4.16bis. before Article 11.4.16., as Article 11.4.15bis. to improve the flow of these articles.

Article 11.4.17.

The Code Commission did not agree with a comment to delete this article and emphasised that this article is not intended to be used as an import requirement but rather a recommendation to mitigate the BSE risk of protein meal. In addition this article is referred to in the revised draft Article 1.8.5.

In the chapeau paragraph, the Code Commission did not agree with a comment to replace 'should' with 'may'. It considered that this article describes a recommendation to mitigate the BSE risk, i.e. to reduce BSE infectivity, and the procedure scientifically sound, and thus the recommendation should be described as what 'should' be done to mitigate the BSE risk.

In the same paragraph, the Code Commission did not agree with a comment proposing to limit the scope of the article to countries that have reported classical BSE cases in indigenous cattle as it considered that the recommendation is potentially relevant for all countries.

In response to a comment to replace 'ruminant proteins' with 'any of those commodities listed in point 1 of Article 11.4.14.', the Commission reiterated that this recommendation should include not only commodities with the greatest BSE infectivity which are described in point 1 of Article 11.4.14. but also protein meal containing ruminant proteins that may contain BSE agents.

Article 11.4.18.

In the title, the Code Commission agreed with a comment requesting alignment with Article 1.8.6. and proposed to delete 'BSE' from the title of Article 1.8.6.

The Code Commission reminded Members that the Commission, based on the proposal from the *ad hoc* Group on BSE surveillance, had proposed extensive amendments to the article on BSE surveillance, including the removal of provisions on point-based BSE surveillance, as a consequence of redefining the goals of BSE surveillance. The Commission encouraged Members to refer to the October 2018 report of the *ad hoc* Group on BSE surveillance for more details.

The Code Commission agreed with a comment stating that an early warning system and an awareness programme should be sufficient to support a negligible BSE risk status and therefore a targeted active surveillance should not be required. The Commission reiterated that the surveillance proposed for BSE focuses on passive surveillance which is a mechanism to demonstrate that the risk of classical BSE is still low. It highlighted that any good early warning systems do include clinical screening and target subpopulations that are more likely to be positive.

In the first paragraph, in response to a comment to describe the goals of the revised surveillance system, the Code Commission explained that this article describes how surveillance for BSE should be designed and implemented, and does not describe the system for surveillance. The Commission reiterated that the goal of the proposed provisions for surveillance is to detect a potential emergence or re-emergence of classical BSE within the cattle population, and not to assess the effectiveness of mitigation measures such as a feed ban. The Commission encouraged Members to refer to 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 for more details.

In point 1(b), the Code Commission agreed with a comment to remove the parentheses around '(head shyness)' as it agreed that low carriage of the head and head shyness are not the same.

In the third paragraph, the Code Commission did not agree with a comment to replace 'spectrum' with 'continuum' as it considered the text clear as written.

The Code Commission did not agree with the request to move the last paragraph of point 1 to the last paragraph of point 2, and explained that the text described general aspects of clinical signs of BSE and thus should remain under point 1.

In point 2, the Code Commission agreed with comments to replace 'symptoms' with 'signs' as it agreed that a symptom is subjective, whereas a sign is objective and observable, and thus 'sign' is relevant for animal diseases. The Commission noted that this change would be made throughout this chapter as well as Chapter 1.8., where relevant.

In the same point, the Code Commission did not agree with a comment to delete 'all'. It clarified that although all animals listed in points 2(a) to 2(d) should be reported to the Veterinary Authority, not all of these animals need to be tested in laboratories. The Commission highlighted that a Member applying for official recognition of a BSE risk status must describe the procedures in place to identify those animals that have been subjected to laboratory testing from those animals reported to the Veterinary Authority. Applying the same rationale, the Commission agreed with a comment to delete the text after point 2(d).

In points 2(c) and 2(d), the Code Commission did not agree with a comment that the text still lacks clarity or may be too restrictive, as it considered the text clear as written.

In point 3(a), the Code Commission did not agree with a comment to amend text to improve clarity, as it considered the text clear as written.

In point 3(c), the Code Commission did not agree with a comment to add 'to accurately confirm or rule out the presence of BSE agents' at the end of the point, as it considered this was implied.

In point 3(d), in response to a comment to add 'classical' before 'BSE positive findings', the Code Commission reiterated its view that all BSE cases need to be followed up in order to properly address the risk of BSE agents being recycled. The Commission explained that the epidemiological

investigation should not be limited to trace-back (to identify the source of the contamination) but should also cover trace-forward (to ensure the BSE case does not enter the animal feed chain). The Commission's rationale also applies to Article 1.8.6.

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

Comments were received from Argentina, Burkina Faso, Cameroon, Canada, New Zealand, South Africa, the USA, Members of the OIE Asia, Far East and Oceania Region, the AU-IBAR, the EU and the WRO.

Article 1.8.1.

In the first paragraph, the Code Commission agreed with a comment to delete 'of the cattle (*Bos indicus* and *Bos taurus*) population' and add '(*Bos indicus* and *Bos taurus*)' after 'within the cattle' for consistency with Chapter 11.4.

Article 1.8.2.

In point 1(b), the Code Commission did not agree with a comment to delete the second 'indigenous', as it considered that the information on the year of birth for each imported case of classical BSE does not provide added value in terms of BSE risk assessment.

Article 1.8.5.

In the first and second paragraph of point 2, the Code Commission did not agree with a comment that atypical BSE's capability of being recycled in a cattle population is negligible if cattle were exposed to feed contaminated with its causal agent. The Commission reiterated that it was presented in the March 2019 report of the *ad hoc* Group on BSE risk assessment and surveillance, as discussed above in Article 11.4.1.

In the first paragraph of point 2(a), the Code Commission did not agree with comments to reinstate 'stock' or replace 'dead animals' with 'fallen stock', and explained that 'dead animals' is the term commonly used throughout the *Terrestrial Code*. The Commission did not agree with a comment to replace 'slaughtered animals' with 'slaughtered cattle', as it considered the change would not provide any additional clarity.

In point 2(a)(i), the Code Commission amended the text in response to comments to improve clarity.

In the third paragraph of point 2(a)(ii), the Code Commission did not agree with a comment to delete '(i.e. cattle 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)' and to create a Glossary definition for 'fallen stock', as it noted that 'fallen stock' is a term that is only used in the BSE chapters (Chapter 11.4. and Chapter 1.8.) and therefore does not meet the criteria for creating a Glossary definition.

In the last sentence of the same paragraph, the Code Commission did not agree with a comment that information on the extent and frequency of use of fertilisers or composted materials is not relevant, as it considered that quantitative information is useful to understand this practice.

In point 2(a)(iv), the Code Commission did not agree with a comment to delete '(classical or atypical)' as it considered it necessary to include 'atypical' here and reiterated that the recycling of not only classical BSE but also atypical BSE should be avoided and that it is important to consider the potential recycling of all BSE agents, including atypical BSE, in the exposure assessment. The Commission noted that this rationale also applies to similar comments submitted for Article 1.8.5.

In the second indent of point 2(b)(ii), the Code Commission agreed with a comment to delete 'cross-' to align with point 1 of Article 11.4.14.

In the third and fourth indents of point 2(b)(ii), in response to a comment to clarify this text, the Code Commission explained that the intention of the third indent is to determine whether commodities with the greatest BSE infectivity are removed from 'fallen stock' and that 'animals condemned at ante-mortem inspection' are subject to a rendering process, whereas the intention of the fourth indent is to determine how 'fallen stock', 'animals condemned at ante-mortem inspection' and 'slaughter waste declared as unfit for human consumption' are disposed of in case that they include the commodities with the greatest BSE infectivity. To clarify the intention, the Commission proposed some amendments in the fourth indent.

In the first indent of point 2(b)(vi), in response to a comment to delete 'or a third party' and stating that a feed ban is the key risk mitigation measure and should have oversight by the Veterinary or Competent Authority, the Code Commission agreed with the rationale and proposed to add 'approved' before 'third party'.

Article 1.8.6.

The Code Commission proposed to amend some wording in this article to ensure alignment with the wording in Article 11.4.18.

In point 3(a), the Code Commission proposed to delete 'how many are involved in testing BSE samples' as it considered this text was ambiguous and unnecessary.

In point 4, in response to a comment that the current wording still implies active targeted surveillance and enhanced passive surveillance without a target of an acceptable amount of testing, the Code Commission considered the text clear as written, and stressed that the proposed BSE surveillance focuses on passive surveillance which is a mechanism to demonstrate that the risk of classical BSE is still low. Therefore, all animals listed in points 2(a) to 2(d) of Article 11.4.18. should be reported to the Veterinary Authority, but not all of these animals need to be tested in laboratories.

In Table 1, the Code Commission did not agree with suggestions to improve clarity of the table, as it considered it clear as written.

In Table 2, in response to a comment to improve clarity of 'Age (in months) at first detection', the Code Commission proposed to replace 'at first detection' with 'at the time of reporting'.

In Table 2, in response to concerns that completing this table would be an administrative burden, the Code Commission reminded Members that the information specified in Articles 1.8.2. to 1.8.6. should be provided by Members who apply for official recognition of BSE risk status, and is different from the information that should be provided as part of the annual reconfirmation process. The Commission requested the OIE Secretariat to consider providing more information to Members on the revised annual reconfirmation process to ensure it is well understood.

c) <u>Glossary definition for 'protein meal'</u>

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

The Code Commission did not agree with a comment to add 'milk and milk products' to the exception because it considered that it is already clear that 'milk and milk products' as per the Glossary definition are not included in the definition for protein meal.

The Code Commission proposed to delete 'blood and blood products' (see Article 11.4.1.).

The Code Commission requested the OIE Secretariat to review the use of terms 'meat-and-bone meal' and 'greaves' throughout the *Terrestrial Code* and report back to the Commission at its February 2022 meeting. At that time the Commission will decide where these terms should be replaced with 'protein meal'. Once the Commission knows the extent of consequential changes required throughout the *Terrestrial Code*, it will decide whether the Glossary definition for protein meal should be proposed for adoption. The Commission also explained that when 'protein meal' is adopted as a Glossary definition, point 4(b) of Article 11.4.1. will be deleted.

The revised Chapter 11.4. Bovine spongiform encephalopathy, Chapter 1.8. Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy, and the proposed Glossary definition for 'protein meal' are presented as **Annex 13**, **Annex 14** and in **Annex 4**, respectively, for Member comments and are proposed for adoption at the 89th General Session in May 2022.

EU comment

The EU thanks the OIE for the latest version of the revised Chapter 11.4. *Bovine spongiform encephalopathy*, the revised Chapter 1.8. *Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy*, and the revised Glossary definition for 'protein meal'. Comments are inserted in the text of Annexes 13, 14 and 4.

6.9. Theileriosis (Chapter 11.10.) and Article 1.3.2.

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

Background

The revised Chapter 11.10. Infection with *Theileria annulata*, *T. orientalis* and *T. parva* was first circulated for comments in September 2017, following the work of the *ad hoc* Group on Theileriosis that met in February 2017. At the Code Commission's February 2018 meeting, in response to some comments which questioned the listing of some *Theileria* spp., the review of comments was put on hold while expert advice was sought regarding listing.

At its September 2019 meeting, the Code Commission was informed that *T. orientalis* (Ikeda and Chitose) had been assessed by experts against the criteria for listing in accordance with Chapter 1.2. and were found to meet the criteria for listing (refer to Annex 19 of the Scientific Commission's February 2019 meeting report). Given that the pathogenic agent was found to meet the criteria for listing, the Code Commission agreed to recommence work on the revised chapter.

At its September 2020 meeting, the Code Commission considered comments received previously on the revised Chapter 11.10. and circulated a revised chapter for comments.

At its February 2021 meeting, the Code Commission agreed to defer its discussion until its September 2021 meeting when they would have received advice from the Scientific and the Laboratories Commissions on selected comments.

The Code Commission noted that the Scientific Commission had acknowledged inconsistencies in the requirements for disease freedom for vector-borne diseases, including demonstrating the absence of competent vectors. The Code Commission considered this issue and agreed that this issue should be considered further before proposing any specific revisions to relevant new or revised chapters.

Discussion

Article 1.3.2.

The Code Commission noted that the listed disease 'Theileriosis' in Article 1.3.2. should be amended to 'Infection with *Theileria annulata*, *T. orientalis* and *T. parva*' to reflect the recent assessments against the listing criteria in accordance with Chapter 1.2., and proposed to amend Article 1.3.2. accordingly.

General comments

In response to a comment to include '*T. mutans*', the Code Commission noted that this species could not be added until it has been assessed against the listing criteria in accordance with Chapter 1.2. The Commission asked that this species be proposed for an assessment.

Article 11.10.3.

The Code Commission, in agreement with the Scientific Commission, did not agree with a comment to add 'and has considered the presence or absence of competent vectors in the epidemiological situation' at the end of point (b) and to delete point (c). However, the Code Commission did not agree with a proposal from the Scientific Commission to add a requirement that 'the country or zone has not reported

any case of Theileriosis for at least two years' to point (c). The Commission agreed that, in accordance with chapters on surveillance, if a country demonstrates the absence of competent vectors for a disease 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.

Regarding a comment seeking clarification on the use of terms 'competent vectors' and 'competent tick vectors' in the *Terrestrial Code* and the inclusion of genera or species of competent vectors in this draft chapter as well as other relevant disease-specific chapters, the Code Commission considered that the term 'competent' referred to a vector's capability to transmit the disease and found no added value on further defining these terms for the purpose of the *Terrestrial Code*. The Commission also explained that it was not always possible to provide a detailed list of competent vectors for every disease and that such a list could even vary by region. It also highlighted that the detailed provisions for surveillance for arthropod vectors is provided in Chapter 1.5. In addition, it encouraged Members to refer to the discussion in item 5.2. of this report, on the recently adopted Chapter 8.18. Infection with *Trypanosoma brucei*, *T. congolense*, *T. simiae* and *T. vivax* and item 4.12. of its February 2021 report.

Article 11.10.5.

In point 2, the Code Commission did not agree with a comment to replace '35 days' with '40 days' to allow for the time taken for testing. The Commission explained that the isolation time was primarily intended to detect potential clinical cases (hence a duration of one incubation period) and that provisions on the testing are described in point 4, not in point 2. In the same point, the Commission did not agree with a proposal to add 'in a herd with bovines that are free from infection with *Theileria*' after 'isolated' and to delete 'in and establishment where no case of infection with *Theileria* has occurred during the preceding two years', as it considered that the establishment for isolation needs to be defined in this point and is clear as written.

In point 3, the Code Commission agreed with a comment to replace 'entrance of the isolation establishment' with 'time of entry to the isolation herd' as it considered that the timing of the acaricide treatment before export is critical but proposed to replace herd with establishment for consistency with wording used in this chapter.

In point 4, with regard to a comment to replace 'serological and agent identification tests' with 'serological or agent identification tests', the Code Commission noted that the Laboratories Commission had considered that both tests are necessary as neither test is very sensitive. However, the Code Commission acknowledged that Table 1 of Chapter 3.4.15. in the *Terrestrial Manual* recognises some serological and agent identification tests as 'recommended method' or 'suitable method' for individual animal freedom from infection prior to movement. Therefore, the Code Commission requested that this issue be raised with the Laboratories Commission and report back to the next meeting of the Code Commission.

In the same point, the Code Commission, in agreement with the Laboratories Commission, agreed with a comment that it is impractical to have testing five days prior to shipment, and proposed amended text.

The revised Chapter 11.10. Infection with *Theileria annulata*, *T. orientalis* and *T. parva* and the revised Article 1.3.2. are presented as **Annex 15** and **Annex 16** respectively for Member comments and are proposed for adoption at the 89th General Session in May 2022.

EU comment

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

6.10. Trichomonosis (Chapter 11.11.)

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

Background

At its September 2020 meeting, the Code Commission revised Articles 11.11.2., 11.11.3. and 11.11.4., to align recommendations with those in Chapter 3.4.15. on 'Trichomonosis' of the *Terrestrial Manual*. The amendments made by the Commission were based on the advice of the Reference Laboratory experts for Trichomonosis. The revised articles were circulated for comment in its September 2020

report. However, due to time constraints, the Commission deferred discussions until its September 2021 meeting.

Discussion

General

In alignment with the changes made in the *Terrestrial Manual*, the Code Commission proposed to replace 'agent identification test' with 'test for the detection of the agent' throughout the text.

Article 11.11.2.

In point 2, in response to a comment seeking clarification as to the time period for which no case of trichomonosis has been reported in the herd, the Code Commission explained that this provision meant that the animals in the herd have never had a case of trichomonosis. The Commission also wished to clarify that 'herd' (a Glossary defined term) refers to a group of animals, and should be distinguished from 'establishment' (a Glossary defined term) which refers to the premises where animals are kept. In point 3, the Commission did not agree with a comment to reinstate 'of vaginal mucus', and reminded Members that details of the appropriate samples for the recommended diagnostic tests are provided in Chapter 3.4.15. of the *Terrestrial Manual* and such details are not included in the *Terrestrial Code*.

The Code Commission agreed that points 2 and 3 should be undertaken in conjunction, and thus proposed to delete 'and/or' after point 2.

Article 11.11.3.

In point 5, the Code Commission did not agree with a comment to reinstate 'of preputial specimens' and reminded Members that details of the appropriate samples for the recommended diagnostic tests are provided in Chapter 3.4.15. of the *Terrestrial Manual*.

The Code Commission proposed to delete 'and/or' and to add 'AND' after point 2, noting that points 1 and 2 have to be undertaken in conjunction with either of points 3, 4 and 5.

Article 11.11.4.

The Code Commission proposed to move point 5 to a new point 1 for a more logical flow.

Noting that the original points 3 and 4 have to be undertaken in conjunction and that it was unnecessary to perform a test for the detection of the agent for donor animals fulfilling the original points 1 and 2, the Code Commission proposed to combine the original points 3 and 4 into new point 4.

The revised Chapter 11.11. Trichomonosis is presented as **Annex 17** for Member comments and is proposed for adoption at the 89th General Session in May 2022.

EU comment

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

6.11. Terminology: Use of the term 'sanitary measure'

Background

Following the adoption of the Glossary definition of 'sanitary measure' at the 87th General Session, the Code Commission requested the OIE Secretariat to assess whether the terms 'sanitary measure' and 'biosecurity' have been used appropriately in the *Terrestrial Code.*

Discussion

In view of the planned work to develop a new chapter on biosecurity, the Code Commission agreed to include the review of the use of the term 'biosecurity' as part of this work.

Regarding the review of the term 'sanitary measure', the Code Commission noted that this term has not been appropriately used in the following articles and proposed the following amendments.

Veterinary legislation (Chapter 3.4., Article 3.4.5.)

In point 1(d), the Code Commission proposed to replace 'sanitary measures' with 'measures and procedures'.

Official health control of bee diseases (Chapter 4.15., Article 4.15.6.)

In point 1, the Code Commission proposed to replace 'sanitary measures' with 'procedures'. In line with this amendment, the Commission also proposed to replace 'measures' in points 2 and 3 with 'procedures'.

Control of biological hazards of animal health and public health importance through ante-and post-mortem meat inspection (Chapter 6.3., Article 6.3.3.)

In the first sentence, the Code Commission proposed to replace 'sanitary measures' with 'hygiene practices and sanitation', in accordance with language used by the Codex Alimentarius Commission.

The revised Articles 4.15.6. of Chapter 4.15. Official health control of bee diseases and Article 6.3.3. of Chapter 6.3. Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection, are presented as **Annex 18**, and are proposed for adoption at the 89th General Session in May 2022.

EU comment

The EU supports the proposed changes to these articles.

7. Texts circulated for comments

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

Comments were received from Australia, Brazil, Canada, Chinese Taipei, Japan, New Caledonia, New Zealand, Switzerland, Thailand, the USA, Zimbabwe, Members of the OIE Americas Region, the AU-IBAR and the EU.

Background

A revised Chapter 8.8. Infection with foot and mouth disease virus has been circulated three times for Member comments, the last time in the Code Commission's September 2020 report. At its February 2021 meeting, the Code Commission agreed to defer discussions on this chapter, noting that it was awaiting the opinion of the Scientific Commission on some points, and the recommendations of a joint TAHSC-SCAD Taskforce (the Taskforce) to clarify the term 'bovine' as used in the chapter, and to review the use of the terms 'case', 'transmission', 'case with clinical signs' and 'infection' in the chapter.

Between June and July 2021, a second meeting of the Taskforce was convened to address the implications of introducing vaccinated animals into an FMD-free country (or zone) where vaccination is not practised (not for direct slaughter), to develop an article on the establishment of a protection zone in line with recently adopted Article 4.4.6., and to address the incursion of African buffalo into an FMD-free country or zone. The Code Commission encouraged Members to refer to the September 2021 report of the Scientific Commission for detailed information on the rationale for some recommendations of the Taskforce.

Discussion

The Code Commission considered Member comments received in February 2021, the recommendations of the Taskforce and a proposal from the OIE 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 revisions in Chapters 14.7. Infection with peste des petits ruminants virus and 15.2. Infection with classical swine fever virus.

The Code Commission noted that the *ad hoc* Group on Foot and mouth disease virus had also proposed 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 an OIE endorsed official control programme for FMD exists, that had been endorsed by the Scientific Commission at its February 2021 meeting. The Code Commission agreed it will review the recommendations of the *ad hoc* Group at its next meeting in February 2022.

The Code Commission noted that some comments, such as those related to safe commodities (Article 8.8.1bis.) received in February 2021, were not addressed at this meeting and would be followed-up with, where necessary (within the framework of general discussions on safe commodities Standard Operating Procedure (SOP), when it continues its discussion on Chapter 8.8. at its next meeting in February 2022.

General comments

With regard to the use of the terms 'infection' and 'transmission', the Taskforce had proposed to keep both terms when describing the demonstration of freedom from FMD: no infection with FMDV in unvaccinated populations and no transmission of FMDV in vaccinated populations. The Taskforce also agreed on the importance of clinical surveillance, mainly in unvaccinated populations, and kept references to 'clinical signs' when it was appropriate but removed them when unnecessary. The Taskforce had also proposed to replace 'case' with 'infection with FMDV' for simplification and harmonisation purposes. The Code Commission agreed with the recommendations of the Taskforce and applied these changes throughout the text where relevant.

The Code Commission agreed with the recommendations of the Taskforce to replace 'bovines' with 'cattle' for consistency with Chapter 11.4. Bovine spongiform encephalopathy. Consequently, the Commission replaced the term 'bovines' by cattle in different parts of the chapter and made reference to water buffaloes in addition to cattle where applicable.

Additionally, the Code Commission reviewed the harmonisation changes and proposed amendments to Articles 8.8.2., 8.8.3., 8.8.5. and 8.8.39.

The Code Commission considered that the proposed amendments to the above points would address selected comments on the text.

Article 8.8.1.

In point 2, the Code Commission agreed with the recommendations of the Taskforce and proposed to delete 'suborder ruminantia and of the', and to add 'and the subfamilies *bovinae, caprinae* and c*ervidae*' to better clarify the scope of susceptible animals. It also agreed with the proposal to add a new point 2bis to clarify that the term 'cattle' as used in the chapter means animals of the species *Bos taurus* or *Bos indicus.*

In view of the above amendment, the Code Commission did not agree with a comment to add 'cloven-hooved' before 'animals'.

In point 4, the Code Commission proposed to add 'or any cause for suspicion of previous association or contact with FMDV' to clearly distinguish the use of the term 'infection' from 'transmission' in the chapter, and to clarify that transmission could occur not just in the absence of clinical signs, but also if there was an epidemiological link with the FMDV.

In point 6, in response to a comment requesting to provide further elaboration on the persistence and shedding of FMDV and the duration of carrier status, the Code Commission reiterated that it considered this addition to be too detailed for a chapter in the *Terrestrial Code*, and that such information would be more appropriate in the *Terrestrial Manual*.

In response to a query on the inclusion of point 7 concerning reference to the *Terrestrial Manual*, the Code Commission confirmed that it is a convention to include this point in the disease-specific chapters of the *Terrestrial Code* and it provides a clear link with the *Terrestrial Manual* when appropriate.

Article 8.8.1bis.

In point 1, in response to a comment regarding the inclusion of the UHT milk on the list of safe commodities, the Code Commission clarified that this was aligned with the current version of the OIE Technical Disease Card on FMD.

In point 3, the Code Commission proposed to replace 'meat and bone meal and blood meal' with 'protein meal' for consistency with the proposed new Glossary definition for protein meal (refer to item 6.8. of this report).

In response to a comment requesting to include the term 'rendering' in the Glossary, the Code Commission discussed the proposal and decided to consider this request at its next meeting.

Article 8.8.2.

In paragraph 3, the Code Commission, in agreement with the Scientific Commission, did not agree with a comment to relocate the penultimate paragraph of Article 8.8.3. to this paragraph. The Code Commission considered this comment to be addressed with the newly proposed Article 8.8.5bis. on Establishment of a protection zone within a country or zone free from FMD.

In points 1 to 4, the Code Commission reminded Members that the proposed amendments were made as part of the harmonisation work in accordance with recently adopted Chapters 14.7. and 15.2.

In point 5, the Code Commission agreed with the recommendations of the Taskforce, and proposed to delete 'measures to prevent the introduction of vaccinated animals, except in accordance with Articles 8.8.8., 8.8.9., 8.8.9bis., 8.8.11., and 8.8.11bis. have been effectively supervised'. The Commission noted that the Taskforce considered that the provisions in the draft revised Articles 8.8.11. and 8.8.12. provided the necessary assurances for the safe trade of vaccinated animals into a free country or zone where vaccination is not practised.

The Code Commission agreed with the proposal of the Taskforce to add point 6 to reflect that vaccination should remain prohibited in the country or zone free from FMD where vaccinated is not practised, although it may have subpopulations of animals that are vaccinated due to the possibility of introducing vaccinated animals.

In the sixth indent, the Code Commission, in agreement with the Scientific Commission, did not accept a comment to add a parenthesis 'including virological and serological surveillance as appropriate for African buffalo within the collection', noting that the zoological collection is already subject to surveillance in accordance with point 4(b) which includes surveillance in accordance with Articles 8.8.40. to 8.8.42. demonstrating no infection or transmission of FMDV. Thus, the same conditions would apply to the African buffalo.

Regarding comments pertaining to the possible incursion of stray African buffalo, the Code Commission noted that the Taskforce had recommended specific conditions to be met in order that a country or zone free from FMD may maintain its free status despite an incursion of African buffalo. While the Code Commission considered that the conditions proposed by the Taskforce were logical, it agreed that such provisions were outside the scope of the *Terrestrial Code*, i.e. to provide conditions for specific epidemiological situations such as incursions of African buffalo from neighbouring infected countries or zones. Consequently, the Code Commission proposed to include a statement that it was possible for a country or zone free from FMD to maintain its free status despite an incursion of African buffalo from a neighbouring infected country or zone provided relevant conditions are met and evidence has been submitted to and accepted by the OIE as part of the reassessment of official status in such circumstances, without prescribing the specific conditions. It would be up to the assessment of the Scientific Commission, who is responsible for evaluating a Member's official disease status to determine whether the free status can be maintained.

Article 8.8.3.

The Code Commission did not agree with a comment to include the reference of point 6 of Article 8.8.40. at the end of the point 1(e), as it considered this to be implicit.

The Code Commission did not agree with comments to move the penultimate paragraph of Article 8.8.3. to original paragraph 2 (now deleted). It considered this comment would be addressed with the newly proposed Article 8.8.5bis. on Establishment of a protection zone within a country or zone free from FMD.

Article 8.8.3bis.

The Code Commission agreed with the recommendation of the Scientific Commission that the two paragraphs at the end of Article 8.8.3. that describe the provisions for changing the vaccination status of a country or zone free from FMD do not fit in Article 8.8.3. and are better placed as a separate Article 8.8.3bis. on Transition of vaccination status in a country or zone free from FMD.

Article 8.8.4. and Article 8.8.4bis.

The Code Commission agreed with the Taskforce proposal to delete point 2(a) given that infection with FMDV in the next point would include a 'case'. In addition, the Commission proposed to replace 'detected' with 'occurred' in point 2(a) of both articles.

Article 8.8.5bis.

The Code Commission noted that the Taskforce had proposed a new Article 8.8.5bis. on Establishment of a protection zone within a country or zone free from FMD in view of recently adopted Article 4.4.6.

Article 8.8.6.

The Code Commission agreed with a comment to add 'previously' before 'free from FMD' in the title of the article for consistency with the text within the article and in line with the harmonisation work done for Chapter 15.2. on the equivalent article.

In paragraph 1, in response to a comment to consider revising the text to address the possibility of establishing multiple containment zones where outbreaks are not epidemiologically linked, the Code Commission agreed with the Scientific Commission that this would be a very exceptional situation and that the current text does not preclude this possibility as long as evidence demonstrates that the incursions are not epidemiologically linked. Therefore, it did not agree to make any further changes to this paragraph.

In paragraph 2, the Code Commission did not agree with comments requesting to state that the containment zone is not considered to be established until approved by the OIE as this is already mentioned in paragraph 3.

In response to a comment querying the deletion of point 3 of paragraph 2, the Code Commission reiterated its explanation in its September 2020 meeting report that the deletion was to minimise duplication with provisions already in point 3 of Article 4.4.7. and to harmonise with other disease-specific chapters.

In paragraph 3, the Code Commission, in agreement with the Scientific Commission, did not agree with comments to add a reference to Article 4.4.7. noting that the first two paragraphs of Article 8.8.6. make a reference to Article 4.4.7.

In paragraph 5, the Code Commission agreed with comments and corrected the reference from point 4(a) to point 4(b).

In the last paragraph, comments were received requesting to increase the time period for the recovery of free status of the containment zone to be achieved from 12 months to 24 months. The Code Commission agreed with the proposal of the Scientific Commission to amend the recovery time to

18 months, in view of the opinion of the Scientific Commission that considering the waiting periods for recovery of status under Article 8.8.7., particularly point 3(b) in which the waiting period is 12 months after the detection of the last case, the recovery of free status of the containment zone was not possible to achieve if the containment zone was established following point 4(b) of Article 4.4.7. It noted the rationale of the Scientific Commission that the intention of the containment zone is for it to be quickly established in the event of FMD outbreaks in a previously free country or zone, to control and eradicate the disease and recover the status as soon as possible. The Code Commission also noted its ongoing discussion with the Scientific Commission concerning the time limit of the containment zone (refer to item 5.2. of this report).

Article 8.8.7.

The Code Commission noted that its proposed amendments to the beginning of points 1 and 2 would address a comment requesting to harmonise the wording used.

Articles 8.8.8. and 8.8.9. (deleted)

In response to comments requesting to include the same requirements for a containment zone as an infected zone, notably in points 1, 2 and 3 of Article 8.8.8., the Code Commission, in agreement with the Scientific Commission, proposed to delete Article 8.8.9. and to include the containment zone in Article 8.8.8. The Code Commission highlighted that a containment zone is considered an infected zone, and therefore added 'including containment zone' to the title of Article 8.8.8.

The Code Commission, in agreement with the Scientific Commission, did not agree with a comment to develop different conditions for the inner and outer zones of a containment zone as the outer zone is still part of the risk management area and therefore considered infected as part of the containment zone.

Article 8.8.9bis and Article 8.8.11.

The Code Commission did not agree with a comment to delete 'or not' in the title of the article and clarified that vaccinated animals may exist in a zone free from FMD where vaccination is not practised, either because the zone has been recently recognised as free without vaccination or as a result of movements in accordance with Article 8.8.11.

In paragraph 1, the Code Commission agreed with comments to delete 'nearest', noting that the nearest slaughterhouse/abattoir may not be the most appropriate for slaughter to take place. However, it did not agree with a comment to delete 'designated'.

In response to a comment requesting to include a new article to provide for the movement of animals from a zone free from FMD where vaccination is practised transiting through a zone free from FMD where vaccination is not practised for export purposes, the Code Commission noted that with the change in Article 8.8.2. that allows the possibility of free status without vaccination to be maintained with the introduction of vaccinated animals into a country or zone free from FMD where vaccination is not practised, the proposal is no longer relevant. Nonetheless, the Code Commission agreed with the recommendation of the Scientific Commission to clarify that whilst vaccinated animals are transiting through an FMD free zone where vaccination is not practised, they should not be in contact with any susceptible animals during transportation to the place of shipment, and proposed a new point 6 in Article 8.8.11.

Article 8.8.11bis.

In point 3, the Code Commission did not agree with a comment to replace 'vehicles/vessels' by 'containers' as it considered that 'vehicles/vessels' may be properly sealed.

Article 8.8.12.

In point 5, the Code Commission acknowledged that the text as written could be confusing, and proposed to split the point into two parts so that it was clear that if the animals were isolated in an establishment that is not a quarantine station, there should be no FMD case within a 10-km radius of the establishment.

Articles 8.8.15. and Article 8.8.16.

In point 1(c)(ii), the Code Commission, in agreement with the Scientific Commission, did not agree with comments to specify the use of a DIVA assay, and clarified that this point was applicable to donor males that have not been vaccinated. Consequently, the Code Commission proposed to add 'have not been vaccinated' at the beginning of the sentence.

In the same point, the Code Commission also noted that whilst there was a defined lower limit of 21 days after collection of semen for testing the donor males for antibodies, an upper limit was not provided. The Code Commission agreed with the recommendation of the Scientific Commission to provide an upper limit of 60 days, noting that the rationale for this proposal was provided in the February 2020 report of the Scientific Commission.

Article 8.8.26. (deleted)

In response to a comment requesting the reinstatement of Article 8.8.26., the Code Commission clarified that it had proposed to delete this article after considering the inclusion of 'meat-and-bone meal' as a safe commodity in Article 8.8.1bis. The Commission further clarified that the term 'protein meal' has been proposed to replace 'meat-and-bone meal' (refer to item 6.8. of this report).

Article 8.8.31.

In point 1, in response to a comment requesting further information on 'any equivalent treatment', the Code Commission clarified that the current recommendation on canning provides the reference point for the selection of other alternative treatments.

Article 8.8.35. and Article 8.8.36.

The Code Commission noted that Articles 8.8.35. and 8.8.36. concerned inactivation parameters for FMDV and that there should not be any differentiation depending on end-use, i.e. for human or animal consumption. In view of this, the Commission proposed to delete Article 8.8.36., and to have a single Article 8.8.35. on the inactivation of FMDV in milk.

Given the above amendment, the Code Commission noted that a comment seeking further specification on the time lapse requirement for the 72°C and a definition for desiccation in point 2 of Article 8.8.36. was no longer relevant. Nonetheless, the Code Commission would refer the Member to the Scientific Commission report of February 2021 which addressed this question.

Article 8.8.39.

The Code Commission proposed amendments to the article as part of the harmonisation work for disease-specific chapters for which the OIE grants official status recognition, in accordance with recently adopted Chapters 14.7. and 15.2.

Article 8.8.40.

In paragraph 4 of point 2, the Code Commission clarified that the addition of the text 'previously or newly introduced vaccinated animals should be considered in the strategy and design of the surveillance programme' was in response to the recommendation of the Taskforce to allow for the introduction of vaccinated animals into a country or zone free from FMD where vaccination is not practised. The Taskforce had highlighted the need to modify the surveillance strategy and design to demonstrate the absence of FMDV in the different subpopulations (vaccinated and unvaccinated) following the introduction of vaccinated animals into a country or zone free from FMD where vaccination is not practised. In such a situation, the Member concerned should demonstrate the absence of infection with FMDV in the unvaccinated subpopulation, and that there has been no transmission of FMDV in the newly introduced or previously vaccinated subpopulation. Evidence to demonstrate this should be documented and included in the dossier for the official recognition and maintenance of free status.

The Code Commission agreed with a comment that serological surveys should not only be performed for non-vaccinated susceptible species that do not show reliable clinical signs, but also to susceptible

species that show reliable clinical signs but which are not subject to regular and frequent observation such that clinical signs could be missed. Therefore in points 7(a)(iii), 7(b)(iv) and 8(b)(iv), the Code Commission, in agreement with the Scientific Commission, proposed to include 'husbandry systems that do not allow sufficient observation'.

In the first indent of point 7(c)(i), in response to comments regarding vaccine matching and potency, the Code Commission agreed with the Scientific Commission that the focus should be on the probability of protection and the different ways to demonstrate an adequate level of protection. The Code Commission agreed with the Scientific Commission's proposed amendment to better clarify that vaccine with high potency of at least 6PD50 or equivalent is one of the ways to achieve this protection.

In the second indent of point 7(c)(ii), the Code Commission, in agreement with the Scientific Commission, did not accept comments to delete 'indirect serological assay (i.e. sera from vaccinated *animals* tested against the field virus)', noting that this is a way to demonstrate an adequate level of protection.

The revised Chapter 8.8. Infection with foot and mouth disease virus is presented as **Annex 19** for Member comments.

EU comment

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

8. Date of next meeting

The next meeting will be held from 1 to 11 February 2022.

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…/Annexes

WORK PROGRAMME FOR
THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

EU comment

The EU thanks the OIE for having taken into consideration comments submitted previously and in general supports the revised work programme of the Code Commission and its prioritisation.

Further to the adoption of the revised chapter on HPAI and the transfer of a revised definition of "poultry" into the Glossary at the 88th OIE General Session in May 2021, we have noted that Chapter 10.9. *Infection with Newcastle disease virus* still contains a definition of poultry that deviates from the one in the Glossary. The EU therefore suggests deleting the definition in Chapter 10.9. and italicising the term "poultry" throughout that chapter, so that the new Glossary definition would apply in the context of Newcastle disease as well. Furthermore, we query whether certain other points in Chapter 10.9. would merit a revision as well (e.g. recovery period).

The EU takes note of the information in Item 5.1.4. of the Code Commission report on the upcoming work on Chapter 6.10. on prudent use of antimicrobial agents and other related chapters, also taking into consideration the recent progress on the revision of the corresponding Codex Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance. We refer to our text proposals provided in December 2018 on Chapter 6.10. (https://ec.europa.eu/food/system/files/2018-12/ia_standards_oie_eu_position_tahsc-report_201809.pdf) and are looking forward to receiving as soon as possible proposals for updating relevant AMR-related chapters. The EU is certainly willing to assist the OIE in this important work.

The EU has taken note of the intention of the OIE to amend the procedures around the notification of emerging diseases of terrestrial animals by way of Standard Operating Procedures. These SOP would foresee a central role for the Scientific Commission in determining what constitutes an emerging disease as defined in the Glossary. It furthermore seems to be the intention of the OIE to establish a list of emerging diseases on the OIE website (see recent OIE Bulletin article for background, https://oiebulletin.com/?p=18968). We have expressed our concerns both orally at the General Session in May 2021 and in an exchange of letters with the OIE Director General, as the EU considers that the proposed new approach is not compatible with the current provisions of the Terrestrial Code and needs to be discussed and agreed with members before it can be implemented. We would therefore encourage the Code Commission to examine the matter from a Terrestrial Code perspective with a view to possibly proposing appropriate amendments to the Code.

Chapter	Issues	Status - September 2021	
		Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)
N.A.	Use of terms: biosecurity / sanitary measures	Circulated for comments	Noted in Sep 2021 TAHSC report (Sep 2021/1)
	Use of terms: disease / infection / infestation	Preparatory work	Refer to Feb 2020 TAHSC report

	Use of terms: animal health status	Preparatory work	Refer to Feb 2020 TAHSC report
	Use of terms: animal-based measures / measurables	Preparatory work	Refer to Feb 2021 TAHSC report
	Use of terms: enzootic / endemic / epizootic / epidemic	Preparatory work	Refer to Feb 2021 TAHSC report
	Use of terms: notify / notifiable disease / report / reportable disease	Preparatory work	Refer to Feb 2019 TAHSC report
User's guide	Revision of the Users' guide (standing item)	Standing item	
Glossary	'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'	Circulated for comments (proposed for adoption in May 2022)	Noted in Sep 2021 TAHSC report (Sep 2018/3)
	'Death', 'euthanasia', 'slaughter' and 'stunning'	Preparatory work	AHG to address Member comments (Sep 2019/2)
	'Case'	Not started	Refer to Sep 2020 TAHSC report and Feb 2020 BSC report
	'Stray dog'	Circulated for comments (proposed for adoption in May 2022)	Noted in Sep 2021 TAHSC report (Sep 2021/1)
	New definition for 'protein meal'	Circulated for comments (proposed for adoption in May 2022)	Noted in Sep 2021 TAHSC report (Feb 2021/2)
	New definitions for 'distress', 'pain' and 'suffering'	Preparatory work	AHG to address Member comments (Sep 2019/2)
	New definitions for 'animal products', 'product of animal origin' and 'animal by-product'	Preparatory work	Refer to Feb 2020 TAHSC report
	New definition for 'swill'	Preparatory work	Noted in Sep 2021 TAHSC report
Section 1			
1.3.	Revision of Article 1.3.2. (Theileriosis)	Circulated for comments (proposed for adoption in May 2022)	Noted in Sep 2021 TAHSC report (Sep 2021/1)
	Listing of Infection with *T. lestoquardi*, *T. luwenshuni* and *T. uilenbergi* (Article 1.3.3.)	Preparatory work	Noted in Sep 2021 TAHSC report Refer to Feb 2020 TAHSC report
	Delisting of *Mycobacterium tuberculosis* (in *Mycobacterium tuberculosis* complex)	Expert consultation	Postponed until Feb 2022
	Delisting of West Nile fever	Preparatory work	Pending assessment by SCAD

	Delisting of Paratuberculosis	Preparatory work	Pending assessment by SCAD
1.8.	Application for official recognition by the OIE of free status for bovine spongiform encephalopathy	Circulated for comments	Noted in Sep 2021 TAHSC report (Sep 2019/4)
Section 3			
3.1., 3.2.	Introduction to recommendations on Veterinary Services (Ch 3.1.) and Quality of Veterinary Service (Ch 3.2.)	Circulated for comments (proposed for adoption in May 2022)	Noted in Sep 2021 TAHSC report (Sep 2021/1)
3.4.	Veterinary legislation	Circulated for comments (proposed for adoption in May 2022)	Noted in Sep 2021 TAHSC report (Sep 2021/1)
Section 4			
4.4.	Zoning and compartmentalisation	Preparatory work	Noted in Sep 2021 TAHSC report
4.6.	Collection and processing of semen of animals	Expert consultation	Noted in Sep 2021 TAHSC report
4.7.	Collection and processing of bovine, small ruminant and porcine semen	Preparatory work	Pending progress of the work on Ch 4.6.
4.8.	Collection and processing of in vivo derived embryos from livestock and equids	Not started	Pending progress of the work on Ch 4.6. and Ch 4.7.
4.9.	Collection and processing of oocytes and *in vitro* produced embryos from livestock and horses	Not started	Pending progress of the work on Ch 4.6. and Ch 4.7.
4.13.	Disposal of dead animals	Preparatory work	Noted in Sep 2021 TAHSC report
4.14.	General recommendations on disinfection and disinsection	Preparatory work	Noted in Sep 2021 TAHSC report
4.X.	New chapter on biosecurity	Preparatory work	Noted in Sep 2021 TAHSC report
Section 5			
General	Revision of Section 5 Trade measures, import/export procedures and veterinary certification (especially Chs 5.4. to 5.7.)	Preparatory work	Noted in Sep 2021 TAHSC report
5.11.	Model veterinary certificate for international movement of dogs, cats and ferrets originating from countries considered infected with rabies	Preparatory work	Pending progress of the work on Ch 8.14.

5.12.	Model passport for international movement of competition horses	Preparatory work	Pending progress of the works on Chs on horse diseases
Section 6			
6.2.	The role of the Veterinary Services in food safety systems	Not started	Pending progress of the work on Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'
6.3.	Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection	Not started	Pending progress of the work on Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'
6.10.	Responsible and prudent use of antimicrobial agents in veterinary medicine	Preparatory work	Noted in Sep 2021 TAHSC report
6.12.	Zoonoses transmissible from non-human primates	Circulated for comments (proposed for adoption in May 2022)	Noted in Sep 2021 TAHSC report (Feb 2021/2)
Section 7			
General	Transport of animals by land, sea and air (Chs 7.2., 7.3. and 7.4.)	Preparatory work	Noted in Sep 2021 TAHSC report
7.5.	Slaughter of animals	Expert consultation	Noted in Sep 2021 TAHSC report
7.6.	Kiling of animals for disease control purposes	Preparatory work	Refer to Feb 2021 TAHSC report
7.7.	Stray dog population control (Dog population management)	Circulated for comments (proposed for adoption in May 2022)	Noted in Sep 2021 TAHSC report (Sep 2020/2)
7.X.	New Chapter on animal welfare and laying hen production system		Under consideration
Section 8			
8.5.	Infection with *Echinococcus granulosus* (Articles 8.5.1. and 8.5.3.)	Circulated for comments (proposed for adoption in May 2022)	Noted in Sep 2021 TAHSC report (Sep 2021/1)
8.8.	Infection with foot and mouth disease virus	Circulated for comments	Noted in Sep 2021 TAHSC report (Sep 2015/3)

8.11.	Infection with *Mycobacterium tuberculosis* complex	Expert consultation	Postponed for Feb 2022
8.13.	Paratuberculosis	Expert consultation	Refer to Sep 2020 TAHSC report
8.14.	Infection with rabies virus	Expert consultation	Noted in Sep 2021 TAHSC report and Sep 2021 SCAD report (Sep 2020/1)
8.15.	Infection with Rift Valley fever virus	Expert consultation	Noted in Sep 2021 TAHSC report and Sep 2021 SCAD report (Feb 2019/3)
8.16.	Infection with rinderpest virus	Circulated for comments (proposed for adoption in May 2022)	Noted in Sep 2021 TAHSC report (Sep 2020/3)
8.X.	New Chapter on Surra	Preparatory work	Noted in Sep 2021 TAHSC report
Section 10			
10.3.	Avian infectious laryngotracheitis	Not started	Refer to Sep 2020 TAHSC report
Section 11			
11.4.	Bovine spongiform encephalopathy	Circulated for comments (proposed for adoption in May 2022)	Noted in Sep 2021 TAHSC report and Sep 2021 SCAD report (Sep 2019/4)
11.5.	Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)	Preparatory work	Postponed until Feb 2022
11.10.	Theileriosis	Circulated for comments (proposed for adoption in May 2022)	Noted in Sep 2021 TAHSC report(Sep 2017/3)
11.11.	Trichomonosis	Circulated for comments (proposed for adoption in May 2022)	Noted in Sep 2021 TAHSC report (Sep 2020/2)
Section 12			
12.1.	African horse sickness	Preparatory work	Refer to Feb 2021 TAHSC and SCAD reports
12.2.	Contagious equine metritis	Expert consultation	Postponed until Feb 2022 (Sep 2020/1)
12.3.	Dourine	Expert consultation	Noted in Sep 2021 TAHSC report

12.4.	Equine encephalomyelitis (Eastern and Western)	Not started	Pending ongoing work on case definition
12.6.	Infection with equine influenza virus	Expert consultation	Postponed until Feb 2022 (Sep 2019/3)
12.7.	Equine piroplasmosis	Expert consultation	Refer to Feb 2021 TAHSC and SCAD reports (Sep 2020/1)
12.11.	Venezuelan equine encephalomyelitis	Not started	Pending ongoing work on case definition
Section 14			
14.8.	Scrapie	Preparatory work	Noted in Sep 2021 TAHSC report
14.X.	New Chapter on Infection with Theileria in small ruminants	Pending *Terrestrial Manual*	Noted in Sep 2021 TAHSC report (Sep 2017/1)
Section 15			
15.3.	Infection with porcine reproductive and respiratory syndrome virus (Article 15.3.9.)	Preparatory work	Refer to Feb 2018 TAHSC report
15.4.	Infection with *Taenia solium* (Porcine cysticercosis) (Articles 15.4.1. and 15.4.3.)	Circulated for comments (proposed for adoption in May 2022)	Noted in Sep 2021 TAHSC report (Sep 2021/1)
Others			
X.X.	New Chapter on Crimean Congo haemorrhagic fever	Not started	Refer to Feb 2016 TAHSC report Pending ongoing work on case definition
X.X.	New Chapter on infection with *Leishmania* spp. (Leishmaniosis)	Preparatory work	Postponed until Feb 2022
X.X.	New Chapter on infection with Middle East respiratory syndrome coronavirus	Preparatory work	Postponed until Feb 2022
X.X.	New Chapter on Camelpox	Not started	Refer to Sep 2020 TAHSC report Pending ongoing work on case definition

List of abbreviations	
AHG	***Ad hoc* Group**
BSC	**Biological Standards Commission**
Ch	**Chapter**
SCAD	**Scientific Commission for Animal Diseases**
TAHSC	**Terrestrial Animal Health Standard Commission**

GLOSSARY

EU comment

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

One comment is inserted in the text below.

~~STRAY DOG~~ FREE-ROAMING DOG

means any *owned dog* or unowned dog that is without ~~not under~~ direct human supervision or control, including *feral* dogs. ~~by a person or not prevented from roaming. Types of stray dog:~~

~~a) free-roaming owned dog not under direct control or restriction at a particular time,~~

~~b) free-roaming dog with no owner,~~

~~c) feral dog: domestic dog that has reverted to the wild state and is no longer directly dependent upon humans.~~

EU comment

The EU queries whether the term "stray dog" will systematically be replaced with "free-roaming dog" in disease specific chapters (e.g. Chapters 8.5., 8.6.), should the revised definition above be adopted, and when these changes will be proposed.

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.

COMPETENT AUTHORITY

means ~~the *Veterinary Authority* or other~~ a Governmental Authority of a Member Country ~~having the responsibility and that has competence for ensuring or supervising~~ having responsibility in the whole or part of the territory for the implementation of ~~animal health and *welfare* measures, international veterinary certification and other~~ ~~any~~ certain standards ~~and recommendations~~ of ~~in~~ the *Terrestrial Code* ~~and in the OIE *Aquatic Animal Health Code* in the whole territory, which are not under the competence of the *Veterinary Authority*~~.

VETERINARY AUTHORITY

means the Governmental Authority of a Member Country~~, comprising the OIE Delegate, *veterinarians*, other professionals and paraprofessionals,~~ having the primary responsibility in the whole territory ~~and competence~~ for coordinating ~~ensuring or supervising~~ the implementation of ~~animal health, and *animal welfare* and veterinary public health measures, international veterinary certification and other~~ the standards ~~and recommendations~~ of ~~in~~ the *Terrestrial Code* ~~in the whole territory~~.

VETERINARY SERVICES

means the combination of ~~the~~ governmental and non-governmental individuals and organisations that perform activities to implement ~~animal health, and *animal welfare* and veterinary public health measures and other~~ the standards ~~and recommendations~~ of ~~in~~ the *Terrestrial Code* ~~and the OIE *Aquatic Animal Health Code* in the territory. The Veterinary Services are under the overall control and direction of the *Veterinary Authority*. Private sector organisations, *veterinarians*, *veterinary paraprofessionals* or aquatic animal health professionals are normally accredited or approved by the *Veterinary Authority* to deliver the delegated functions~~.

Edited definitions in clean text:

COMPETENT AUTHORITY

means a Governmental Authority of a Member Country having responsibility in the whole or part of the territory for the implementation of certain standards of the *Terrestrial Code*.

VETERINARY AUTHORITY

means the Governmental Authority of a Member Country having the primary responsibility in the whole territory for coordinating the implementation of the standards of the *Terrestrial Code*.

VETERINARY SERVICES

means the combination of governmental and non-governmental individuals and organisations that perform activities to implement the standards of the *Terrestrial Code*.

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CHAPTER 3.1.

INTRODUCTION TO RECOMMENDATIONS ON VETERINARY SERVICES

EU comment

The EU supports the proposed changes to this chapter.

Article 3.1.1.

Veterinary Services are critical to global and national health security, food security and food safety, agricultural and rural development, poverty alleviation, safe national and *international trade*, *wildlife* health and environmental protection; as such they are considered a global public good. To achieve these goals, *Veterinary Services* require good governance, including effective policy and management, personnel and resources, veterinary professionals and interaction with stakeholders in a One Health approach, involving all relevant sectors and disciplines across the human-animal-environment interface.

Member Countries have the sovereign right to structure and manage the delivery of animal health, *animal welfare* and veterinary public health in the veterinary domain in their countries as they consider appropriate. The veterinary domain covers a broad scope of possible activities. Section 3 focuses on aspects of the *Veterinary Services* that enable the OIE standards to be met even when under the responsibility of one or more *Competent Authorities*.

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

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

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

CHAPTER 3.2.

QUALITY OF VETERINARY SERVICES

EU comment

The EU supports the proposed changes to this chapter.

[…]

Article 3.2.3.

Policy and management

Veterinary Services should have the leadership, organisational structure and management systems to develop, implement and update policies, legislation and programmes, incorporating *risk analysis*, and epidemiological, economics and social science principles. Decision-making by *Veterinary Services* should be free from undue financial, political and other non-scientific influences.

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

This component should comprise the following specific elements:

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

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

3) capability to perform *risk analysis* and cost–benefit analysis to define, review, adapt and resource policies and programmes;

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

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

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

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

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

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

[…]

Article 3.2.9.

Veterinary medicinal products

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

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

This component should comprise the following specific elements:

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

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

    b) responsible and prudent use of *veterinary medicinal products*, including the labelling, distribution, sale, dispensing, prescription, administration and appropriate safe storage and disposal of these products;

2) *risk management* and *risk communication* for antimicrobial use and antimicrobial resistance, based on *risk assessment*. This includes *surveillance* and control of the use of antimicrobials and the development and spread of antimicrobial resistant pathogens in animal production and food products of animal origin. This should be coordinated using a One Health approach, and in accordance with Chapter 3.4. and relevant chapters of Section 6.

[...]

CHAPTER 3.4.

VETERINARY LEGISLATION

EU comment

The EU supports the proposed changes to this chapter.

[…]

Article 3.4.5.

Competent Authorities

Competent Authorities should be legally mandated, have the necessary technical, administrative and infrastructure capacity and be organised to ensure that all necessary actions are taken in a timely, coherent and effective manner to address animal health, *animal welfare* and veterinary public health matters of concern.

Veterinary legislation should provide for a chain of command that is effective, as short as possible, and with all responsibilities clearly defined. For this purpose, the responsibilities and powers of *Competent Authorities*, from the central level to those responsible for the implementation of legislation in the field, should be clearly defined. Where more than one *Competent Authority* is involved, for example in relation to environmental, food safety or other public health matters, including biological threats and natural disasters, a reliable system of coordination and cooperation should be in place, including clarifying the role of each *Competent Authority*.

Competent Authorities should appoint technically qualified officials to take any actions needed for implementation, review and verification of compliance with the *veterinary legislation*, respecting the principles of independence and impartiality prescribed in Article 3.2.2.

1. Necessary powers of the Competent Authority

The *veterinary legislation* should also ensure that:

a) the *Competent Authority* has all the necessary legal authorities to achieve the purposes of the legislation, including the powers to enforce the legislation;

b) while executing their legal mandate, officials are protected against legal action and physical harm for actions carried out in good faith and in accordance with professional standards;

c) the powers and functions of officials are explicitly listed to protect the rights of stakeholders and the general public against any abuse of authority. This includes respecting confidentiality and transparency, as appropriate; and

d) at least the following powers are available through the primary legislation:

i) access to premises and *vehicles/vessels* for carrying out inspections;

ii) access to documents;

iii) application of specific ~~*sanitary measures*~~ measures and procedures such as:

– taking samples;

– retention (setting aside) of *commodities*, pending a decision on final disposition;

– seizure of *commodities* and fomites;

– destruction of *commodities* and fomites;

– suspension of one or more activities of a facility;

- temporary, partial or complete closure of facilities;
- suspension or withdrawal of authorisations or approvals;
- restrictions on the movement of *commodities*, *vehicles/vessels* and, if required, other fomites and people;
- listing disease for mandatory reporting; and
- ordering of *disinfection*, *disinfestation* or pest control;

iv) establishment of compensation mechanisms.

These essential powers should be clearly identified because they can result in actions that may conflict with individual *rights* ascribed in fundamental laws.

2. Delegation of powers by the Competent Authority

The *veterinary legislation* should provide the possibility for *Competent Authorities* to delegate specific powers and tasks related to official activities. The specific powers and tasks delegated, the competencies required, the bodies or officers to which the powers and tasks are delegated, the conditions of supervision by the *Competent Authority* and the conditions of withdrawals of delegations should be defined.

[…]

Article 3.4.11.

Veterinary medicinal products

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

1. General measures

Veterinary legislation should provide a basis for actions to address the following elements:

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

b) regulation of the authorisation, importation, manufacture, wholesale, retail, usage of, commerce in, and disposal of ~~safe and effective~~ *veterinary medicinal products*.

2. Raw materials for use in veterinary medicinal products

Veterinary legislation should provide a basis for actions to address the following elements:

a) quality standards for raw materials used in the manufacture or composition of *veterinary medicinal* products and arrangements for checking quality; and

b) restrictions on substances in *veterinary medicinal products* that may, through their effects, interfere with the interpretation of veterinary diagnostic test results or the conduct of other veterinary checks.

3. Authorisation of veterinary medicinal products

a) *Veterinary legislation* should ensure that only authorised *veterinary medicinal products* may be placed on the market.

b) Special provisions should be made for:

i) *veterinary medicinal products* incorporated into *feed*;

ii) products prepared by authorised *veterinarians* or authorised pharmacists;

iii) emergencies and temporary situations;

iv) establishment of maximum residue limits for active substances and withdrawal periods for relevant *veterinary medicinal products* containing these substances; and

v) restrictions of use of *veterinary medicinal products* for food-producing animals.

c) *Veterinary legislation* should address the technical, administrative and financial conditions associated with the granting, suspension, renewal, refusal and withdrawal of authorisations.

d) In defining the procedures for seeking and granting, suspending, withdrawing, or refusing, authorisations, the legislation should:

i) describe the responsibilities of the relevant *Competent Authorities*; and

ii) establish rules providing for transparency in decision-making.

e) *Veterinary legislation* may provide for the possibility of recognition of the equivalence of authorisations.

4. Facilities producing, storing and wholesaling veterinary medicinal products

Veterinary legislation should provide a basis for actions to address the following elements:

a) registration or authorisation of all operators manufacturing importing, exporting, storing, processing, wholesaling or otherwise distributing *veterinary medicinal products* or raw materials for use in making *veterinary medicinal products*;

b) definition of the responsibilities of operators;

c) good manufacturing practices and good distribution practices as appropriate;

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

e) mechanisms for traceability and recall.

5. Retailing, use and traceability of veterinary medicinal products

Veterinary legislation should provide a basis for actions to address the following elements:

a) control over the distribution of *veterinary medicinal products* and arrangements for traceability, recall and conditions of use;

b) establishment of rules for the prescription and provision of veterinary medicinal products to end users, including appropriate labelling;

c) restriction to *veterinarians* or other authorised professionals and, as appropriate, authorised *veterinary paraprofessionals*, of commerce in *veterinary medicinal products* that are subject to prescription;

d) obligation of *veterinarians*, other authorised professionals or authorised *veterinary paraprofessionals* to inform end users of the withdrawal periods of relevant *veterinary medicinal products* and the obligation of end users to observe those withdrawal periods when using those products;

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

f) the regulation of advertising claims and other marketing and promotional activities;

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

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

[...]

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CHAPTER 6.12.

ZOONOSES TRANSMISSIBLE FROM NON-HUMAN PRIMATES

EU comment

The EU supports the proposed changes to this chapter.

[…]

Article 6.12.4.

Quarantine requirements for non-human primates from an uncontrolled environment

Veterinary Authorities of *importing countries* should require for shipments which originate from the wild or other sources where they were not subjected to permanent veterinary supervision:

1) the presentation of the documentation referred to in Article 6.12.3.;

2) the immediate placement of the animals in a *quarantine station* meeting the standards set in Chapter 5.9. for at least 12 weeks; and during this quarantine:

   a) all animals to be monitored daily for signs of illness and, if necessary, be subjected to a clinical examination;

   b) all animals dying for any reason to be subjected to complete post-mortem examination at a *laboratory* approved for this purpose;

   c) any cause of illness or death to be determined before the group to which the animals belong is released from quarantine;

   d) animals to be subjected to the following diagnostic tests and treatments in accordance with Chapter 4.16.:

Disease/agent	**Animal groups**	**Schedule**	**Methods**
Endo- and ectoparasites	All species	At least two tests, one of which should be at the start, the other towards the end of the quarantine.	Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.
Tuberculosis (*Mycobacterium tuberculosis* complex)	Marmosets and tamarins	Two tests at an interval of 2 to 4 weeks.	Skin test or serology. In-vitro gamma interferon assay or polymerase chain reaction (PCR) assay. The skin test using mammalian tuberculin (old tuberculin) is the most reliable of all. Skin tests in marmosets, tamarins or small prosimians should be performed in the abdominal skin rather than in the eyelid. In some species (e.g. orang utan), skin tests for tuberculosis are notorious for false positive results. Comparative tests using both mammalian and avian PPD, together with cultures, radiography, ELISA, in-vitro gamma interferon assay and PCR of gastric or bronchial lavage, faeces or tissues may eliminate confusion.
	Prosimians, New World monkeys, Old World monkeys, gibbons and great apes	At least three tests at intervals of 2 to 4 weeks.	

Disease/agent	Animal groups	Schedule	Methods
Other bacterial pathogenic agents (*Salmonella*, *Shigella* and *Yersinia* and others as appropriate)	All species	Daily test for 3 days after arrival, and at least one or two more tests at intervals of 2 to 4 weeks.	Faecal culture. The fresh faeces or rectal swabs should be cultured immediately or be placed immediately in the appropriate transportation medium.
~~**Hepatitis B**~~	~~Gibbons and great apes~~	~~First test during first week; second test after 3 to 4 weeks.~~	~~Serological tests for anti-hepatitis B core antigen and for hepatitis B surface antigen, and additional parameters as appropriate.~~

Veterinary Authorities of *importing countries* should recognise the public health importance of zoonoses listed in the table ~~below~~ above as well as measles (a human disease, sometimes affecting non-human primates), hepatitis A, monkey pox, Marburg disease or Ebola/Reston virus, retroviruses, etc., even though this article does not recommend specific testing or treatment protocols for these agents during the quarantine period. *Veterinary Authorities* should recognise that, if animals are infected, the importation and spread of many such agents will be best controlled by the detection of clinical signs of disease during a 12-week quarantine period.

Certain endemic viruses, such as herpesviruses or retroviruses, may be present in both wild and captive populations of primates. These viruses are often asymptomatic in primate species. If animals are being imported to be introduced to other populations of the same species, it may be advisable to determine if the animals selected for importation have similar viral profiles to the established population.

[…]

Article 6.12.6.

Certification and quarantine requirements for other non-human primates from premises under veterinary supervision

Veterinary Authorities of *importing countries* should require:

for prosimians, New World monkeys, Old World monkeys, gibbons and great apes from premises under veterinary supervision

1) the presentation of an *international veterinary certificate* attesting that the shipment meets the requirements specified in Article 6.12.3., and that the animals:

   a) are either born in the premises of origin or have been kept there for at least two years;

   b) come from premises which are under permanent veterinary supervision, and where a suitable health monitoring programme is followed, including microbiological and parasitological tests as well as necropsies;

   c) have been kept in buildings and enclosures in which no *case* of tuberculosis has occurred during the last two years prior to shipment;

   d) come from premises in which no *case* of tuberculosis or other major zoonoses including rabies has occurred during the last two years prior to shipment in the building where the animals were kept;

   e) were subjected to a tuberculosis test on two occasions with negative results, at an interval of at least two weeks between each test during the 30 days prior to shipment;

   f) were subjected to a diagnostic test for pathogenic enteric bacteria including *Salmonella*, *Shigella* and *Yersinia*;

   g) were subjected to diagnostic tests for, and appropriate treatment against, endo- and ectoparasites;

~~h) were subjected to a diagnostic test for hepatitis B virus and their current status documented (gibbons and great apes only);~~

2) the placement of the animals in a *quarantine station* for at least 30 days, and during this period:

   a) all animals to be monitored daily for signs of illness and, if necessary, subjected to a clinical examination;

   b) all animals dying for any reason to be subjected to complete post-mortem examination at a laboratory approved for this purpose;

   c) any cause of illness or death to be determined before the group to which the animals belong is released from quarantine;

   d) animals to be subjected to the following diagnostic tests and treatments in accordance with Chapter 4.16.:

Disease/agent	**Animal groups**	**Schedule**	**Methods**
Tuberculosis *(Mycobacterium tuberculosis* complex)	All species	One test.	Skin test or serology. In-vitro gamma interferon assay or polymerase chain reaction (PCR) assay. (See further comments in the Table of Article 6.12.4.)
Other bacterial pathogenic agents (*Salmonella*, *Shigella* and *Yersinia* and others as appropriate)	All species	Daily test for 3 days after arrival, and another test at least one week later.	Faecal culture. (See further comments in the Table of Article 6.12.4.)
Endo- and ectoparasites	All species	At least two tests, one of which should be at the start, the other towards the end of the quarantine.	Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.

Veterinary Authorities of *importing countries* may not normally require any tests for viral diseases. However, stringent precautions to ensure human health and safety should be followed as recommended in Article 6.12.7.

Article 6.12.7.

Precautionary measures to be followed by staff exposed to non-human primates or to their body fluids, faeces and tissues

The presence in most non-human primates of some zoonotic agents is almost unavoidable, even after release from quarantine. The relevant Authorities should, therefore, encourage the management of institutions whose staff are exposed to non-human primates or their body fluids, faeces or tissues (including when performing necropsies) to comply with the following recommendations:

1) to provide staff with training in the proper handling of primates, their body fluids, faeces and tissues, with respect to zoonoses containment and personal safety;

2) to inform their staff that certain species should be considered as having lifelong *infections* with some zoonotic agents, e.g. Asian macaques with Herpes B virus;

3) to ensure that the staff follows personal hygiene practices, including the use of protective clothing, and the prohibition of eating, drinking and smoking in potentially infective areas;

4) to implement a screening programme for personnel health, including monitoring for tuberculosis, pathogenic enteric bacteria and endoparasites and other agents that are deemed necessary;

5) to implement an immunisation programme as appropriate, including e.g. tetanus, measles, poliomyelitis, rabies, hepatitis A ~~and B~~, and other diseases, such as yellow fever, endemic in the area of origin of the African and American non-human primates;

6) to develop guidelines for the prevention and treatment of zoonoses that may be transmitted by bites and scratches, e.g. rabies and herpes viruses;

7) to issue to their staff a card which states that they work with non-human primates or with their body fluids, faeces or tissues, and which may be presented to the medical profession in case of illness;

8) to dispose of carcasses, body fluids, faeces and tissues in a manner which is not detrimental to public health.

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CHAPTER 7.7.

DOG POPULATION MANAGEMENT

EU comment

The EU thanks the OIE for having taken into consideration comments submitted previously. We welcome and in general support the revision of Chapter 7.7.

Specific comments are inserted in the text below.

Article 7.7.1.

Introduction

Dog Population Management (DPM) refers to the holistic approach that aims to improve the welfare of dogs, reduce problems they may present and create harmonious co-existence with people and their environment. Dogs are present in every human society around the world and are valued for the range of roles they fulfil. However, they can present public health and safety, and animal health and *animal welfare* issues, especially when free to roam.

DPM ~~is an integral part of~~supports effective and sustainable rabies control programmes and the control of other zoonoses. Recognising that mass culling of dogs is ineffective and may be counterproductive, reducing dog population size is not an effective means of reducing rabies *prevalence* ~~[~~(WHO, 2018)~~]~~. However, DPM can contribute to rabies control by reducing population turnover, therefore supporting maintenance of herd immunity within a vaccinated dog population. The components of population turnover most relevant for rabies control are the reduction in the birth of unwanted puppies that would be at risk of remaining unvaccinated and the improve~~ing~~ment of welfare and life expectancy of vaccinated dogs.

Reproduction control as part of DPM also reduces breeding behaviours which may increase the *risk* of rabies transmission due to increased contact rates between dogs.

Promotion of *responsible dog ownership* as part of DPM ~~can~~strengthens owner motivation, knowledge and therefore behaviour in caring for their dogs, including timely rabies *vaccination* of *owned dogs* to maintain immunity.

EU comment

As regards rabies related aspects, the EU in general notes that this chapter as drafted mainly addresses the situation in the many countries around the world affected by dog-mediated rabies. However this is not the case for all countries. Indeed, in countries free of rabies, routine rabies vaccination of dogs is often not required. Rather, rabies vaccination is primarily used in such countries when required for dogs travelling abroad. The EU therefore suggests adding the following paragraph to Article 7.7.1.:

"Routine vaccination of dogs against rabies may not be required in countries that can demonstrate freedom of dog-mediated rabies in accordance with Chapter 8.14.".

~~The OIE recognises the importance of~~It is important to manage~~ing~~ dog populations without~~causing unnecessaryanimalsuffering~~ compromising animal welfare, in accordance with Chapter 7.1.

Article 7.7.~~4~~.2

Definitions

For the purpose of this chapter:

Dog Population Management programme means a combination of DPM measures that enhance the care of dogs and influence dog population dynamics to sustainably improve dog health and welfare, public health and safety, and the environment, ~~and~~ while taking into consideration related economic benefits and costs.

Rabies means dog-mediated rabies.

Article 7.7.~~2~~3.

Scope

The scope of this chapter is to provide recommendations for the management of dog (*Canis lupus familiaris*) populations to improve human health and safety, animal health and *animal welfare* and to minimise their potential negative socio-economic and environmental impacts. The recommendations will also assist Members in the implementation of zoonotic disease control programmes, in particular ~~such as with a focus on~~ *infection* with rabies virus, in accordance with Chapter 8.14.

EU comment

The EU would like to propose the following revision:

"The scope of this chapter is to provide recommendations for the management of dog (*Canis lupus familiaris*) populations, and more specifically free-roaming dog population dynamics, to improve human health and safety, animal health and *animal welfare* and to minimise their potential negative socio-economic and environmental impacts."

Justification

In September 2018, the Code Commission agreed to revise Chapter 7.7 to ensure that stray dog population control was aligned with the OIE Global Strategy to end human death due to dog-mediated rabies. It seems therefore appropriate to refer to this population type in the scope of the revised chapter.

Article 7.7.~~3~~4.

Guiding principles

Building upon the guiding principles described in Chapter 7.1., the following apply:

– DPM has direct benefits to public health and safety, and to animal health and welfare.

– Dogs are domesticated species and therefore dependent on human communities, thus there is an ethical responsibility to ensure their health and welfare even in the absence of ownership.

– Recognising the diversity of stakeholders in the management of dog populations, it is crucial to clarify roles and responsibilities.

– Dog ecology is linked with human activities. Therefore, effective management of dog populations should be accompanied by changes in human behaviour, including promotion of *responsible dog ownership*.

– Acknowledging that the *owned dog* population is a common source of free-roaming dogs, DPM programmes should consider all dogs.

– Understanding local dog population dynamics and community attitudes is a key element ~~to~~ in ~~determine~~ determining whether and how DPM programmes might contribute to rabies control and which tools would be most successful.

– Considering that sources and drivers of free-roaming dogs and management goals differ across communities, DPM should be individually tailored ~~at~~ to local and national ~~level~~contexts.

– DPM programmes should be designed to be sustainable, aligned with legislative requirements, evaluated and ~~refined~~ adaptable.

~~Article 7.7.4.~~

~~**Definitions for the purpose of this chapter**~~

~~means a combination of DPM measures that enhance the care of dogs and influence dog population dynamics to sustainably improve dog health and welfare, public health and safety, and the environment, and while taking into consideration related economic benefit and costs.~~

~~**Rabies** means dog-mediated rabies.~~

~~**Free-roaming dog** means any *owned dog* or unowned dog that is without direct human supervision or control.~~

Article 7.7.5.

Dog Population Management programme objectives

DPM programmes may include the following objectives:

– promote and establish *responsible dog ownership*;

– improve health and welfare of dog populations;

– reduce the number of free-roaming dogs to a manageable level;

– stabilise the dog population by reducing turnover;

– reduce *risks* to public health and safety including dog bites, traffic accidents, and zoonotic diseases such as rabies;

– contribute towards eradicating dog-mediated human rabies~~by 2030~~;

– reduce nuisance free-roaming dogs may cause (e.g. environmental impact, negative publicity directed at governments, tourism disincentives);

– prevent harm to livestock and other animals;

– prevent ~~dog~~illegal trade and trafficking of dogs.

Article 7.7.6.

Roles and responsibilities

As a cross-sectoral subject, DPM requires a high level of engagement and collaboration ~~between~~ among *Competent Authorities* responsible for animal health and welfare, food safety and public health, in line with the One Health approach.

DPM activities performed by *Veterinary Services* or other *Competent Authorities* should be integrated, to the greatest extent possible, with the activities of all other responsible agencies.

Articles 7.7.7. and 7.7.8. describe the roles and responsibilities ~~that~~ of different organisations ~~may play~~ in the ~~planning and implementation~~development of DPM programmes, at the local and national ~~and local~~ levels.

Article 7.7.7.

Competent Authority for D~~d~~og P~~p~~opulation M~~m~~anagement

The development ~~and implementation~~of DPM occurs at the local level through specific DPM programmes, whose success requires a supportive and enabling environment created by the *Competent Authority* at the national level. As DPM is relevant to several governmental agencies and various stakeholders, a multi-sectorial group should establish governance and coordinate actions across governmental agencies and programmes, including those focusing on zoonotic diseases where dogs play a role, such as rabies.

1. Governance

   DPM should be identified as the responsibility of a *Competent Authority*, which may be the *Veterinary Authority*. A ~~N~~national ~~level~~ action plan provides the details of actions which support the implementation of DPM programmes and coordinate with other action plans, such as those focused on dog-related zoonoses. These plans are led by this *Competent Authority* and developed in collaboration with the multi-sectorial group.

2. Legislation

Implementation of DPM programmes requires the support of a suitable regulatory framework (see Article 7.7.9.). Further secondary regulations provide customisations ~~adaptations~~to suit local requirements.

3. Enforcement

The *Competent Authority* can support enforcement of legislation through guidelines on enforcement procedures/practices, training~~,~~ and funding of enforcement agencies, and defining penalties.

4. Funding

To establish sustainable DPM with long-lasting impacts, the *Competent Authority* and multi-sectorial group should establish a policy and legislative basis for sufficient funding of national action plans and DPM programmes. The One Health concept ~~provides~~strengthens ~~to~~ the argument for increasing the priority of DPM across the animal health, environmental and public health sectors.

5. Training and support

~~Training of professionals including *veterinarians* and providing accessibility to appropriate drugs at local, national or regional level led by the *Competent Authority* would support achievement of minimum standards across DPM Programmes~~To support ~~minimum standards across~~ DPM programmes, the relevant *Competent Authority* should lead on the training of professionals, including *veterinarians*, and ensure they have access to appropriate *veterinary medicinal products* for the implementation of DPM measures. The *Competent Authority* should support DPM through national level communication and education initiatives.

Article 7.7.8.

Other organisations and actors involved in D~~d~~og P~~p~~opulation M~~m~~anagement

The following may have a role in the development of DPM programmes ~~[~~(Paolini *et al.*, 2020)~~]~~:

1. Veterinary Authority

The *Veterinary Authority* plays a lead role in preventing zoonotic diseases and ensuring *animal welfare* and should be involved in DPM, coordinating its activities with other relevant *Competent Authorities*.

2. Veterinary Services

Veterinary Services should play an active role and coordinate their activities with relevant *Competent Authorities*, and may be responsible for the organisation, implementation and supervision of DPM programmes.

3. Other governmental agencies

The responsibilities of other governmental agencies will depend on the *risk* being managed and the objective or nature of the DPM measures implemented.

a) Public health

~~The ministry or other~~Governmental agencies responsible for public health would normally play a leadership role and may have legislative authority in dealing with zoonotic diseases and regarding other human health *risks* (e.g. free-roaming dogs on roads; dog bites).

b) Environmental protection

Environmental protection ~~governmental~~agencies may take responsibility for problems associated with free-roaming dogs when they present a *hazard* to the environment (e.g. control of ~~*feral*~~dogs in national parks; prevention of predation ~~to~~ on *wildlife* or transmission of diseases to *wildlife*) or where a lack of environmental controls encourage dogs to roam.

c) Education

Governmental agencies responsible for ~~The Ministry of E~~education ~~can~~ may play a key role in promoting *responsible dog ownership* and dog bite prevention programmes ~~at~~in schools~~level~~.

d) Local authorities

In many countries, local authorities are responsible for the implementation of DPM programmes and the enforcement of legislation relating to dog ownership (e.g.~~,~~ *registration*, identification, *vaccination*, leash laws, animal abandonment). This should be done with the support and enabling environment created by the *Competent Authority.*

4. Civil Society

The responsibilities of civil society stakeholders will depend on their involvement with the DPM measures implemented.

a) Dog owners

When a person takes on the ownership of a dog, there should be an immediate acceptance of responsibility for that dog, and for any offspring it may produce, for the duration of its life or until a subsequent owner is found. The owner's responsibilities should include providing for the health and welfare of the dog and mitigating negative impacts on public health and the environment, in accordance with Article 7.7.17.

b) Dog breeders and sellers

Dog breeders and sellers have the same responsibilities as dog owners and in addition should comply with the recommendations, in accordance with Article 7.7.15.

5. Advisory group

The development of ~~a~~DPM programmes and a national action plan should also benefit from the support of ~~an~~advisory groups, which should include *veterinarians*, experts in dog ecology, dog behaviour and zoonotic diseases, and representatives of relevant stakeholders (local authorities, public~~human~~ health services or authorities, environmental control services or authorities, non-governmental organisations and the public).

Article 7.7.9.

Regulatory framework

DPM legislation is a key element for the sustainability and efficiency of DPM programmes. It ~~can~~ensures that DPM programmes are ~~is~~ carried out with respect to *animal welfare* guiding principles (see Chapter 7.1.).

Regulations related to the following areas may support successful DPM programmes; these may be found in a DPM regulatory framework or other regulatory frameworks:

– ~~O~~owners' obligations regarding the principles of *responsible dog ownership*, including *animal welfare*;

– *animal welfare* obligations of authorities;

– *registration* and identification of dogs in ~~a~~centralised or interoperable databases;

EU comment

The EU would like to propose the following revision:

"– *registration* and identification of dogs ~~in a centralised or interoperable databases~~;"

Justification

This Article should be limited to defining the main areas needed to support DPM programmes. The EU agrees that registering and identifying dogs are part of such supporting measures. However, the possible practical ways to do so should be described in the article specifically dealing with this aspect (i.e. Article 7.7.14). In addition, this would be consistent with the approach in Article 7.7.13.

– authorisation and licensing of dog breeders and sellers;

– authorisation and licensing of dog shelters, rehoming centres and holding facilities;

EU comment

The EU would like to propose the following revision:

"– registration or authorisation and licensing of dog breeders and sellers;

– registration or authorisation and licensing of dog shelters, rehoming centres and holding facilities;"

Justification

Authorisation and licensing is a complex administrative procedure that should be limited only to those dog breeders, sellers, dog shelters, rehoming centres and holding facilities that pose the higher risks. For the others, registration should be sufficient. This would also be in line with the provisions of Article 7.7.15.

– licensing ~~practice~~of *veterinarians*~~veterinary medicine, including surgery~~;

– licensing preparation, use and sale~~s~~ of *veterinary medicinal products*;

– preventive ~~and medical~~measures against rabies and other zoonotic diseases;

– dog movements and trade at international and national levels;

– waste management.

This regulatory framework must be designed with both incentive measures for compliance and penalties for non-compliance.

EU comment

The EU would like to propose the following revision:

"This regulatory framework must be designed with both incentive measures for compliance and penalties for non-compliance and should be commensurate to the national context."

Justification

The regulatory framework proposed in this article should be considered as a toolbox and be adapted to the national context, and particularly the outcomes of the initial assessment provided in Article 7.7.10.

Article 7.7.10.

~~**Assessment, monitoring and evaluation**~~**Evidence-based programme development**

~~DPM programmes should be regularly evaluated and adapted to improve effectiveness and to respond to changes in wider context that influence dog population dynamics. This requires an evidence-base from data collected through initial assessment and continued *monitoring* using objective methods.~~

Development of DPM programmes should include an initial assessment and ongoing adaptation based on continued monitoring and evaluation using objective methods. This evidence-based approach improves programme effectiveness and informs responses to changes in the wider context that influence dog population dynamics.

Recognising the different needs of communities and the multi-sectorial roles in DPM, it ~~this~~should be conducted with the involvement of advisory groups and relevant authorities.

Competent Authorities should support evidence-based DPM programmes ~~assessment, monitoring and evaluation~~by:

– identifying qualified personnel and ~~D~~developing training and tools to help with implementing data collection (assessment~~,~~ and *monitoring*) and use (planning and evaluation);

– ensuring ~~Providing~~ the budget of DPM programmes includinges ~~the~~not only the costs for the initial assessment but also for *monitoring* and evaluation activities;

– ~~E~~establishing standardised indicators with feasible and repeatable methods of measurement that can be used across locations and over time, to support subsequent evaluations and compare performance between different DPM programmesit should be expected that DPM programmes will also use and benefit from their own context-specific indicators and methods of measurement;

– ~~E~~encouraging the use of *monitoring* data for evaluation, learning and subsequent amendments~~adaptation~~ of DPM programmes.

Article 7.7.11.

DPM programme ~~development~~assessment and planning

The initial DPM programme development stages of assessment and planning. ~~Developing a DPM~~ should provide the evidence required for planning and ~~requires an evidence-based approach. Areas for assessment that provide this evidence should~~ include:

1) Review of the current regulatory framework and evaluation of the efficiency and effectiveness of DPM control measures used historically and currently.

2) Identification of the priority issues related to dogs from the perspective of all relevant stakeholders. The resolution of these issues will form the objectives of DPM programmes. Establishing baselines and *monitoring* methods for indicators reflecting each objective allows for later evaluation of efficiency and effectiveness. Identifying which dogs are associated with the priority issues may include *owned dogs*.

3) Exploration of dog population dynamics in the whole dog population (not limited to the current free-roaming dog population) to identify the sources of free-roaming dogs:

   – *owned dogs* that roam freely;

   – dogs that have been lost or abandoned, including puppies resulting from uncontrolled breeding of *owned dogs*;

   – unowned dogs that roam freely and reproduce.

4) Identification~~y~~ of people's knowledge, attitudes and practices ~~of~~ regarding dog care and responsibility ~~over~~for *owned dogs* and unowned dogs. ~~Further, c~~Citizens' attitudes towards potential control measures should also be explored. This information can be used to ensure the acceptability of the DPM programme ~~acceptability~~ to local communities and its effectiveness at changing human behaviours.

5) Estimating dog population size and demography:

   Dog population size estimates can help with planning DPM programmes. Accuracy of estimates is typically improved with more time-consuming methods. Where resources are limited, a rough estimate may be sufficient at the outset. This estimate may be refined by *monitoring* population coverage achieved by the implementation of measures and comparing this to the number of dogs receiving these measures (e.g.~~,~~ rabies *vaccination* and sterilisation in 'Catch, Neuter, Vaccination and Return') (see Article 7.7.19).

   For evaluation of DPM programme effectiveness, *monitoring* changes in population trends (e.g. changes in the density of free-roaming dogs along routes designed to traverse areas of high free-roaming dog density~~on public streets~~, proportion of lactating females and presence of puppies) may be sufficient, rather than investing in repeated estimates of population size [(Hiby and Hiby, 2017)~~]~~. Methods to estimate population size may also measure demographic factors such as age, sex, sterilisation and reproductive status (lactation and pregnancy in females) to allow for refinement of estimates to sub-populations of relevance.

   Available methods for population size estimates include the following:

– *Owned dogs*: dDog *registration* databases, household questionnaires (to estimate proportion of dog-owning households and mean number of dogs per dog-owning household), post-*vaccination* campaign coverage and animal ownership surveys as part of human census.

– Free-roaming *owned dogs*: hHousehold questionnaires including questions or visible inspection of whether *owned dogs* are confined or allowed to roam unsupervised.

– All free-roaming dogs, including both owned roaming and unowned:

a) Direct observation of free-roaming dogs during surveys along routes designed to be representative of the area of interest and unbiased with regard to free-roaming dog density~~through public streets at peak roaming time; capturing of these data~~ can provide the mean number of free-roaming dogs per km of street surveyed. This can be extrapolated by the estimated total street length within the~~defined~~ area of interest to estimate the total number of free-roaming dogs on the street at the time of survey; some free-roaming dogs will not have been visible during the survey and so this is an underestimate of the total free roaming dog population [(Meunier et al~~.~~., 2019)].

b) Mark–resight is a method that aims to estimate population size, considering that not all animals are visible to direct observation on a survey. This is achieved by first marking dogs with temporary marks such as paint, or photographs for individual recognition~~.~~ ~~or~~ The survey can opportunistically make use of marks applied as part of control measures to indicate a dog's treatment status, such as collars or paint applied ~~during *vaccination*~~to identify a dog as vaccinated and ear notches or tags applied under anaesthetic to identify a dog as sterilised during neutering in 'Catch, Neuter, Vaccination and Return' measures (see Article 7.7.19.)~~programmes~~. In subsequent surveys, ~~Then noting~~the proportions of marked and unmarked dogs are noted~~during subsequent surveys~~. Mark–resight methods rely on assumptions that may not hold true in dog populations, such as equal resighting probability ~~in~~ for marked and unmarked dogs, lack of immigration/emigration and no or measurable mark loss.

Mark–resight is a relatively resource intensive method ~~as~~ when compared ~~to~~ with direct observation which may limit the extent of the area that can ~~be~~ feasibly be surveyed.

Mark–resight and direct observation may be done concurrently in a sample of areas to estimate the proportion of free-roaming dogs visible during direct observation. This proportion can be used to correct the data regarding those dogs missed during direct observation over a larger geographical area.

Article 7.7.12.

DPM programme monitoring and evaluation

Later stages of DPM programme development should include monitoring and evaluation. *Monitoring* aims to check the progress of DPM programme measures against targets and support performance management. It should allow for regular adjustments of implementation of measures and collection of data on indicators of objectives. It should also include *monitoring* of costs associated with measures and costs or savings relating to objectives, to support cost–benefit analysis.

Evaluation is a periodic assessment of progress using data collected through *monitoring*, usually carried out at milestones to assess whether the DPM programme is achieving the desired objectives and to adapt the DPM programme to improve effectiveness and efficiency. Where methods of *monitoring* are equivalent – clearly defined, repeatable and consistent –, evaluation can compare effectiveness and efficiency across DPM programmes.

Indicators are the measurable ~~signs~~results of objectives. Indicators of DPM objectives may include:

– *Owned dog* population size, demographics and whether they are receiving *responsible dog ownership* (can include their *vaccination* status, sterilisation, *registration*, identification, level and method of confinement and how they were acquired).

– Free-roaming dog population density, demography (age, sex, sterilisation, lactating females and puppies) and welfare (e.g. body condition score ~~and~~, presence of a skin problem) recorded by direct observation of free-roaming dogs on surveys along standardised routes.

– *Prevalence* of zoonotic diseases in both the animal and human populations~~;~~ , for example~~,~~ rabies ~~and~~ or echinococcosis ~~*Echinococcus*~~ Chapter 8.14. and Chapter 8.5.

– Knowledge, attitudes and practices of communities relating to the free-roaming dog population, and dog owner knowledge, attitudes and practices ~~of~~ regarding *responsible dog ownership*.

– Dog population movements from owned to unowned dogs or from confined to free-roaming dogs (based on investigations and monitoring).

– Adoption or reuniting facility performance including intake, adoption rates, welfare state of dogs in their care, mortality and *euthanasia* rates.

– Dog bites reported to health centres or number of rabies post-exposure prophylaxis courses provided to the exposed individuals, or the cost incurred by the public health authorities for provision of post-exposure prophylaxis.

– Number and nature of complaints about dogs to local government authorities.

– Compensation costs relating to dog-related damages to people, livestock, or property.

Article 7.7.13.

Recommendations for DPM measures

The recommendations for DPM measures in Articles 7.7.14. to 7.7.24. should be implemented in accordance with the national context and local circumstances.A combination of the following measures should be used for a successful DPM programme:

– *Rregistration* and identification of dogs;

– Rregulation of Ccommercial dog breeding and sale;

– Ccontrol of national and international (export and import) dog movements;

– Ppromoting *responsible dog ownership*;

– Rreproductive control;

– 'Catch, Neuter, Vaccination and Return';

– Rreuniting and adoption;

– Aaccess to veterinary care;

– Eenvironmental controls;

– Eeducation on safe dog–human interaction.

These recommendations for DPM measures are described in detail in Articles 7.7.14. to 7.7.24. and should be implemented in accordance with the national context and local circumstances.

Article 7.7.14.

Registration and identification of dogs

Outcomes of *registration* and identification of dogs include the following:

– supports for the enforcement of legislation through proof of ownership;

– improvesment of the success rate in reuniting lost dogs with their owners;

– enablesd enabling traceability in commercial breeding and sale;

– encouragesment of responsible ownership behaviours;

– supports for an animal health programme, e.g., mandatory rabies *vaccination* and traceability.

These outcomes require widespread adoption of *registration* and identification.

Competent Authorities should ensure that ~~a~~centralised or interoperable database~~s~~ are~~is~~ established for dog *registration* to allow ~~for~~ reuniting of identified dogs with registered owners across the territory. *Competent Authorities* should ensure there is an enforcement system in place with the capacity to deliver appropriate methods of identification to all dogs (such as microchipping or Quick Response tags [QR tags]), read identification when a dog is found (using scanners or other devices) and access the *registration* database to retrieve owner details.

EU comment

The EU would like to add the following sentence at the end of the paragraph:

"Such databases may be developed and operated on a public-private partnership basis."

Justification

The development of registration and identification database for dogs should not lead to duplication of already existing databases in certain countries and allow involvement of the private and/or NGO sectors as commonly promoted by the OIE.

Owners need to be informed and able to access identification services and the *registration* system both initially to enter each dog and~~,~~ to update ~~contact~~information~~,~~ when required. ~~There is a change of ownership or the dog dies.~~

EU comment

The EU would like to propose the following revision:

"Owners need to be informed and, under conditions to be defined by Competent Authorities, able to access identification services and the registration system both initially to enter each dog and, to update ~~contact~~ information~~,~~ when required"

Justification

Direct access by owners to the database with possibility to modify the data may be risky, and may not be an option in existing national databases. While not being opposed in principle to give access to the database to dog owners under certain circumstances, it looks more appropriate that actions on the database be subject to specific conditions clearly spelled out by the Competent Authorities.

Article 7.7.15.

Regulation of c~~C~~ommercial dog breeding and sale

Outcomes of regulating commercial breeding and sale as a DPM measure include:

– protection of dog health and welfare~~,~~;

– avoidance of abandonment~~,~~;

– transparency in dog breeding and sales.

Competent Authorities should require mandatory *registration* of all breeders and sellers. For commercial breeders and sellers, where the number of litters produced per year exceeds a threshold set by regulations, a further requirement for licensing ~~can~~may be imposed, including the requirement for inspection before trade can begin.

Advertisements for dog sales should be required to carry the *registration* or licence number of the breeder and seller.

To ensure dog~~s~~ traceability, the breeder should be established through identification and *registration* as the first owner.

The seller should ensure that *registration* details of the dog are updated with those of the first buyer following transfer of ownership.

Regulations of breeding practices should include limits on number of litters, minimum breeding age (to protect the health and welfare of the dam), good health of both parents and avoidance of selective breeding that leads to inherited diseases and extreme conformations. Regulations ~~of~~ for both breeders and sellers should also outline specific requirements for accommodation, veterinary care, husbandry, puppy socialisation and habituation to their environment, minimum puppy age before leaving the dam and training of staff. Sales of ~~puppies or adult~~dogs should be limited to adult~~s~~ buyers, and unregulated sales ~~exhibitions or from the street~~ should be banned.

Article 7.7.16.

Control of national and international (export or import) dog movements

International movements of dogs (import and export) should comply with trade measures, import or export procedures and veterinary certification in accordance with ~~according to~~Chapters 5.11., 7.2., 7.3., 7.4. and 8.14.

Movement of dogs within a country should be under the responsibility of the owner, with the following outcomes:

– reducing the *risk* of contagious diseases spread~~,~~;

– protecting public health and safety~~,~~;

– protecting *wildlife* and livestock~~,~~;

– protecting dog *welfare*.

Article 7.7.17.

Promoting responsible dog ownership

1) Owning a dog is a choice and should result in a mutually beneficial relationship. The benefits of dog ownership come with responsibilities. Promoting *responsible dog ownership* through education and enforcement of national and local regulations is a core component of a DPM programme to achieve the following outcomes:

   – improv~~e~~ing the health and welfare of dogs;

   – support ing the human–animal bond;

   – minimis~~e~~ing the *risk* that dogs pose to household members and the community;

   – reduc~~e~~ing the number of dogs allowed to roam.

2) Education on *responsible dog ownership* (for the currently *owned dog* and any offspring it produces for its lifetime or until the responsibility is passed to the next owner) should address the following~~elements~~:

   – provid~~e~~ing appropriate care to ensure the welfare of the dog and any offspring according to the dog's five welfare needs (suitable environment, suitable diet, housed with or apart from other animals, ability to exhibit normal behaviour and protect~~ed~~ion from pain, suffering, injury~~,~~ and disease) in order to meet the internationally recognised 'five freedoms' (see point 2 of Article 7.1.2.);

   – encourag~~e~~ing appropriate behaviours, reducing unwanted behaviours (including dog bites) and supporting the dog's ability to cope with its environment through attention to socialisation and ~~training~~ reward-based training and recognition of dog behavioural signs;

   – ensure the *registration* and identification of dogs (see Article 7.7.14.);

   – ensure access to preventive and therapeutic veterinary care (see Article 7.7.21.);

   – prevent~~ing~~ negative impacts of dogs on the community, via pollution (e.g. faeces and noise), *risks* to human health through bites or traffic accidents and *risks* to other dogs, *wildlife*, livestock and other companion animal species;

   – control ~~of~~dog reproduction (see Article 7.7.18.);

   – arrang~~e~~ing for ~~the care of the~~ dogs to be cared for when the owner is unable to do so.

3) Achieving sustained and widespread responsible ownership requires an understanding of barriers and motivations for responsible behaviour and taking action to address these. This ~~will~~ is likely to require a

combination of legislation, public awareness and enforcement, behaviour change campaigns, formal education in schools and encouragement through the building of social expectations. It may also be necessary to improve availability and accessibility ~~to~~ of resources supporting responsible ownership, such as veterinary care, identification and *registration* services and measures for control of zoonotic diseases.

Article 7.7.18.

Reproductive control

1) Outcomes of controlling reproduction in dogs include the following:

   – prevent~~s~~ing the birth of unwanted puppies;

   – help~~s~~ing address the imbalance between reproduction and demand for dogs;

   – reduce~~s~~ing the size of the free-roaming dog population.

2) Efficient use of reproduction control does not require a ~~limiting~~limit on overall population size. To ensure best use of resources, focus should be on controlling reproduction of females most likely to be the source of unwanted and free-roaming dogs.

3) Methods of controlling reproduction will require direct veterinary input to individual animals. Involvement of both private and public veterinary sectors may be required to meet demand for services. Subsidisation of sterilisation programmes by government or other organisations may be considered to encourage uptake. The control of reproduction in *owned dogs* is essentially the responsibility of owners and should be incorporated in~~to~~ promotion of responsible ownership (see Article 7.7.17.).

4) Methods for controlling reproduction in dogs include:

   – surgical sterilisation;

   – non-surgical fertility control, ~~is~~i.e. the prevention of reproduction without the use of surgery~~.~~, ~~sterilisation or contraception,~~ including chemical and immunological approaches;

   – confinement or separation~~/confinement~~ of female dogs during oestrus from unsterilised males.

5) Surgery has the primary advantage of being permanent. Surgical sterilisation must be carried out by a *veterinarian* and must include good animal handling, good surgical technique, a good standard of asepsis, appropriate anaesthesia and proactive, multi-modal pain management maintained throughout and adjusted to the individual animal as needed. This requires *monitoring* during surgery and post-operatively for the whole recovery period. It requires suitably trained *veterinarians* and *veterinary paraprofessionals* and access to appropriate drugs and equipment. *Competent Authorities* are responsible for ensuring access to training and authorised drugs that are not counterfeit,~~drugs~~ to ensure surgical sterilisation can be performed safely.

6) Castration of male dogs is ~~generally~~preferred over vasectom~~ies~~my ~~as~~ because, unlike castration, vasectomy does not reduce sex hormone levels and therefore has no mechanism to reduce ~~sex~~-specific behaviours such as roaming, territory marking and fighting due to hormonal aggression (Houlihan, 2017; McGreevy *et al.*, 2018). Females may be surgically sterilised by ovariohysterectomy~~,~~ or ovariectomy~~, hysterectomy or tubal ligation~~.~~.~~Tubal ligation and hysterectomy are not recommended ~~as~~ because the female will be under ovarian hormonal influence~~s~~ and will continue to show sexual behaviour~~.~~, increasing susceptibility to diseases such as transmissible venereal tumours and pyometra where uterine tissue remains. However, effects of sterilisation on non-hormone related behaviours cannot be generalised; hence, just as with any surgical procedure, the *veterinarian* should use their professional judgement when recommending gonadectomy for individual patients.

7) Any chemicals or drugs used in controlling reproduction should be shown to have appropriate safety, quality and efficacy for the function required and be used in accordance with the manufacturer's recommendations and *Competent Authority*'s regulations. In the case of non-surgical sterilants and contraceptives in the research phase, trials ~~may~~will need to be completed before use.

Article 7.7.19.

'Catch, Neuter, Vaccination and Return'

'Catch, Neuter, Vaccination and Return' provides an approach to controlling the reproduction of unowned dogs as a source of free-roaming dogs. This is not a stand-alone solution to DPM and must be used in combination with other measures addressing other sources of free-roaming dogs. It can be considered a method of managing the current free-roaming dog population *in situ* on the streets and hence an alternative to removal for reuniting and adoption (see Article 7.7.20.).

In collaboration with the local community, identified unowned dogs are caught, provided with health care (including rabies *vaccination*), evaluated for adoption, and, if adoption is not feasible, sterilised, and released to their local community at or near the place of capture. This method is more likely to be accepted in the situation where the presence of free-roaming dogs is widespread and well tolerated by the local community.

This method is not applicable in all situations and may be illegal in countries or regions where legislation prohibits the abandonment of dogs and authorities perceive the release of sterilised dogs as a form of abandonment. Problems caused by dogs, such as noise, faecal pollution, bite injuries and traffic accidents, would not be alleviated as dogs are returned to the local community and their movements are not restricted. Where owners have limited access to affordable reproduction control for their dogs, Cconsideration should be given to the risk that 'Catch, Neuter, Vaccination and Return' could encourage owners to access free sterilisation by allowing their owned dogs to roam abandonment of unwanted dogs. To avoid this risk, promoting responsible dog ownership (Article 7.7.17) and ensuring access to reproduction control for owned dogs (Article 7.7.18) should be implemented alongside 'Catch, Neuter, Vaccination and Return'.In the situation where many free-roaming dogs are owned, a DPM programme that focuses on neuteringsterilisation and responsible ownership may be more appropriate.

It is recommended that, before adopting this approach, a cost–benefit analysis is conducted. Factors such as the monetary costs, impact on culture of ownership and public safety should be assessed as well as the benefits for *disease* control and *animal welfare*, as well as and any societal benefits.

If this measure is implemented, the *Competent Authority* should ensure the following are addressed:

– engaging local communities to understand, support, design and be an active part of 'Catch, Neuter, Vaccination and Return' activities and *monitoring* of released dogs, in particular in the case of dogs cared for by the community;

– use of humane methods for catching, transporting and holding dogs;

– correct surgical technique with a good standard of asepsis, anaesthesia and analgesia, followed by post-operative care (see Article 7.7.18.);

– disease control may include *vaccination* (e.g., rabies) and treatments and testing for diseases (e.g., leishmaniasis) followed, as appropriate, by treatment or *euthanasia* of the dog;

– 'Ccatch, Nneuter, Vaccination and Rreturn' is not suitable for all dogs and should be applied on an individual basis. Health assessment and behavioural observation may be used to assess if whether dogs are suitable for release; – if they are not suitable for release or adoption, *euthanasia* should be considered;

– permanent marking (e.g., tattoo or microchip) to indicate that the animal has been sterilised; individual identification also allows for tracking of *vaccination* status and treatment history. A visible form of identification (e.g. collar, tag or ear notch) may also be used to prevent unnecessary recapture. As with surgical sterilisation, the same principles of asepsis, anaesthesia and multi-modal pain management are relevant to the application of tags and notches because these are also surgical procedures. *Monitoring* of released dogs should include issues of mark loss, *infection* and *infestation*;

– the dog should be returned to a place that is as near as possible to the place of capture;

– the behaviour and welfare of dogs after release should be monitored and action taken if required.

Article 7.7.20.

Reuniting and adoption

Free-roaming dogs can be removed to housing facilities for reuniting with their owners, or adopted. This addresses only the current free-roaming population and not the source of these dogs, hence must be used in combination with other measures to prevent replacement of removed dogs. These facilities can also offer the option for owners to relinquish dogs they can no longer care for, as an alternative to abandonment. Evidence collected about dogs and dog owner practices during DPM programme development must confirm that reuniting and adoption is are probable and achievable before developing reuniting and adoption facilities. Without sufficient adoptive homes or systems

for reuniting, facilities quickly fill to capacity, creating an ineffective and expensive measure. The *Competent Authority* should establish and enforce regulations for facilities providing reuniting and rehoming services to ensure capture, transport, and holding of dogs ~~is~~ are done humanely.

Dogs that are removed from a community may be reunited with the owner or adopted. There should be provision for holding the dogs for a reasonable period to allow for reuniting with the owner and, as appropriate, for rabies observation. Reuniting and adoption provide an opportunity to promote responsible ownership and good animal health care (including rabies *vaccination* and sterilisation). The suitability of dogs should be assessed and matched with available owners. The effectiveness of adoption may be limited by the number of adoptive homes.

Efforts should be made to transport animals for the shortest distance and least amount of time possible. Relocation for adoption should first be considered locally, then expanded to the nearest available locations. This minimises the stress associated with transportation of dogs and reduces the risk of spreading zoonotic or other pathogens to new areas. If transport is needed, it should be done in accordance with Chapter 7.1.

Dogs that are removed from a community may be too numerous or may be unsuitable for adoption. If acceptable to the local community, 'Catch, Neuter, Vaccination and Return'~~(see Article 7.7.19)~~ may provide an alternative approach~~(see Article 7.7.19.)~~. If *euthanasia* of these unwanted animals is the only option, the procedure should be conducted in accordance with Article 7.7.27.

Article 7.7.21.

Access to veterinary care

Access to veterinary care ~~delivered by V~~*~~veterinary S~~ervices*positively impacts animal health, *animal welfare* and public health through provision of preventive and therapeutic veterinary care to dogs in a community. Increased interactions with V*~~v~~eterinary S~~s~~ervices* provide additional opportunities to educate dog owners on *responsible dog ownership* (see Article 7.7.17.). From a DPM perspective, the prevention and control of disease, treatment of illness and injury, and *euthanasia* to end suffering where treatment is not feasible potentially reduce abandonment of sick or injured dogs.

Veterinary care should be part of DPM programmes and contribute to disease control by creating healthier populations of dogs with reduced population turnover. Herd immunity for rabies control is supported by DPM through improvement in the survival of vaccinated dogs and reducing birth of unvaccinated puppies through surgical sterilisation. Guidance on implementing dog rabies *vaccination* campaigns is provided in Chapter 8.14.

Preventive veterinary care is central to zoonotic disease control and *surveillance*. DPM programmes should encompass or align with all disease control measures relevant to dogs. This includes rabies *vaccination*, deworming (in particular for *Echinococcus granulosus*) and prevention and control of other pathogens.

Veterinary S~~s~~ervices should identify 'at *risk*' populations of dogs that do not have reliable access to basic veterinary care. *Competent Authorities* should facilitate access to veterinary care. Potential solutions may include subsidising costs and organising outreach *veterinary services*.

Article 7.7.22.

Environmental controls

Actions ~~should~~can be taken to exclude dogs from uncontrolled sources of food (e.g. protecting rubbish dumps and *abattoirs* and installing animal-proof rubbish containers). ~~Chapter 8.5. provides additional recommendations on environmental controls for the prevention and control of *Echinococcus granulosus*.~~Environmental control should be linked to other DPM measures, to avoid *animal welfare* problems and reduce public health risks from a sudden reduction in food sources.

Article 7.7.23.

Education on safe dog–human interaction

The most effective means of reducing the occurrence of dog bites are education on safe interaction with dogs and owner responsibility for training and managing dogs as part of *responsible dog ownership*. Young children are the group at highest *risk* for dog bites. Public education programmes focus~~s~~ed on appropriate dog-directed behaviour have been demonstrated to be effective in reducing the occurrence of dog bite~~s~~ and these programmes should be encouraged. *Competent Authorities* should seek advice from dog behaviour experts in developing dog safety education programmes.

Education programmes inon appropriate bite treatment, ~~and when necessary~~including post-exposure prophylaxis where rabies is a risk, are encouraged for all ages ~~groups is encouraged~~.

Article 7.7.24.

Specific considerations for Ddog Ppopulation Mmanagement activities

The following activities ~~Articles 7.7.25. to 7.7.27. are recommendations for activities that~~may be required as part of the implementation of the DPM ~~above~~measures described in Article 7.7.13.:

– Dog capture and handling;

– Dog housing;

– *Euthanasia.*

~~*Euthanasia* of dogs, used alone, is not effective for DPM. If used, it should be done humanely (see Article 7.7.27.) and implemented in combination with other measures as part of a DPM programme~~.

Article 7.7.25.

Dog capture and handling

Humane capture and handling aim to prevent animal suffering and distress. ~~It~~ They can also bring other benefits, including reduced injuries to handlers, easier handling of dogs in future and modelling positive handling to owners and the public.

Competent Authorities should develop appropriate legislation and training to promote humane handling and enforce regulations against cruel methods, such as ~~, including~~ the use of tongs and uncovered wire loops. *Animal welfare* and operator safety outcomes are improved when the personnel conducting capture and handling have a complete understanding of, and proficiency in, the capture and handling method to be used.

Competent Authorities and *Vveterinary Ssservices* should ensure their staff and volunteers expected to handle dogs have received rabies pre-exposure *vaccination* and are provided with clear protocols for treating injuries, including dog bites.

EU comment

The EU would like to propose the following revision:

"*Competent Authorities* and *Veterinary Services* should ensure their staff and volunteers expected to handle dogs have received rabies pre-exposure *vaccination,* where appropriate and are provided with clear protocols for treating injuries, including dog bites."

Justification

The EU agrees that reducing risks incurred by handlers is of utmost importance. However, it should be noted that rabies pre-exposure vaccination of all staff and volunteers may not be done on a routine basis in all countries. This depends on the rabies status of the country. It is therefore proposed to make such vaccination risk-determined and give some flexibility to adapt it to the role played by the staff and volunteers when participating in dog handling activities.

The least aversive method of capture and handling should be used to minimise harm and discomfort to the dog, while also considering safety of the handler. Further, handlers should strive to make the handling experience as positive as possible from the perspective of the dog; this includes looking for ways to reward the dog during handling.

Handlers should use minimum *restraint* to provide the dog with opportunities to exert choice and control, so that they cope better with the handling.

Article 7.7.26.

Dog housing

Competent Authorities should develop minimum standards for the housing (physical facilities) and care of dogs by providing a suitable environment, a suitable diet, a house which keeps them with or apart from other animals, allows them to exhibit normal behaviour and provide protection from pain, suffering, injury and disease in order to meet the internationally recognised 'five freedoms'. ~~to ensure the physical, mental and social needs of dogs are met~~Enforcement of these standards ~~are~~ is supported by licensing and inspection of facilities (Barnard *et al.*, 2014). The following minimum standards should be considered:

~~a~~1. Facilities

- sustainable finances to cover ongoing running costs;
- site selection: access to drainage, waste disposal, water and electricity ~~are~~ is essential and environmental factors such as noise and pollution should be considered;
- kennel size, design and occupancy, taking into account exercise ~~and~~, expected length of stay ~~into account~~ and ~~providing~~sufficient area for dogs to separate the functions of eating or drinking, resting, urinating and defecating, as well as maintaining acceptable environmental temperatures;
- disease control measures including isolation and *quarantine station*;
- maximum capacity of the facility.

~~b~~2. Management

- provision of adequate fresh water and nutritious food;
- regular hygiene and cleaning;
- routine inspection, handling and exercise of the dogs;
- *monitoring* of physical and behavioural health and provision of required veterinary treatments under veterinary supervision, including routine and preventive veterinary care and *euthanasia*;
- policies and procedures to respect the maximum capacity for the facility and action when this is reached, assessment of dog health and behaviour, animal care, intake, treatment, adoption, sterilisation and *euthanasia*;
- provision of sufficient numbers of appropriately skilled staff and training of staff in safe, appropriate and positive handling of dogs;
- record keeping, animal identification and reporting to the *Competent Authority*~~.~~;
- provision of opportunities for conspecific socialisation, human socialisation, enrichment and locomotory activity as appropriate to the individual.

~~c~~3. Assessment

Dog housing performance may be assessed using the following measurables:

- body condition score, skin condition, disease *incidence*, injuries and mortality, reaction to humans and conspecifics;
- expression of species-specific behaviours reflecting a positive emotional state;
- housing must provide adequate space appropriate to the age, size, weight~~,~~ and breed of the dog, and ~~that~~ allow~~s~~ the dog to engage in normal body movements, including the ability to sit, stand up, turn about freely, or lie recumbent in a natural position, stretch, move their head, hold the tail erect while standing, and comfortably eat, drink, urinate and defecate;
- hygiene, cleaning, drainage and housing materials should prevent an excessive accumulation of faeces and food waste, to prevent soiling of dogs in the enclosure, and reduce disease *hazards*, insects, pests and odours;
- ventilation should allow dogs to ~~comfortably~~ maintain normal body temperature comfortably and provide good air quality;
- protection from harmful extremes of temperature, air movement, moisture, light and other climatic elements to ensure proper health and well-being of the dog.

Article 7.7.27.

Euthanasia

Euthanasia of dogs, used alone, is not effective for DPM. If used, it should be done humanely and implemented in combination with other measures as part of a DPM programme to achieve effective long-term management. Reducing dog population size is not an effective means of reducing the number of rabies cases [(WHO, 2018)].

As a process, *euthanasia* involves pre-*euthanasia* and handling procedures, *euthanasia* methods and agents, confirmation of *death*, and carcass disposal. When *euthanasia* is practised, the general principles in the *Terrestrial Code* should be applied, with the emphasis on using practical methods which achieve the most rapid, painless and distress-free-*death* possible while ensuring operator safety. *Euthanasia* should be conducted under the supervision of a *veterinarian*. To ensure *animal welfare* and operator safety, the personnel conducting *euthanasia* should have a complete understanding of, and proficiency in, the *euthanasia* method to be used.

a1) Restraint

When a dog needs to be restrained for any procedure, including *euthanasia*, this should always be done with full regard for operator securitysafety and *animal welfare*. Animal handling should also minimise distress experienced by the dog prior to loss of consciousness. Some *euthanasia* methods should be used inwith prior sedation or anaesthesia to be considered humane. Regardless of the *euthanasia* method used, it is advisable to perform pre-*euthanasia* sedation or anaesthesia should be usedto minimise anxiety or facilitate safe *restraint*.

b2) Euthanasia methods

The following are recommended methods of canine *euthanasia*:

– intravenous barbiturates;

– intraperitoneal barbiturates in small dogs or puppies, to be used only if the intravenous route is not feasible;

– intravenous anaesthetic overdose;

– inhaled anaesthetic overdose in small dogs (not neonates).

If anaesthetised:

– administration of barbiturates by alternative routes (intracardiac, intrarenal, intrahepatic, intraosseous).

If sedated:

– intravenous *euthanasia*-specific formulation of embutramide, chloroquine and lidocaine;

– intravenous *euthanasia*-specific formulation of embutramide, mebezonium and tetracaine.

Methods, procedures and practices that are unacceptable as primary methods of *euthanasia* on *animal welfare* grounds include air embolism, asphyxiation, burning, chloral hydrate, chloroform, cyanide, decompression, drowning, exsanguination, formalin, household products and solvents, pesticides and herbicides, hypothermia, insulin, neuromuscular blocking agents (magnesium sulphate, potassium chloride, nicotine and all curariform agents), manually applied blunt force trauma to the head, rapid freezing, thoracic compression, strychnine, nitrous oxide, ether, kill-trapping, CO from engine fumes, CO_2 if the required concentration and flow rates are not regulated and monitored, free-bullet without proper anatomical placement at close range by highly trained personnel, penetrating captive bolt followed by pithing, electrocution if not already under general anaesthesia,and *stunning* without a secondary kill method.

c3. Confirmation of death

For all methods of *euthanasia* used, *death* should be confirmed before animals are disposed of or left unattended.

A combination of criteria is most reliable in confirming *death*, including lack of pulse, breathing, and corneal reflex, and response to firm toe pinch; inability to hear respiratory sounds and heartbeat by use of a

stethoscope; greying of the mucous membranes; and rigor mortis. None of these signs alone, except rigor mortis, confirms *death*. If an animal is not dead, another humane method of *euthanasia* should be performed.

~~d~~4. Carcass disposal

Carcasses should be disposed of in a manner that complies with legislation. Attention should be paid to the *risk* of residues occurring in the carcass. Incineration is generally the safest ~~way~~ means of carcass disposal (see Chapter 4.13.).

References [Note: references will be removed when the chapter is adopted.]

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CHAPTER 8.16.

INFECTION WITH RINDERPEST VIRUS

EU comment

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

The EU queries whether potential and suspect *cases* can be confirmed or infirmed in a national laboratory to become *cases* or be ruled out, or whether this imperatively needs to be done at an OIE Reference Laboratory in order to meet the case definition. Indeed, this is not clear from the text: according to point 2(c)(ii) of Article 8.16.1., a potential *case* remains a suspect *case* when the diagnostic test is performed outside an OIE Reference Laboratory, and neither the case definition in point 2(b) of Article 8.16.1., nor Article 8.16.3. are explicit about this. Rather, the wording of the first paragraph of Article 8.16.3. is blurry about confirmation of potential *cases*, while the second paragraph of that article seems to make confirmation of suspect *cases* by an OIE Reference Laboratory optional, which would be inconsistent with point 2(c)(ii) of Article 8.16.1. Also point 1 of Article 8.16.5. does not explicitly require confirmation in an OIE Reference Laboratory ("should"), while point 2 of that article refers to what those laboratories should do in case of such confirmation (with reference to the case definition in Article 8.16.1.).

Further comments are inserted in the text below.

Article 8.16.1.

General provisions

1) The global eradication of rinderpest has been achieved and was announced in mid-2011 based on the following:

   a) Evidence demonstrating that there is no significant likelihood that rinderpest virus (RPV) remains in susceptible domesticated or *wildlife* host populations anywhere in the world.

   b) OIE Member and non-member countries have completed the pathway defined by the OIE for recognition of national rinderpest freedom and have been officially recognised by the OIE as free from *infection* with RPV.

   c) All *vaccinations* against rinderpest are banned and have ceased throughout the world. A ban on *vaccination* against rinderpest means a ban on administering any vaccine containing RPV or any components derived from RPV to any animal.

   However, RPV-containing material including live vaccines continue**s** to be held in a number of institutions around the world and this poses a *risk* of virus re-introduction into susceptible animals. Therefore, Member Countries should not manipulate~~ion of~~ existing RPV-containing material, ~~and synthesis~~ or synthesise or produce ~~other forms of production of~~ RPV-containing material, ~~is forbidden~~ unless authorised by the FAO and OIE.

EU comment

The EU thanks the OIE for having addressed its previous comment on the paragraph above in relation to a cross-reference to the relevant Resolution adopted by the World Assembly. We can support the paragraph with the amended wording as proposed ("should not ... unless authorised" instead of "manipulation ... is forbidden").

   As sequestration and destruction of virus stocks proceed, the *risks* of re-occurrence of *infection* are expected to ~~progressively~~ diminish progressively. The possibility of deliberate or accidental release of virus demands continuing vigilance, especially in the case of those countries hosting an institution holding RPV-containing material.

This chapter takes into account the global freedom status of rinderpest and provides recommendations to prevent re-emergence of the disease, to ensure adequate *surveillance* and protection of livestock and to manage any re-emergence and facilitate recovery of global freedom from rinderpest.

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

a) Rinderpest is defined as an *infection* of susceptible animals with RPV, with or without clinical signs.

b) The following defines the occurrence of a *case* of *infection* with RPV:

i) RPV has been isolated from a susceptible animal or a product derived from that animal and identified; or

ii) viral antigen or viral RNA specific to RPV has been identified in samples from a susceptible animal; or

iii) antibodies that are not a consequence of *vaccination* to RPV have been identified in a susceptible animal with either epidemiological links to a confirmed or suspected *outbreak* of rinderpest, or showing clinical signs consistent with recent *infection* with RPV.

c) The following defines a 'suspected *case*' of ~~rinderpest~~ *infection* with RPV:

i) a potential *case* for which other diseases compatible with 'stomatitis-enteritis syndrome' have been ruled out by clinical ~~or~~ and laboratory investigation; or

II) a potential *case* which has given a positive reaction in a diagnostic test for RPV conducted outside of an OIE reference laboratory for rinderpest; or

iii) the detection of RPV-specific antibodies that are not a consequence of *vaccination* in a susceptible animal with or without clinical signs.

d) The *incubation period* for ~~rinderpest~~ *infection* with RPV shall be 21 days.

e) RPV-containing material means field and laboratory strains of RPV; vaccine strains of RPV including valid and expired vaccine stocks; tissues, sera and other material from animals known or suspected to be infected; laboratory-generated diagnostic material containing live virus, recombinant morbilliviruses (segmented or nonsegmented) containing unique RPV nucleic acid or amino acid sequences~~,~~; and full length genomic material including ~~virus~~ viral RNA and its cDNA copies.

Subgenomic fragments of RPV genome (either as plasmids or incorporated into recombinant viruses) that cannot be incorporated into a replicating morbillivirus or morbillivirus-like virus are not considered to be RPV-containing material, neither are sera that have been either heat-treated to at least 56°C for at least two hours, or shown to be free from RPV genome sequences by a validated RT-PCR assay.

3) For the purposes of this chapter:

a) 'Susceptible animals' means domestic, *feral, captive wild* and *wild* artiodactyls.

b) A 'potential *case*' of *infection* with RPV means a susceptible animal showing clinical signs consistent with 'stomatitis–enteritis syndrome' and where these signs cannot be ascribed to another disease compatible with 'stomatitis–enteritis syndrome' by clinical or epidemiological ~~considerations or appropriate laboratory~~ investigation.

The occurrence of a potential *case* should draw special attention if it is linked to identified risks such as proximity to facilities holding RPV-containing material.

c) 'Stomatitis–enteritis syndrome' is defined as fever with ocular and nasal discharges in combination with clinical signs of erosions in the oral cavity with diarrhoea, dysentery, dehydration or death or necropsy findings of haemorrhages on serosal surfaces, haemorrhages and erosions on alimentary mucosal surfaces and lymphadenopathy.

4) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.16.2.

1. Safe commodities during global freedom

When authorising import or transit of ~~the~~ *commodities* of susceptible animals, *Veterinary Authorities* should not require any conditions related to rinderpest.

2. Safe commodities in the event of re-emergence of rinderpest

Regardless of the rinderpest status of the *exporting country*, *Veterinary Authorities* should not require any conditions related to rinderpest for:

a) semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather, e.g. wet blue and crust leather) ~~which have been submitted to the usual chemical and mechanical processes in use in the tanning industry~~;

b) *meat products* in hermetically sealed containers with a F_0 value of 3 or above;

c) gelatine.

Article 8.16.2bis.

Article 8.16.3., Article 8.16.4. and point 1 of Article 8.16.5. apply during global freedom.

Articles 8.16.5. to 8.16.13. apply in the event of re-emergence of rinderpest.

~~First section: applicable during global freedom~~

Article 8.16.3.

Ongoing surveillance post global freedom

All countries in the world, whether or not Member Countries of the OIE, have completed all the procedures necessary to be recognised as free from rinderpest ~~*infection*~~, and annual re-confirmation of ~~rinderpest absence~~ absence of *infection* with RPV is no longer required. However, rinderpest should still be notifiable in the whole territory and countries are still required to carry out general *surveillance* in accordance with Chapter 1.4. to detect rinderpest should it recur and to comply with OIE reporting obligations concerning the occurrence of unusual epidemiological events in accordance with Chapter 1.1. Countries should either maintain the capacity for local investigation of potential *cases* or have protocols in place to send samples from such potential *cases* to an OIE Reference Laboratory for routine checking. Countries should also maintain national contingency plans for responding to events suggestive of rinderpest including the checking of potential *case*s and the prompt identification of suspected *case*s.

EU comment

The EU acknowledges that all countries in the world are obliged to keep rinderpest notifiable in the whole territory of their country. The EU supports this unique obligation on all countries in the present chapter due to the global freedom of rinderpest. However, such an obligation can only be justified by the global freedom of the disease, and is thus a distinct feature of rinderpest.

The Global Rinderpest Action Plan (GRAP) complements all national and regional contingency plans and lays out the roles and responsibilities of all relevant stakeholders to prepare for, prevent, detect, respond to and recover from a rinderpest *outbreak*. If needed, expertise from the region or continent, or international organisations may be requested to provide resources to help confirm or rule out ~~if~~ whether the potential *case* meets the definition for a suspected *case* or a *case* ~~of rinderpest~~.

Article 8.16.4.

Annual update on RPV-containing material

Annual reports on RPV-containing material should be submitted to the OIE each year by the *Veterinary Authority*

of a Member Country hosting an institution or institutions holding RPV-containing material, using the online platform designated for such a purpose. A final report should be submitted to the OIE for each institution when all RPV-containing materials have been destroyed and no new related activities are foreseen.

~~Second section: applicable in the event of re-emergence of rinderpest~~

Article 8.16.5.

Response to a recurrence of rinderpest

1. Procedures to be followed in the event of the suspicion of rinderpest

Any suspected *case* of *infection* with RPV should be immediately ~~notified~~ reported to the *Veterinary Authority.*

Veterinary Authorities shall immediately notify any suspected *case* of *infection* with RPV to the OIE.

EU comment

The EU acknowledges that any suspected case of infection with RPV shall immediately be notified to the OIE. A chapter specific definition of a 'suspected case' is provided in Article 8.16.1. The EU supports the obligation to notify suspected cases immediately to the OIE in the present chapter due to the specific definition of a suspected case and the global freedom of rinderpest. However, an obligation to notify suspicions is at present only justified in connection with the distinctive feature of rinderpest being globally eradicated.

Upon detection of a suspected *case*, the national contingency plan should be implemented immediately. If the presence of rinderpest cannot be ruled out or if there is a positive reaction in a diagnostic test for RPV conducted outside of an OIE Reference Laboratory for rinderpest, samples should be collected in accordance with the *Terrestrial Manual* and dispatched to one of the appointed OIE Reference Laboratories for rinderpest for confirmation and, if applicable, for molecular characterisation of the virus to facilitate identification of its source. A full epidemiological investigation should be conducted simultaneously to provide supporting information and to assist in identifying the possible source and spread of the virus.

2. Procedures to be followed after confirmation of rinderpest

Veterinary Authorities shall immediately notify any *case* of *infection* with RPV to the OIE.

A *case* of *infection* with RPV shall constitute a global emergency requiring immediate, concerted action for its investigation and elimination.

Immediately following the confirmation of the presence of RPV, viral RNA or antibody as described in Article 8.16.1., the appointed OIE Reference Laboratory for rinderpest should inform the country concerned, the OIE and the FAO, allowing the initiation of the response operations described in the GRAP.

When epidemiological investigation has indicated the extent of the infected area, zoning can be implemented for the purposes of disease control. In the event of a limited *outbreak*, a *containment zone* may be established in accordance with Article 8.16.8.

Emergency *vaccination* is acceptable only with rinderpest vaccines produced in accordance with the *Terrestrial Manual*. Vaccinated animals should always be clearly and permanently identified at the individual level.

Global rinderpest freedom is suspended and the *sanitary measures* for trade with the infected country or countries shall be those in Articles 8.16.12. and 8.16.13.

Article 8.16.6.

Country free from rinderpest

In the event of re-emergence of rinderpest, all OIE Member Countries without a *case* will remain free from rinderpest. However, all OIE Member Countries will be asked to provide a *risk assessment* to the OIE and free status will be suspended if their *risk assessment* is not accepted by the OIE.

Some countries will be at heightened *risk*. In particular, countries meeting the conditions below would be regarded as being at heightened *risk* and should carry out appropriate *surveillance*, capable of detecting the presence of *infection* with RPV even in the absence of clinical signs; this may be achieved through a *surveillance* programme in accordance with Article 8.16.11. in addition to ongoing *surveillance* in accordance with Article 8.16.3.~~:~~

1) countries that are adjacent to a country infected with RPV; or

2) countries that have relevant epidemiological or ecological links through trade or animal movements to a country infected with RPV.

Article 8.16.7.

Country infected with RPV

A country infected with RPV is one in which a *case* of ~~rinderpest~~ *infection* with RPV has occurred.

Article 8.16.8.

Establishment of a containment zone within a country previously free from rinderpest

In the event of a limited *outbreak* within a country previously free of rinderpest, a *containment zone* for the purposes of disease control and eradication ~~can~~ should be established in accordance with Article 4.4.7. Notwithstanding the establishment of a *containment zone* for disease control and eradication, *international trade* in *commodities* of susceptible species from the entire country will be limited to the *safe commodities* listed in point 2 of Article 8.16.2. until free status is recovered.

EU comment

We take note of and agree with the explanation given in the report (last paragraph of p. 22) for not agreeing with a previous EU comment requesting a change in Article 8.16.5. to replace "may" with "should" in relation with the establishment of a containment zone, for consistency with the wording in the paragraph above. We would therefore request replacing "should" with "may" in the paragraph above, for consistency with the fourth paragraph of point 2 of Article 8.16.5. as well as point 1 of Article 4.4.7., and because the choice of disease control measures indeed is the prerogative of Members (as suggested by the last paragraph of Article 4.4.3.).

Furthermore, the EU suggests deleting the word "safe" from the paragraph above, as it is not necessary, and for consistency with the changes suggested in Article 8.16.13.

Finally, we suggest adding the words "for the whole country in accordance with Article 8.16.9." at the end of the paragraph to avoid possible confusion. Indeed, point 5 of Article 4.4.7. indicates recovery of free status of the areas outside the containment zone once the containment zone has been established, however that is not consistent with what is intended in the context of this chapter.

Article 8.16.9.

Recovery of free status for a country

Should a *case* of ~~rinderpest~~ *infection* with RPV occur, a country is considered infected with RPV until shown to be free from rinderpest in accordance with the procedures below.

The time needed to recover ~~rinderpest~~ free status of a country depends on the methods employed to achieve the elimination of *infection*.

One of the following waiting periods is applicable:

1) when a *stamping-out policy* has been applied:

   a) three months after the *disinfection* of the last affected *establishment* where a *stamping-out policy* without *vaccination* and targeted *surveillance* in accordance with Article 8.16.11. have been applied; or

   b) three months after the *disinfection* of the last affected *establishment* and the *slaughter* of all vaccinated animals, where a *stamping-out policy*, emergency *vaccination* and targeted *surveillance* in accordance with Article 8.16.11. have been applied; or

   c) 18 months after the *disinfection* of the last affected *establishment* and the last *vaccination*, where a *stamping-out policy*, emergency *vaccination* not followed by the *slaughter* of all vaccinated animals, and targeted *surveillance* in accordance with Article 8.16.11. have been applied;

2) when a *stamping-out policy* is not practised, the above waiting periods do not apply. Instead, the country must be in compliance with the requirements below:

   a) have a record of regular and prompt animal disease reporting in accordance with Chapter 1.1.;

   b) send a declaration to the OIE stating that:

      i) there has been no *case* of ~~rinderpest~~ *infection* with RPV during the past 24 months;

      ii) no suspected *case* of *infection* with RPV ~~*infection*~~ has been found during the past 24 months;

      iii) no *vaccination* against rinderpest has been carried out during the past 24 months;

   c) supply documented evidence that targeted *surveillance* for *infection* with RPV in accordance with Chapter 1.4. and Article 8.16.11. is in operation and that regulatory measures for the prevention and control of rinderpest have been implemented;

   d) not have imported, since the cessation of *vaccination*, any animals vaccinated against rinderpest.

In the scenarios mentioned in points 1(a), (b) and (c) and in point 2 above, the recovery of free status requires an international expert mission to verify the successful application of containment and eradication measures, as well as a review of documented evidence by the OIE. The country shall be considered free only after the outcome of the mission and submitted evidence ~~has~~ have been accepted by the OIE.

Article 8.16.10.

Recovery of global freedom

The suspension of global freedom will be lifted when all countries infected with RPV have recovered freedom in accordance with Article 8.16.9.

Unless it is verified through an OIE expert mission that the conditions below are met for all countries having experienced an *outbreak* within 12 months of suspension, then global rinderpest freedom is lost and recovery of freedom would require an assessment of free status of all countries by the OIE. If the conditions below are met within 12 months, then global freedom will remain suspended, subject to periodic review by the OIE.

1) The *outbreak* is limited to a country or *zone*, without any further *outbreaks* outside the ecosystem of the first *outbreak*.

2) The *outbreak* is handled in a prompt and efficient manner, with robust control measures including movement controls, which were rapidly implemented and were shown to be successful in mitigating the spread of rinderpest and reducing its incidence.

Article 8.16.11.

Surveillance for recovery of ~~rinderpest~~ free status

A country infected with RPV applying for recovery of ~~rinderpest~~ free status in accordance with Article 8.16.9. should provide evidence demonstrating effective *surveillance* in accordance with Chapter 1.4. and the points below.

1) The target for *surveillance* should be all populations of ~~rinderpest~~ susceptible ~~species~~ animals within the country. In certain areas some *wildlife* populations, such as African buffaloes, act as sentinels for ~~rinderpest~~ *infection* with RPV.

2) An awareness programme should be established for all animal health professionals including *veterinarians*, both official and private, and livestock owners to ensure that ~~rinderpest's~~ clinical and epidemiological characteristics of rinderpest and *risks* of its recurrence are understood. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any potential *case*.

3) Differing clinical presentations can result from variations in levels of innate host resistance (*Bos indicus* breeds being more resistant than *B. taurus*), and variations in the virulence of the attacking strain. In the case of sub-acute (mild) cases, clinical signs are irregularly displayed and difficult to detect. Experience has shown that syndromic *surveillance* strategies, i.e. *surveillance* based on a predefined set of clinical signs (~~i.e.~~ 'stomatitis–enteritis syndrome'), are useful to increase the sensitivity of the system.

4) Given these differing clinical presentations, virological *surveillance* should be conducted in addition to clinical surveillance. A procedure should be established for the rapid collection and transport of samples from suspected *cases* to an appointed OIE Reference Laboratory for rinderpest.

5) Since rinderpest is an acute *infection* with no known carriers, serological *surveillance* should be conducted to detect mild *infections* that are not detected clinically. There are no serological means to differentiate animals infected with field virus from vaccinated animals. Consequently, serological surveys should target unvaccinated animals and young animals devoid of maternal antibodies.

~~2~~Article 8.16.12.

Recommendations for importation of ~~rinderpest~~ susceptible animals and their products ~~except safe commodities in point 2 of Article 8.16.2~~ from countries free from rinderpest

1) For ~~rinderpest~~ susceptible animals, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the animals remained in a country free from rinderpest since birth or for at least 30 days prior to shipment. Animals must not transit through a country infected with RPV, in accordance with Chapter 5.7.

2) For *fresh meat* or *meat products* (except those listed in point 2 of Article 8.16.2.) of susceptible animals, for *milk or milk products* from susceptible animals, and for all products of animal origin intended for use in animal feeding, for agricultural use or for industrial use, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting the entire consignment of product is derived from animals that remained in a country free from rinderpest since birth or for at least 30 days prior to *slaughter* or harvesting of the product.

3) For semen and oocytes of susceptible animals, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

   a) the donor animals showed no clinical signs of ~~rinderpest~~ *infection* with RPV on the day of collection and had been kept in a country free from rinderpest for at least 30 days prior to collection;

   b) the semen and oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.6., 4.7. or 4.9., as relevant.

4) For *in vivo* derived embryos of susceptible animals, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

   a) the donor females showed no clinical signs of ~~rinderpest~~ *infection* with RPV on the day of collection and had been kept in a country free from rinderpest for at least 30 days prior to collection;

   b) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.8. and 4.10., as relevant.

Article 8.16.13.

Recommendations for importation from countries ~~infected with~~ not free from rinderpest

~~In the event of re-emergence of rinderpest,~~ From countries not free from rinderpest, only ~~*safe commodities*~~ listed in point 2 of Article 8.16.2. can be traded.

CHAPTER 8.5.

INFECTION WITH *ECHINOCOCCUS GRANULOSUS*

EU comment

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

Article 8.5.1.

General provisions

Echinococcus granulosus (E. granulosus) is a widely distributed cestode (tapeworm). The adult worms occur in the small intestine of canids (definitive host). Larval stages (hydatid) occur in tissues of liver, lung and other organs of other mammals (intermediate host), including humans. *Infection* with the larval stage of the parasite in the intermediate host, referred to as 'cystic echinococcosis' or 'hydatidosis', is associated with significant economic losses in livestock production and causes a major disease burden in humans.

For the purposes of the *Terrestrial Code*, *infection* with *E. granulosus* is defined as a zoonotic parasitic *infection* of canids, ungulates and macropod marsupials with *E. granulosus* (ovine, bovine, cervid, camelid and porcine strains).

For the purposes of this chapter, offal is defined as internal organs of ungulates and macropod marsupials.

Transmission of *E. granulosus* to canids occurs through ingestion of hydatid-infected offal.

Infection in intermediate hosts, as well as in humans, occurs by ingestion of *E. granulosus* eggs from contaminated environments. In humans, *infection* may also occur following contact with infected canids or by consumption of food or water contaminated with *E. granulosus* eggs from canine faeces.

Infection in humans can be prevented by good food hygiene and personal hygiene, community health education and preventing *infection* of canids. Collaboration between the *Competent Authority* and the public health authority is an essential component in preventing and controlling *E. granulosus* transmission.

This chapter provides recommendations for prevention of, control of, and *surveillance* for *infection* with *E. granulosus* in dogs and livestock.

When authorising the import or transit of the *commodities* covered in this chapter, with the exception of those listed in Article 8.5.2., *Veterinary Authorities* should apply the recommendations in this chapter.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

[...]

Article 8.5.3.

Programmes for the prevention and control of infection with *E. granulosus*

In order to prevent and control *infection* with *E. granulosus*, the *Veterinary Authority* or other *Competent Authority* should carry out community awareness programmes about the risk factors associated with transmission of *E. granulosus*, the role of dogs (including *stray dogs*) and the importance of *responsible dog ownership*. The *Veterinary Authority* or other *Competent Authority* should also implement the following prevention and control measures.

1. Prevention of infection in dogs (owned and stray)

   a) Dogs should not be fed offal unless it has been treated in accordance with Article 8.5.6.

   b) Dogs should be prevented from scavenging on dead ungulates and macropod marsupials. Dead animals should be disposed of in accordance with Article 4.13.6.

c) The *Veterinary Authority* or other *Competent Authority* should ensure that *slaughterhouses/abattoirs* have implemented measures that prevent access of dogs to the premises, and to animal carcasses and waste containing offal.

d) When livestock cannot be slaughtered in a *slaughterhouse/abattoir* and are slaughtered on-farm, dogs should be prevented from having access to raw offal, and not be fed offal unless it has been treated in accordance with Article 8.5.6.

2. Control of infection in dogs (owned and stray)

a) For control of *stray dog* populations, the *Veterinary Authority* or other *Competent Authority* should implement relevant aspects of Chapter 7.7.

b) Dogs known to be infected or suspected of having access to raw offal or in contact with livestock should be dewormed at least every 4-6 weeks with praziquantel (5 mg/kg) or another cestocidal product with comparable efficacy. Where possible, faeces excreted up to 72 hours post treatment should be disposed of by incineration or burial.

c) In areas of persistent transmission, the *Veterinary Authority* and other *Competent Authority* should collaborate to identify the possible origins of the *infection*, and review and amend the control programme, as appropriate.

3. Control of infection in livestock

a) The *Veterinary Authority* should ensure that all slaughtered livestock are subjected to post-mortem *meat* inspection in accordance with Chapter 6.3., including inspection of offal for hydatids.

b) When hydatids are detected during post-mortem *meat* inspection:

~~c)~~ i) offal containing hydatids should be disposed of in accordance with Article 4.13.6., or treated in accordance with Article 8.5.6.;

~~d)~~ ii) an investigation should be carried out by the *Veterinary Authority* and other *Competent Authority* to identify the possible origin of the *infection*, and review and amend, as appropriate, the control programme.~~;~~

c) Control programmes should include the *vaccination* of livestock with the objective of decreasing the prevalence of *infection* in livestock.

EU comment

The new point c) under above is very general and certainly not valid across the board in all countries and all situations. We suggest therefore to make it more specific and insert the words "In highly endemic areas," before "control programmes should include [...]".

[...]

CHAPTER 15.4.

INFECTION WITH *TAENIA SOLIUM* (PORCINE CYSTICERCOSIS)

EU comment

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

Comments are inserted in the text below.

Article 15.4.1.

General provisions

Taenia solium (T. solium) is a zoonotic parasite of pigs and occasionally of other animals. *T. solium* is a cestode (tapeworm) that is endemic in large areas of Latin America, Asia and sub-Saharan Africa. The adult cestode occurs in the small intestine of humans (definitive host) causing taeniosis. The larval stage (cysticercus) occurs in striated muscles, subcutaneous tissues and central nervous system of pigs (intermediate hosts), causing cysticercosis. Other suids and dogs can be infected but are not epidemiologically significant. Humans may also become infected with the larval stage through the ingestion of eggs shed in faeces of infected humans. The most severe form of human *infection* by the larval stage is neurocysticercosis which causes neurological disorders including seizures (epilepsy) and sometimes death. Cysticercosis, although normally clinically inapparent in pigs, is associated with significant economic losses due to carcass condemnation and decreased value of pigs, and causes a major disease burden in humans.

EU comment

The EU suggests deleting the words "that is endemic in large areas of Latin America, Asia and sub-Saharan Africa" from the above paragraph. Indeed, that information is neither accurate, nor necessary in the context of the Terrestrial Code. Other disease-specific chapters do not usually contain such information. Rather, current information on disease occurrence is available in OIE-WAHIS.

In humans, taeniosis occurs following ingestion of pig *meat* containing viable cysticerci and can be prevented by avoiding consumption of raw or undercooked contaminated pig *meat*. In humans, cysticercosis occurs following ingestion of *T. solium* eggs and can be prevented by avoiding exposure to *T. solium* eggs through detection and treatment of human tapeworm carriers, community health education, appropriate sanitation, personal hygiene, and good food hygiene. Collaboration between the *Veterinary Authority* and the public health authority is essential in preventing and controlling *T. solium* transmission.

In pigs, cysticercosis occurs by ingestion of *T. solium* eggs from faeces, or environments contaminated with faeces of humans harbouring adult *T. solium*.

For the purposes of the *Terrestrial Code*, *infection* with *T. solium* is defined as an *infection* of pigs.

The aim of this chapter is to reduce the risk of *infection* with *T. solium* of humans and pigs and to minimise the international spread of *T. solium*. The chapter provides recommendations for prevention, control and *surveillance* of *infection* with *T. solium* in pigs.This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005).

When authorising the import or transit of the *commodities* covered in this chapter, with the exception of those listed in Article 15.4.2., *Veterinary Authorities* should apply the recommendations in this chapter.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

[…]

Article 15.4.3.

Measures to prevent and control infection with *T. solium*

The *Veterinary Authority* and other *Competent Authorities* should carry out community awareness and education programmes on the risk factors associated with transmission of *T. solium* emphasising the role of pigs and humans.

The *Veterinary Authority* or other *Competent Authorities* should promote the comprehensive *animal health management* of pigs, which should include the following measures:

EU comment

The EU queries whether the term "animal health management" is right in this context, as cysticercosis is normally clinically inapparent in pigs as mentioned in the first paragraph of Article 15.4.1.

1. Prevention of infection in pigs

   Transmission of *T. solium* eggs from humans to pigs can be avoided by:

   a) preventing the exposure of pigs to environments contaminated with human faeces;

   b) preventing the deliberate use of human faeces as pig *feed* or the use of pigs as a means of human faeces disposal;

   c) preventing the use of untreated sewage effluent to irrigate or fertilise land to be used by pigs for forage or for food crops;

   d) ensuring that any treated sewage effluent used to irrigate or fertilise land to be used by pigs for forage or for food crops has been treated in a manner shown to inactivate *T. solium* eggs;

   e) providing adequate toilet and sanitation facilities for people in areas and *establishments* where pigs are kept to prevent the exposure of pigs and their environment to human faeces~~.~~;

   f) vaccinating pigs in combination with an anthelmintic treatment in accordance with the *Terrestrial Manual*.

2. Control of infection in pigs

   a) The *Veterinary Authority* should ensure that all slaughtered pigs are subjected to post-mortem *meat* inspection in accordance with Chapter 6.3., and with reference to Chapter 3.9.5. of the *Terrestrial Manual*.

   b) When cysticerci are detected during post-mortem *meat* inspection:

      i) if cysticerci are detected in a carcass of a pig in multiple locations (systemic infection), that carcass and its viscera, as well as all pigs from the same *establishment* of origin should be disposed of in accordance with Article 4.13.6.;

      ii) if only localised cysticerci are detected in a carcass of a pig, the *meat* from that carcass and from all pigs from the same *establishment* of origin should be treated in accordance with Article 15.4.6. or may be disposed of in accordance with Article 4.13.6.;

      iii) an investigation should be carried out by the *Veterinary Authority* and the public health authority to identify the possible source of the *infection* in order to target an intervention;

      iv) post-mortem examination of pigs at *slaughter* from known infected *establishments* should be intensified until evidence has been obtained indicating that the *infection* has been eliminated from the *establishment*.

   An optimal control programme should include detection and treatment of human tapeworm carriers and control of sewage used for agricultural production.

[…]

_____

CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

EU comment

The EU thanks the OIE for the latest version of the revised Chapter 11.4. on bovine spongiform encephalopathy. The EU appreciates the amendments introduced in the draft to address some of the comments transmitted in February 2021.

The EU disagrees with the position of the OIE to not reinstate 'protein meal derived from ruminants has not been fed to ruminants' as a requirement to obtain official BSE risk status. The EU considers that Article 11.4.3. should lay down more clearly what requirement Member must fulfil to be granted official BSE risk status. Rather to be implied, the prevention of feeding ruminants with ruminants derived protein meal should explicitly be laid down as a requirement to obtain official BSE risk status.

Additionally, the EU considers that the implementation of a feed-ban should be a mandatory risk mitigation measure in countries where livestock industry practices do not prevent cattle from being fed with ruminant-derived protein meal. The EU considers that there is no alternative risk mitigation measures in this case to ensure that the risk of recycling is negligible.

The EU reiterates that total transparency must be ensured on the criteria to determine and validate the "date from which the risk of BSE agents being recycled within the cattle population has been negligible". Therefore, the EU will follow very carefully the outcome of the BSE ad hoc Group from November 2021 on this issue, and the following discussion to be held in the next meeting of the Commission in February 2022.

Detailed comments are provided in the text below.

EU comment

The EU thanks the OIE to have ensured consistency throughout the text by using systematically the wording "the risk of BSE being recycled within the cattle population".

Article 11.4.1.

General provisions

1) The recommendations in this chapter are intended to mitigate the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agents in cattle only. BSE manifests in two main forms: classical BSE and atypical BSE. 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 population. ~~Oral exposure to contaminated *feed* is the main route of transmission of classical BSE.~~ Given that cattle have been experimentally infected by the oral route with a low molecular weight type of atypical BSE (L-type BSE~~,~~), atypical BSE is also ~~potentially~~ considered capable of being recycled in a cattle population if cattle are orally exposed to contaminated *feed*.

2) BSE primarily affects cattle. Other animal species may be naturally and experimentally susceptible to BSE, but they are not regarded as being epidemiologically significant, particularly when feeding ruminants with ruminant-derived protein meal is not ~~practiced~~practised.

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

~~1~~a) 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~~.

~~2~~b) The occurrence of a BSE *case* is defined by the immunohistochemical (IHC) or immunochemical detection of ~~PrP^{BSE}~~PrP^{Sc} in brain tissue of a bovid of the species *Bos taurus* or *Bos indicus*. ~~, with d~~Discrimination between atypical and classical BSE strains is based on the Western immunoblot banding pattern, as described in the *Terrestrial Manual*.

EU comment

The EU thanks the OIE to have adjust point b) as suggested.

4) For the purposes of this chapter:

~~3~~a) 'Cattle' means ~~a~~ bovids of the species *Bos taurus* or *Bos indicus.*

~~4~~b) 'Protein meal' means any final or intermediate solid protein-containing product, obtained when animal tissues are rendered, excluding ~~blood and blood products,~~ peptides of a molecular weight less than 10,000 daltons and amino~~-~~ acids.

EU comment

The EU thanks the OIE to have adjust point b) as suggested.

5) When *commodities* are imported in accordance with this chapter, the BSE risk of the *importing country* or *zone* of destination is not affected by the BSE risk of the *exporting country*, *zone* or *compartment* of origin.

6) Standards for diagnostic tests are described in the *Terrestrial Manual.*

Article 11.4.1bis.

Safe commodities

When authorising the importation or transit of the following *commodities* derived from cattle, *Veterinary Authorities* should not require any conditions related to BSE, regardless of the BSE risk posed by the cattle population of the *exporting country*, *zone* or *compartment*:

1) *milk* and *milk products*;

2) semen and *in vivo* derived cattle embryos collected and handled in accordance with the relevant chapters of the *Terrestrial Code*;

3) hides and skins;

4) gelatine and collagen;

5) tallow with maximum level of insoluble impurities of 0.15% in weight and derivatives made from this tallow;

~~6)~~ ~~tallow derivatives;~~

~~7~~6) dicalcium phosphate (with no trace of protein or fat~~).~~);

7) ~~foetal~~ fetal blood.

Other *commodities* of cattle 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 population by identifying all potential factors associated with the occurrence of BSE and their historic perspective. Member Countries should review the *risk assessment* annually to determine whether the situation has changed.

   ~~A~~The *risk assessment* for the purpose of BSE, based on the framework provided by Article 2.1.4., consists of:

   a) Entry assessment

      ~~An~~The entry assessment evaluates the likelihood that the classical BSE agent has been introduced into the country, *zone* or *compartment* ~~via imported~~through the importation of the following *commodities*~~.~~ in the preceding eight years:

      i) ~~C~~cattle;

      ii) ~~R~~ruminant-derived protein meal;

      iii) ~~F~~*feed* (except packaged and labelled pet food ~~not intended for pets~~) that contains ruminant-derived protein meal;

      iv) ~~F~~fertili~~z~~sers that contain ruminant-derived protein meal;

      v) ~~A~~any other *commodity* that either is or could be contaminated by *commodities* listed in Article 11.4.14.

   b) Exposure assessment

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

      The first step in the exposure assessment involves an evaluation of livestock industry practices through a consideration of the impact of:

      i) Livestock industry practices ~~on~~ preventing cattle from being fed ruminant-derived protein meal, taking account of:

         – demographics of the cattle 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 mitigation measures specifically targeting BSE may also need to be included through ~~a~~ consideration of the impact of:

      ii) Specific risk mitigation measures ~~on~~ preventing cattle from being fed ruminant-derived protein meal, taking account of:

         – the nature and scope of a *feed* ban on feeding ruminants with protein meal derived from ruminants;

         – the fate of *commodities* with the greatest BSE infectivity (those *commodities* listed in point 1 of Article 11.4.14.);

- parameters of the rendering process;
- prevention of cross-contamination during rendering, *feed* production, transport, storage and feeding;
- an awareness programme under the scope of the *feed* ban;
- monitoring and enforcement of the *feed* ban.

Depending on the outcome of the exposure assessment, a consequence assessment (in point (c) below) may not be required.

c) Consequence assessment

~~A~~The consequence assessment evaluates the likelihood of cattle becoming infected ~~with~~ following exposure to the BSE agents together with the likely extent and duration of any subsequent recycling and amplification within the cattle population during the preceding eight years. The factors to be considered in the consequence assessment are:

i) age at exposure;

ii) production type;

iii) the impact of cattle industry practices or the implementation of ~~BSE~~ 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 BSE agents ~~have been~~ being recycled ~~in~~ within the cattle 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 population has been negligible.

EU comment

The EU thanks the OIE to have amended this paragraph as suggested.

2) ~~the~~ The ongoing implementation of a *surveillance* programme for classical BSE in the cattle population in accordance with Article 11.4.18.;

3) ~~the~~ The history of occurrence and management of BSE *cases*.

Article 11.4.3.

Negligible BSE risk

The BSE risk of ~~the cattle population of~~ a country~~,~~ or *zone* ~~or *compartment*~~ can be considered to be negligible if all the following conditions for the cattle 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 has been conducted, and the Member Country has demonstrated through documented evidence that the ~~likelihood~~risk of BSE agents being recycled ~~in~~ within the cattle population has been negligible ~~as the result of:~~.

~~EITHER:~~

~~a) livestock industry practices ensuring that protein meal derived from ruminants has not been fed to ruminants;~~

~~OR~~

~~b) effective and continuous mitigation of each identified risk ensuring that protein meal derived from ruminants has not been fed to ruminants.~~

EU comment

The EU disagrees with the position of the OIE to not reinstate 'protein meal derived from ruminants has not been fed to ruminants' as a requirement to obtain official BSE risk status.

The EU takes note of the Report of the meeting of the OIE terrestrial animal health standards commission from September 2021, which provides that "*the code Commission did not agree with a comment to reinstate the deleted point 1(a) 'Protein meal derived from ruminants has not been fed to ruminants', as it was not needed here, since it was covered by the preceding article."* and *"The Commission noted that Members need to demonstrate that any assessed risks have been properly mitigated in order to obtain official BSE risk status, and that would imply the prevention of feeding ruminants with ruminant-derived protein meal.*"

The EU considers that Article 11.4.3 should lay down more clearly what requirement Member must fulfil to be granted official BSE risk status.

Rather to be implied, the prevention of feeding ruminants with ruminants derived protein meal should explicitly be laid down as a requirement to obtain official BSE risk status.

Article 11.4.2 does not fully cover this issue. Article 11.4.2 provides that the exposure assessment should involve an evaluation of the impact of livestock industry practices on preventing cattle from being fed ruminant-derived protein meal, and where relevant, an evaluation the impact of specific risk mitigation measures on preventing cattle from being fed ruminant-derived protein meal. However, this Article does not explicitly lay down that the exposure assessment should result in demonstrating that ruminants have not been fed with ruminants derived protein meal.

Additionally, the EU considers that the implementation of a feed ban, as mentioned in Article 11.4.2. b) ii), should be a mandatory risk mitigation measure in countries where livestock industry practices do not prevent cattle from being fed with ruminant-derived protein meal.

Indeed, the EU considers that there is no alternative risk mitigation measures in this case to ensure that the risk of recycling is negligible. Additionally, the EU considers that it is important to keep the feed ban as an explicit requirement in the BSE chapter of the OIE Code, as Members' knowledge and awareness of the aim and the value of such a measure will diminish over time.

The EU suggests the following amendment:

"A risk assessment as described in Article 11.4.2. that has identified all potential risk factors associated with the occurrence of BSE has been conducted, and the Member Country has demonstrated through documented evidence that the risk of BSE agents being recycled in within the cattle population has been negligible, <u>as the result of:</u>

<u>EITHER:</u>

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

In countries where livestock industry practices do not prevent cattle from being fed with ruminant-derived protein meal, the specific risk mitigation measures presented in the risk assessment described in Article 11.4.2. should include a feed ban."

2) The *surveillance* provisions as described in Article 11.4.~~20~~18. have been implemented.

3) EITHER:

a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported or has been diagnosed as atypical BSE as defined in this chapter;

OR

b) if there has been an indigenous *case* of classical BSE:

~~EITHER~~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 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 and the ~~likelihood~~risk of BSE agents being recycled within the cattle population has continued to be negligible.

EU comment

The EU considers that the word "mitigated", which is usually translated into French as "atténué", is too weak. The EU suggests to replace "mitigated" by "suppressed", "removed", "controlled" or "brought under control".

4) Any *cases* of BSE that have been detected have been completely destroyed or disposed of to ensure that they do not enter the animal *feed* chain.

The country or the *zone* will be included in the list of countries or *zones* posing a negligible risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1 to 4 above. Documented evidence should be resubmitted annually for points 1 to 4 above.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

Article 11.4.3bis.

Recovery of negligible BSE risk status

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

EU comment

The approach should be consistent with the one in Article 11.4.2.

The EU suggests the following amendment:

"Should an indigenous case of classical BSE in an animal born ~~within the preceding eight years~~ after the date from which the risk of BSE agents being recycled within the cattle population has been negligible occur in a country or zone recognised as posing a negligible risk for BSE, the status of the country or zone is suspended."

In addition, please consider adding in this Article a provision stating that "the date from which the risk of BSE agents being recycled within the cattle population has been negligible" should be re-assessed taking into account the outcomes of the investigations on the source of infection.

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 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.

EU comment

The EU thanks the OIE to have amended this paragraph as requested.

~~Article 11.4.6.~~

~~**Recommendations for importation of cattle from a country, zone or compartment posing a negligible BSE risk**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that cattle selected for export came from a country, *zone* or *compartment* posing a negligible BSE risk.~~

Article 11.4.7.

Recommendations for importation of cattle from a country, zone or compartment posing a negligible or controlled BSE risk

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

1) theThe cattle selected for export:

1) came from a country, *zone* or *compartment* posing a negligible or controlled BSE risk and are identified through an *animal identification system* enabling each *animal* them to be traced throughout its their lifetime;.

AND EITHER:

2) theThe cattle 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 likelihoodrisk of the BSE agents being recycled in within the cattle population has been demonstrated to be negligible;.

EU comment

The EU thanks the OIE to have amended this Article, as well as Articles 11.4.10. , 11.4.12 and 11.4.13, as regards to take into account all the places where an animal has been kept before the export.

The EU suggests to harmonise the amendment introduced in this Article with the ones introduced in Articles 11.4.10. , 11.4.12 and 11.4.13, and delete "come from a country, zone or compartment posing a negligible or controlled BSE risk" in the first indent. Indeed, the title of the Article already provides that the requirement apply to cattle coming from country, zone or compartment posing a negligible or controlled BSE risk.

The EU suggests the following amendment:

"1) The cattle selected for export came from a country, zone or compartment posing a negligible or controlled BSE risk and are identified through an animal identification system enabling them to be traced throughout their lifetime;

AND EITHER

2) The cattle selected for export were born and kept in a country, zone or compartment posing a negligible or controlled BSE risk after the date from which the risk of BSE agents being recycled within the cattle population has been demonstrated to be negligible;."

OR

3)

a) are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime; and

b) are it It is demonstrated as havingthat the cattle selected for export have not been fed protein meal derived from ruminants.

Article 11.4.8.

Recommendations for importation of cattle from a country 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) theThe cattle selected for export are identified by a permanent individual through an *animal identification system* from birth enabling each *animal* them to be traced throughout its their lifetime;.

2) ~~are~~it ~~It~~ is demonstrated ~~as having~~ that the cattle selected for export have not been fed protein meal derived from ruminants.

~~Article 11.4.9.~~

~~**Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a negligible BSE risk**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the cattle from which the *fresh meat* and *meat products* were derived:~~

~~1) came from a country, *zone* or *compartment* posing a negligible BSE risk;~~

~~2) have been subjected to an ante-mortem inspection with favourable results.~~

Article 11.4.10.

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

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

1) the cattle from which the *fresh meat* and *meat products* were derived ~~came from a country, *zone* or *compartment* posing a controlled BSE risk~~negligible or controlled BSE risk and are identified through an *animal identification system*;

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;

EU comment

The EU thanks the OIE to have amended this paragraph as suggested.

OR

4) the *fresh meat* and *meat products*:

   a) derived from cattle not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to *slaughter*; and

   b) were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

      i) the *commodities* listed in point~~s~~ 1~~) a) and 1) *b)*~~ of Article 11.4.14.;

      ii) mechanically separated *meat* from the skull ~~and~~nor or from the vertebral column ~~from~~ of cattle over 30 months of age.

Article 11.4.11.

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

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

1) the cattle from which the *fresh meat* and *meat products* were derived~~:~~

~~a)~~ are identified through an *animal identification system*;

2) it is demonstrated ~~as having~~that the cattle from which the *fresh meat* and *meat products* were derived have not been fed protein meal derived from ruminants;

~~b~~3) the cattle from which the *fresh meat* and *meat products* were derived:

a) were subjected to an ante-mortem inspection with favourable results;

~~c~~b) were not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to *slaughter*;

~~2~~4) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

a) the *commodities* listed in point~~s~~ 1~~)~~ ~~*a) and 1) b)*~~ of Article 11.4.14.;

b) mechanically separated *meat* from the skull ~~and~~nor or from the vertebral column ~~from~~ of cattle over 30 months of age.

Article 11.4.12.

Recommendations for importation of cattle-derived protein meal from a country, zone or compartment posing a negligible BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the cattle from which the protein meal was derived ~~came from a country, *zone* or *compartment* posing a negligible BSE risk. 1) came from a country, *zone* or *compartment* posing a negligible BSE risk;~~

2) were ~~are~~ identified through an *animal identification system* and were born and kept in ~~the~~ a country, *zone* or *compartment* posing a negligible BSE risk after the date from which ~~during the period when~~ the risk of ~~the~~ BSE agents being recycled ~~in~~ within the cattle population has been demonstrated to be negligible.

Article 11.4.13.

Recommendations for importation of blood and blood products derived from cattle (except ~~foetal~~ fetal blood)

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

EITHER:

~~1) the blood and blood products came from a country, *zone* or *compartment* posing a negligible or controlled BSE risk; and~~

~~OR~~

~~1~~2) the ~~blood and blood products came from a country, *zone* or *compartment* posing a controlled BSE risk and the~~ cattle 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

The EU thanks the OIE to have amended this paragraph as suggested.

OR

23) the blood and blood products were:

a) collected from cattle not subjected to a *stunning* process~~, or to any other procedure that can contaminate the blood with nervous tissue,~~ with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate the blood with nervous tissue, prior to *slaughter*; and

b) collected and processed in a manner that ensures they are not contaminated with nervous tissue.

Article 11.4.14.

Recommendations in relation to the trade of the commodities with the greatest BSE infectivity

~~1)~~ Unless covered by other articles in this chapter, the following *commodities* ~~originating from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk, and any *commodity* contaminated by them,~~ should not be traded ~~for the preparation of food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices~~:

~~a~~1~~)~~) ~~distal~~ Distal ileum from cattle of any age; ~~*b)*~~ skull, brain, eyes, vertebral column and spinal cord from cattle that were at the time of *slaughter* over 30 months of age~~.~~; or any *commodity* contaminated by them, for the preparation of protein products, food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices, which originate from a country, *zone* or *compartment* posing:

a) an undetermined BSE risk;

b) a controlled BSE risk or a negligible BSE risk if the *commodities* are derived from cattle born before the ~~period when~~ date from which the risk of ~~the~~ BSE agents being recycled ~~in~~ within the cattle population has been demonstrated to be negligible.

EU comment

The EU noted the position of the OIE to not insert "or death" in this paragraph.

2) Protein products, food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices prepared using *commodities* listed in point~~s~~ 1~~) *a)* or 1) *b)*~~ above ~~of this article, which originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk, should not be traded~~.

3) Cattle-derived protein meal~~,~~ or any *commodities* containing such product~~s~~~~,~~ which originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk~~, should not be traded~~.

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

Article 11.4.15.

Recommendations for importation of tallow (other than as defined in Article 11.4bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1) ~~the tallow~~ came from a country, *zone* or *compartment* posing a negligible BSE risk; or

2) ~~the tallow~~ is derived from cattle which have been subjected to an ante-mortem inspection with favourable results, and has not been prepared using the *commodities* listed in ~~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.

EU comment

The EU reiterates its comment that, in order to clarify that the expression 'that uses high temperature and pressure' only applies to the transesterification process, point 3 should be amended as follow:

'3) have been produced by hydrolysis, saponification, or by transesterification that uses high temperature and pressure.' "

Please note that Annex 7 of the report of the meeting of the OIE Scientific Commission for animal diseases of September 2021, p.58, provides that "The Group suggested a minor amendment in Point 3 of this Article to improve clarity.", while point 3 has not been amended in the present version. Additionally, this comment is not addressed in the report of the Code Commission meeting held in September.

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 protein meal

The following procedure should be used to reduce the infectivity of any ~~transmissible spongiform encephalopathy~~BSE agents ~~which~~that may be present during the production of protein meal containing ruminant proteins~~.~~:

1) ~~T~~the raw material should be reduced to a maximum particle size of 50 mm before heating~~.~~;

2) ~~T~~the raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

Article 11.4.18.

Surveillance

~~1) *Surveillance* for BSE consists of the regular reporting of animals with clinical signs suggestive of BSE to the *Veterinary Authority* for subsequent investigation and diagnosis. The credibility of the *surveillance* programme is supported by:~~

~~a) compulsory notification of BSE throughout the whole territory by all those stakeholders involved in the rearing and production of livestock including farmers, herdsmen, *veterinarians*, transporters and *slaughterhouse/abattoir* workers;~~

~~b) an ongoing awareness programme to ensure that all stakeholders are familiar with the clinical signs suggestive of BSE as well as the reporting requirements;~~

~~c) appropriate *laboratory* investigations in accordance with the *Terrestrial Manual* and follow-up field investigation as necessary of all clinical suspects.~~

~~2~~1) BSE is a progressive, fatal disease of the nervous system of cattle that usually has an insidious onset and that is refractory to treatment. A range of clinical signs that vary in severity and between animals have been described for classical BSE:

a) progressive behavioural changes that are refractory to treatment such as increased excitability, depression, nervousness, excessive and asymmetrical ear and eye movements, apparent increased salivation, increased licking of the muzzle, teeth grinding, hypersensitivity to touch and/or sound (hyperaesthesia), tremors, excessive ~~vocalization~~vocalisation, panic-stricken response and excessive alertness;

b) postural and locomotory changes such as abnormal posture (dog sitting), abnormal gait (particularly pelvic limb ataxia), low carriage of the head, (~~head shyness~~), difficulty avoiding obstacles, inability to stand and recumbency;

c) ~~generalized~~generalised non-specific signs such as reduced *milk* yield, loss of body condition, weight loss, bradycardia and other disturbances of cardiac rhythm.

Some of these signs are also likely to be relevant for atypical BSE, particularly those associated with difficulty in rising and recumbency. A nervous form of atypical BSE resembling classical BSE may be observed with over-reactivity to external stimuli, unexpected startle responses and ataxia. In contrast, a dull form of atypical BSE may be observed, with dullness combined with a low head carriage and compulsive behaviour (licking, chewing, pacing in circles).

The clinical signs of BSE usually progress on a spectrum over a few weeks to several months, but ~~in~~on rare occasions cases can develop acutely and progress rapidly. ~~In the continuum of the disease spectrum, t~~The~~The~~ final stages of the disease are characterised by recumbency, coma and death.

~~Cattle displaying some of the above mentioned progressive neurological signs without signs of infectious illness, and that are refractory to treatment, are candidates for examination.~~

Since these signs are not pathognomonic for either classical or atypical BSE, all Member Countries with cattle populations ~~may~~ are likely to observe individual animals displaying clinical signs suggestive of BSE. ~~The rate at which they are likely to occur~~General statements about the likely frequency of occurrence of such animals cannot be ~~reliably predicted~~made as they will vary depending on the epidemiological situation in a particular country. ~~In addition, in~~

2) *Surveillance* for BSE consists of the reporting of all animals that ~~lie on the continuum of the~~ show ~~symptoms~~ signs of the clinical spectrum of BSE ~~spectrum~~ to the *Veterinary Authority* for subsequent investigation and follow-up.

In those countries where cattle are intensively reared and subjected to regular observation, it is likely that ~~such~~ animals that display clinical signs suggestive of BSE will be more readily seen. Behavioural changes, ~~that~~ 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 systems, however, where cattle are not monitored as closely, situations may ~~inevitably~~ arise where an animal might be considered as a clinical suspect, yet if it ~~was~~ 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* candidates should take into account that the vast majority of BSE *cases* 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 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:

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).

EU comment

The EU noted the position of the OIE to not amend point c) and d).

~~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.~~

EU comment

The report of the TAHSC provides that "*the Code Commission did not agree with a comment to delete 'all'* " in the text after point 2(d). Yet, the entire text after point 2(d) has been cut and pasted in the text before 2(a), with the exception of "All".

The EU suggest to re-insert "All" in the text before 2(a):

"~~T~~All the following animals that lie on the continuum of the disease clinical spectrum of BSE should be targeted for BSE surveillance and 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:"

Indeed, the EU acknowledges that this provision does not mean that all of these animals must be tested in laboratories, but considers that it is important to provide that all these animals must be targeted for surveillance, and where appropriate, tested.

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 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 candidates for BSE *surveillance*, for determination of animals to be subjected to laboratory testing, for the collection and submission of samples for laboratory testing, and for follow-up epidemiological investigation for BSE positive findings.

DRAFT CHAPTER 1.8.

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

EU comment

The EU thanks the OIE for the latest version of the revised Chapter 1.8.

The EU considers that the implementation of a feed-ban should be a mandatory risk mitigation measures in countries where livestock industry practices do not prevent cattle from being fed with ruminant-derived protein meal.

The EU reiterates that total transparency must be ensured on the criteria to determine and validate the "date from which the risk of BSE agents being recycled within the cattle population has been negligible". Therefore, the EU will follow very carefully the outcome of the BSE ad hoc Group from November 2021 on this issue, and the following discussion to be held in the next meeting of the Commission in February 2022.

Detailed comments are provided in the text below.

Article 1.8.1.

Guidelines

In accordance with Article 11.4.2., the bovine spongiform encephalopathy (BSE) risk of ~~the cattle (*Bos indicus* and *Bos taurus*) population of~~ a country or *zone* is determined on the basis of a *risk assessment* that evaluates the risk of BSE agents (classical and atypical) being recycled within the cattle (*Bos indicus* and *Bos taurus*) population by identifying all potential factors associated with the occurrence of BSE, the ongoing implementation of a *surveillance* programme, and the history of occurrence and management of BSE *cases*.

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

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:

– ~~T~~the history of occurrence and management of BSE *cases* in the country or *zone* (Article 1.8.2.)

– ~~L~~legislation (Article 1.8.3.)

– ~~V~~veterinary system (Article 1.8.4.)

– BSE risk assessment (Article 1.8.5.)

– BSE surveillance (Article 1.8.6.).

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

Article 1.8.2.

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

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

1) If a *case* of BSE has ever been diagnosed in the country or *zone*, indicate the total number of BSE *cases*, and:

   a) Provide a table of aggregated data on all *cases* of BSE encountered in the country or *zone*, by type (classical or atypical), origin (indigenous or, if imported, the country of origin), and the year of birth;

   b) For the past eight years, provide a table to indicate, for each *case*, the year of occurrence, the origin (indigenous or, if imported, the country of origin), the type (classical or atypical), and the year of birth of each indigenous *case* of classical BSE.

EU comment

The EU noted the position of the OIE to not delete the second "indigenous" in point b), considering that the information on the year of birth for each imported case of classical BSE does not provide added value in terms of BSE risk assessment.

However, the EU considers that the year of import of imported cases of classical BSE would provide added value in terms of BSE risk assessment, e.g. to determinate where the contamination occured. Therefore, the EU would like to suggest to following amendment:

"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 (or, if imported, the year of import) of classical BSE".

2) If there have been *cases* of BSE, confirm that they were excluded from the *feed* chain and describe how this was achieved. In the table under Article 1.8.3. provide details of the national legislation, regulations and *Veterinary Authority* directives that describe these procedures.

Article 1.8.3.

Legislation

Provide a table listing all relevant legislation, regulations, *Veterinary Authority* directives, legal instruments, rules, orders, acts, decrees, etc., related to BSE. For each, provide the date of promulgation and implementation as well as a brief description of the relevance to mitigating ~~against~~ the risks associated with BSE. The table should include the legislation, regulations and directives referred to in the core document of the dossier. These instruments may be provided as annexes or as weblinks to supporting documents.

Article 1.8.4.

Veterinary system

The quality of the *Veterinary Services* of a Member is important to the establishment and maintenance of confidence in its *international veterinary certificates* by the *Veterinary Services* of other Members (Article 3.2.1.). 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 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 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 identification, registration, *traceability* and movement control systems that provide guidance, set standards or provide third party audits; include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

Article 1.8.5.

BSE risk assessment

1~~.~~) Entry assessment

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

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

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

– ~~C~~cattle~~.~~;
– ~~R~~ruminant-derived protein meal~~.~~;
– ~~F~~*feed* (~~not intended for pets~~except packaged and labelled pet food) that contains ruminant-derived protein meal~~.~~;
– ~~F~~fertilizers that contain ruminant-derived protein meal~~.~~;
– ~~A~~any other *commodity* that either is or could be contaminated by *commodities* listed in Article 11.4.14.~~, e.g. over 30 months old cattle carcass or half carcass from which the spinal cord and vertebral column were not removed, originating from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk.~~

a) For each *commodity* listed above indicate ~~if~~ whether they were imported in the preceding eight years, and if so, from which countries.

For each *commodity* listed above describe the import requirements applied by the applicant country or *zone* and how they are related to the BSE risk status of the *exporting country* or *zone* and whether or not they are consistent with, or provide an equivalent level of assurance ~~with~~ to, the recommendations laid out in Chapter 11.4. for the importation of such a *commodity*. Where the import requirements are not consistent with the recommendations in Chapter 11.4. but are considered to provide an equivalent level of assurance, provide an explanation outlining the rationale and supporting evidence. In situations where an import requirement does not provide an equivalent level of assurance to the relevant measure in Chapter 11.4., provide an explanation of how this is likely to impact the entry assessment.

Describe the importation process for these *commodities* and how are they controlled, regulated and monitored by the *Competent Authority* with references as appropriate to the relevant legislation in the table under Article 1.8.3. Provide supporting evidence of the importation process including, where relevant, import permits or their equivalent, and examples of *international veterinary certificates* issued by *exporting countries*.

Describe the intended end use of the imported *commodities*, for example: cattle 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 being exposed to the BSE agents either through imported *commodities* (classical BSE) or as a result of the presence of BSE agents (classical or atypical BSE) ~~in~~ within the indigenous cattle population of the country or *zone*.

EU comment

The exposure assessment should also evaluate the likelihood of cattle being exposed to the BSE agents as a result of the presence of BSE agents in imported cattle.

Therefore, the EU suggests the following amendment:

"As described in Article 11.4.2., an exposure assessment evaluates the likelihood of cattle being exposed to the BSE agents either through imported *commodities* (classical BSE) or as a result of the presence of BSE agents (classical or atypical BSE) within the ~~indigenous~~ cattle population of the country or zone".

For the purposes of undertaking an exposure assessment for the evaluation of BSE status, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.). At its discretion, the applicant Member may provide the information requested for a different period (i.e. longer than eight years for those applying for a negligible risk status, or for the ~~time~~ 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 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~~10., 11.4.12. ~~, and~~ 11.4.13. and 11.4.14.).

EU comment

The EU thanks the OIE for having amended the cross-references with Chapter 11.4, as suggested.

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 from being fed ruminant-derived protein meal and, depending on the outcome of this step, an evaluation of the impact of specific mitigation measures on preventing cattle from being fed ruminant-derived protein meal.

a) Livestock industry practices~~.~~

Because oral exposure to contaminated *feed* is the principal route of transmission of the BSE agents, the exposure assessment begins with a detailed description of the cattle population and associated industry practices, with a particular emphasis on: feeding practices; disposal of dead ~~stock~~ animals and waste from slaughtered animals; rendering; and production, distribution and storage of *feed* that may lead to cattle being exposed to potentially contaminated *feed*.

EU comment

The EU suggests the following amendment to include more explicitly the collection of by-products and derived products in the detailed description:

"Because oral exposure to contaminated feed is the principal route of transmission of the BSE agents, the exposure assessment begins with a detailed description of the cattle population and associated industry practices with a particular emphasis on feeding practices; disposal of dead animals and waste from slaughtered animals; collection of by-products and derived products ; ~~and~~ rendering; and production, distribution and storage of feed that may lead to cattle being exposed to potentially contaminated feed."

The intent of this section is not to describe the implementation and enforcement of measures specifically targeting the exposure of the cattle population to BSE agents (such as a legislated *feed* ban) as they will be considered where relevant in Section *b) An evaluation of BSE specific mitigation measures*. The intention here is to evaluate the likelihood and extent of exposure of the cattle population to the BSE agents, given the ongoing livestock industry practices in a country or *zone*.

i) Demographics of the cattle population and production and farming systems.

Describe the composition of the cattle population and how the cattle industry is structured in the country or *zone*, considering the types of production, ~~systems, including all that apply,~~ such as dairy, beef rearing, ~~feedlot, fattening~~ and beef finishing, and the farming systems, such as intensive, extensive, ~~semi-~~semi-intensive, transhumant, pastoral, agropastoral, and mixed-species farming. The description should include the number and size of *herds* ~~farms~~ in each type of production and farming system.

ii) Feeding practices.

For each type of production system, describe the rearing and production practices related to feeding ruminants of various ages, including the types of *feed* and *feed ingredients* (animal or plant based). Where animal-based ingredients are used, describe whether or not they are derived from rendered products of ruminant or non-ruminant origin as well as the respective proportions used.

Provide an indication of the proportion of the national *feed* production prepared commercially (including local mills) or mixed on farm using either imported or domestically produced ingredients.

Describe whether or not fertili~~z~~sers containing ruminant-derived protein meal, composted materials derived from fallen stock (i.e. cattle 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 graze or where forage is harvested for feeding to cattle. Where such fertili~~z~~sers 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 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 are slaughtered (for example, on farm, at a *slaughterhouse/abattoir* or *market*) together with the respective proportions and associated ages.

Describe whether or not places where animals are slaughtered are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Describe how animals condemned at ~~ante-~~ante-mortem inspection and waste declared as unfit for human consumption from slaughtered animals are processed, disposed of or destroyed, including composting, burial, rendering, incineration or other industrial uses such as salvaging and crushing bones for use in animal *feed*. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

iv) Rendering practices~~.~~

Rendering is a process by which animal material is transformed into products such as protein meal that may be used in animal *feed*. It provides the pathway for the introduction of the BSE agents (classical or atypical) into the animal feed chain.

Describe whether or not there are any rendering facilities in the country or *zone*, if they are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Using tables as appropriate, for each of the preceding eight years, provide a breakdown of the number of rendering facilities operating, indicating for each facility:

– the source and types of raw materials handled;

– whether or not they receive and process material from a particular species or process mixed materials including those derived from ruminants;

– whether or not ruminant waste is segregated from non-ruminant waste and if so how segregation is maintained to avoid potential cross-contamination of non-ruminant rendered materials during processing, storage and transport of rendered products, for example through dedicated lines, storage bins or silos, transport vehicles or establishments;

– the parameters of the rendering process (time, temperature, pressure, etc.);

– the type and intended end use of 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 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 *Competent Authority*.

v) Feed production, labelling, distribution and storage~~.~~

Where rendered products are used as ingredients in the production of animal *feed* the exposure of cattle to the BSE agents (classical and atypical) may arise as a result of the use of rendered products containing materials of ruminant origin as ingredients in cattle *feed* or as a result of cattle *feed* being cross-contaminated when such products are used in the production of *feed* for other species.

Describe whether ~~or not~~ facilities producing *feed* for ruminant or non-ruminant livestock as well as pets are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

EU comment

The EU suggests the following amendment in order to clarify which facilities are referred to (the current wording could suggest that only mixed facilities are concerned):

"Describe whether facilities producing feed, in particular feed for ruminant livestock ~~or~~, for non-ruminant livestock ~~as well as~~, and for pets, are required to be registered or approved by the Veterinary Services or other Competent Authority and if they are subject to official veterinary control or supervision."

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 *Competent Authority*.

vi) Conclusions for livestock industry practices~~:~~

– Given the livestock industry practices described above, is the likelihood that the cattle population has been exposed to either classical or atypical BSE during the preceding eight years negligible or non-negligible?

– Clearly and concisely describe the rationale leading to the conclusion reached.

– Where the likelihood estimate is negligible, proceed to *Section 4) Risk 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~~.~~

EU comment

The EU considers that the implementation of a feed-ban should be a mandatory risk mitigation measures in countries where livestock industry practices do not prevent cattle from being fed with ruminant-derived protein meal.

The EU considers that there is no alternative risk mitigation measures in this case to ensure that the risk of recycling is negligible, as shown by the information requested in Section b), which almost exclusively relates to the implementation of a feed ban.

If the OIE disagrees, the EU kindly requests the OIE to provide examples of risk mitigation measures, which would be sufficient to ensure that the risk of recycling is negligible in these countries in absence of feed ban.

The EU suggests therefore the following amendments in section b)

"For those countries that have reported classical BSE cases in indigenous cattle, it is apparent that their historic livestock industry practices did not prevent the recycling of the BSE agent in within their cattle populations. These countries, together with others

whose livestock industry practices would have been conducive to recycling, ~~may have~~ must 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 measures specifically targeting BSE have been and continue to be effectively implemented and enforced.

i) The nature and scope of a feed ban.

~~Indicate if whether there is a ban on feeding ruminants with protein meal derived from ruminants.~~

~~Where a feed ban has been implemented, c~~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."

"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:"

"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:"

For those countries that have reported classical BSE *cases* in indigenous cattle, it is apparent that their historic livestock industry practices did not prevent the recycling of the BSE agent ~~in~~ within their cattle population~~s~~. These countries, together with others whose livestock industry practices would have been conducive to recycling~~,~~ may have implemented specific measures, such as through a legislated *feed* ban~~,~~ to ensure that the likelihood of recycling would be negligible. To qualify for official recognition of a BSE risk status, these countries need to demonstrate that the measures specifically targeting BSE have been and continue to be effectively implemented and enforced.

i) The nature and scope of a feed ban~~.~~

Indicate ~~if~~ whether there is a ban on feeding ruminants with protein meal derived from ruminants.

Where a *feed* ban has been implemented, clearly and concisely describe the date it was introduced, its nature and scope and how it has evolved over time.

In addition, if the *feed* ban has been implemented through national legislation, provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

ii) Commodities with the greatest BSE infectivity~~.~~

Indicate whether ~~or not~~ any of those *commodities* listed in point 1 of Article 11.4.14. are removed from the carcass at the time of *slaughter* or subsequent fabrication or processing.

If so, also:

– Describe how they are disposed 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 *Competent Authority*.

EU comment

The EU thanks the OIE for the clarification provided in these indents.

In addition, if there is specific national legislation concerning the definition, identification, removal and disposal or destruction of those *commodities* listed in point 1 of Article 11.4.14., provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

iii) Parameters of the rendering process~~:~~

Describe whether or not the parameters of the rendering process are prescribed in legislation and if they are consistent with, or provide an equivalent level of assurance to, the procedures for the reduction of BSE infectivity in ruminant-derived protein meal as described in Article 11.4.17. Provide details of the legislation, if applicable, in the table under Article 1.8.3.

iv) Cross-contamination~~:~~

Describe the measures in place to prevent cross-contamination during rendering, *feed* production, transport, storage and feeding such as dedicated facilities, lines and equipment, as well as measures to prevent misfeeding, such as the use of warning labels. Provide information as to whether any of these measures are prescribed in legislation and if facilities involved in rendering and *feed* production are required to be registered or approved under the *feed* ban by the *Veterinary Services* or other *Competent Authority*.

v) Awareness programme under the scope of the feed ban~~:~~

Provide information on the existence of any ongoing awareness programmes or other forms of guidance given to all those stakeholders involved in rendering, *feed* production, transport, storage, distribution, sale and feeding under the scope of the *feed* ban. Provide examples of communication materials including publications, brochures and pamphlets.

vi) Monitoring and enforcement of the feed ban~~:~~

Describe how the *feed* ban, if implemented, has been and continues to be monitored and enforced. Provide information on:

- official oversight from the *Veterinary Authority*, other *Competent Authority* or an *approved* third party;
- training and accreditation programmes for inspectors;
- the planned frequency of inspections~~,~~ and the procedures involved including manuals and inspection forms;
- sampling programmes and *laboratory* testing methods used to check the level of compliance with the *feed* ban and cross-contamination;
- options available to deal with infractions (non-compliance~~s~~) such as recalls, destruction and monetary penalties.

Provide information on the ongoing results of the official inspection programme for each of the preceding eight years~~.~~, using tables as appropriate:

- planned *versus* actual delivery inspections at rendering facilities, *feed* mills, farms, etc., with an explanation of any significant ~~variance~~ variation and how ~~they~~ it may have impacted the programme;
- number and type of samples taken during inspections to verify that ruminant *feed* does not contain or is not ~~cross~~ cross-contaminated with rendered products containing ruminant material (excluding those listed in Article 11.4.1bis.). Provide information by year, by source (rendering facility, *feed* mill or farm), indicating the *laboratory* test(s) used and the results obtained;
- the types of infractions (non-compliance) that occurred and corrective actions undertaken;
- any infractions (non-compliance~~s~~) that were likely to have led to cattle being exposed to *feed* contaminated with ruminant material (excluding those listed in Article 11.4.1.bis) and how they were resolved.

vii) Conclusions for the evaluation of ~~BSE~~ BSE-specific risk mitigation measures~~.~~

- In evaluating the effectiveness of a *feed* ban, if implemented, for each of the preceding eight years, consideration needs to be given to:
  - the management of *commodities* listed in point 1 of Article 11.4.14., and the associated likelihood that these materials, or other materials ~~cross~~ cross-contaminated by them, may have entered the animal feed chain;
  - the rendering industry and the associated likelihood that rendered products containing ruminant material may retain BSE infectivity;
  - the *feed* industry, and the associated likelihood that *feed* for cattle may contain or has been cross-contaminated with ruminant-derived 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 population has been exposed to either classical or atypical BSE negligible or non-negligible?
- Clearly and concisely describe the rationale leading to the conclusion reached.
- Where the likelihood estimate is negligible, proceed to *Section 4) Risk estimation*.
- Where the likelihood estimate is non-negligible, proceed to *Section 3) Consequence assessment*.

3~~.~~) Consequence assessment

While uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated *feed*, it is reasonable to assume for the purposes of a consequence assessment, that the likelihood of cattle becoming infected would be similar to that for classical BSE.

As described in Article 11.4.2., a consequence assessment evaluates the likelihood of cattle becoming infected following exposure to the BSE agents (classical or atypical) together with the likely extent and duration of any subsequent recycling and amplification.

For the purposes of undertaking a consequence assessment for the evaluation of BSE risk status, the period of interest is the preceding eight years.

Considering that, for all practical purposes, oral exposure to contaminated *feed* is the principal, if not the only, route of transmission of the BSE agents, to initiate a cycle of BSE infectivity within a cattle population the following series of events would need to unfold:

- *commodities* listed in point 1 of Article 11.4.14. from an infected animal are included in raw materials that are rendered into ruminant-derived protein meal;
- the rendering process does not destroy infectivity of the BSE agent(s);
- the ruminant-derived protein meal is incorporated as an ingredient in cattle *feed*, or cattle *feed* is cross-contaminated during *feed* production, distribution and storage, or cattle are incorrectly fed with *feed* intended for non-ruminant species that includes the ruminant-derived protein meal as an ingredient;
- one or more animals that ingest contaminated *feed* become infected;

– the infected animal survives long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically;

– *commodities* listed in point 1 of Article 11.4.14. are then included in raw materials that are rendered into ruminant-derived protein meal, completing one cycle.

Recycling arises when this cycle is repeated one or more times. Any level of recycling within a given period is sufficient to conclude that the consequences of exposure to contaminated *feed* for that period within the cattle population are non-negligible.

a) Factors to consider when evaluating the likely extent of recycling of the BSE agents within a cattle population:

i) Age at exposure~~.~~

Animals less than 12 months of age are considered to be much more susceptible to *infection* than older animals, which are likely to be increasingly refractory to *infection* as they mature.

ii) Production type~~.~~

– Calves reared as replacement animals for the breeding herd~~.~~

Cattle exposed to BSE agents at less than 12 months of age and destined to enter the breeding *herd* are much more likely to become infected and survive long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically. If these materials were rendered and subsequently contaminated cattle *feed*, it is highly likely that some level of recycling would occur.

– Feedlot cattle~~.~~

Even if cattle reared in a feedlot that were destined to be slaughtered within the next two to six months were to become infected after consuming contaminated *feed*, the likelihood that they would have reached the later stages of a protracted incubation period (when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically) would essentially be negligible.

Considering that mature cattle are likely to be much more refractory to *infection* than animals within their first year of life, even if they were to consume contaminated *feed*, it is highly unlikely that those *commodities* listed in point 1 of Article 11.4.14. would pose a threat if they were rendered and subsequently contaminated cattle *feed*.

iii) The impact of livestock industry practices or the implementation of measures under a *feed* ban~~.~~

When evaluating the potential for the recycling of the BSE agents ~~in~~ within the cattle population where an infraction (non-compliance) has occurred that may have led to *feed* being ~~cross~~ contaminated, it is important to consider the impact of both the livestock industry practices and the ongoing measures under a *feed* ban. Even if an infraction that arose several years ago led to susceptible young animals becoming infected, in evaluating the likelihood of recycling in future years, consideration would need to be given to the effectiveness of the *feed* ban in subsequent years or whether or not any changes to livestock industry practices may have influenced the exposure risk.

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 population has been exposed to the BSE agents, what is the likelihood that they have been recycled within the cattle population during the preceding eight years?

Clearly describe the rationale leading to the conclusions reached.

4~~.~~) 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 BSE agents ~~have been~~ being recycled ~~in~~ within the cattle population ~~through the feeding of ruminant-derived protein meal~~.

a) Provide a summary of the entry and exposure assessments and the conclusions reached.

b) If applicable, provide a summary of the consequence assessment, and the conclusions reached.

c) ~~When the condition of point 1 of Article 11.4.3. has not been met, that is, it cannot be demonstrated that for at least eight years the risk that the BSE agents have been recycled in the cattle population has been negligible, provide an explanation for the period of time within the preceding eight years for which it can be considered that the risk has been negligible. Clearly~~ Indicate the ~~period of time for~~date from which it can be considered that the risk of BSE agents being recycled ~~in~~ within the cattle population has been negligible. Provide explanations and clearly describe the rationale leading to the conclusions reached.

Article 1.8.6.

~~BSE s~~Surveillance

Article 11.4.18. describes the criteria that underpin a credible *surveillance* programme, together with an overview of the range and progression of clinical signs that cattle affected by BSE are likely to exhibit.

Requirements under point 2 of Article 11.4.18. are focused on subsets of the cattle population where ~~disease~~ 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 (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 the date of implementation of any supporting legislation and associated policies making notification of BSE compulsory. Indicate if a definition for a ~~"~~"BSE suspect~~"~~" exists. If appropriate, outline relevant legislation in the table under Article 1.8.3.

b) Describe the supportive measures in place for notification of animals that ~~lie on the continuum~~ show ~~symptoms~~ signs of the clinical ~~BSE~~ spectrum of BSE, 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 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 reporting 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* in the country or *zone* for testing, or if suspicious or positive samples are referred to ~~a *laboratory*~~ *laboratories* outside the country, provide the names of the *laboratories* in other countries providing the service, as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

c) Describe the diagnostic protocol and tests used for processing samples for classical and atypical BSE and how they may have evolved over time, indicating: ~~what is~~ the primary test used~~?~~; ~~what would be~~ the series of secondary tests performed, if any, depending on the results of the primary test (i.e. negative, positive and inconclusive)~~?~~; and what test would be undertaken if discordant results arise between primary and secondary tests ~~arise~~ (e.g. primary positive result followed by a secondary negative result)~~?~~.

4.) Evaluation procedures and protocols to identify and report potential candidates for BSE surveillance, to determine animals to be subjected to laboratory testing, to collect and submit samples for laboratory testing, and to follow up 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 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, *animal handler*, *veterinarian*, etc.)~~,~~; (2) the criteria to determine which of these reported animals need to be tested for BSE (e.g. the criteria used by the *veterinarian* that allows the discrimination of reported animals subject to laboratory testing)~~,~~; (3) the collection and submission of samples for testing in a laboratory~~,~~; and (4) a follow-up epidemiological investigation for BSE positive findings.

EU comment

The EU noted the position of the OIE on the investigation of atypical BSE cases.

It is important that appropriate procedures and protocols are in place to ensure that BSE can be definitively ruled out on the list of differential diagnoses.

a) List the common cattle disorders with clinical signs compatible with BSE in the country or *zone*. If available, provide the incidence/prevalence of these disorders, ideally by production system (e.g. dairy, beef) and by age group.

b) Describe the procedures and protocols in place for reporting animals potentially ~~lying on the continuum~~ 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 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 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 displaying progressive behavioural or neurological signs suggestive of BSE that are refractory to treatment		
(B) Cattle showing behavioural or neurological signs that did not pass the ante-mortem inspection at slaughterhouses/abattoirs		
(C) Cattle presented as downers (non-ambulatory) with an appropriate supporting clinical history		
(D) Cattle found dead (fallen stock) with an appropriate supporting clinical history		

EU comment

The EU noted the position of the OIE to not harmonise the wording of points (C) and (D) with the one used in Article 11.4.18.

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 the time of reporting ~~first detection~~	Type of production system (dairy, beef, mixed, etc.)	Description of observed clinical signs	Clinical presentation (A, B, C or D)	Final diagnosis (if BSE, specify the strain)	For a BSE case, indicate the origin (indigenous or imported; if imported, indicate the country of birth)

EU comment

The EU thanks the OIE for clarifying that information specified in Articles 1.8.2. to 1.8.6. should be provided by Members who apply for official recognition of BSE risk status, and is different from the information that should be provided as part of the annual reconfirmation process.

Article 1.8.7.

Recovery of BSE risk status

Following the occurrence of an indigenous *case* of classical BSE in an animal born within the preceding eight years in a country or *zone* with a negligible BSE risk status ~~of a country or *zone*~~, the outcome of the investigation together with any additional measures implemented that confirm or ensure that the risk of BSE agents being recycled within the cattle population continues to be negligible should be provided with reference to the provisions in Article 1.8.5. as appropriate. Information in relation to other sections need to only be supplied if relevant.

CHAPTER 11.10.

INFECTION WITH *THEILERIA ANNULATA*, *T. ORIENTALIS* AND *T. PARVA*

EU comment

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

One comment is inserted in the text below.

Article 11.10.1.

General provisions

Animals susceptible to *infection* with *Theileria* are bovines (*Bos indicus*, *B. taurus* and *B. grunniens*), water buffaloes *(Bubalus bubalis)*, African buffaloes *(Syncerus caffer)*, sheep *(Ovis aries)*, goats *(Capra hircus),* camels (*Camel dromedarius* and *C. bactrianus)* and some *wild* ruminants.

Infection with *Theileria* can give rise to disease of variable severity and to *Theileria* transmission. *Theileria* may persist in ruminants for their lifetime. Such *animals* are considered carriers.

For the purposes of the *Terrestrial Code*, *infection* with *Theileria annulata*, *T. orientalis* and *T. parva* ~~are~~ is defined as a tickborne *infection* of bovines and water buffaloes with *T. annulata, T. orientalis* Ikeda, *T. orientalis* Chitose and *T. parva*.

For the purposes of this chapter, *Theileria* means *T. annulata, T. orientalis* Ikeda, *T. orientalis* Chitose and *T. parva.*

The following defines the occurrence of *infection* with *Theileria*:

1) *Theileria* has been identified in a sample from a bovine or water buffalo; or

2) antigen or nucleic acid specific to *Theileria* has been identified in a sample from a bovine or water buffalo showing clinical signs consistent with *infection* with *Theileria*, or epidemiologically linked to a suspected or confirmed *case*, or giving cause for suspicion of previous association with *Theileria*; or

3) antibodies specific to *Theileria* have been detected in a sample from a bovine or water buffalo that either shows clinical signs consistent with *infection* with *Theileria*, or is epidemiologically linked to a suspected or confirmed *case* or giving cause for suspicion of previous association with *Theileria*.

EU comment

The EU suggests inserting the words "<u>, that are not a consequence of vaccination,</u>" after "antibodies specific to Theileria", for consistency with other case definitions in the Code.

For the purposes of the *Terrestrial Code*, the *incubation period* for *infection* with *Theileria* shall be 35 days.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 11.10.2.

Safe commodities

When authorising the import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Theileria*-related conditions regardless of the *infection* with *Theileria* status of the *animal population* of the *exporting country*:

1) *meat* and *meat products*;

2) *casings*;

3) *milk* and *milk products*;

4) gelatine and collagen;

5) tallow;

6) semen and embryos;

7) hooves and horns;

8) bones.

Article 11.10.3.

Country or zone free from infection with *Theileria*

1) A country or a *zone* may be considered free from *infection* with *Theileria* when the disease is notifiable in the entire country, importation of bovines and water buffaloes and their *commodities* is carried out in accordance with this chapter, and:

   a) the country or *zone* is historically free as described in Article 1.4.6.; or

   b) a *surveillance* programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with *Theileria* in the country or *zone* for at least two years; or

   c) an ongoing *surveillance* programme in accordance with Chapter 1.5. has found no competent tick *vectors* for at least two years in the country or *zone*.

2) A country or *zone* free from *infection* with *Theileria* in which ongoing *vector surveillance*, performed in accordance with Chapter 1.5., has found no competent tick *vectors* will not lose its free status through the introduction of vaccinated, test-positive or infected bovines or water buffaloes from infected countries or *zones*.

3) A country or *zone* free from *infection* with *Theileria* will not lose its status as a result of introduction of seropositive or vaccinated bovines, water buffaloes or their *commodities*, provided they were introduced in accordance with this chapter.

Article 11.10.4.

Recommendations for importation from countries or zones free from infection with *Theileria*

For bovines and water buffaloes

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

1) showed no clinical sign of *infection* with *Theileria* on the day of shipment;

2) come from a country or *zone* free from *infection* with *Theileria*.

Article 11.10.5.

Recommendations for importation from countries or zones not free from infection with *Theileria*

For bovines and water buffaloes

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

1) showed no clinical sign of *infection* with *Theileria* and no *infestation* with tick *vectors* on the day of shipment;

2) were kept isolated for at least 35 days prior to shipment, in an e*stablishment* where no *case* of *infection* with *Theileria* has occurred during the preceding two years;

3) were treated with a registered acaricide, the efficacy of which has been confirmed in relation to the area of origin of the *animals*, at the ~~entrance~~ time of entry into ~~of~~ the isolation *establishment* and then at regular intervals, according to manufacturer's instructions, allowing continuous protection against ticks until their shipment ~~48 hours prior to entry to the *establishment*, no more than two days after entering the *establishment* and three days prior to shipment~~;

4) were subjected to serological and agent detection tests with negative results on samples taken immediately prior to ~~on~~ entry and at least 25 days after entry into~~to~~ the isolation *establishment*~~and five days before shipment~~.

Article 11.10.6.

Recommendations for importation of hides and skins from countries or zones not free from infection with *Theileria*

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

1) dry-salted or wet-salted for a period of at least 14 days prior to dispatch; or

2) treated for a period of at least seven days in salt (NaCl) with the addition of 2% sodium carbonate (Na_2CO_3); or

3) dried for a period of at least 42 days at a temperature of at least 20°C; or

4) frozen to at least -20°C for at least 48 hours.

Article 11.10.7.

Recommendations for importation of trophies derived from susceptible ~~wild~~ ruminants from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products have been processed to ensure the destruction of tick *vectors*.

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY THE OIE

EU comment

The EU supports the proposed changes to this chapter.

[…]

Article 1.3.2.

The following are included within the category of cattle diseases and *infections*:

– Bovine anaplasmosis
– Bovine babesiosis
– Bovine genital campylobacteriosis
– Bovine spongiform encephalopathy
– Bovine viral diarrhoea
– Enzootic bovine leukosis
– Haemorrhagic septicaemia
– Infection with lumpy skin disease virus
– Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)
– Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
– ~~Theileriosis~~ Infection with *Theileria annulata*, *Theileria orientalis* and *Theileria parva*
– Trichomonosis.

[…]

CHAPTER 11.11.

TRICHOMONOSIS

EU comment

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

Article 11.11.1.

General provisions

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 11.11.2.

Recommendations for the importation of cattle for breeding

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

1) the animals showed no clinical sign of trichomonosis on the day of shipment;

2) the animals were kept in a *herd* in which no *case* of trichomonosis has been reported; ~~and/or~~

3) ~~for~~ females which have been mated~~, direct microscopic examination and culture of vaginal mucus were negative~~ were subjected to a~~n~~ test for the detection of the agent ~~identification test~~ with a negative result~~s~~.

Article 11.11.3.

Recommendations for the importation of bulls for breeding (natural service or artificial insemination)

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

1) the animals showed no clinical sign of trichomonosis on the day of shipment;

2) the animals were kept in a *herd* in which no *case* of trichomonosis has been reported; ~~and/or~~

AND

3) the animals have never been used for natural service; or

4) the animals have only mated virgin heifers; or

5) the animals were subjected to ~~a direct microscopic and cultural examination of preputial specimens~~ a~~n~~ test for the detection of the agent ~~identification test~~ with a negative result~~s~~.

Article 11.11.4.

Recommendations for the importation of bovine semen

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

1) the semen was collected, processed and stored in accordance with Chapter 4.6. and 4.7.;

AND

~~1~~2) the donor animals have never been used for natural service; or

~~2~~3) the donor animals have only mated virgin heifers; or

~~3~~4) the donor animals were kept in an *establishment* or *artificial insemination centre* where no *case* of trichomonosis has been reported~~;~~ and

~~4)~~ ~~the donor animals~~ were subjected to ~~a direct microscopic and cultural examination of preputial specimens~~ an test for the detection of the agent ~~identification test~~ with a negative result.~~;~~

~~5~~) ~~the semen was collected, processed and stored in accordance with Chapter 4.6. and 4.7.~~

TERMINOLOGY: USE OF THE TERM 'SANITARY MEASURE'

EU comment

The EU supports the proposed changes to these articles.

Article 4.15.6.

Conditions for sanitation and disinfection or disinfestation of apicultural equipment

Veterinary Authorities or other *Competent Authorities* of countries are requested to regulate the use of products and means for sanitation and *disinfection* or *disinfestation* of apicultural equipment in their own country, taking into account the following recommendations.

1) Any apicultural equipment kept in an *establishment* which has been recognised as being affected with a contagious disease of bees should be subjected to ~~*sanitary measures*~~ procedures ensuring the elimination of pathogens.

2) In all cases, these ~~measures~~ procedures comprise the initial cleaning of the equipment, followed by sanitation or *disinfection* or *disinfestation* depending on the disease concerned.

3) Any infested or contaminated equipment which cannot be subjected to the above-mentioned ~~measures~~ procedures should be destroyed, preferably by burning.

4) The products and means used for sanitation and *disinfection* or *disinfestation* should be accepted as being effective by the *Veterinary Authority* or other *Competent Authority*. They should be used in such a manner as to exclude any risk of contaminating the equipment which could eventually affect the health of bees or adulterate the products of the hive.

Article 6.3.3.

Hygienic practice throughout the meat production chain

The Codex Alimentarius Code of Hygienic Practice for Meat (CHPM) constitutes the primary international standard for *meat* hygiene and incorporates a *risk*-based approach to application of ~~*sanitary measures*~~ hygiene practices and sanitation throughout the *meat* production chain. Ante-mortem inspection is described as a primary component of *meat* hygiene before *slaughter*, and post-mortem inspection is described as a primary component of process control in post-slaughter *meat* hygiene. The CHPM specifically recognises the dual objectives that *slaughterhouse/abattoir* inspection activities deliver in terms of animal and public health.

The CHPM does not provide inspection measures for specific *hazards*, which remain the responsibility of national competent authorities. The animal and public health *risks* associated with livestock populations vary across regions and animal husbandry systems, and ante- and post-mortem inspection needs to be tailored to the individual country situation and its animal and public health objectives.

The CHPM provides a platform for development of *meat* hygiene systems that are based on *risk assessment*. There are few *risk assessment* models and little relevant scientific information available on public health *hazards* derived specifically from *animals* and their products, making difficult the development of *risk*-based standards for foodborne diseases and zoonoses. While this scientific information is being accumulated, ante- and post-mortem inspection systems will remain dependent on traditional approaches.

CHAPTER 8.8.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

EU comment

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

Comments are inserted in the text below.

Article 8.8.1.

General provisions

1) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with foot and mouth disease virus (FMDV). Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contacts between them. Amongst *Camelidae*, only Bactrian camels *(Camelus bactrianus)* are sufficiently susceptible to have potential for epidemiological significance. Dromedaries *(Camelus dromedarius)* are not susceptible to *infection* with FMDV while South American camelids are not considered to be of epidemiological significance.

2) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the ~~suborder *ruminantia* and of the~~ family *suidae* and the subfamilies *bovinae, caprinae* and *cervidae* of the order *Artiodactyla*, and *Camelus bactrianus* with FMDV.

EU comment

The EU does not support replacing the suborder ruminantia with subfamilies bovinae, caprinae, cervidae in point 2 above, as this means significantly narrowing down the list of species in the definition of FMD. Indeed, e.g. cervidae, giraffidae, antilocapridae and moschidae would no longer be included, although depending on the local circumstances and practices their epidemiological role may be significant.

In this regard, it should also be noted that the list of susceptible species in point 1 above is much wider, yet not clearly defined. This may be problematic, as e.g. Article 8.8.5bis recommends restrictions on movement of susceptible animals, but then these are not defined, and some may not be covered by the definition of FMD.

We would suggest clearly defining the species in both points 1 and 2 above, that should be aligned as much as possible, excluding from 2 only those species whose epidemiological role is not significant.

2bis) For the purposes of this chapter, 'cattle' means animals of the species *Bos taurus* or *Bos indicus*.

3) The following defines the occurrence of *infection* with FMDV:

a) FMDV has been isolated from a sample from an animal listed in point 2; or

b) ~~viral~~ antigen or ~~viral~~ ribonucleic acid specific to FMDV has been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or

c) antibodies to structural (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* of FMD, or giving cause for suspicion of previous association or contact with FMDV.

EU comment

In relation to the case definition in point 3 above, the EU notes that the Biological Standards Commission is proposing amendments to the corresponding Terrestrial Manual chapter, that have been circulated for member comments in October 2021, with a view to adoption in May 2022. As noted in the BSC report (Section 9.2.1.) and in the draft revised Manual Chapter 3.1.8., the presence of FMDV is confirmed by antigen or nucleic acid detection tests, while virus isolation is not essential. However, it will be essential to confirm the presence of FMDV following virus isolation by an antigen or nucleic acid detection test. Text is also being added in the Manual chapter concerning confirmation of a case of FMD. The EU encourages the Code Commission to closely coordinate with the BSC on this matter in order to avoid any possible inconsistency between the two standards.

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.

EU comment

The EU notes that transmission of FMDV in vaccinated animals would have consequences for the status of free from FMD with vaccination (point 1 a) of Article 8.8.3.). Point 4 above however is not entirely clear on whether such transmission of FMDV constitutes a case as defined in point 3 and would thus need to be notified to the OIE within 24 hours of detection. If that is the intention, the EU suggests reviewing the case definition in point 3 in order to make this very clear.

5) For the purposes of the *Terrestrial Code*, the *incubation period* of FMD shall be 14 days.

6) *Infection* with FMDV can give rise to *disease* of variable severity and to ~~FMDV~~ transmission of FMDV. FMDV may persist in the pharynx and associated lymph nodes of ruminants for a variable but limited period of time beyond 28 days after *infection*. Such animals have been termed carriers. ~~However,~~ The only persistently infected species from which transmission of FMDV has been proven is the African buffalo *(Syncerus caffer)*. However, transmission from this species to domestic livestock is rare.

~~7) This chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of *infection* with, FMDV and transmission of FMDV in the absence of clinical signs.~~

~~8~~7) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.8.1bis.

Safe commodities

When authorising import or transit of the following *commodities, Veterinary Authorities* should not require any type of FMD-related conditions, regardless of the FMD status of the *exporting country* or *zone*:

1) UHT *milk* and derivatives thereof;

2) *meat* in hermetically sealed container with a F_0 value of 3 or above;

3) ~~*meat* and bone meal and blood~~ *protein* meal;

4) gelatine;

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

Other *commodities* of susceptible species can be traded safely if in accordance with the relevant articles in this chapter.

Article 8.8.2.

~~FMD free~~ Country or zone free from FMD where vaccination is not practised

In defining a *zone* where *vaccination* is not practised the principles of Chapter 4.~~3~~4. should be followed.

Susceptible animals in the ~~FMD free~~ country or *zone* free from FMD, where *vaccination* is not practised should be protected by the application of *biosecurity* ~~measures~~ that prevents the entry of FMDV into the free country or *zone*.

Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*.

EU comment

The three paragraphs above should be deleted, for consistency with Article 8.8.3. and as these issues are now dealt with in the newly proposed Article 8.8.5bis.

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:

EU comment

The EU queries whether the reference to point 2 of Article 1.4.6. above automatically excludes countries having wild African buffalo populations, known to be persistently infected, from acquiring free status. Indeed, point 2(a)(iv) of Article 1.4.6. requires that "the infection or infestation is not known to be established in wildlife within the country or zone". If that is the case, the clause on African buffalo incursion at the end of this article will not work.

This is also relevant for Article 8.8.3.

~~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, habitat and indication of disease occurrence through passive *surveillance* of *wild* and *feral* susceptible animals in the country or *zone*;

EU comment

The EU questions the relevance and need to make it a prerequisite for free status that the Veterinary Authority has current knowledge of the distribution and habitat of wild and feral susceptible animals in the country or zone. The EU acknowledges that according to the report, the proposed new text of point 3 above was made as part of the harmonisation with recently adopted Chapters 14.7. and 15.2. However, Article 14.7.3. does not include a similar requirement. Point 3 in article 15.2.3. was made to harmonise Chapter 15.2. (CSF) with Chapter 15.1. (ASF). In Chapter 15.1., "the Veterinary Authority has current knowledge of the species of wild and feral pigs and African wild suids present, their distribution and habitat in the country or zone" is a point in Article 15.1.3. (the article on "General criteria for the determination of the ASF status of a

country, zone or compartment") and not in Article 15.1.4. (the article on "Country or zone free from ASF"). The unique situation in relation to ASF is that a country or zone can become free from ASF in domestic and captive wild pigs even though there are cases of infection with ASFV in feral or wild suids. In such a situation it is indeed relevant for the Veterinary Authority to have current knowledge of the species of wild and feral pigs and African wild suids present, their distribution and habitat in the country or zone. This is not the case in relation to FMD, where cases of infection with FMDV in feral or wild susceptible animals will mean that the free status is lost. The EU therefore suggests to delete point 3 of Article 8.8.2. and thereby harmonise the proposed text with the recently adopted chapter 14.7.

This comment is relevant also in relation to point 1 d) of Article 8.8.3. below.

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 does not support allowing the importation of vaccinated animals into a country or zone officially free of FMD where vaccination is not practised.

Indeed, removing the requirement to prohibit the entry of vaccinated animals into a country or zone officially free of FMD where vaccination is not practised is a significant change in the OIE Code and in the approach to OIE official status for FMD. As indicated in section 8.1.1. of the September 2021 meeting report of the Scientific Commission (*Taskforce on Chapter 8.8. 'infection with foot and mouth disease virus'*), importing vaccinated animals into an officially free country represents significant changes in the surveillance strategy of the importing country.

This, in practice, puts additional and significant burden (administrative, diagnostic and logistical) on the importing country to maintain its officially free status for FMD towards the OIE, 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).

Therefore, putting this additional burden in the importing country (which already undergoes significant surveillance and administrative requirements) to maintain its officially free status appears unjustified.

5) ~~d)~~ measures to prevent the introduction of the *infection* have been in place: in particular, the importations or movements of *commodities* into the country or *zone* have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*.: ~~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 a~~Animals introduced for direct *slaughter* in accordance with Articles 8.8.8., 8.8.9. and 8.8.11bis. ~~were~~ should be subjected to ante- and post-mortem inspections in accordance with Chapter 6.3~~2~~. ~~with favourable results~~. For ruminants the head, including the pharynx, tongue and associated lymph nodes, was either destroyed or treated in accordance with Article 8.8.31.;

EU comment

Editorial: in the paragraph above, it should be "8.8.9bis" (not "8.8.9.").

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 point~~s 1 to 4~~ ~~3~~ 4~~are~~ ~~is~~ are fulfilled, the status of a country or *zone* will not be affected by applying official emergency *vaccination* to FMD susceptible animals in zoological collections in the face of a FMD threat identified by the *Veterinary Authorities*, provided that the following conditions are met:

– the zoological collection has the primary purpose of exhibiting animals or preserving rare species, has been identified, including the boundaries of the facility, and is included in the country's contingency plan for FMD;

– appropriate *biosecurity* measures are in place, including effective separation from other susceptible domestic *population*s or *wildlife*;

– the animals are identified as belonging to the collection and any movements can be traced;

– the vaccine used complies with the standards described in the *Terrestrial Manual*;

– *vaccination* is conducted under the supervision of the *Veterinary Authority*;

– the zoological collection is placed under *surveillance* for at least 12 months after *vaccination*.

~~In the event of the application for the status of a new FMD free *zone* where *vaccination* is not practised to be assigned to a new *zone* being adjacent to another FMD free *zone* of the same status where *vaccination* is not practised, it should be stated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of animals between the *zones* of the same status in accordance with Chapter 4.3.~~

~~In the case of an incursion of stray African buffalo, a *protection zone* according to Article 4.4.6. should be established to manage the threat and maintain the free status of the rest of the country.~~

~~If A~~a ~~*protection zone* used is established, to preserve the *status* of a free country or *zone* from a newly identified likelihood of introduction of FMDV it should comply with Article 4.4~~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 may maintain its free status despite an incursion of African buffalo from a neighbouring infected country or *zone* provided that the relevant conditions are met and documented evidence has been submitted to and accepted by the OIE.

EU comment

The EU queries what the "relevant conditions" are that are being referred to in the paragraph above, and suggests either briefly mentioning them (e.g. "the surveillance programme substantiates the absence of transmission of FMDV"), or including a reference to the relevant article(s) in this chapter or to another text where these are specified (e.g. Chapter 1.11., or guideline). The EU considers that the text as proposed is unacceptable, as it is too vague for such an important exception. We would need to know exactly what the conditions are, before being in a position to decide whether or not to accept this new clause.

Furthermore, the EU suggests inserting the words "where vaccination is not practiced" after "free from FMD" in the first line of the paragraph above. This would prevent any possible confusion and clearly distinguish from the status described in Article 8.8.3. where this clause is not being suggested.

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, 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;

   f) *vaccination* has been carried out following appropriate vaccine strain selection;

g) measures to prevent the introduction of *infection* have been in place: in particular, the importations or movements of *commodities* into the country or *zone* have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*;

2~~3~~) for the past 24 months ~~supply documented evidence that~~:

a) appropriate *surveillance* ~~to detect clinical signs of FMD~~ has been implemented in accordance with Articles 8.8.40. to 8.8.42. ~~has been implemented to detect clinical signs of FMD for the past two years~~ and demonstrates points 1(a) and 1(b) above. ~~no evidence of that there has been no:~~

~~i) *infection* with FMDV in unvaccinated animals for the past two years 12 months;~~

~~ii) FMDV transmission of FMDV in vaccinated animals for the past 12 months;~~

~~b) regulatory measures for the prevention and early detection of FMD have been implemented for the past 12 months two years;~~

~~c) compulsory systematic *vaccination* in the target *population* has been carried out to achieve adequate *vaccination* coverage and population immunity for the past 12 months two years;~~

~~d) *vaccination* has been carried out following appropriate vaccine strain selection for the past 12 months two years;~~

~~4) describe in detail and supply provide documented evidence that for the past 12 months the following have been properly implemented and supervised:~~

~~a) in case of FMD free *zone*, the boundaries of the proposed FMD free *zone* have been established and effectively supervised;~~

~~b) the boundaries and *biosecurity* measures of any *protection zone*, if applicable have been established and effectively supervised;~~

~~c) the system for preventing the entry of FMDV into the proposed FMD free country or *zone*, in particular the measures described in Articles 8.8.8., 8.8.9. and 8.8.12. has been established and effectively supervised;~~

~~d) the control of the movement of susceptible animals and their products into the proposed FMD free country or *zone* has been effectively implemented and supervised.~~

The country ~~Member Country~~ or ~~the proposed free~~ *zone* will be included in the list of ~~FMD free~~ countries or *zones* free from FMD where *vaccination* is practised in accordance with Chapter 1.6.~~only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE~~.

Retention on the list requires annual reconfirmation of compliance with all points above and relevant provisions under point 4 of Article 1.4.6. Documented evidence should be resubmitted ~~that the information in points 2, 3 and 4 above be re-submitted~~ annually for all points above. ~~and~~ Any changes in the epidemiological situation or other significant events ~~including those relevant to points 3b) and 4~~ should be ~~reported~~ notified to 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 for the new status is not provided within 24 months then the status of the country or *zone* as being free with *vaccination* will be suspended. If the country does not comply with requirements of Article 8.8.2., evidence should be provided within three months that it complies with Article 8.8.3. Otherwise the status will be withdrawn.

EU comment

For reasons of clarity and consistency, the EU suggests amending the 3rd sentence of the paragraph above as follows:

"If the ~~dossier~~ application for the new status is not provided within 24 months, ~~then~~ the status of the country or zone as being free from FMD where ~~with~~ vaccination is practiced will be suspended.".

Furthermore, the last sentence of the paragraph above is unclear:

- the words "or zone" should be inserted after "If the country";

- clarification seems necessary as to what event the three months refer to (e.g. decision by OIE that the requirements of Article 8.8.2. are not complied with);

- finally, it is not clear how compliance with Article 8.8.3. can be demonstrated within 3 months (especially point 1(e), i.e. compulsory systematic vaccination has been carried out for the past 12 months [possible solution: cf. paragraph below that mentions "... that it complies with ... for this time period"]).

If a Member Country that meets the requirements of a country or *zone* free from FMD where *vaccination* is not practised and is recognised by the OIE as such, wishes to change its status to country or *zone* free from FMD where *vaccination* is practised, it should provide the OIE with an application and a plan following the structure of the Questionnaire ~~of Article 1.6.6., indicating the intended date of beginning of *vaccination*~~. The status as country or *zone* free from FMD where *vaccination* is not practised ~~of this country or *zone*~~ remains unchanged until the application and plan are approved by the OIE. As soon as recognised free with *vaccination* the country or *zone* will begin the *vaccination*. The Member Country should provide evidence within six months that it complies with Article 8.8.3. for this time period. Otherwise the status will be withdrawn.

EU comment

For reasons of clarity and consistency, the EU suggests amending the 3rd sentence of the paragraph above as follows:

"As soon as recognised free from FMD where ~~with~~ vaccination is practiced, the country or zone will begin the vaccination.".

~~If a country needs to define a *protection zone* in accordance with Article 4.34.6. in response to an increased risk, including by the application of *vaccination*, once a the *protection zone* has been approved by the OIE, the freedom of the rest of the country or *zone* remains unchanged.~~

~~In the event of the application for the status of a new FMD free free *zone* where *vaccination* is practised to be assigned to a new *zone* being adjacent to another FMD free *zone* of the same status where *vaccination* is practised, it should be stated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of animals between the *zones* of the same status in accordance with Chapter 4.3.~~

EU comment

The EU queries why the last paragraph above is proposed to be deleted.

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~~.

EU comment

Editorial: in the paragraph above, it should be "Chapter 4.4. and 4.5." (not "4.45.").

A Member Country wishing to establish a ~~FMD free~~ *compartment* free from FMD where *vaccination* is not practised should:

1) have a record of regular and prompt animal *disease* reporting and, if not ~~FMD~~ free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;

2) declare for the ~~FMD~~ free *compartment* that:

   ~~a)~~ t~~here has been no case of FMD during the past 12 months;~~

   a~~b~~) no ~~evidence of~~ *infection* with FMDV has ~~been~~ ~~found~~ ~~detected~~ occurred during the past 12 months;

   ~~c~~b) *vaccination* against FMD is prohibited;

   ~~d~~c) no animal vaccinated against FMD within the past 12 months is in the *compartment*;

   ~~e~~d) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;

   ~~f~~e) documented evidence shows that *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation;

   ~~g~~f) an *animal identification* and *traceability* system in accordance with Chapters 4.2~~1~~. and 4.3~~2~~. is in place;

3) describe in detail:

   a) the animal *subpopulation* in the *compartment*;

   b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out in accordance with point 1.

The *compartment* should be approved by the *Veterinary Authority*. The ~~first~~ approval should only be granted when no *infection* ~~case~~ or transmission of FMDV has occurred within a 10 ~~ten~~ kilometre radius of the *compartment* during the ~~past~~ three months prior to the effective establishment of the *biosecurity plan*.

Article 8.8.4bis.

Compartment free from FMD where vaccination is practised

A *compartment* free from FMD where *vaccination* is practised can be established in either a free country or *zone* where *vaccination* is practised or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.~~3~~4. and 4.~~4~~5. should be followed. Susceptible animals in the free *compartment* should be separated from any other susceptible animals by the application of an effective *biosecurity plan*.

EU comment

Editorial: in the paragraph above, it should be "Chapter 4.4. and 4.5." (not "4.45.").

A Member Country wishing to establish a *compartment* free from FMD where *vaccination* is practised should:

1) have a record of regular and prompt animal *disease* reporting and, if not free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;

2) declare for the free *compartment* where *vaccination* is practised that:

   ~~a)~~ ~~there has been no case of FMD during the past 12 months;~~

   ab) no ~~evidence of *infection* with~~ *infection* or transmission of FMDV has ~~been found~~ occurred during the past 12 months;

c) compulsory systematic *vaccination* is carried out using a vaccine that complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection. The *vaccination* coverage and population immunity are closely monitored;

d) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;

e) documented evidence shows that regular clinical, serological and virological *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation, so as to detect *infection* at an early stage with a high level of confidence;

f) an *animal identification* and *traceability* system in accordance with Chapters 4.~~1~~2. and 4.~~2~~3. is in place;

3) describe in detail:

a) the animal *subpopulation* in the *compartment*;

b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out according to point 1 and the *vaccination* plan;

c) implementation of points 2(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~~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

EU comment

The EU questions the level of detail in this new article, given there is a detailed article on protection zone in Chapter 4.4.

Susceptible animals in the 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*.

EU comment

Editorial: in the first line of the paragraph above, please replace "the" with "a" before "country or zone free from FMD should".

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:

EU comment

Editorial: the wording in the paragraph above should be revised, as the requirements of Article 4.4.6. cannot be submitted to the OIE.

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;

6) *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.

EU comment

Editorial: insert "a" before "biosecurity plan" in point 6 above.

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 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. Should the Member Country wish to maintain *vaccination* in the *protection zone*, Article 8.8.3bis applies.

EU comment

For clarity reasons, the EU suggests inserting "the second paragraph of" before "Article 8.8.3bis applies" in the paragraph above.

Furthermore, for reasons of consistency, the EU suggests replacing "Member Country" with "Veterinary Authority".

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. For the establishment of a *containment zone* after an *outbreak* in the *protection zone*, the *Veterinary Authority* should submit as soon as possible an application in accordance with Articles 4.4.7. and 8.8.6. 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*.

EU comment

The establishment or not of a containment zone is voluntary (i.e. use of "may" in Article 4.4.7.). It is not entirely clear from the paragraph above that establishing a containment zone in a protection is also optional. The EU thus suggests amending the wording of the second sentence of the paragraph above as follows:

"~~For the establishment of a containment zone after an outbreak in the protection zone,~~ A containment zone may be established within a protection zone. ~~t~~The Veterinary Authority should submit as soon as possible an application in accordance […]".

Similar changes could subsequently also be included in Article 4.4.6.

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.

EU comment

For reasons of consistency, the EU suggests replacing "Member Country" with "Veterinary Authority" in the paragraph above.

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, 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~~.

EU comment

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

"In the event of outbreaks within a country or zone previously free from FMD where vaccination is either practiced or not, including within a protection zone, ~~with or without vaccination~~, a containment zone, which includes all epidemiologically linked outbreaks, may be established~~,~~ in accordance with Article 4.4.7., to minimise the impact on the country or zone.".

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit 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:

EU comment

Please delete the words "for the Member Country" in the paragraph above, as they are superfluous.

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;~~

3~~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*;~~

4~~8~~) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in place in the *containment zone* and in the rest of the country or *zone*;

5~~9~~) measures that prevent the spread of FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place.

~~The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established.~~ The free status of the ~~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 5~~9~~ above. ~~*Commodities* from susceptible animals for *international trade* should be identified as to their origin, either from inside or outside the *containment zone*.~~

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

In the event of occurrence of *infection* with FMDV in unvaccinated animals or transmission of FMDV in vaccinated animals in the outer zone of a *containment zone* established in accordance with point 4(~~a~~b) of Article 4.4.7., the approval of the *containment zone* is withdrawn and the 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 months of its approval and follow the provisions of Article 8.8.7.

EU comment

The EU questions whether the time limit suggested above for recovery of status of the containment zone is necessary at all. Indeed, 18 months seem rather short, given the options in Article 8.8.7., especially the one on "vaccination to live".

Furthermore, there are no consequences described in case recovery is not achieved within that time limit. What would be the status in the containment zone, or the status of the rest of the country?

Article 8.8.7.

Recovery of free status ~~(see Figures 1 and 2)~~

1) When ~~a~~ *infection* with FMD~~V~~ ~~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 1.6.6., has been accepted by the OIE.

EU comment

Editorial: it should be "Chapter 1.11." instead of "Article 1.6.6." in the paragraph above.

   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 1.6.6., has been accepted by the OIE.

EU comment

Editorial: it should be "Chapter 1.11." instead of "Article 1.6.6." in the paragraph above.

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

EU comment

Editorial: as there is only one waiting period described in point 2 above, the last sentence should read as follows:

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

3) When ~~a case of~~ *infection* with FMDV occurs in a ~~FMD free~~ country or *zone* previously free from FMD where *vaccination* is practised, one of the following waiting periods is required to regain this free status:

EU comment

The EU suggests that transmission of FMDV in vaccinated animals be explicitly added in the text of point 3 above. Indeed, it is not clear from the text whether transmission in vaccinated animals is covered in the above.

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

EU comment

Editorial: it should be "Articles 8.8.40." in the last line of point a) above.

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.

When~~re~~ emergency *vaccination* is not applied, the above waiting periods do not apply, and Article 8.8.3. applies.

~~The country or *zone* will regain the status of FMD free country or *zone* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.~~

4) When ~~a~~ ~~FMD~~ ~~case of~~ *infection* with FMDV occurs in a ~~FMD free~~ *compartment* free from FMD, Article 8.8.4. or Article 8.8.4bis. applies.

5) Member Countries applying for the recovery of status should do so only when the respective requirements for the recovery of status are met. When a *containment zone* has been established, the restrictions within the *containment zone* should be lifted in accordance with the requirements of this article only when ~~the *disease*~~ FMD has been successfully eradicated within the *containment zone*.

EU comment

The second sentence of point 5 above is not entirely clear: there are no requirements for lifting of restrictions described in this article. I may need to be reworded as follows:

"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 FMD has been successfully eradicated within the containment zone and status has been regained following the provisions of this article."

For Member Countries not applying for recovery within 24 months after suspension, the provisions of Article 8.8.2., Article 8.8.3. or Article 8.8.4. apply.

EU comment

For clarity reasons, please insert "of status" after "24 months after suspension" in the paragraph above.

Furthermore, please add "or Article 8.8.4bis" after "8.8.4." (for completeness, and in consistency with point 4 above).

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

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

EU comment

Editorial: in the paragraph above, replace "the" with "a" before "~~nearest~~ designated".

1) no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;

2) the animals were kept in the country or *zone* of origin for at least three months prior to movement;

3) the animals are transported under the supervision of the *Veterinary Authority* in a *vehicle*, directly from the *establishment* of origin to the *slaughterhouse/abattoir*;

4) if transiting an infected *zone*, the animals were not exposed to any source of FMDV during transportation to the *place of shipment*.

Article 8.8.10.

Recommendations for importation from ~~FMD free~~ countries, ~~or~~ zones or compartments free from FMD where vaccination is not practised ~~or FMD free compartments free from FMD~~

For FMD susceptible animals

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

1) showed no clinical sign of FMD on the day of shipment;

2) were kept since birth or for at least the past three months in a ~~FMD free~~ country, ~~or~~ *zone* or *compartment* free from FMD where *vaccination* is not practised ~~or a FMD free *compartment*~~ free from FMD;

3) if transiting an infected *zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*.;

4) if previously vaccinated, comply with point 4 of Article 8.8.11.

Article 8.8.11.

Recommendations for importation from ~~FMD free~~ countries, ~~or~~ zones or compartments free from FMD where vaccination is practised

For domestic ruminants and pigs

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

1) showed no clinical sign of FMD on the day of shipment;

2) were kept since birth or for at least the past three months in a ~~FMD free~~ country, ~~or~~ *zone* or *compartment* free from FMD where *vaccination* is practised;

3) if not vaccinated were subjected to ~~a~~ virological and serological tests for FMD with negative results on samples collected not earlier than 14 days before the shipment;

4) if vaccinated were subjected to virological and NSP serological tests for FMD with negative results on samples collected not earlier than 14 days before the shipment;

EU comment

Editorial: in points 3 and 4 above, please delete "the" before "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

It is not clear what is meant by "transportation to the place of shipment". Would such transportation not be part of the shipment?

This comment is relevant also for point 4 of Article 8.8.11bis.

Article 8.8.11bis.

Recommendations for the importation from a ~~free~~ country, zone or compartment free from FMD where vaccination is practised

For vaccinated animals destined for slaughter

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

1) no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to shipment;

2) the animals were kept in the country, *zone* or *compartment* of origin since birth or for at least three months prior to shipment;

3) the animals were transported under the supervision of the *Veterinary Authority* directly from the *establishment* of origin in sealed *vehicles/vessels*;

4) if transiting an *infected zone*, the animals were not exposed to any source of FMDV during transportation to the *place of shipment*.

Article 8.8.12.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV, where an official control programme exists

For domestic ruminants and pigs

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

1) the animals showed no clinical sign of FMD on the day of shipment;

2) pigs have not been fed swill not complying with Article 8.8.31bis.;

3~~2~~) prior to isolation, the animals were kept in the *establishment* of origin:

a) for 30 days, or since birth if younger than 30 days, if a *stamping-out policy* is applied to control FMD in the *exporting country* or *zone*, or

b) for three months, or since birth if younger than three months if a *stamping-out policy* is not applied to control FMD in the *exporting country* or *zone*;

4~~3~~) the *establishment* of origin is covered by the *official control programme* and FMD has not occurred within it ~~the *establishment* of origin~~ for the relevant period as defined in points ~~2~~3(a) and ~~2~~3(b) above;

5~~4~~a) the animals were isolated 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

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~~, or the *establishment* is a *quarantine station*~~;

6~~5~~) the animals were not exposed to any source of FMDV during their transportation from the *establishment* to the *place of shipment*.

~~Article 8.8.13.~~

~~**Recommendations for importation from FMD free countries, or *zones* free from FMD where vaccination is not practised or FMD free compartments free from FMD**~~

~~For fresh semen of domestic ruminants and pigs~~

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

~~1) the donor males:~~

~~a) showed no clinical sign of FMD on the day of collection of the semen;~~

~~b) were kept for at least three months prior to collection in a FMD free country, or *zone* free from FMD where *vaccination* is not practised or FMD free *compartments* free from FMD;~~

~~c) were kept in an *artificial insemination centre* where none of the animals had a history of *infection* with FMDV;~~

~~2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.~~

Article 8.8.14.

Recommendations for importation from ~~FMD free~~ countries, ~~or~~ zones or compartments free from FMD where vaccination is not practised ~~or FMD free compartments free from FMD~~

For fresh and frozen semen of domestic ruminants and pigs

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

1) the donor males:

   a) showed no clinical sign of FMD on the day of collection of the semen ~~and for the following 30 days~~;

   b) were kept for at least three months prior to collection in a ~~FMD free~~ country, ~~or~~ *zone* or *compartment* free from FMD where *vaccination* is not practised ~~or FMD free *compartments* free from FMD~~;

   c) were kept in an *artificial insemination centre*;

EU comment

In relation to point 1c) above, the EU queries for how long the donor males need to have been kept in the artificial insemination centre before collection. Indeed, it is not clear from the text whether a specific time period is required for that at all (as is the case for point 1b) i.e. 3 months).

2) the semen was collected, processed and stored in accordance with Chapters 4.~~5~~6. and 4.~~6~~7.

Article 8.8.15.

Recommendations for importation from ~~FMD free~~ countries ~~or~~, zones or compartments free from FMD where vaccination is practised

For frozen semen of domestic ruminants and pigs

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

1) the donor males:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept for at least three months prior to collection in a ~~FMD free~~ country, ~~or~~ *zone* or compartment free from FMD where *vaccination* is practised;

   c) either

      i) have been vaccinated at least twice~~,~~ with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;

      or

      ii) have not been vaccinated and were subjected, not less than 21 days and not more than 60 days after collection of the semen, to tests for antibodies against FMDV, with negative results;

2) the semen:

   a) was collected, processed and stored in accordance with Chapters 4.~~5~~6. and 4.~~6~~7.;

   b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor ~~animals~~ males were kept showed any clinical sign of FMD.

Article 8.8.16.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV

For frozen semen of domestic ruminants and pigs

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

1) the donor males:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept in an *artificial insemination centre* ~~where~~ to which no animal had been added in the 30 days before collection, and within a 10-kilometre radius of which, ~~that~~ FMD has not occurred ~~within a 10 kilometre radius of the *artificial insemination centre* for~~ in the 30 days before and after collection;

   c) either

      i) have been vaccinated at least twice~~,~~ with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;

      or

      ii) have not been vaccinated and were subjected, not less than 21 days and not more than 60 days after collection of the semen, to tests for antibodies against FMDV, with negative results;

2) the semen:

   a) was collected, processed and stored in accordance with Chapters 4.~~5~~6. and 4.~~6~~7.;

   b) was subjected, with negative results, to a test for evidence of FMDV if the donor male has been vaccinated within the 12 months prior to collection;

   c) was stored in the country of origin for a period of at least one month following collection, and that during this period no animal on the *establishment* where the donor males were kept showed any sign of FMD.

~~Article 8.8.17.~~

~~**Recommendations for the importation of *in vivo* derived embryos of bovines cattle**~~

~~Irrespective of the FMD status of the *exporting country*, *zone* or *compartment*, *Veterinary Authorities* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of bovines cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in accordance with the relevant provisions of Chapters 4.7. and 4.9., as relevant.~~

Article 8.8.18.

Recommendations for importation 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~~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., as relevant.

Article 8.8.19.

Recommendations for importation from ~~FMD free~~ countries ~~or~~, zones or compartments free from FMD where vaccination is practised

For *in vitro* produced embryos of ~~bovines~~ ~~cattle~~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 after collection, to tests for antibodies against FMDV, with negative results;

2) fertilisation was achieved with semen meeting the conditions referred to in Articles ~~8.8.13.,~~ 8.8.14., 8.8.15. or 8.8.16., as relevant;

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

Article 8.8.20.

Recommendations for importation from ~~FMD free~~ countries ~~or~~, zones or compartments free from FMD where vaccination is not practised ~~or FMD free compartments free from FMD~~

For fresh meat or meat products of FMD susceptible animals

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

1) have been kept in a ~~FMD free~~ country or *zone* or *compartment* free from FMD where *vaccination* is not practised ~~or FMD free *compartment* free from FMD~~, or ~~which~~ have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;

EU comment

Editorial: in point 1 above, it should be “country, zone or compartment”.

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

Article 8.8.21.

Recommendations for importation from ~~FMD free~~ countries ~~or~~, zones or compartments free from FMD where vaccination is practised

For fresh meat and meat products of ruminants and pigs

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

1) have been kept in the ~~FMD free~~ country or *zone* or *compartment* free from FMD where *vaccination* is practised, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;

EU comment

Editorial: in point 1 above, it should be "country, zone or compartment".

2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections ~~for FMD~~ with favourable results;

3) for ruminants the head, including the pharynx, tongue and associated lymph nodes, has been excluded from the shipment.

Article 8.8.22.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV, where an official control programme exists

For fresh meat of ~~bovines~~ ~~cattle~~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 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~~cattle and water buffaloes were loaded, directly from the *establishment* of origin or *quarantine station* to the approved *slaughterhouse/abattoir* without coming into contact with other FMD susceptible animals which do not fulfil the required conditions for export;

   e) have been slaughtered in an approved *slaughterhouse/abattoir*:

      i) which is officially designated for export;

      ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;

   f) were subjected to ante- and post-mortem inspections in accordance with Chapter 6.~~2~~3., with favourable results ~~have been subjected, with favourable results, to ante-mortem inspection within 24 hours of *slaughter* and to post-mortem inspections within 24 hours before and after *slaughter* with no evidence of FMD~~;

2) comes from deboned carcasses:

   a) from which the major lymphatic nodes have been removed;

b) which, prior to deboning, have been submitted to maturation at a temperature greater than + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was less than 6.0 when tested in the middle of both the longissimus dorsi muscle.

Article 8.8.22bis.

Recommendations for importation 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 8.8.23.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV

For meat products of FMD susceptible animals

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

1) the entire consignment of *meat products* come from animals which have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections ~~for FMD~~ with favourable results;

2) the *meat products* have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.31.;

3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMDV.

Article 8.8.24.

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

For milk and milk products (other than those defined in Article 8.8.1bis.) intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

EU comment

For reasons of consistency with wording in other chapters, it should be "listed" instead of "defined" in the sentence above. Indeed, there is no definition for what is UHT milk in Article 8.8.1bis.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a ~~FMD free~~ country, *zone* or *compartment* free from FMD, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.

Article 8.8.25.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV, where an official control programme exists

For milk and milk products (other than those defined in Article 8.8.1bis.)

EU comment

For reasons of consistency with wording in other chapters, it should be "listed" instead of "defined" in the sentence above. Indeed, there is no definition for what is UHT milk in Article 8.8.1bis.

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

1) these products:

   a) originate from *establishments* which were not infected or suspected of being infected with FMD at the time of *milk* collection;

   b) have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.35. and in Article 8.8.36.;

2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

~~Article 8.8.26.~~

~~**Recommendations for importation from FMD infected countries or zones infected with FMDV**~~

~~For blood-meal and meat-meals from FMD susceptible animals~~

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

~~1) the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.;~~

~~2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.~~

Article 8.8.27.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV

For wool, hair, bristles, raw hides and skins from FMD susceptible animals

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

1) these products have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Articles 8.8.32., 8.8.33. and 8.8.34.;

2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMDV.

Veterinary Authorities should authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather such as wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 8.8.28.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV

For straw and forage

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

1) are free of grossly identified contamination with material of animal origin;

2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:

   a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ~~ten~~ 10 minutes,

   b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35-40% in a chamber kept closed for at least eight hours and at a minimum temperature of 19°C;

OR

3) have been kept in bond for at least four months before being released for export.

Article 8.8.29.

Recommendations for importation from ~~FMD free~~ countries~~or~~, zones or *compartments* free from FMD, ~~where~~ whether vaccination ~~either~~ is practised or ~~is~~ not ~~practised~~

For skins and trophies derived from FMD susceptible wildlife

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products are derived from animals that have been killed in ~~such~~ a country or *zone* free from FMD or which have been imported from a country, *zone* or *compartment* free from FMD.

Article 8.8.30.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV

For skins and trophies derived from FMD susceptible wildlife

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

Article 8.8.31.

Procedures for the inactivation of FMDV in meat and meat products

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

1. Canning

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

2. Thorough cooking

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

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

3. Drying after salting

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

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

Article 8.8.31bis.

Procedures for the inactivation of FMDV in swill

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

1) the swill is maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or

2) the swill is maintained at a temperature of at least 121°C for at least ten minutes at an absolute pressure of 3 bar; or

3) the swill is subjected to an equivalent treatment that has been demonstrated to inactivate FMDV.

Article 8.8.32.

Procedures for the inactivation of FMDV in wool and hair

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

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

2) chemical depilation by means of slaked lime or sodium sulphide;

3) fumigation with formaldehyde in a hermetically sealed chamber for at least 24 hours;

4) for wool, industrial scouring which consists of the immersion ~~of wool~~ in a water-soluble detergent held at 60-70°C;

5) for wool, storage ~~of wool~~ at 4°C for four months, 18°C for four weeks or 37°C for eight days.

Article 8.8.33.

Procedures for the inactivation of FMDV in bristles

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

1) boiling for at least one hour; or

2) immersion for at least 24 hours in a 1% aqueous solution of formaldehyde.

Article 8.8.34.

Procedures for the inactivation of FMDV in raw hides and skins

For the inactivation of FMDV present in raw hides and skins for industrial use, the following procedure should be used: treatment for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na_2CO_3).

Article 8.8.35.

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

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

~~1)~~ ~~a process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]),~~ ; ~~or~~

~~2~~1) if the *milk* has a pH less than 7.0, a process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]) ~~,~~ ; or

~~3~~2) if the *milk* has a pH of 7.0 or greater, the HTST process applied twice.

~~Article 8.8.36.~~

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

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

~~1)~~ ~~the HTST process applied twice; or~~

~~2)~~ ~~HTST combined with another physical treatment, e.g., maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with desiccation~~ ; ~~or~~

~~3)~~ ~~UHT combined with another physical treatment referred to in point 2 above.~~

Article 8.8.37.

Procedures for the inactivation of FMDV in skins and trophies from susceptible wildlife ~~susceptible to the disease~~

For the inactivation of FMDV present in skins and trophies from susceptible *wildlife* ~~*wild animals* susceptible to FMD~~, one of the following procedures should be used prior to complete taxidermal treatment

1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed; or

2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher); or

3) soaking, with agitation, in a 4% (weight/volume) solution of sodium carbonate (Na_2CO_3) maintained at pH 11.5 or greater for at least 48 hours; or

4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at pH less than 3.0 for at least 48 hours; wetting and dressing agents may be added; or

5) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na_2CO_3).

EU comment

The EU suggests replacing the word "wildlife" with "animals" throughout the article above. Indeed, skins and trophies of domestic animals are commonly produced and would not require any different treatment. Reference is also made to draft Article 11.10.7. (cf. Annex 15 of this report).

Article 8.8.38.

Procedures for the inactivation of FMDV in casings of ruminants and pigs

For the inactivation of FMDV present in casings of ruminants and pigs, the following procedures should be used: treating for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl, $a_w < 0.80$), or with phosphate

supplemented salt containing 86.5% NaCl, 10.7% Na_2HPO_4 and 2.8% Na_3PO_4 (weight/weight/weight), either dry or as a saturated brine (a_w< 0.80), and kept at a temperature of greater than 12°C during this entire period.

Article 8.8.39.

OIE endorsed official control programme for FMD

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

~~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 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:

EU comment

For clarity reasons, please insert "the description of" before "an official control programme" in the paragraph above.

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;~~

~~c) documentation indicating that the *official control programme* for FMD is applicable to the entire country;~~

~~4) submit a dossier on the epidemiology of FMD in the country describing the following:~~

~~a) the general epidemiology in the country highlighting the current knowledge and gaps and the progress that has been made in controlling FMD;~~

~~b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all FMD *outbreaks* in order to reduce the incidence of FMD *outbreaks* and to eliminate FMDV transmission of FMDV in at least one *zone* in the country;~~

~~c) the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;~~

~~5) submit evidence that FMD *surveillance* is in place:~~

~~a) FMD *surveillance* is in place, taking into account provisions in accordance with Chapter 1.4. and the provisions on *surveillance* of this chapter;~~

~~b) it has have diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains;~~

~~6) where *vaccination* is practised as a part of the *official control programme* for FMD, provide:~~

~~a) evidence (such as copies of legislation) that *vaccination* of selected *populations* is compulsory;~~

~~b) detailed information on *vaccination* campaigns, in particular on:~~

~~i) target populations for *vaccination*;~~

~~ii) monitoring of *vaccination* coverage, including serological monitoring of population immunity;~~

~~iii) technical specification of the vaccines used, including matching with the circulating FMDV strains, and description of the licensing procedures in place;~~

~~iv) the proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;~~

~~7) provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.~~

~~The Member Country's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence, based on the provisions of Article 1.6.11., has been accepted by the OIE.~~

The country will be included in the list of countries having 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 *population*s. Within vaccinated *population*s, serological surveys to demonstrate no evidence of ~~FMDV~~ transmission of FMDV should target animals that are less likely to show vaccine-derived antibodies to ~~non-structural proteins~~ NSP, such as young animals vaccinated a limited number of times, or unvaccinated animals. In any unvaccinated *subpopulation*, *surveillance* should demonstrate no evidence of *infection* with FMDV.

Surveillance strategies employed for establishing and maintaining a *compartment* should identify the prevalence, distribution and characteristics of FMD outside the *compartment*.

3. 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 and pigs). The Member Country should justify the *surveillance* strategy chosen and the frequency of sampling as adequate to detect ~~the presence of~~ ~~FMDV~~ *infection* with, or transmission of, FMDV in accordance with Chapter 1.4. and the epidemiological situation.

The design of the sampling strategy should incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing should be adequate to detect *infection* or transmission if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member Country should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the prevailing or historical epidemiological situation, in accordance with Chapter 1.4.

5. Follow-up of suspected cases and interpretation of results

An effective *surveillance* system will identify suspected *cases* that require immediate follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Samples should be taken and submitted for diagnostic testing, unless the suspected *case* can be confirmed or ruled out by epidemiological and clinical investigation. Details of the occurrence of suspected *cases* and how they were investigated and dealt with should be documented. This should include the results of diagnostic testing and the control measures to which the animals concerned were subjected during the investigation.

The sensitivity and specificity of the diagnostic tests employed, including the performance of confirmatory tests, are key factors in the design, sample size determination and interpretation of the results obtained. Selection of diagnostic tests and interpretation of results should take into account ~~The sensitivity and specificity of the tests used should be validated for~~ the *vaccination* or *infection* history and production class of animals in the target population.

The *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following-up positive~~s~~ results to determine with a high level of confidence, whether or not they are indicative of *infection* or transmission. This should involve supplementary tests and follow-up investigation to collect diagnostic material from the original *epidemiological unit* and *herds* which may be epidemiologically linked to it.

Laboratory results should be examined in the context of the epidemiological situation. Corollary 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 without vaccination or early recovery of free status with vaccination in the area(s) where emergency vaccination has been applied but not followed by the slaughtering of all vaccinated animals

EU comment

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

"Additional measures for early recovery of ~~free~~ status as free from FMD where ~~without~~ vaccination is not practiced or early recovery of ~~free~~ status as free from FMD where ~~with~~ vaccination is practiced in the area(s) where emergency vaccination has been applied but not followed by the slaughtering of all vaccinated animals".

In addition to the general conditions described in this chapter, a Member Country seeking either recovery of status of a country or *zone* previously free from FMD where *vaccination* is not practised, including a *containment zone*, or recovery of status of a country or *zone* previously free from FMD where *vaccination* is practiced, earlier than the six months as specified respectively under point 1c) of Article 8.8.7. or under point 3a) of Article 8.8.7. should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved when answering the relevant questionnaire in Chapter 1.11. by demonstrating compliance with either a) or b) and c) below, in the area(s) where emergency *vaccination* has been applied. It is advisable that countries should consider the different

options for the recovery of a free status when control measures are first implemented at the onset of the *outbreak* in order to plan for the applicable requirements to be met.

EU comment

For reasons consistency, the EU suggests replacing the word "countries" with "the Competent Authority" in the last sentence of the paragraph above.

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 with *vaccination* in the area outside of the area(s) where emergency *vaccination* has been applied.

EU comment

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

"Additional measures for early recovery of ~~free~~ status as free from FMD where ~~with~~ vaccination is practiced 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 3a) of Article 8.8.7. should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved either by meeting the requirements listed in a) below or by demonstrating compliance with the requirements listed in b) and c) below, when answering the questionnaire in Article 1.11.2. or Article 1.11.4.

With regard to the *surveillance* requirements listed in b), it should be noted that clinical signs may not be apparent in the routinely vaccinated *population*. The expression of clinical signs would depend on the relationship between the virus strain used in the routine *vaccination* to the virus that caused the *outbreak*. For example, following an incursion of a new serotype it would be expected that the routinely vaccinated animals would show clinical signs if infected. In contrast, following an incursion of a serotype or strain covered by the vaccine it would be expected that most of the routinely vaccinated animals would be protected and therefore less likely to be infected and to show clinical signs if infected. Other factors such as *vaccination* coverage and timing of *vaccination* could influence the likelihood of *infection* and expression of clinical signs.

It is advisable that countries should consider the different options for the recovery of a free status when control measures are first implemented at the onset of the *outbreak* in order to plan for the applicable requirements to be met.

EU comment

For reasons consistency, the EU suggests replacing the word "countries" with "the Competent Authority" in the paragraph above.

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.

EU comment

The EU suggests inserting the words "Field samples or" before "FMDV isolates should" in the paragraph above. Indeed, not all laboratories are in a position to isolate the virus in order to send isolates to the OIE Reference Laboratory in order to establish "the molecular, antigenic and other biological characteristics of the causative virus, as well as its source".

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 *population*s, ~~structural protein~~ SP tests may be used to screen sera for evidence of ~~FMDV~~ *infection* with, ~~or transmission of,~~ FMDV or to detect the introduction of vaccinated *animals*. In vaccinated *population*s, ~~structural protein~~ SP tests may be used to monitor the serological response to the *vaccination*.

EU comment

In the paragraph above, the EU suggests moving the third sentence to the end of the paragraph, and to slightly amend it as follows:

“The SP tests are serotype specific and for optimal sensitivity one should select an antigen or virus closely related to the field strain expected or vaccine strain used.”

Indeed, the clause “for optimal sensitivity one should select antigen or virus closely related to” is relevant both for screening sera for FMDV infection and for monitoring serological response to vaccination.

For optimal sensitivity, when looking for FMDV infection, the antigen should be closely related to the field strain, whereas when looking for vaccine-induced antibodies, the antigen should be closely related to the vaccine strain.

~~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 are usually found only up to six months of age but in some individuals and in some other species, maternal antibodies can be detected for longer periods);

– non-specific reactivity of the serum in the tests used.

1. Procedure in case of positive test results

The proportion and strength of seropositive reactors should be taken into account when deciding if they are *laboratory* confirmed reactors or further investigation and testing are required.

When false positive results are suspected, seropositive reactors should be retested in the *laboratory* using repeat and confirmatory tests. Tests used for confirmation should be of high diagnostic specificity to minimise false positive test results. The diagnostic sensitivity of the confirmatory test should approach that of the screening test.

All *herds* with at least one ~~*laboratory* confirmed~~ reactor that has been confirmed in a *laboratory* should be investigated. The investigation should examine all evidence, which may include the results ~~of virological tests and~~ of any further serological tests ~~that might~~ used to confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to ~~FMDV~~ transmission of FMDV, as well as of virological tests. This investigation should document the status for each positive *herd*. Epidemiological investigation should be continued concurrently.

Clustering of seropositive results within *herds* or within a region should be investigated as it may reflect any of a series of events, including the demographics of the *population* sampled, vaccinal exposure or the presence of *infection* or transmission. As clustering may signal *infection* or transmission, the investigation of all instances should be incorporated in the survey design.

Paired serology can be used to identify ~~FMDV~~ transmission of FMDV by demonstrating an increase in the number of seropositive *animals* or an increase in antibody titre at the second sampling.

The investigation should include the reactor *animals*, susceptible *animals* of the same *epidemiological unit* and susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animals*. The *animals* sampled should be identified as such and remain in the *establishment* pending test results, should be ~~clearly identified,~~ accessible and should not be vaccinated during the investigations, so that they can be retested after an appropriate period of time. Following clinical examination, a second sample should be taken, after an appropriate time has elapsed, from the *animals* tested in the initial survey with emphasis on *animals* in direct contact with the reactors. If the *animals* are not individually identified, a new serological survey should be carried out in the *establishments* after an appropriate time, repeating the application of the primary survey design. If FMDV is not circulating, the magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample.

In some circumstances, unvaccinated sentinel *animals* may also be used. These can be young *animals* from unvaccinated dams or *animals* in which maternally conferred immunity has lapsed and preferably of the same species as in the positive sampling units. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the *animals* of the *epidemiological unit* under investigation for at least two *incubation periods*. ~~and~~ If there is no transmission of FMDV, they ~~should~~ will remain serologically negative ~~if FMDV is not circulating~~.

2. Follow-up of field and laboratory findings

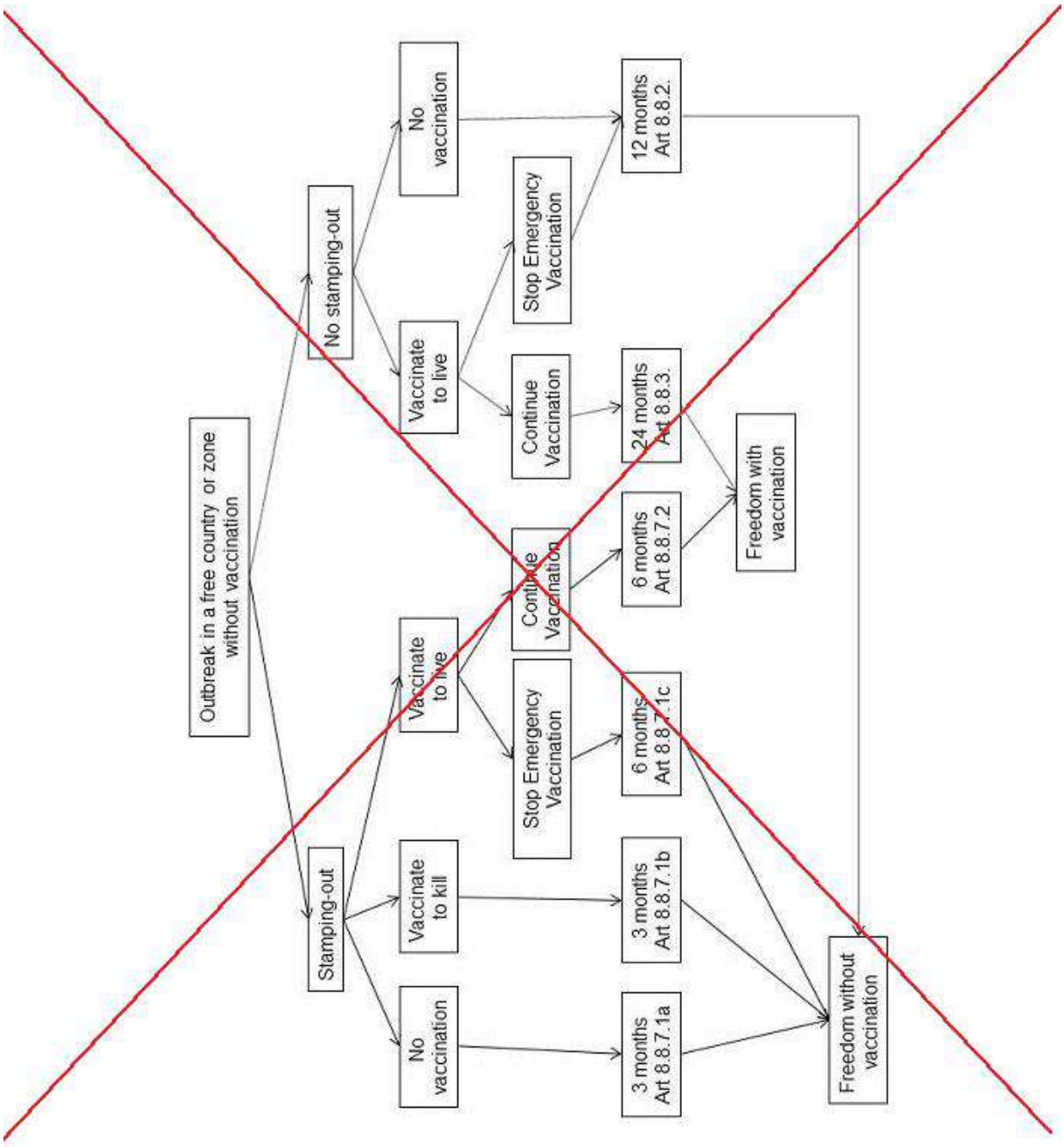
If transmission is demonstrated, an *outbreak* is declared.

It is difficult to determine ~~T~~the significance of small numbers of seropositive *animals* in the absence of current FMDV transmission ~~is difficult to determine~~. Such findings may be an indication of past *infection* followed by recovery or by the development of a carrier state, in ruminants, or due to non-specific serological reactions. Antibodies to ~~nonstructural proteins~~ NSP may be induced by repeated *vaccination* with vaccines that do not comply with the requirements for purity. However, the use of such vaccines is not permissible in countries or *zones* applying for an official status. In the absence of evidence of ~~FMDV~~ *infection* with, and transmission of, FMDV, such findings do not warrant the declaration of a new *outbreak* and the follow-up investigations may be considered complete.

However, if the number of seropositive *animals* is greater than the number of false positive results expected from the specificity of the diagnostic tests used, susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animals* should be investigated further.

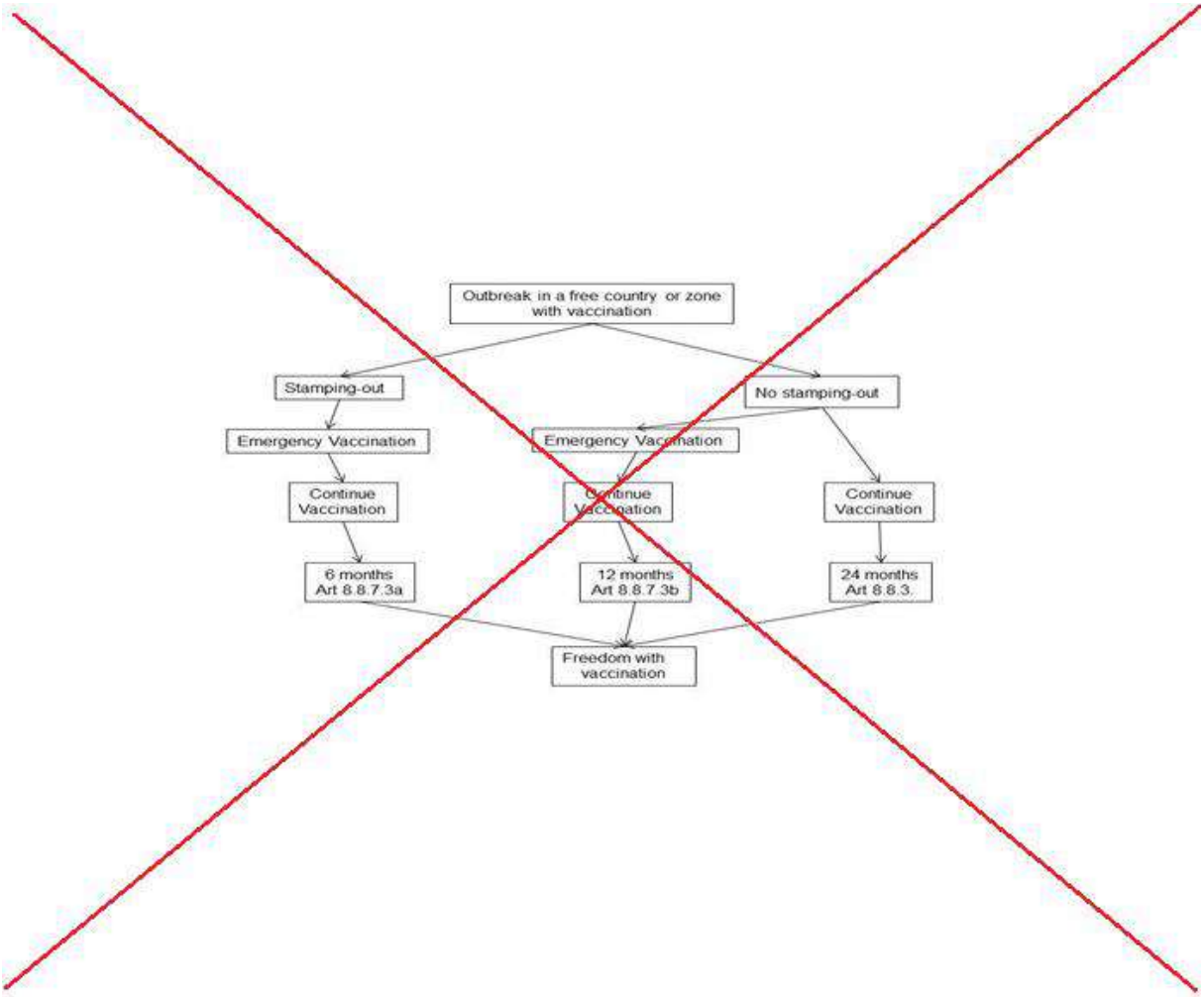
~~Abbreviations and acronyms:~~	
~~ELISA~~	~~Enzyme-linked immunosorbent assay~~
~~VNT~~	~~Virus neutralisation test~~
~~NSP~~	~~Nonstructural protein(s) of foot and mouth disease virus (FMDV)~~
~~3ABC~~	~~NSP antibody test~~
~~SP~~	~~Structural protein of foot and mouth disease virus~~

Fig. 1. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak of FMD in a previously free country or zone where vaccination is not practised



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

Fig. 2. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak of FMD in a previously free country or zone where vaccination is practised



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

Fig. 3. Schematic representation of laboratory tests for determining evidence of infection with FMDV by means of serological surveys