Report of the Meeting of WOAH Terrestrial Animal Health Standards Commission

Annex 1

Original: English (EN)

6 to 16 February 2024
Paris

EU	**The EU would like to commend WOAH for its work and thank in particular the Code Commission for having taken into consideration EU comments on the Terrestrial Code submitted previously.** **A number of general comments on the part A of the February 2024 meeting report of the Code Commission as well as the intended positions of the EU on the draft Terrestrial Code chapters proposed for adoption at the 91st WOAH General Session are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report (appended as Annexes 4 to 21 to this document).** **The EU would like to stress once again its continued commitment to participate in the work of WOAH and to offer all technical support needed by the Code Commission and WOAH ad hoc groups for future work on the Terrestrial Code.**

Introduction and Members contribution

This report presents the work of the WOAH Terrestrial Animal Health Standards Commission (hereinafter 'the Code Commission') who met in Paris, France from 6 to 16 February 2024.

The Code Commission wished to thank the following Members for providing written comments for the WOAH *Terrestrial Animal Health Code* (hereinafter 'the *Terrestrial Code*') : Argentina, Australia, Brazil, Canada, China (People's Republic of), Chinese Taipei, Colombia, Japan, New Caledonia, New Zealand, Norway, Singapore, South Africa, Switzerland, Thailand, the United Kingdom (UK), the United States of America (USA), Members of the WOAH Americas Region, the Member States of the European Union (EU) and the African Union Inter-African Bureau for Animal Resources (AU-IBAR) on behalf of African Members of WOAH. The Commission also wished to thank the following organisations for providing comments: the International Coalition for Farm Animal Welfare (ICFAW), International Egg Commission (IEC), World Renderers Organizations (WRO), and to acknowledge the valuable advice and contributions from numerous experts of the WOAH scientific network.

The Code Commission reviewed all comments that were submitted prior to the deadline and were supported by a rationale. Due to the large number of comments, the Commission was not able to provide a detailed explanation of the reasons for accepting or not each of the comments considered and focused its explanations on issues deemed significant. Where amendments were of an editorial nature, no explanatory text has been provided. The Commission wished to note that when texts proposed by Members to improve clarity were not accepted, it was because it considered the text was clear as currently written. The Commission made amendments to draft texts, where relevant, in the usual manner by 'double underline' and 'strikethrough'. In

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relevant Annexes, amendments proposed at this meeting are highlighted in yellow to distinguish them from those made previously.

Status of annexes

Texts in **Part A** (Annexes 4 to 21) will be proposed for adoption at the 91st General Session in May 2024. Texts in **Part B** (Annexes 3 and 22 to 26) are presented for comments. Text in Part C (Annex 27) is presented for information.

How to submit comments

The Code Commission strongly encourages WOAH Members and International Organisations with a WOAH Cooperative Agreement to participate in the development of WOAH International Standards by submitting comments on topics and relevant annexes of this report.

Engagement of Members and International Organisations in the standard setting process through the submission of comments is critical to ensure that the Commission's work is science-based, takes into consideration the different contexts among Members and relevant stakeholders, and enables the implementation of standards. To ensure that comments are considered, they should be submitted by the deadline and in the format described in the guidance and SOP documents available on the Delegate's website and the WOAH public website.

Comments that are not correctly formatted as described in the guidance, may not be considered by the Commission. Any questions on the requirements for formatting and submission of comments should be sent to TCC.Secretariat@woah.org

The Commission also draws the attention of Members to those instances where the Scientific Commission for Animal Diseases (the Scientific Commission), the Biological Standards Commission, a Working Group or an *ad hoc* Group have addressed specific comments or questions and proposed answers or amendments. In such cases the rationale is described in the respective reports of the relevant entity and Members are encouraged to review these reports together with the report of the Code Commission. These reports are not annexed to the Commission's report. Instead, they are available on the dedicated webpages on the WOAH website, e.g., *ad hoc* Group reports: https://www.woah.org/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/

Deadline for comments

Comments on relevant texts in this report (Part B) must be received by 12 July 2024 to be considered by the Code Commission.

Where to send comments

All comments should be sent to TCC.Secretariat@woah.org

Date of the next meeting

The Code Commission noted that the dates for its next meeting will be confirmed following the Commission election at the 91st General Session in May 2024.

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1. Welcome

1.1. WOAH Director General and Deputy Director General-International Standards and Science

Dr Monique Eloit, WOAH Director General and Dr Montserrat Arroyo, WOAH Deputy Director General, International Standards and Science (DDG ISS), met with the Aquatic Animals Commission, the Scientific Commission and the Code Commission on 14 February 2024, to welcome all Commission members and thank them for their ongoing contributions to the work of WOAH. Dr Eloit thanked the Commissions members for their hard work throughout this term and the tremendous amount of work achieved. She acknowledged that this was the last meeting of the current term for each of the Specialist Commissions and wished them all well, whether standing for re-election or stepping down.

Dr Eloit provided updates on the selection process for election to any of the four Specialist Commissions and on the current review of the WOAH's Basic Texts that will be presented to the World Assembly at the 91st General Session in May 2024. Dr Eloit highlighted there will be a global focus on antimicrobial resistance (AMR) throughout 2024, including a UN General Assembly high-level meeting in September 2024 to highlight the global public health threat of AMR, and that WOAH will continue to participate actively in these fora and discussions on AMR.

Dr Arroyo recognised the work of each of the three Commissions present throughout this term, with an overview of key accomplishments, and commended them on their commitment to this work.

Dr Arroyo provided a brief update on a number of horizontal topics, including the WOAH Standards Online Navigation Tool project, the decision to freeze the Diagnostic Kit Register activities, General Session kiosk topics, work on the coordination of the WOAH standard-setting process, and the publication of comments.

Dr Arroyo thanked the Commission Presidents for agreeing to deliver pre-General Session webinars again this year and emphasized that they are an important contribution to the engagement of Members and partners in the standard-setting process. Dr Arroyo noted that the pre-General Session webinars will be held on 16 April, 17 April and 18 April from 12:00 – 14:00 (CEST) for the Biological Standards Commission, the Code Commission and the Aquatic Animals Commission, respectively. The webinars will have simultaneous interpretation into French and Spanish and will be recorded and uploaded onto the WOAH website.

Commission members thanked Dr Eloit and Dr Arroyo for their appreciation and these updates, and for their leadership and support throughout the current term. They also acknowledged the important work of the Secretariats in support of their work.

2. Adoption of the agenda

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

3. Cooperation with Other Specialist Commissions

3.1. Scientific Commission for Animal Diseases

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

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

Assessments of pathogenic agents against the listing criteria in Chapter 1.2. 'Criteria for the inclusion of diseases, infections and infestations in the WOAH list'

The Code Commission considered the conclusions of the Scientific Commission provided in its September 2023 report on the assessment of equine encephalitides and infection with *Theileria orientalis* (Ikeda and Chitose) and agreed that they meet the listing criteria. The Commission noted that the assessment reports did not provide sufficient information on the role of the different animal hosts and their significance in the epidemiology of the disease. The Code Commission highlighted that, as previously agreed between the two Commissions, this information was essential for any further step after the assessment, such as proposing potential amendments to Chapter 1.3., or the development or revision of a disease-specific chapter, notably to be used for case definitions.

The Commission requested the Secretariat to review the Standard operating procedure for listing decisions for pathogenic agents of terrestrial animals and associated guidelines to ensure they include the necessary steps for the systematic consideration of the role of animal hosts in the epidemiology of the disease, to identify those which should be included in the case definition, or be considered for the development of status conditions, trade recommendations or surveillance strategies.

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

The Code Commission noted the conclusion of the Scientific Commission provided in its September 2023 report on the annual reassessment of infection with SARS-CoV-2 as an emerging disease, based on the Standard operating procedure for determining whether a disease should be considered as emerging, which considered that SARS-CoV-2 should not be assessed for listing but should continue to be considered an emerging disease. The Code Commission noted that the Scientific Commission would discuss this point again at its meeting in September 2024.

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

The Bureaus (i.e. the President and two Vice-Presidents) of the Code Commission and the Scientific Commission held a meeting chaired by Dr Arroyo (WOAH DDG ISS). The purpose of the meeting was to provide joint updates on relevant standing items, to agree on how to address any points that may impact the potential adoption of some standards, and to agree on the plans to undertake work of common interest.

At the meeting, the Bureaus were updated on ongoing works based on the SOP for listing decisions for pathogenic agents and the SOP for determining whether a disease should be considered as emerging. The Bureaus also agreed to submit Nairobi sheep disease virus to an assessment against the criteria for listing and agreed on the next tranche of case definitions to be developed to support notification of terrestrial animal listed diseases.

The Bureaus discussed specific points of chapters that are proposed for adoption in 2024:

- Chapter 8.8. 'Infection with foot and mouth disease virus' and Chapter 1.11. (see Item 5.7. of this report);
- Chapters 11.5. 'Infection with *Mycoplasma mycoides subsp. Mycoides* SC (Contagious bovine pleuropneumonia)' and 12.1. 'Infection with African horse sickness virus': acknowledging the impact of the adoption of the revised chapters would entail on the procedure on annual reconfirmation for maintenance of officially recognised status or African horse sickness (AHS) of Members for those two diseases, and the related administrative work for both Members and WOAH, the Bureaus agreed that it would be beneficial that the revised Chapter 11.5. and the revised Chapter 12.1. are not presented for adoption at the upcoming General Session, and rather re-examined in September after review of possible consequences on the procedure by the Secretariat. (See items 4.2.11. and 4.2.13. of this report).

The Bureaus also discussed plans for the following works which require coordination between the Commissions:

- Chapter 4.4. ‘Zoning and compartmentalisation’, and possible development of a new Chapter 4.Y. ‘Implementation of zoning’ (see Item 4.2.5. of this report);
- Chapter 14.8. ‘Scrapie’ (see Item 4.2.14. of this report);
- Revision of *Terrestrial Code* chapters on equine encephalitides (see Item 4.2.10. of this report);
- Framework *for Terrestrial Code* standards (see Item 7.3. of this report);
- Animal hosts to be targeted by WOAH Standards for a listed disease and the associated implications on notification obligations (see Item 4.2.1. of this report).

3.2. Biological Standards Commission

The Secretariat updated the Code Commission on relevant activities of the Biological Standards Commission, including the list of chapters in the *Terrestrial Manual* that will be updated during the 2024/2025 review cycle.

Given that the revision of some of these chapters could potentially impact the corresponding chapters in the *Terrestrial Code*, the Code Commission committed to working closely with the Biological Standards Commission to ensure that relevant amendments in the corresponding chapters of the *Terrestrial Code* and the *Terrestrial Manual* are properly coordinated.

At its February 2024 meeting, the Code Commission considered the recommendations from the Biological Standards Commission on the possible impact of updates in the following *Manual* chapters to be proposed for adoption in 2024:

- Chapter 3.4.1. ‘Bovine anaplasmosis’
- Chapter 3.4.7. ‘Bovine viral diarrhoea’
- Chapter 3.1.19. ‘Rift Valley fever (infection with Rift Valley fever virus)’
- Chapter 3.6.9. ‘Equine rhinopneumonitis (infection with equid herpesvirus-1 and -4)’
- Chapter 3.8.12. ‘Sheep pox and goat pox’
- Chapter 3.9.1. ‘African swine fever (infection with African swine fever virus)’

The Code Commission did not agree with the recommendation to add precision to testing methods and treatments in *Terrestrial Code* Chapter 11.1. ‘Bovine anaplasmosis’, explaining that these provisions were already in the *Manual*, which is referred to at the beginning of the chapter.

The Commission agreed to update the taxonomy of the pathogenic agents in the new Chapter 11.X. ‘Infection with bovine pestiviruses (bovine viral diarrhoea)’ currently being circulated (see item 4.2.12. of this report).

The Code Commission noted the recommendations on Chapter 12.8. ‘Infection with equid herpesvirus-1 (Equine rhinopneumonitis)’ of the *Terrestrial Code*, and its taxonomy.

The Code Commission also noted recommendations on Chapter 15.1. ‘Infection with African swine fever virus’, related to the inclusion of a new section on the quality of vaccines in *Terrestrial Manual* Chapter 3.9.1., which could be taken into consideration in future work, after the revised *Manual* chapter has been adopted.

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

The Code Commission wished to thank the Biological Standards Commission for providing inputs to support the decisions of the Code Commission on relevant comments. The Code Commission reminded

Members that its consideration of the Biological Standards Commission's responses to specific chapters are noted under the relevant agenda item of this report and encouraged Members to read the Biological Standards Commission's report for the details.

3.3. Aquatic Animals Health Standards Commission

The Secretariat updated the Code Commission on progress made by the Aquatic Animals Commission on the items that had been identified as of common interest at a meeting of the Bureaus of the Code Commission and the Aquatic Animals Commission held in September 2023.

The Code Commission was informed that the Aquatic Animals Commission had reviewed the usage of the Glossary definitions '*Competent Authority*', '*Veterinary Authority'*, and '*Aquatic Animal Health Services*' throughout the *Aquatic Code* and that the amendments will be proposed for adoption in May 2024.

The Commission was also informed that the Aquatic Animals Commission had sent questionnaires to Members to provide their experiences, proposals and opinions with regard to the implementation of compartmentalisation. The Code Commission considered a discussion paper that collated and summarised Member comments for the revision in the *Aquatic Code* of Chapter 4.3. 'Application of compartmentalisation' and gave some complementary considerations regarding existing standards in the *Terrestrial Code*.

The Code Commission noted that the Aquatic Animals Commission had considered Member comments on the draft new *Aquatic Code* Chapter 4.X. 'Emergency disease preparedness' and Chapter 4.Y. 'Outbreak management' and committed to continue liaising with the Aquatic Animals Commission when working on a new chapter of the *Terrestrial Code* on emergency management (see item 4.2.3.).

The Code Commission acknowledged ongoing fruitful collaboration with the Aquatic Animals Commission.

4. Work Programme and priorities

4.1. Comments received on the Code Commission Work Programme

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

The Code Commission noted comments expressing support to the Code Commission work programme. Comments to propose new work are addressed in item 4.4 of this report; comments on work items discussed in this meeting are addressed in the corresponding items.

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

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

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

4.2.1. Animal hosts to be targeted by WOAH Standards for a listed disease

Background

At its September 2023 meeting, following the work to develop the Framework for *Terrestrial Code* Standards, the Code Commission discussed the need to better define which animal hosts should

be included in a disease-specific chapter of the *Terrestrial Code*, taking into account their epidemiological significance in relation to the respective disease, and how this would be addressed in the corresponding chapter of the *Terrestrial Manual*.

The Code Commission considered how disease-specific chapters address animal hosts for different purposes: 'animals susceptible to the disease'; 'animals referred to in the definition of the disease'; 'animals targeted for defining animal health status(es)'; 'animals targeted for surveillance' and 'animals for which trade recommendations are provided' and noted that there were differences among chapters, and agreed to develop a clear and consistent approach to define how animal hosts for a listed disease are included in the *Code* and *Manual*, clarifying its purpose and implications in collaboration with the Scientific Commission and the Biological Standards Commission.

Discussion

The Commission agreed to the establishment of a dedicated task force between the Code Commission, the Scientific Commission and the Biological Standards Commission to develop a consistent approach on the assessment of animal hosts of listed diseases to determine whether and how they should be referred to in the *Terrestrial Code* and the *Terrestrial Manual*, and the consequences for Members' notification obligations and status recognition and for trade and surveillance requirements.

EU	**Item 4.2.1. The EU strongly supports the establishment of the described task force for susceptible hosts. This would be very useful indeed to better describe and justify the various obligations and recommendations within disease-specific chapters.**

4.2.2. Wildlife health

Background

At its September 2021 meeting, the Code Commission discussed a proposal from the WOAH Working Group on Wildlife (WGW) to develop a new chapter in the *Terrestrial Code* on surveillance of diseases of wildlife. The Commission discussed this proposal and provided feedback and requested the WGW to consider its comments before progressing with this work. In February 2022, the Code Commission was informed that the WGW had progressed other work related to this request. The Commission agreed to continue discussing the possible inclusion of new items related to wildlife health management in its work programme at its next meeting.

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

In February 2023, the Commission and the Chair of the Working Group agreed to foster a closer collaboration to promote early identification of potential cooperative work in standards development for the *Terrestrial Code* and to include possible contributions from the WGW to relevant items in the Code Commission's work programme.

Since September 2023, the WGW has been providing comments on relevant chapters being circulated, and an effective collaboration was being driven by the Secretariat to promote the contribution of the WGW at early stages of the relevant work items.

Discussion

The Secretariat updated the Commission on the progress of the ongoing exchanges with the WGW and commended the interest and engagement of the Group to actively contribute to the Code Commission's work to review and develop the *Terrestrial Code*.

The Code Commission acknowledged that the WGW has made valuable comments to different items at this meeting, which are addressed specifically in each report item. The Commission reaffirmed its commitment to continue working collaboratively towards improving how the *Terrestrial Code* addresses wildlife health.

EU	**Item 4.2.2. The EU would like to raise some concerns regarding the recent activities of the Working Group on wildlife.** **The EU commends the work of the WGW. However, when this work has some potential impact on WOAH Standard Setting or directly impacting Member Countries rights and obligations, e.g. the results of the ad hoc group on emerging diseases, any item of work should first be included in the respective work programmes of the Specialist Commissions, so that the Member Countries' Delegates can comment on its opportunity and priority.**

4.2.3. Emergency management

Background

At the 89th General Session of the World Assembly of WOAH Delegates, Resolution No.28 was adopted following the presentation of the Technical Item on emergency management, which recommended that WOAH ensures its International Standards further integrate emergency management.

In April 2023, WOAH hosted a Global Conference on Emergency Management which rallied support through a diverse multi-sectoral audience to further support efforts to strengthen capacities of Veterinary Services in emergency management.

As part of the work to progress on the outputs of the conference and its previous work to further integrate emergency management into its work programme, in September 2023 the Code Commission reviewed and supported a proposal from the Secretariat to draft standards on emergency management. The Commission requested the Secretariat to develop a plan to undertake this work, including Terms of Reference for an *ad hoc* Group, if relevant, and report back at its next meeting.

Discussion

The Code Commission discussed the proposed approach and draft Terms of Reference for an *ad hoc* Group prepared by the Secretariat to develop standards on emergency management for the *Terrestrial Code*.

The Commission agreed that this would support the evolving needs of Veterinary Services and address gaps in the existing standards, an important task considering the increasingly complex risk landscape. The Commission agreed that the new standards would be applicable to all hazards and types of emergencies and could have horizontal impact across the *Terrestrial Code*.

The Commission agreed to the draft Terms of Reference and provided the following recommendations regarding the future work of the *ad hoc* Group. First, to facilitate the work of the proposed *ad hoc* Group, the Secretariat should conduct an initial scoping of the *Terrestrial Code* and identify relevant texts dealing with emergency management and provide this review to the *ad*

hoc Group. Second, the Commission recommended that the content should be focused on principles of emergency management, cover preparedness and not be prescriptive as the details would be covered by existing separate guidelines. Third, it was also recommended that the Terms of Reference allow for multiple options to integrate emergency management in the *Code*, such as a new chapter, a revision of existing chapters or a combination of both.

The Commission proposed that the *ad hoc* Group include a member of the Scientific Commission, and considered that since the Aquatic Animals Commission would identify important parallels in the *Aquatic Code*, this work should be initiated in close coordination between both commissions from its early stages.

The Commission requested the Secretariat to report back on progress at its next meeting.

4.2.4. Revision of Chapter 1.6. Procedures for official recognition of animal health status, endorsement of an official control programme, and publication of a self-declaration of animal health status, by WOAH

Background

At its September 2022 meeting, the Code Commission considered a request from a Member to amend Chapter 5.8. 'International transfer and laboratory containment of animal pathogenic agents', and to improve clarity as to whether Members can hold pathogenic agents in laboratories without affecting their animal health status. The Code Commission noted that in addition to Chapter 5.8., references relevant to recommendations for laboratories were also included in Chapter 3.2., Chapter 3.4, and Chapters 1.7. to 1.12. in the *Terrestrial Code* and in Chapters 1.1.3. and 1.1.4. of the *Terrestrial Manual*. The Code Commission agreed that this specific request should be addressed in the context of official status recognition by amending Chapter 1.6.

At its February 2023 meeting, the Code Commission agreed to develop a new Article 1.6.4. to clarify that the presence of a pathogenic agent in an approved laboratory with an appropriate level of containment and biosecurity in accordance with the *Terrestrial Manual* (as it can be the case, e.g., for vaccine or antigen banks, or for reference laboratories) will not impact the animal health status of a country or zone. The Commission also agreed to cover in the same article other similar provisions currently included in other horizontal chapters and requested the opinion of the Scientific Commission on this proposal.

Discussion

The Code Commission considered the feedback from the Scientific Commission at its September 2023 meeting and agreed to its opinion that the Glossary definition for 'laboratories' was limited to diagnostic purposes and that it was relevant to also consider other animal facilities.

The Commission reviewed the draft new text of Article 1.6.4. and agreed to include in its work programme the revision of the Glossary definition for 'laboratory', in consultation with the Biological Standards Commission, to also consider approved facilities used for other purposes than diagnostic, such as research on pathogenic agents, animal experiments or challenging animals by exposure to pathogenic agents to produce biological products.

The Commission noted that this chapter was closely related with the ongoing work for the revision of some chapters in Section 5 of the *Terrestrial Code* and of the draft Chapter on Biosecurity and requested the opinion of both *ad hoc* Groups on this proposal before progressing work.

4.2.5. Revision of Chapter 4.4. Zoning and compartmentalisation

Background

At its September 2021 meeting, the Code Commission discussed specific issues raised in the context of the 88th General Session on several texts that were adopted at that General Session. Among these topics, the Commission agreed to a comment to consider amending Article 4.4.7. of Chapter 4.4. 'Zoning and compartmentalisation' to clarify whether a time limit should be defined for a containment zone. The Code Commission recalled that a similar proposal had been made by the Scientific Commission and 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.

At its February 2023 meeting, the Code Commission noted the opinion of the Scientific Commission regarding how the proposed amendment could be applied to diseases for which WOAH grants an official animal health status.

At its September 2023 meeting, the Code Commission considered the proposed revised Article 4.4.7. and some relevant comments received on disease-specific chapters that had been circulated for comment that highlighted differences in Members understanding of critical aspects of the implementation of zoning. The Commission noted that a thematic study was being undertaken by the WOAH Observatory on this topic that could provide valuable information on the current state of implementation of related WOAH Standards and challenges faced by Members, and agreed not to proceed with its review of the revised Article 4.4.7., but rather to expand the scope of this work item to clarify critical concepts in Chapter 4.4. 'Zoning and compartmentalisation' and the development of a new chapter on the implementation of zoning. The Commission requested the Secretariat to prepare a background paper to be considered in collaboration with the Scientific Commission at February 2024 meetings.

Discussion

The Commission reviewed a background paper prepared by the Secretariat, together with the outcomes of the Observatory Thematic Study on Zoning (See item 7.8. of this report) and discussed at length the different considerations for this work. The Commission agreed to request that an *ad hoc* Group be convened to develop a new Chapter 4.X. 'Implementation of zoning' for the *Terrestrial Code* and to also review relevant points in Chapter 4.4. 'Zoning and compartmentalisation' to ensure consistency and complementarity between the two chapters.

The Commission highlighted the critical points that should be taken into consideration for the upcoming work. The Commission noted that the new Chapter 4.X. should address the basic definitions of 'zoning' as a fundamental animal health management tool, and separately describe the different objectives and contexts of use. Furthermore, the chapter should clarify the principles for the definition of the animal health status of established zones and include information relevant to Chapter 1.6. with regards to the procedures for official recognition of animal health status, endorsement of an official control programme, and publication of a self-declaration of animal health status. The new chapter should also define the interrelation between implementation of zoning and the recognition of zoning for international trade purposes. The Commission also requested that this work also include a review of the relevant Glossary definitions.

The Code Commission requested the Secretariat to draft the Terms of Reference for an *ad hoc* Group to undertake this work for consideration by the Code Commission and the Scientific Commission at their September 2024 meetings.

4.2.6. Revision of Chapter 4.7. Collection and processing of bovine, small ruminant and porcine semen (Complete revision)

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.*

In September 2023, the Commission highlighted that the current Chapter 4.7. should be revised, aiming for a full new text providing recommendations for all species covered in the new Chapter 4.6. (i.e. bovids, equids, small ruminants, suids and cervids) and should only address WOAH listed diseases. The Commission noted that, after having a draft text, the relevant provisions in the disease-specific chapters of the *Terrestrial Code* will also have to be reviewed for consistency.

The Code Commission requested the Secretariat to convene the *ad hoc* Group to proceed with the revision of Chapter 4.7., as complementary to the revised Chapter 4.6.

Discussion

The Secretariat updated the Code Commission on the progress of the comprehensive revision of Chapter 4.7.

The Secretariat informed that the work of the *ad hoc* Group had already started, and an electronic consultation was ongoing to seek advice of additional experts to cover the broad range of animal species to be addressed by the revised Chapter.

The Code Commission requested the Secretariat to report back on progress at its September 2024 meeting.

4.2.7. New chapter on biosecurity (Chapter 4.X.) and associated Glossary definitions

Comments on new Chapter 4.X. were received from Argentina, Australia, Canada, China (People's Republic of), Chinese Taipei, Japan, New Caledonia, New Zealand, Switzerland, the USA, the AU-IBAR, the EU, the IEC and the WGW.

Comments on the revised associated Glossary definitions were received from Argentina, China (People's Republic of), New Caledonia, Switzerland, the USA, the African Union and the EU.

Background

In September 2017, the Code Commission discussed the importance of biosecurity for disease prevention and control and, due to its relevance in both horizontal and disease-specific chapters, agreed to develop a new chapter on biosecurity for the *Terrestrial Code* and added this to its work programme.

In September 2022, the Code Commission requested that an *ad hoc* Group be convened to initially develop a chapter structure, to describe the content of each article and to revise the associated Glossary definitions for the consideration of the Code Commission and the Scientific Commission.

In February 2023, after considering the *ad hoc* Group's work and feedback from the Scientific Commission, the Code Commission agreed that the proposed structure of the new Chapter 4.X., and the overall content were appropriate and requested that the *ad hoc* Group be reconvened to draft a new chapter and to revise current Glossary definitions for 'biosecurity' and 'biosecurity plan', and to propose a new definition for 'swill'.

At its September 2023 meeting, the Code Commission considered the *ad hoc* Group's report and reviewed the draft new Chapter 4.X. the proposed revised Glossary definitions for 'biosecurity' and 'biosecurity plan', and a new definition for 'swill', together with input from the Scientific Commission. The Code Commission circulated the draft new Chapter 4.X. and the revised Glossary definitions and the new definition for comments.

The topic was also discussed between the Code Commission and the Aquatic Animals Commission to seek consistency between the respective Codes.

Discussion

The Code Commission noted that this is the first time the proposed new chapter and the associated Glossary definitions have been circulated for comments and acknowledged the numerous comments received. The Commission requested that the *ad hoc* Group on Biosecurity be reconvened to undertake a thorough revision of the text in response to the comments received. The Commission considered all the comments and provided guidance on key areas for the *ad hoc* Group as noted below.

a) Existing Glossary definitions 'biosecurity' and 'biosecurity plan' and proposal of a new definition 'swill'

'Biosecurity'

The Code Commission did not agree to a comment to expressly add 'vectors' to the definition, noting that vectors are already covered by the definition because they are one means by which pathogenic agents are spread.

The Code Commission did not agree with a request to use the term 'hazards' instead of 'pathogenic agents.' The term 'hazard' is defined, but it is not appropriate as a replacement because it also includes chemical and physical agents which are not in the scope of the term 'biosecurity'. The Commission agreed to add to its work programme the consideration for the development of a definition for 'pathogenic agent'.

'Swill'

The Code Commission did not agree with a comment to change the definition to 'a mixture of meals that people leave and discard after a meal, including table leftovers, kitchen processing leftovers and kitchen waste.' The Commission explained that the proposed text does not address food waste from other pathways such as food processing. In addition, it does not address that food waste has to contain animal products intended for feeding, which is precisely the risk factor associated to swill.

The Code Commission did not agree with a comment that 'swill' must be treated per definition, because the disease risk occurs when swill is not properly treated, and the *Terrestrial Code* provides recommendations for the treatment of swill.

b) Draft new Chapter 4.X. Biosecurity

The Code Commission agreed with several comments that the proposed chapter is too detailed in various articles, which makes it ineffective for use with multiple scenarios and species. The Commission requested that the *ad hoc* Group focus on biosecurity principles applicable in all situations, as a basis for potential detailed guidance documents that address more specific scenarios.

The Code Commission agreed with comments that the roles of the Competent Authorities, Veterinary Authority, operators, veterinarians and other stakeholders need to be clarified in the chapter. The Commission stated that, in general terms, Veterinary Authority and Competent Authorities are responsible for legal frameworks and guidance for implementation of biosecurity and for providing relevant training to stakeholders. Operators are responsible to develop and implement biosecurity plans adapted to their production and context and consistent with the framework or guidance provided by the Veterinary Authority and Competent Authorities.

The Code Commission agreed with several comments on the need for consistent use of terminology around 'cleaning,' 'cleansing,' 'disinfection' and 'decontamination.' The Commission reminded Members that the Glossary definition for 'disinfection' includes 'cleansing', but questioned if this was still appropriate. The Commission requested the *ad hoc* Group to agree on appropriate terminology and ensure that it is used consistently throughout the chapter. The Commission also agreed to include in its work programme the revision of the Glossary definition for 'disinfection' and requested the *ad hoc* Group to also undertake this work.

The Code Commission did not agree with comments to include specific references to animal welfare, as this was out of the scope of this chapter.

The Code Commission discussed comments about the scope of the chapter, whether wildlife should be included and in what context. The Commission considered that many of the biosecurity measures recommended in the chapter were difficult to apply to wildlife, but requested the *ad hoc* Group to take this into consideration in the structure of the chapter to possibly include considerations on wildlife separately or as a subset of other recommendations, and how the One Health approach in general could be considered in the chapter.

The Code Commission also agreed with comments that the biosecurity recommendations in the chapter seemed more appropriate for large scale operations and less applicable to smaller operations and requested the *ad hoc* Group to take this into consideration when determining the best way to structure the chapter and the level of detail.

The Commission requested that the Secretariat provide an update on progress of this work at its next meeting.

4.2.8. Revision of Chapters 5.4. to 5.7. and associated Glossary definitions

Background

At its September 2017 meeting, the Code Commission agreed to include a review of Section 5. 'Trade measures, import/export procedures and veterinary certification', on its work programme to better support Members in managing the risks of introduction of diseases through the importation of commodities. At its September 2021 meeting, the Commission reviewed the current chapters of Section 5 and agreed that the revision of Chapters 5.4. to 5.7. should be given priority.

At its February 2022 meeting, the Code Commission requested that an *ad hoc* Group be convened to progress this work and discussed several points that it considered important to include in the draft Terms of Reference for the *ad hoc* Group and encouraged Members to submit comments on these points.

At its September 2022 meeting, the Code Commission considered comments received and finalised the draft Terms of Reference for the *ad hoc* Group.

At its February 2023 meeting, the Code Commission considered the *ad hoc* Group report and agreed with the *ad hoc* Group's proposal to replace the four current chapters (Chapters 5.4., 5.5., 5.6. and 5.7.) with three new chapters that will provide recommendations on measures and procedures that are applicable during 'exportation (from the origin to the point of exit of the exporting country)', 'transit' and 'importation (from arrival to the point of entry until clearance)', respectively. The Commission also agreed with the proposal to develop a fourth chapter to address key requirements (e.g., border control/inspection posts, quarantine facilities). In its September 2023 meeting, the Code Commission considered the *ad hoc* Group's report and the draft of the new Chapter 5.4. 'Measures and procedures applicable in the exportation of commodities', Chapter 5.6. 'Measures and procedures applicable in the importation of commodities' and associated Glossary definitions. The Code Commission circulated the new Chapters 5.4. and 5.6. and revised and new Glossary definitions for comments and requested that the *ad hoc* Group be reconvened to complete drafting the remaining texts.

Discussion

The Commission considered the comments received on the revised Chapters 5.4. and 5.6., as well as on several associated Glossary definitions that were circulated in its September 2023 meeting report.

The Code Commission noted that this was the first time the proposed new chapter and the associated Glossary definitions had been circulated for comments and acknowledged the numerous comments received. The Commission also reviewed the report of the November 2023 meeting of the *ad hoc* Group on Revision of Chapters 5.4. to 5.7. of the *Terrestrial Code*, together with the proposed draft revised Chapters 5.5. and 5.7. prepared by the *ad hoc* Group.

The Commission requested that the *ad hoc* Group be reconvened to undertake further revision of the texts in response to the comments received. The Commission considered all the comments and provided guidance on key areas for the *ad hoc* Group as noted below.

a) Glossary definitions

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

Discussion

'Border inspection post'

The Code Commission considered a comment to add 'official' to clarify the veterinary inspection described in this definition, and it agreed to request the *ad hoc* Group to clarify the usage of relevant terms not only in this definition but also in draft revised chapters on trade (Chapters 5.4. to 5.7.).

'Point of exit'

The Code Commission noted comments expressing support for the proposed new Glossary definition.

'Quarantine station'

The Code Commission reviewed the comments and proposed some amendments. The Commission agreed to forward the amended text to the *ad hoc* Group for its consideration.

'Container'

The Code Commission noted comments expressing support for the revised Glossary definition.

'Vessel/vehicle'

The Code Commission noted comments expressing support for the revised Glossary definition.

For the terms 'container' and 'vessel/vehicle', the Commission requested the Secretariat to develop the revised definitions in conjunction with other chapters in the *Terrestrial Code* currently under revision, such as chapters on animal welfare during transport (see item 4.2.9 of this report).

The Commission agreed that the revision of these Glossary definitions would proceed concurrently with the work on the revision of Chapters 5.4. to 5.7. The Commission requested the Secretariat to report the results of the *ad hoc* Group at its September 2024 meeting.

b) Revised Chapter 5.4. Measures and procedures applicable in the exportation of commodities and Revised Chapter 5.6. Measures and procedures applicable in the importation of commodities

Comments on Chapter 5.4. were received from Argentina, Australia, Canada, China (People's Republic of), Japan, Norway, Switzerland, AU-IBAR and the EU.

Comments on Chapter 5.6. were received from Argentina, Australia, Canada, Japan, New Caledonia, Norway, Switzerland, AU-IBAR, and the EU.

Discussion

The Code Commission agreed with comments that several terms used throughout the draft Chapters 5.4. to 5.7., such as 'business operators', 'importers, 'exporters', 'official control' and 'status of commodities', should be clarified.

The Code Commission agreed with comments that the responsibilities of the *Veterinary Authority*, the *Competent Authorities* and *Veterinary Services* should be clarified throughout the draft Chapters 5.4. to 5.7.

c) *Ad hoc* Group report and draft revised Chapters 5.5. and 5.7.

The Code Commission reviewed the new draft Chapter 5.5. 'Measures and Procedures Applicable in the Transit of Commodities', the new draft Chapter 5.7 'Border Inspection Posts and Quarantine Centres', and new draft Glossary definitions for 'point of entry', 'point of exit', and 'transit country'. The Commission agreed with the *ad hoc* Group proposal that these definitions will help improving consistency in usage and understanding of Chapter 5.5 as it relates to other trade chapters under revision.

The Code Commission noted that some of the recommendations that were made for Chapters 5.4 and 5.6 will also be applicable to Chapter 5.5. and 5.7 and should be addressed by the *ad hoc* Group at the same time. The Code Commission reviewed the draft texts and provided additional guidance for the *ad hoc* Group to consider when reviewing the two chapters.

The Code Commission also discussed the possibility to develop an introductory chapter to Section 5, similar to what is done for other Sections of the *Terrestrial Code*. The Commission agreed that this could provide background and clarity on the objective and content of the different chapters in the Section. The Code Commission requested the *ad hoc* Group to consider whether this would be a useful feature that could address some of the redundancies in Chapters 5.4 to 5.7.

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

Background

During the first WOAH Animal Welfare Global Forum 'Animal Transport: A Shared Responsibility' held in April 2019, participants emphasised the importance of revising the *Terrestrial Code* chapters on the welfare of animals during transport by land, sea and air (Chapters 7.2., 7.3. and 7.4.), taking into account the latest information in animal welfare science, notably in the use of animal-based measures.

In February 2021, the Code Commission considered the Forum recommendations and agreed to include a review of these chapters in its work programme.

At its September 2022 meeting, the Commission requested that an *ad hoc* Group be convened to commence work on Chapters 7.2. and 7.3.

At its September 2023 meeting, the Code Commission considered the history of Chapter 7.4. 'Transport of animals by air' and the link to the International Air Transport Association (IATA) Live Animal Regulations (LAR). The Commission noted that, at the 49th General Session in 1981, WOAH "…officially approved the IATA Live Animals Regulations (LAR) as the guideline for the carriage of live animals by air" and that this decision was validated in Resolution No.1 of the 50th General Session in 1982. The Code Commission requested that the Secretariat discuss with the *ad hoc* Group options for including general animal welfare recommendations referring to air

transport in a generic chapter on animal transport or within Chapters 7.2. and 7.3. and keep the specific aspects, such as recommendations on stocking density, in the IATA LAR guideline. The Commission noted the importance of ensuring that the relevant content of the IATA LAR guideline would be publicly available for use by Veterinary Authorities and relevant stakeholders and that there are mechanisms for Members to propose changes to the text of LAR guideline, and recommended Members to apply the provisions of such IATA LAR guideline. The Commission requested that the Secretariat continue to engage with IATA to explore these aspects and report back to its February 2024 meeting.

a) Revision of Chapters 7.2. Transport of animals by sea and Chapter 7.3. Transport of animals by land

Discussion

The Secretariat updated the Commission on the outcomes of the first meeting of the *ad hoc* Group for the revision of Chapter 7.2. 'Transport of animals by land' and Chapter 7.3. 'Transport of animals by sea', held from 28-30 November 2023 at WOAH Headquarters.

The Code Commission considered the proposal of the *ad hoc* Group to merge Chapters 7.2. and 7.3. and agreed that due to the significant duplication of the content in both chapters, merging the two chapters with the new title of "Transport of animals by land and water" would be beneficial for the end user.

The Code Commission agreed with the proposal of the *ad hoc* Group to follow a similar structure of the recently revised Chapter 7.5. 'Animal welfare during slaughter', including 'animal-based measures' to assess the welfare of animals during the whole transport operation.

The Code Commission requested that the *ad hoc* Group be reconvened to continue work of the new revised Chapter 7.X. 'Transport of animals by land and water' as well as any relevant Glossary definitions. The Commission requested that the *ad hoc* Group also discuss whether the chapter could include recommendations on transport of animals by air and thus become a general chapter on transport of animals.

The Commission requested that the Secretariat provide an update on progress of the *ad hoc* Group's work at its September 2024 meeting,

b) Revision of Chapter 7.4. Transport of animals by air

Discussion

The Secretariat updated the Commission on the outcomes of discussions with the International Air Transport Association (IATA) Live Animal and Perishable Board (LAPB) regarding options that could be considered for the revision of Chapter 7.4. 'Transport of animals by air'. The Secretariat reminded the Commission that currently some of the recommendations in Chapter 7.4 are a duplication of the IATA Live Animal Regulation (LAR) and vice versa and it is difficult to ensure that Chapter 7.4 and the IATA LARs are always aligned.

The Code Commission reiterated the importance of ensuring that the relevant content of the IATA LAR be publicly available for use by Veterinary Authorities and relevant stakeholders and that there are mechanisms for Members to propose changes to the text of the LAR. The Commission requested the Secretariat to analyse some options to include relevant information regarding the transport of animals by air, which is not currently in the LAR in the new Chapter 7.X. 'Transport of animals by land and water' and requested that the *ad hoc* Group review these options.

The Commission requested the Secretariat to provide an update on progress at its September 2024 meeting.

4.2.10. Revision of chapters on equine encephalitides (Chapter 8.10. Japanese encephalitis, 12.4. Equine encephalitis (Eastern and Western) and 12.11. Venezuelan equine encephalomyelitis)

Background

In September 2022, the Code Commission agreed to include the revision of Chapter 8.10. 'Japanese encephalitis' in its work programme following requests from Members. The Commission also noted that the revisions of Chapter 12.4. 'Equine encephalomyelitis (Eastern and Western)' and Chapter 12.11. 'Venezuelan equine encephalomyelitis' had been included in its work programme in February 2020, but that work had not been yet initiated.

Considering the epidemiological similarities across these three diseases, the Commission agreed to undertake the revision of these three disease-specific chapters together, to ensure a consistent logic is applied to all three chapters. The Commission also agreed that Chapter 8.21. 'West Nile fever' should also be taken into consideration.

While acknowledging that a major revision of these chapters will be needed, before discussing revised texts of the chapters, the Code Commission requested a scientific assessment of the animal hosts, their epidemiological role and their relevance for surveillance and disease prevention and control be undertaken in collaboration with the Scientific Commission together with an assessment of these diseases against the criteria for the inclusion of diseases, infections and infestations in the WOAH list of notifiable terrestrial animal diseases in accordance with Chapter 1.2. of the *Terrestrial Code*.

The Code Commission was informed by the Secretariat that the requested assessments for Japanese encephalitis, equine encephalomyelitis (Eastern and Western), and Venezuelan equine encephalomyelitis had been undertaken by subject-matter experts.

The Commission acknowledged the progress of this work and agreed with the proposed next steps and reminded that Chapter 8.21. 'West Nile fever' should also be taken into consideration for the future work to ensure a consistent approach for these diseases.

Discussion

The Code Commission considered the conclusions of the Scientific Commission provided in its September 2023 report on the assessment of Japanese encephalitis (JE), Eastern (EEE) and Western equine encephalomyelitis (WEE), and Venezuelan equine encephalomyelitis, and agreed that they meet the listing criteria. The Commission noted that the assessment reports did not provide sufficient information on the role of the different animal hosts and their significance in the epidemiology of the disease, as previously agreed between the two Commissions. The Commission highlighted that it considered this information essential to review the corresponding chapters in the *Terrestrial Code* and requested that these considerations be explicitly discussed by the *ad hoc* Group.

The Code Commission agreed to revise *Terrestrial Code* chapters on equine encephalitides and considered the draft Terms of Reference for an *ad hoc* Group.

The Code Commission revised the Terms of Reference to clarify that the *ad hoc* Group should consider all chapters that address the five enchepalitides [i.e., EEE, WEE, JE, West Nile fever and VEE]; assess whether Eastern and Western equine encephalomyelitis should be covered in separate chapters; define the animal hosts to be targeted for each disease, and whether the names of diseases containing specific country names should be re-considered, taking into account the relevant WHO guidelines.

The Code Commission requested the Secretariat to report back at its September 2024 meeting.

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

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

Background

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

At its September 2022 meeting, the Code Commission considered the amendments proposed by the Secretariat for harmonisation, as well as other changes that had been proposed by the *ad hoc* Group on CBPP in October 2015 and considered by the Scientific Commission at its February 2016 meeting. The Code Commission reviewed all proposals and introduced additional amendments for clarity and consistency with other chapters and circulated the revised chapter for comments.

The revised Chapter 11.5. 'Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)' has been circulated three times for comments.

Discussion

General Comments

The Code Commission noted comments expressing support for the proposed amendments.

The Code Commission addressed all comments received and requested that the Secretariat forward some specific comments to the Scientific Commission and the Biological Standards Commission for their advice.

Acknowledging the agreement between the Bureaus of the Code Commission and the Scientific Commission regarding the impact that the potential adoption of the revised Chapters 11.5. and 12.1. would entail on the procedure on annual reconfirmation for maintenance of officially recognised status of CBPP or AHS of Members and the related administrative work for both Members and WOAH, the Code Commission agreed not to propose the chapter for adoption at the 91st General Session and rather re-examine in September after review of possible consequences on the procedure by the Secretariat.

The Commission agreed to address this chapter with the inputs from the Scientific Commission and the Biological Standards Commissions, at its September 2024 meeting.

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

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

Background

In September 2022 the Code Commission agreed to add the development of a new Chapter 11.X. 'Infection with bovine pestiviruses (bovine viral diarrhoea)' to its work programme and drafted a new chapter, consisting of one single article for the general provisions, including the definition of its occurrence, based on a case definition endorsed by the Scientific Commission.

At the September 2023 meeting, the Code Commission also agreed to amend the disease name in Article 1.3.2. to 'Infection with bovine pestiviruses (Bovine viral diarrhoea)' and to circulate the proposed amendment for comments.

The proposed new Chapter 11.X. 'Infection with bovine pestivirus (Bovine viral diarrhoea)', was circulated three times, the last time in the September 2023 meeting report.

Discussion

Article 11.X.1.

In the first paragraph, the Code Commission acknowledged comments proposing amendments to the taxonomy of pestivirus, due to a change at the International Committee on Taxonomy of Viruses (ICTV), that had revised the species names for bovine pestiviruses by adopting the binomial species names in November 2022. The Commission noted the agreement of the Biological Standards Commission to this proposal, which will also be proposed for the corresponding *Terrestrial Manual* Chapter that is currently being revised.

In point 1, the Code Commission did not agree with comments to limit the case definition and subsequent notification to persistently infected animals, based on the justification already provided in the Code Commission reports from the February and September 2023 meetings. The Commission did not agree either with a comment to add a new point 3 referring to definition of occurrence based on serological positivity, based on the rationale provided in the February 2023 and September 2023 meetings reports. Referring to these two comments, the Commission reminded Members that the definition of occurrence is set for the mandatory notification to WOAH of confirmed cases, and they are not intended for epidemiological investigations of suspect cases, for which Members are not precluded from using other diagnostic methods, or for disease control strategies, for the purpose of which different definitions may be used by Members.

Noting that the amendments being proposed to the definition of the pathogenic agents would depend on the adoption of the proposed revised *Terrestrial Manual* Chapters at the upcoming General Session, the Commission agreed not to propose this chapter for adoption at the 91st General Session, but to address this item again at its September 2024 meeting.

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

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

Background

At its February 2021 meeting, the Code Commission agreed to review Chapter 12.1. 'Infection with African horse sickness virus', to harmonise the provisions for official recognition and maintenance of free status, and endorsement and maintenance of official control programmes with other disease-specific chapters with official recognition of status.

At its September 2022 meeting, the Code Commission reviewed the amendments proposed by the Secretariat for harmonisation, as well as other changes that had been proposed by the *ad hoc* Group in December 2016 and considered by the Scientific Commission in February 2021, and amended the draft chapter, as relevant, and circulated the revised text for comments.

The revised Chapter 12.1. 'Infection with African horse sickness virus' was circulated three times for comment.

Discussion

General Comments

The Code Commission noted comments expressing support for the proposed amendments.

The Code Commission addressed all comments received and requested that the Secretariat forward some specific comments to the Scientific Commission for its advice.

Acknowledging the agreement between the Bureaus of the Code Commission and the Scientific Commission regarding the impact that the potential adoption of the revised Chapters 11.5. and 12.1. would entail on the procedure for annual reconfirmation for maintenance of officially recognised AHS or CBPP status of Members and the related administrative work for both Member and WOAH, the Code Commission agreed not to propose the chapter for adoption at the 91st General Session and rather re-examine in September after review of possible consequences on the procedure by the Secretariat.

The Commission agreed to address this chapter with the inputs from the Scientific Commission, at its September 2024 meeting.

4.2.14. Revision of Chapter 14.8. Scrapie and use of terms 'greaves'

Comments were received from Canada, China (People's Republic of), Switzerland, the UK, the EU and the WRO.

Background

At its February 2021 meeting, the Code Commission noted that a revision of Chapter 14.8. 'Scrapie' had been on its work programme for many years and agreed to progress this work.

At its September 2021 meeting, the Code Commission reviewed a background document prepared by the Secretariat and recalled the previous discussions between the Code Commission and the Scientific Commission on this chapter and noted that the main issue pending 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. Therefore, the Commission requested that an assessment against the listed criteria be conducted following the relevant SOP. In February 2022, the Secretariat informed the Code Commission that the WOAH DDG ISS had considered the request for an assessment and concluded that an assessment was not justified. The Code Commission noted that the Scientific Commission was informed of this decision at its February 2022 meeting and encouraged Members to refer to that report for more information.

At its February 2023 meeting, in response to comments to prioritise the work to review Chapter 14.8., the Code Commission agreed to progress this work, noting that the Members requested that, as part of the update, live animal testing and testing for genetic resistance to scrapie be included as valid methods for ensuring the safe trade of sheep and goats. At its September 2023 meeting, the Code Commission considered a discussion paper prepared by the Secretariat and noted that there was no precedent in the *Terrestrial Code* of providing such recommendations that take into account genetic resistance of animal hosts to a disease, and that it would need in-depth discussions, including consultations with the Scientific Commission, the Biological Standards Commission and relevant experts, when drafting the revised chapter.

In September 2023, the Code Commission acknowledged that a range of requests to revise Chapter 14.8. had been submitted by Members over the last years and requested that the Secretariat develop a plan to undertake the revision of the chapter, including Terms of Reference for an *ad hoc* Group. At the same time, the Commission noted that the term 'greaves' was only used in Chapter 14.8. and reviewed the use of the term in the chapter, and, considering the recent adoption of a revised Glossary definition for 'protein meal', the Code Commission agreed to remove 'greaves' from the Glossary and from Chapter 14.8. Acknowledging that a revision of Chapter 14.8. would be undertaken after its next meeting to address other issues previously raised by some Members, the Commission agreed to circulate for comments the proposed removal of the term 'greaves'.

Discussion

a) Revision of Chapter 14.8. Scrapie

The Code Commission reviewed the draft Terms of Reference for the *ad hoc* Group who will revise Chapter 14.8 'Scrapie' taking into consideration some Member comments already sent on some specific issues. The Commission reminded Members that this revision will be comprehensive to ensure it reflects the latest scientific knowledge.

The Code Commission noted the requested consideration of diagnostic tests on live animal and testing for genetic resistance to scrapie as valid methods for ensuring the safe trade of sheep and goats. The Commission agreed to include these considerations in the reviewed Terms of Reference to ensure they would be considered by the *ad hoc* Group. The Commission requested the Secretariat to also discuss this point further with the Biological Standards Commission.

The Code Commission requested the "ecre'ariat to report back on progress at its September 2024 meeting.

b) Use of term 'greaves' in Chapter 14.8.

Comments were received from Canada, China (People's Republic of), Switzerland, the UK, the EU and the WRO.

The Code Commission noted comments expressing support for the proposed deletion of the term 'greaves' from Chapter 14.8 'Scrapie'.

General Comments

In response to a comment noting that there is no code-line for 'protein meal' in the World Customs Organization (WCO) Harmonized Commodity Description and Coding System (generally referred to as "Harmonized System" or simply "HS"), the Code Commission explained that the purpose of the use of specific terms in the *Terrestrial Code* differs from the purpose of codes in the Customs HS and therefore there is not always a need to align terminologies. Nevertheless, the Code Commission suggested that the Secretariat communicate with the WCO to discuss harmonisation of some terminologies between the two organisations. The Code Commission reminded Members that a certifying veterinarian could include additional information in the international veterinary certificate when trading protein meal, such as source species and ingredients.

Acknowledging that no objection has been raised to the proposed removal of the term 'greaves' from Chapter 14.8. the Commission agreed that this will be done in the upcoming revision of the chapter.

4.2.15. New chapter on Crimean-Congo haemorrhagic fever

Background

In February 2016, the Code Commission agreed to include the development of a disease-specific chapter on Crimean-Congo haemorrhagic fever (CCHF) in its work programme, in response to a Member comment.

In February 2022, in response to a comment to develop a new chapter for CCHF as it is high priority zoonotic disease in Asia and Africa, the Code Commission agreed to initiate this work once a draft case definition was developed by the Scientific Commission and recognised this item as priority.

Discussion

The Code Commission was informed that the Scientific Commission, at its September 2023 meeting, had endorsed a draft case definition for infection with Crimean-Congo haemorrhagic fever virus (CCHFV) that had been developed by subject-matter experts, and that it had been posted on the WOAH website to facilitate Members notification, in the absence of a *Terrestrial Code* chapter.

The Code Commission was also informed that the corresponding Chapter 3.1.5. 'Crimean-Congo haemorrhagic fever' of the *Terrestrial Manual* has been amended to include serological tests, taking into consideration the new draft case definition, and would be proposed for adoption at the 91st General Session in May 2024.

The Code Commission reviewed the draft case definition with a view to developing a new chapter, consisting of one single article for the general provisions, including the definition of the disease and of its occurrence. The Commission noted that some of the amendments being proposed in the *Terrestrial Manual* were critical to developing a disease-specific chapter in the *Terrestrial Code* and agreed to postpone this work until after the adoption of Chapter 3.1.5. of the *Terrestrial Manual*.

4.3. Items under consideration for inclusion in the work programme

The Code Commission discussed several topics for which a request for inclusion in the Commission's work programme had been previously considered, but a decision was not yet made pending the provision of more data or information. The Code Commission highlighted the following topics for which a decision was made at this meeting:

4.3.1. Infection with *Theileria 26urnetii*, *T. orientalis* and *T. parva* (Chapter 11.10.)

Background

The revised Chapter 11.10. 'Infection with *Theileria 26urnetii, T. orientalis* and *T. parva'* was adopted during the 89th General Session in May 2022, but, at the time of adoption, the President of the Code Commission noted some comments raised during or submitted before the General Session that would be considered at a future meeting of the Commission.

At its September 2022 meeting, the Code Commission did not agree with a comment that *T. orientalis* should be delisted, noting that the listing assessment had been well justified and that the chapter only refers to *T. orientalis Ikeda* and *T. orientalis Chitose* and not the other strains of T. orientalis. Nevertheless, the Commission requested the Secretariat to seek further advice from the Scientific Commission, to review and consider the references provided by the Members along with their comments, before further considering this item for inclusion in the work programme.

In February 2023, the Scientific Commission noted the request and sought the advice from the experts who had conducted the listing assessment in 2019. The Scientific Commission considered the expert advice at its September 2023 meeting and forwarded its opinion to the Code Commission.

Discussion

The Commission agreed with the opinion from the experts and the Scientific Commission that there is significant evidence of clinical signs, pathogenicity and economic losses associated with infection with Ikeda and Chitose strains of *T. orientalis*, and therefore *T. orientalis (Ikeda and Chitose)* should remain listed.

With this consideration, the Code Commission agreed that there was no need to add any further work on this matter to its work programme.

4.4. New requests for inclusion in the work programme

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

4.4.1. Revision of Chapter 8.13. New World screwworm (*Cochliomyia hominivorax*) and Old World screwworm (*Chrysomya bezziana*)

The Code Commission considered a proposal from the Scientific Commission to amend Chapter 8.13. 'New World screwworm (*Cochliomyia hominivorax*) and Old World screwworm (*Chrysomya bezziana*)', to incorporate a draft case definition for New World Screwworm and Old World Screwworm that had been developed by subject-matter experts and endorsed by the Scientific Commission at its September 2023 meeting.

The Chapter 8.13. was first adopted in 1992 and updated in 1998. The current chapter contains recommendations for international trade but lacks definition of the diseases and their occurrence.

The Code Commission considered the draft case definition and requested that the Scientific Commission clarify some points on the epidemiological significance of animal hosts, notably birds, noting the divergent opinions of experts. The Code Commission also discussed whether to develop separate disease-specific chapters, noting that the diseases are found in different areas of the world and are caused by different pathogenic agents with possibly different epidemiological patterns, and thus requested the opinion of the Scientific Commission on this point too.

The Code Commission agreed to ©de ©his it©m in its work programme, and to consider progressing it once these points have been clarified.

4.4.2. Revision of Chapter 8.7. Infection with epizootic haemorrhagic disease virus

Background

The Commission was informed on a comment seeking clarification about differences between the English, French and Spanish versions of Chapter 8.7. 'Infection with epizootic haemorrhagic disease (EHD)'. The English version of Chapter 8.7. defines EHD as an infection of cervids and 'bovids' with EHD virus, while the French and Spanish versions use the terms 'bovins' and 'bovinos', respectively. In line with recent agreement at the Code Commission and the amendments proposed to the User's Guide, in the English version, 'bovids' would include cattle, goats and sheep, whereas for the French and Spanish versions, 'bovins' and 'bovinos' respectively, refer only to Bovinae subfamily, which excludes goats and sheep. This difference between the three versions has consequences on the scope of the chapter, as well as on the species to which the trade articles would apply.

Discussion

The Code Commission considered the current Chapter 8.7. and the *Terrestrial Manual* Chapter 3.1.7. 'Epizootic haemorrhagic disease (Infection with epizootic haemorrhagic disease virus)'. The Commission acknowledged the abovementioned differences and highlighted that Chapter 3.1.7. of the *Terrestrial Manual* states that 'EHD is a vector-borne infectious noncontagious viral disease of domestic and wild ruminants, primarily white-tailed deer and cattle. Sheep, goats and camelids might also be susceptible but usually do not develop overt disease.'

The Code Commission reviewed the history of the development of Chapter 8.7, which was first adopted in 2015, and last updated in 2016, and agreed that an editorial error had been made in the adopted English version in 2015. The Commission confirmed that the Spanish and French versions were correct.

The Commission requested the Secretariat to amend the 2024 English edition of the *Terrestrial Code* by replacing 'bovids' with 'bovines'.

Nevertheless, noting that almost ten years had elapsed since the last revision of Chapter 8.7 and that the *Terrestrial Manual* was updated in 2021, and that there has been an evolution in the epidemiology of the disease, including emergence and spread in Europe, the Commission agreed to include a comprehensive review of Chapter 8.7. in its work programme. The Commission requested the Secretariat to undertake an analysis, in consultation with experts and the Scientific Commission, on the points to be taken into consideration in a future revision.

4.4.3. New requests from Members

a) 'Extruded dry pet food'

The Code Commission acknowledged a request to further specify the thermal nature of the extrusion process of "extruded dry pet food" for its inclusion as a safe commodity in relevant disease-specific chapters of the *Terrestrial Code*.

The Code Commission noted that this item was in its work programme and that work had been ongoing. Nonetheless, the Commission reminded Members that the *Terrestrial Code* does not provide standards for processing of commodities and that the Commission normally refers to other international standards, or guidelines or advice provided by partner international organisations representing the industry sectors, on globally standardised industrial practices or processing to support the inclusion in safe commodities in relevant chapters. For this specific commodity, the Commission has worked in close cooperation with the Global Pet Food Alliance (GAPFA). The Commission invited Members to also refer to Item 5.13. of this report.

b) Implications of historical detections of pathogenic agents on animal health status

The Code Commission acknowledged a comment referring to the rapid advancements in diagnostic sequencing technologies, particularly in the field of metagenomics, which has increased the capacity and research focus for pathogen detection globally. The comment highlighted that sequencing performed on historical samples (e.g. archived samples or museum specimens or samples/specimen banks) dating back decades or even centuries can offer valuable insights into pathogen ecology, history, and epidemiology, but noted that the potential implications on the notification obligations or animal health status of such historical detections is unclear within the *Terrestrial Code*.

The Code Commission noted t"at n' specific modifications were requested and that the Commission had not been informed of any specific issue in this regard that would necessitate any changes in the *Terrestrial Code*. The Commission also noted that 'notification' in the Code Glossary was related to the occurrence of disease, infection of infestation, which are all related to animals and that any new diagnostic technologies should be first validated, in accordance with the *Terrestrial Manual*. The Commission requested the Secretariat analyse this request further and to report back to the Commission if any potential impacts on the *Terrestrial Code* are identified.

c) Reinstation of low pathogenic avian influenza in poultry as a listed disease

The Code Commission considered a comment requesting reinstating low pathogenic avian influenza (LPAI) in poultry as a listed disease, because high pathogenicity avian influenza (HPAI) clade 2.3.4.4b virus has evolved and acquired new characteristics, including increased infectiousness to wild birds and a heightened ability to adapt to various species achieved through genetic reassortment with LPAI viruses as evidenced by a new research paper.

The Code Commission noted that the listing of avian influenza viruses had been recently reviewed, as well as the corresponding standards, and stressed that the current priority was for Members to implement the revised standards and that further changes should only be based on broader evidence gathering, including those from the implementation of the new standards. Also, the Commission highlighted that in the past, notification of LPAI in poultry had led to serious and unjustified trade restrictions and had not contributed to the improvement of the global epidemiological situation of HPAI. The Commission did not agree to request a new assessment of

low pathogenic avian influenza in poultry as a listed disease but requested that the Secretariat inform the Scientific Commission and the WOAH DDG ISS of this comment.

d) Revision of Glossary definition for 'poultry'

Background

In May 2023, at the 90th General Session, some Members requested that the revision of the definition of 'poultry' be included in the Commission's work programme to ensure it provided Members with greater flexibility and to clarify issues for non-poultry birds or birds that played no epidemiologically significant role.

At its September 2023 meeting, the Code Commission considered the request as well as comments received to review the Glossary definition for 'poultry' and agreed to add the revision of the definition for 'poultry' to its work programme as priority 4, noting that this work should be addressed as part of its future work to review Section 10 Aves.

Discussion

The Code Commission considered requests from some Members to increase the priority order for the work item on a revision of the definition of 'poultry'. The Commission thanked the Members for the thorough information provided on the implementation challenges for the current definition in the context of recent global epidemics of avian influenza but was not able to agree on a suitable amendment that could address these challenges and be circulated at this stage. The Commission reminded that, being a Glossary definition, its application was not limited to one disease but to the whole *Terrestrial Code*, and that careful consideration should be given before introducing further changes.

The Commission acknowledged the challenges raised and agr©ed to increase the priority of this item to priority order '2' and requested the Secretariat to engage in consultation with experts to prepare for further discussion at the next Code Commission meeting in September 2024.

4.4.4. Prioritisation of items in the work programme

Based on several considerations and the progress of the different topics since its last meeting, as well as relevant exchanges during this meeting, the Code Commission discussed the prioritisation of ongoing and future work, and agreed to amend the work programme as presented below:

New items added:

- Consideration to determine whether several types of highly processed products (such as blood meal, dried plasma, rendered fats, and hydrolysed protein) have a globally standardised production process and meet criteria to be considered safe commodities as regards to specific diseases.
- Revision of the Glossary definition for 'disinfection'
- Development of a new Glossary definition for 'pathogenic agent'
- Revision of the Glossary definition for 'laboratory'
- Development of a new Glossary definition for 'isolation'
- Development of a new Glossary definition for 'suspected case'
- Revision of Chapter 8.7. 'Infection with epizootic haemorrhagic disease virus'
- Revision of Chapter 8.13. 'New world screwworm (*Cochliomyia hominivorax*) and Old world screwworm (*Chrysomya bezziana*)'.

The Code Commission updated its work programme in accordance with the changes in the priorities or the level of advancement of respective items.

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

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

The Commission reminded Members that, a©though it reviews its work programme at each meeting and reconsiders the prioritisation of items according to changes in necessity and urgency, it would not significantly modify the prioritisation order frequently.

Additionally, the Commission thanked Members who commented on work items at an early stage, and encouraged Members to also consider the work items in the Commission's work programme that have not yet started or are in preparation (prioritisation orders 3 and 4). Members are invited to submit to the Secretariat their points of interest for a specific work, as well as available information, evidence, or expertise that could be taken into consideration in each work.

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

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

5. Texts proposed for adoption in May 2024

The Code Commission discussed the following new or revised texts that will be proposed for adoption at the 91st General Session in May 2024.

5.1. Glossary

a) 'animal products', 'germinal products' and 'commodity'

Comments were received from the USA and the EU.

Background

At its September 2019 meeting, the Code Commission considered the use of the terms 'commodity', 'animal product', 'product of animal origin' and 'animal by-product' for the purposes of the *Terrestrial Code* based on a discussion paper prepared by a Commission member. The Commission acknowledged the importance of clarifying the use of these terms and whether to develop definitions for some of them. It agreed to continue this work between sessions.

At its February 2020 meeting, the Code Commission considered again this issue and agreed to discuss it further at its future meetings.

At its February 2023 meeting, the Code Commission agreed that the Glossary definition for 'commodity' should be revised and new definitions should be developed for 'animal product' and 'germinal products', and worked on a draft text and sent proposed revised and new definitions for comments.

At its September 2023 meeting, the Code Commission noted that all comments received were in support of the proposed amendments. The revised Glossary definition for 'commodity' and the new Glossary definitions for 'animal product' and 'germinal products' were circulated for comments.

Discussion

The Code Commission noted comments in support of the proposed amendments.

'animal product'

The Code Commission did not agree with a comment to add 'by-product' as it considered that it was implicitly included in the proposed text.

The Code Commission did not agree with a comment to add 'or produced using', as the term as defined implied that the product actually contains some material derived from animals, whatever the production process.

The Commission did not agree with a comment to include 'germinal products' in the definition as it considered that it would be confusing to have too many subsets in Glossary definitions, as 'animal product' is already a type of commodity, as 'germinal products', and both cover specific usages for the purposes of the Code.

'germinal products'

The Code Commission noted comments expressing support for the proposed new Glossary definition.

'commodity'

The Code Commission did not agree with a comment to delete 'germinal products' from the definition, since it did not agree that the proposed definition for 'animal product' includes 'germinal products', which is a type of commodity per se.

The revised Glossary definition for 'commodity' and the new Glossary definitions for 'animal product' and 'germinal products' are presented as part of Annex 4 and will be proposed for adoption at the 91st General Session in May 2024.

b) New Glossary definition for 'biological products'

Comment was received from New Zealand.

Background

At its February 2023 meeting, the Code Commission discussed the terms 'commodity', 'animal product', 'product of animal origin' and '(animal) by-product' for the purposes of the *Terrestrial Code*. The Commission agreed to develop a new Glossary definition for 'animal product' and to revise the Glossary definition for 'commodity'. In addition, the Commission proposed a new Glossary definition for 'germinal products' (see item (a) above).

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

At its September 2023 meeting, the Code Commission considered an analysis prepared by the Secretariat presenting the use of 'biological product' in the *Terrestrial Code* and related terms in the *Terrestrial Manual*, as well as Glossary definition for 'biological product' in the *Aquatic Code*. The Code Commission developed a new definition for 'biological product', which was agreed by the Biological Standards Commission, and circulated the proposed new definition for comments.

Discussion

The Code Commission did not agree with a comment to replace 'reagents' with 'agents', but it agreed to delete the term 'reagents' for clarity.

The new Glossary definition for 'biological product' is presented as part of Annex 4, and will be proposed for adoption at the 91st General Session in May 2024.

c) 'artificial insemination centre'

Background

As part of the work to revise Chapter 4.6. 'General hygiene in semen collection and processing centres' (see item 5.3. of this report) the Commission agreed to replace the term 'artificial insemination centre' with 'semen collection centre'. The Commission also introduced editorial amendments noting that 'approved' was a defined term, and the definition of 'semen collection centre" includes the condition of approval. The Commission circulated the revised text for comments.

Discussion

The Code Commission noted comments expressing support for the proposed amendments.

The replacement of the Glossary definition for 'artificial insemination centre' with 'semen collection centre' is presented as part of Annex 4 and will be proposed for adoption at the 91st General Session in May 2024.

d) 'greaves'

Background

At its September 2023 meeting, noting that the Glossary definition for 'protein meal', which was adopted at the 90th General Session in May 2023, covers both Glossary definitions for 'meat-and-bone meal' (that was removed from Glossary in May 2023) and 'greaves', the Code Commission agreed to remove 'greaves' from the Glossary and from Chapter 14.8. (refer to item 4.2.14. of this report). The proposed deletion was circulated for comments.

Discussion

The Code Commission noted all comments received were in support of the proposed deletion of 'greaves' from the Glossary.

The deletion of definition for 'greaves' is presented as part of Annex 4 and will be proposed for adoption at the 91st General Session in May 2024.

e) Definitions for 'death', 'euthanasia', 'slaughter', 'stunning', and 'suffering'

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

Background

As part of the work to revise Chapter 7.5. Animal welfare during slaughter, the Code Commission agreed to revise the Glossary definitions for ‘death’, ‘euthanasia’, ‘slaugh‘er’ and 'stunning’.

Discussion

The Code Commission considered the comments r‘ceived.

'death’ (deletion)

The Commission noted that no specific comment was received on the proposed deletion of the Glossary definition for ‘death’.

‘euthanasia’

The Code Commission agreed with comments to delete the words ‘for welfare purposes’ as euthanasia could be performed for reasons other than animal welfare.

The Commission did not agree with a comment to delete the mention of a rapid and irreversible loss of consciousness, as this is an essential part of the welfare concerns when performing euthanasia.

‘slaughter’

The Commission noted that no specific comment was received on the revised Glossary definition for ‘slaughter’.

‘stunning’

The Code Commission did not agree with a comment to reword the definition as it did not improve the clarity.

The revised Glossary definitions for ‘euthanasia’, ‘slaughter’ and ‘stunning’, and the deletion of the definition for ‘death’, are presented as part of Annex 4, and will be proposed for adoption at the 91st General Session in May 2024.

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

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

Background

During recent work on the development of new or revised disease-specific chapters, the Code Commission noted the several issues in Chapter 1.3. ‘Diseases, infections and infestations listed by WOAH’ and agreed to amend Chapter 1.3. to:

- reorder the articles to align with the order used in Sections of Volume II,
- align the animal categories noted in the first paragraph of each article with titles of relevant Sections of Volume II, i.e., scientific names of animal categories, using ‘nouns’, not ‘adjectives’ (e.g. replace “The following are included within the category of equine diseases and infections” with “The following are included within the category of diseases and infec33urnetif equidae.”),
- reorder the diseases in each article in alphabetical order; and
- change disease names to align with the title of the corresponding disease-specific chapter, as relevant.

Noting that these were editorial changes, at its September 2023 meeting, the Commission considered that these amendments could be presented for adoption at the 91st General Session in May 2024.

Also, in view of the progress of several new and revised disease-specific chapters, the Code Commission had agreed to circulate the following changes in names of listed diseases:

- in Article 1.3.1., to replace 'Q fever' with 'Infection with *34urnetiid burnetii* (Q fever)'; in Article 1.3.1., to replace 'Surra (*Trypanosoma evansi*)' with 'Infection with *Trypanosoma evansi* (Surra)';

- in Article 1.3.2., to replace 'Bovine viral diarrhoea' with 'Infection with bovine pestiviruses (Bovine viral diarrhoea)';

- in Article 1.3.4. to replace 'Contagious equine metritis' with 'Infection with *Taylorella equigenitalis* (Contagious equine metritis)'; in Article 1.3.4. to replace 'Equine piroplasmosis' with 'Infection with *Theileria equi* and *Babesia caballi* (Equine piroplasmosis)';

- in Article 1.3.7. to replace 'Rabbit haemorrhagic disease' with 'Infection with pathogenic rabbit lagoviruses (Rabbit haemorrhagic disease)';

- in Article 1.3.9. to replace 'Camelpox' with 'Infection with camelpox virus'.

Discussion

The Code Commission considered the difference in the order in which the diseases are presented in the three linguistic versions, as it follows the alphabetical order for each language. The Commission noted that the order between the articles in Chapter 1.3. Diseases, infections and infestations listed by WOAH and Sections of the *Terrestrial Code* should be the same. However, since the list is presented with the names of diseases only, the Commission noted that there is no negative impact from this difference in the three versions.

The Code Commission reminded Members that the name of 'Nipah virus encephalitis' and entry of the disease in the list of Chapter 1.3. will be amended and proposed closer to adoption of the new draft Chapter 8.Y.

In response to a comment on the harmonisation of 'equine encephalitis (Eastern)' of Article 1.3.1. and the Section 12 Equidae of the *Terrestrial Code*, the Commission noted that the revision of chapters on equine encephalitides will be discussed by the *ad hoc* Group and the harmonisation will be considered accordingly (see item 4.2.10. of this report).

The Code Commission agreed with a comment to apply consistent spelling for 'hemorrhagic' or 'haemorrhagic' in the names of the diseases Crimean-Congo hemorrhagic fever and Infection with epizootic hemorrhagic disease virus. However, noting possible inconsistencies with the spelling used in the corresponding chapters of the *Terrestrial Manual*, and with the International Committee on Taxonomy of Viruses (ICTV) spelling, the Commission requested the Secretariate to further coordinate with the Biological Standards Commission to harmonise both the *Manual* and the *Code* with the ICTV.

The Code Commission agree" wit' a comment to add '(*Pasteurella multocida* serotypes 6:b and 6:e)' to the name of 'Haemorrhagic septicaemia' to align with the title of corresponding chapter of the *Terrestrial Code*.

In response to a comment that the names 'fowl typhoid' and 'pullorum disease' are separated in Article 1.3.3. of the *Terrestrial Code*, while they are grouped in *Manual* Chapter 10.7.3. 'Fowl typhoid and pullorum disease', the Code Commission noted that it will be considered after the case definitions of these diseases are developed.

The revised Chapter 1.3. 'Diseases, infections and infestations listed by WOAH' is presented as Annex 5 (in track changes) and Annex 6 (cleaned text) and will be proposed for adoption at the 91st General Session in May 2024.

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

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

Background

At its September 2019 meeting, the Code Commission requested that an *ad hoc* Group be convened to revise Chapter 4.6. 'General hygiene in semen collection and processing centres' and Chapter 4.7. 'Collection and processing of bovine, small ruminant and porcine semen', as well as provisions in relevant disease-specific chapters of the *Terrestrial Code*. The *ad hoc* Group was also requested to consider the inclusion of provisions to address semen of equids in relevant chapters.

The *ad hoc* Group met virtually during 2020 and 2021 and produced a revised draft Chapter 4.6., which was considered by the Code Commission at its September 2021 and September 2022 meetings.

The revised Chapter 4.6. 'General hygiene in semen collection and processing centres' was circulated three times for comments, the first time in the Code Commission September 2022 meeting report.

At its September 2023 meeting, the Code Commission also circulated a proposed amendment to the Glossary definition, replacing the term 'artificial insemination centre' with 'semen collection centre' for consistency. (see item 5.1. of this report)

Discussion

General comments

The Code Commission noted comments expressing support for the proposed amendments.

Article 4.6.1.

In the first paragraph, the Code Commission agreed with a comment to delete 'will' before 'reduce' as this is an objective of the chapter. The Commission made additional amendments for clarity. The Code Commission did not agree to add 'other microorganisms, some of which may be' before the 'pathogenic' as the text was clear as written and refers to WOAH listed diseases.

In the second paragraph, the Code Commission agreed with a comment to delete the first sentence as it was considered redundant.

In the third paragraph, the Code Commission did not agree with a comment to delete 'or for domestic distribution' as it considered that the Veterinary Authority should provide the regulatory framework and standards not only for international trade but also for domestic distribution, and this chapter will also be suitable to prevent the spread of diseases at national level.

Article 4.6.2.

In the first paragraph, the Code Commission did not agree with a comment to reinstate the sentence 'The semen collection centre should be approved by the Veterinary Authority', as this is already addressed by the use of the Glossary term 'approved' and the definition of the term "semen collection centre."

In the last sentence of the third paragraph, the Code Commission did not agree with a comment to replace 'Veterinary Services' with 'Veterinary Authority'. The Commission highlighted that not all issues should necessarily be reported to the Veterinary Authority and hence, the term Veterinary Services is deemed

more adequate as it covers a broader range of possible schemes of supervision and communication, including with government authorities, such as the Veterinary Authority. The Code Commission highlighted that the roles of the Veterinary Services and Veterinary Authority were mentioned in Article 4.6.1.

In the fourth paragraph, the Code Commission did not agree with a comment to add additional biosecurity measures for equipment used and procedures in the semen collection centre, as it was already covered in point 6.

In point 2, in response to a comment to clarify the meaning of 'other animals', the Code Commission explained that it did not refer to multiple species for semen collection as written in the first sentence, but to animals for other purposes (for example riding horses or dogs for herding donor animals).

The Code Commission agreed to include a new point 3, in response to with a comment to include recommendations on the need for the isolation facility to be cleaned and disinfected before each batch of animals enters the facility.

Article 4.6.3.

In the first paragraph, the Code Commission did not agree to add 'and' after 'housing' as the text was clear as written and refers to 'housing pens.' The Code Commission agreed to delete 'and the bedding renewed as often as necessary to ensure it is dry and clean' as it was clearly addressed in a sentence below in the sixth paragraph of this article.

Article 4.6.4.

In the fourth paragraph, the Code Commission did not agree with a comment to add 'in case of contact with animals that do not meet the same health requirements as those in the centre' at the end of the paragraph, as the current text provided the necessary flexibility.

In the sixth paragraph, the Code Commission agreed with a comment to add 'be designed in such a way as to' after 'should' as it is considered grammatically correct.

In the seventh paragraph, the Code Commission did not agree with a comment to add sentences referring to the cleaning and disinfection of the floor and walls of the semen collection area as this article was about the semen processing facility and these actions are covered in Article 4.6.2.

Article 4.6.5.

In the fifth paragraph, in response to a comment to add 'and equipment for preparation and cleaning of artificial vaginas and' after surfaces, the Code Commission did not agree as it was considered not relevant there and already included in the eighth paragraph.

In the sixth paragraph, in response to a comment to delete 'animal health status', the Code Commission recalled the previous discussion at the September 2023 meeting to amend the term 'animal health status' and replaced it with 'health requirements.' The Code Commission also made additional amendments to improve clarity.

In point 6 of the last paragraph, the Code Commission agreed with a comment to introduce a recommendation to explicitly capture the need to provide in the international veterinary certificate information about the antibiotics used and added a new sentence at the end of the point to capture that.

Article 4.6.6.

In the second paragraph, the Code Commission agreed with a comment to add 'Cryogenic tanks, if not new, should be disinfected before being introduced to the semen collection centre' at the beginning of the paragraph, to ensure safety of storage.

In the third paragraph, the Code Commission did not agree with a comment to delete 'safe' before 'disinfection', as considered it should be done safely for the semen.

In the sixth paragraph, the Code Commission agreed with a comment to add a sentence addressing the need for detailed storage and identification information to be ensured for international trade purposes, as it considered this addition would provide added value for the safety of the storage.

The Code Commission agreed with a comment to add a sentence 'Only semen from the same species and from donors that meet the same health requirements should be stored in same liquid nitrogen.' and proposed to add it as a seventh paragraph as it considered that it was relevant to ensure safety of the stored semen.

The revised Chapter 4.6. 'General hygiene in semen collection and processing centres' is presented as Annex 7 and will be proposed for adoption at the 91st General Session in May 2024.

5.4. Collection and processing of bovine, small ruminant and porcine semen (Chapter 4.7.) (Partial revision)

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

Background

As noted in the items 5.3. and 4.2.6. of this report, the Code Commission agreed to undertake a full revision of 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'.

At its September 2023 meeting, the Commission highlighted that the current Chapter 4.7. should be fully revised. Noting that the revised Chapter 4.6. was being circulated and would be proposed for adoption in May 2024, the Commission agreed to propose at the same time the deletion of current Articles 4.7.5., 4.7.6. and 4.7.7., to avoid inconsistencies after the potential adoption of the proposed new text for Chapter 4.6.

Discussion

The Code Commission noted comments expressing support for the proposed amendments.

The Commission noted several comments outside of the scope of this partial revision, referring to inconsistencies between some articles in the current Chapter 4.7. and some disease-specific chapters. The Commission reminded Members that relevant articles will be addressed in the comprehensive revision of Chapter 4.7. (see item 4.2.6. of this report) and requested the Secretariat to ensure these comments are taken into consideration during that revision.

Article 4.7.2.

In point b, in response to a comment that there was no Article 8.11.5., the Code Commission agreed to amend 'point 3 or 4 of Article 8.11.5.' with 'Article 8.12.7.', as it provided the correct information. Nevertheless, the Commission reminded Members that the comprehensive revision of this chapter will ensure having no cross-references to any disease-specific chapter.

The partially revised Chapter 4.7. 'Collection and processing of bovine, small ruminant and porcine semen' is presented as Annex 8 and will be proposed for adoption at the 91st General Session in May 2024.

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

Comments were received from Australia, Canada, China (People's Republic of), Colombia, Japan, New Caledonia, Switzerland, the UK, the USA, the AU-IBAR and the EU.

Background

At its February 2019 meeting, the Code Commission agreed to include the revision of Chapter 6.10. 'Responsible and prudent use of antimicrobial agents in veterinary medicine' in its work programme, in response to Member comments.

Based on advice from the WOAH Working Group on Antimicrobial Resistance (AMR Working Group), the Commission agreed not to launch the work to review Chapter 6.10. until the revision of the Codex Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005) had been finalised and adopted, to avoid inconsistencies between the respective texts.

At its February 2022 meeting, the Code Commission noted that the revised Codex Code of Practice had been adopted in November 2021, and agreed to initiate the development of a revised Chapter 6.10. in collaboration with the AMR Working Group.

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

At its February 2023 meeting, the Code Commission considered all comments received and requested the advice of the AMR Working Group to address some of them.

At its September 2023 meeting, the Code Commission considered the feedback from the AMR Working Group and further amended the text and circulated it for comments.

The Code Commission also requested the Biological Standards Commission to provide its opinion on comments referring to the establishment of clinical breakpoints. The Biological Standards Commission addressed this request at its September 2023 and February 2024 meetings.

The revised chapter 6.10. has been circulated twice for comments.

Discussion

General comments

The Code Commission noted comments expressing support for the revised chapter.

The Code Commission did not agree with a comment to have separate descriptions'for the 'Responsibilities of vete'inarians' in handling food-producing and non-food-producing animals. The Commission acknowledged that food-producing animals and non-food producing animals are kept for different purposes and that antimicrobial use occurs in very different contexts and settings. Selection of antimicrobials for use in these two categories of animals still needs to follow the same principles for responsible and prudent use of antimicrobials. The Commission stressed that cost of antimicrobial treatment is not part of these principles.

The Commission discussed a request for advice on the use of italics for some defined Glossary terms, such as '*animal*' or '*feed*', which could be used in different manners and contexts. The Commission agreed that a defined term that is a noun should be in italics only if it is used as a noun; but if this noun is used as an adjective and not just a part of another defined term, it should not be in italics (example: an *animal*, animal health, animal environment, animal species, *animal welfare*).

Title of the Chapter

The Code Commission did not agree with a request to amend the chapter title from 'Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine' to 'Responsible and Prudent Veterinary Medical Use of Antimicrobial Agents', as it was deemed unnecessary and that changing the title of the chapter at this point of the review process could be detrimental and misleading to Members.

Article 6.10.1.

In the second paragraph, the Code Commission discussed a request to add 'prescribing' to the existing list of activities. The Commission agreed to add the term 'prescription' for additional clarity, especially as prescription rules differ between countries and it could help to discourage the use of antimicrobials without a prescription.

In the third paragraph, the Code Commission agreed with comments to amend the text and added 'the indications for use' after 'relevant regulatory approval' and added 'including off label use'. The Commission considered that these changes improved the clarity of the paragraph. The Commission agreed to add the text 'All measures to keep animals healthy, such as preventing infectious animal diseases through vaccination, biosecurity measures, good agricultural and animal husbandry practices and adequate nutrition', to improve clarity. The Code Commission agreed with a comment to reinstate 'good agricultural', as the alternative 'farming' was not easily translatable.

Article 6.10.2.

In the first paragraph, the Code Commission did not agree with a comment to remove 'veterinary medical', because 'Veterinary medical use of antimicrobial agents' is already defined in Article 6.9.2.

In point 1 of the first paragraph, the Code Commission did not agree with a comment to delete 'both' and 'and safety'. The Commission agreed that irresponsible use of an antimicrobial, such as incorrect dosing and route of administration or inappropriate use for the age or species, could have a negative impact on animal health or welfare. The Commission agreed with a comment to replace the current text with 'the effectiveness of antimicrobial agents used in veterinary and human', amending the text accordingly.

In point 3 of the first paragraph, the Code Commission agreed with a comment to delete 'relevant animal', and noted that some other comments were also addressed by this amendment. The Code Commission agreed with a comment to delete point 4, due to the similarities with point 1 and noted that this amendment also addressed several other comments.

In point 5 of the first paragraph, the Code Commission agreed with a comment to replace 'consumer' with 'human', for consistency and clarity.

In the second paragraph, the Code Commission agreed with a comment to add the term 'antimicrobial resistant' before 'microorganisms' for clarity. The Commission also agreed with a comment to delete 'relevant animal' as it was considered unnecessary and for consistency with amendments made in previous points. The Code Commission agreed to delete 'and' and add 'and alternatives to the use of antimicrobials'. In the same sentence, the Commission agreed that access to diagnostic tests is key to ensure responsible use of antimicrobials and added 'access to laboratory testing' after vaccination strategies.

Article 6.10.3.

In the first paragraph of point 1, the Code Commission did not agree with comments to include 'crop' as this was already covered by the term 'plant' used in the text. The Commission also did not agree with the addition of 'relevant animal' before 'environment', as it was considered unnecessary here. The Commission agreed with a comment indicating that development and implementation of training sessions for professionals was key for the implementation of the national plans and agreed to add 'and professional training programmes' after 'communication strategies'.

In the second paragraph of point 1, the Code Commission agreed with a comment to replace 'educate' with 'inform' for clarity.

In the third paragraph of point 1, the Code Commission agreed with a comment to delete 'as appropriate' for clarity.

In the fifth paragraph of point 2, the Code Commission agreed with a comment to replace the redundant ‘treatment, control and prevention of diseases’ with ‘veterinary medical use, which excludes growth promotion’, more clearly defining the scope of the regulatory approval.

In the seventh paragraph of point 2, the Code Commission did not agree with a comment to revert from ‘may’ to ‘should’, as it did not add clarity, and referred to the rationale provided by the AMR Working Group in its August 2022 report. The Commission did not agree to delete ‘as relevant’, as it referred to withdrawal periods that are not applicable to companion animals, which are also covered by this chapter. The Code Commission agreed with a comment to replace ‘treatment’ with ‘administration’, since prevention and control of diseases are also appropriate uses.

In the eighth paragraph of point 2, the Code Commission agreed with a comment to replace ‘treatment’ with ‘other’ and to add ‘the use of’ for clarity. The Commission did not agree with a comment to include a reference to the WHO List of Critically Important Antimicrobials. The Commission considered that this would be redundant as the recommendations included in the WOAH List of Antimicrobials of Veterinary Importance already take into consideration the WHO List of Critically Important Antimicrobials.

In point 3, the Code Commission did not agree with a comment to remove ‘antimicrobial agents and’ from the title or to amend the subtitle to add ‘containing antimicrobial agents’ after ‘veterinary medicinal products’. The Commission agreed that the use of “antimicrobial agents” refers to antimicrobials as raw materials that are used to prepare Veterinary Medicinal Products (VMP) and compounded (i.e. extemporaneous) products, not only as feed additives.

In the first indent of point 4(a)(i), the Code Commission did not agree with a comment to replace ‘pathogenic agents’ with ‘pathogens’ and ‘non-pathogenic’ agents with ‘non-pathogens’ as it did not add clarity. The Commission did, however, agree that a definition of ‘pathogenic agents’ should be considered for inclusion in the Glossary in the future.

In the third indent of point 4 (a)(i), the Code Commission did not agree with a comment to remove the last sentence. The Commission considered that the rationale provided was not sufficient to warrant the change and that the text was correct as written.

In the fourth indent of point 4(a)(ii), the Code Commission did not agree with a comment to add ‘when possible’ as it did not add clarity to the text. Nevertheless, the Code Commission agreed to add ‘as appropriate’ to the chapeau text of point 4(a)(ii), while deleting it at the third indent.

In point 4(b), the Code Commission agreed with a comment to delete ‘therapeutic’ to align with the removal of the word in other parts of the chapter. The Commission discussed the potential need for a definition of the term ‘antimicrobial resistance determinants’ but no change was made at this time.

In point 8(j), the Code Commission agreed with a comment to replace ‘and route of administration’ with ‘(i.e. dose, frequency of dosing and route and duration of administration)’, to emphasise all components of dosage regimes.

In point 8(s), the Code Commission agreed with a comment and amended the text for clarity.

In point 9, the Code Commission did not agree with a comment to replace ‘veterinary medicinal product’ with ‘antimicrobial agent’. The Commission considered that while antimicrobial susceptibility testing is conducted with the antimicrobial agent, the Competent Authority regulates the use of the veterinary medicinal product and the post-marketing AMR surveillance would be related to the product for which the regulatory approval was given.

In point 10, the Code Commission did not agree with a comment to delete the heading. The Commission noted that although part of its content is repeated in the text under it, a heading was still considered necessary.

In the fourth paragraph of point 10, the Code Commission agreed with a comment to replace ‘Competent Authority’ by ‘Veterinary Services’ and also added ‘and implement’ after ‘develop’ because it is the

Veterinary Services that should develop and implement effective procedures for these activities.

In point 11(b), the Code Commission agreed with a comment to amend the text for clarity.

In point 13, the Code Commission agreed to the addition of ‘breeders’ and ‘owners’ for consistency with other instances throughout the text and the *Terrestrial Code*.

In point 15, the Code Commission agreed to replace ‘industry’ with ‘private’ to ensure funding from the private sector other than industry, such as academia or foundations, is covered. In the following sentence, the Commission agreed to add ‘including’ and remove ‘but not limited to’ for clarity.

Article 6.10.4.

I©oint 1(c), the Code Commission agreed with a comment to amend the text for better grammar and clarity.

In point 3(b), the Code Commission agreed with a comment to add ‘or to the general public’ after ‘keeper,’ because the general public also plays a role in the responsible use of antimicrobials and tackling AMR.

Article 6.10.5.

The Code Commission agreed with a comment to insert ‘sale’ in point 2 and replace ‘supply’ with ‘sale’ in point 2(a) to cover all transactions, purchases and sales.

Article 6.10.6.

In the second paragraph, the Code Commission agreed with a comment to include ‘the use of’ before ‘antimicrobials’ because there is no agreed definition of the term ‘alternatives to antimicrobials’ and no specific regulatory requirements for such products.

In point 1(f), the Code Commission agreed with a comment to replace ‘appropriate’ with ‘adequate’; and to delete the end of the sentence after ‘supportive therapy’ and replace it with ‘if appropriate’ for clarity.

In point 2(d), the Code Commission did not agree with a comment to add ‘prescribing guidelines’ because it considered that appropriate prescribing guidelines may not be available in all countries for the target animal species and pathogenic agents. The Commission replaced ‘and route of administration’ with ‘(i.e. dose, frequency of dosing and route and duration of administration)’ for clarity.

In the heading of point 3, the Code Commission agreed with a comment to add ‘veterinary medical’ after ‘Appropriate’ and delete ‘veterinary medicinal’ after ‘selected’, to better reflect the content of point 3 and make it consistent with other part of the chapter and the code.

In the first paragraph of point 3, the Code Commission agreed with a comment to add ‘exclude growth promotion and’ after ‘should’, for consistency with the definition of ‘veterinary medical use’ and the point 2 of Article 6.10.2. on the regulatory approval.

In the second paragraph of point 3, the Code Commission agreed with comments to amend the text and agreed to remove ‘the food animal’ before ‘breeder’ and add ‘or any other person responsible for administering the product’ after ‘keeper,’ as it considered this made the text more inclusive and added clarity.

In the third paragraph of point 3, the Code Commission did not agree with a comment to add the recommendation that the veterinary medical use of veterinary medical products should be in line with the Summary of Product Characteristics (SPC), or equivalent; it was not considered to add clarity to the text and it is already covered in other sections of this article. The Commission also did not agree with a comment to replace ‘and’ with ‘or’ in the same paragraph.

In point 4(h), the Code Commission did not agree with a comment to add 'duration' when referring to treatment schedules as it considered that a schedule normally includes the duration.

Article 6.10.8.

In point 2(j), the Code Commission did not agree with a comment to amend the text for veterinarians to be responsible for maintaining data corresponding to the use of antimicrobials by the breeders. The Commission reminded Members that this point has been addressed in previous meetings, and that whoever has the data should maintain it, either the veterinarians, the breeders or others.

In point 2(k)(i), the Code Commission agreed with a comment to add 'or the active pharmaceutical ingredient' after 'product', for proper use of the term.

Article 6.10.9.

In point 4, the Code Commission did not agree with comments to amend this text for editorial purposes, as it did not add clarity.

The revised Chapter 6.10. 'Responsible and prudent use of antimicrobial agents in veterinary medicine' is presented as Annex 9 and will be proposed for adopti[on] at the 91st General Session in May 2024.

5.6. Slaughter of animals (Chapter 7.5.)

Comments on Chapter 7.5. were received from Australia, China (People's Republic of), Colombia, New Caledonia, New Zealand, Norway, South Africa, Switzerland, Thailand, the UK, the USA, the AU-IBAR and the EU.

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 as well as the revision of associated Glossary definitions (see item 5.1 of this report)

The *ad hoc* Group has met on eight occasions since 2018 to develop a revised draft Chapter 7.5.

The revised Chapter 7.5. and associated Glossary definitions have been circulated five times for comments.

Discussion

The Code Commission considered the comments received and proposed the following amendments.

General Comments

The Code Commission did not agree with the comment to add Oxford commas in several Articles, as they are not in line with WOAH's style guide.

The Code Commission did not agree with several comments to replace 'killing' with 'slaughter', as the use of one term or the other will depend on the context of the Article.

The Code Commission did not agree with a comment in several articles regarding the identification of animal-based and other measures, the addition of 'reflex' and 'absence of'' and the deletion of 'or' because they refer to the same indicator and are normally assessed at the same time.

Article 7.5.2.

In the second paragraph, the Code Commission discussed a request to add ‘camels’ as part of the scope of this chapter. Due to the number of camelids slaughtered globally, particularly in the Middle East and Africa, the Commission decided to include ‘camelids’, noting that there may be some exceptions where species-specific recommendations are needed. In the same paragraph, the Code Commission agreed to delete ‘and’ to simplify the sentence structure.

Article 7.5.5.

In the first paragraph, the Code Commission did not agree with the comment to include ‘considered alongside animal-based measures’ at the end of the paragraph, because the insertion of a comma would be sufficient instead. In the same paragraph, the Commission did not agree to add ‘always’ as this is implicit from the nature of the recommendations.

Article 7.5.7.

In the second paragraph, the Commission did not agree with the comments to add ‘suffering’ to this list of signs to be identified by animal handlers. Suffering has been previously removed from the draft chapter and replaced by ‘pain, fear and distress’.

Article 7.5.8.

In the first paragraph, the Code Commission did not agree to include a list of parts of a slaughterhouse or abattoir, as it was agreed that examples were not necessary.

In the first paragraph, seventh indent, the Code Commission agreed with a request to delete ‘need’ as it was unnecessary in this sentence.

In the second paragraph, the Commission did not agree to replace ‘to eliminate’ with ‘be free from’, as the addition did not add clarity to the sentence.

Article 7.5.9.

In the first paragraph, the Code Commission agreed with a comment to replace ‘specification’ with ‘capacity’, as ‘capacity’ is a more accurate term and easier to understand.

Article 7.5.10.

In the first paragraph, the Code Commission did not agree with a comment to add ‘and thus minimize negative experiences during the sacrifice of animals’ as it considered it redundant.

In the second paragraph the Commission agreed with a comment to replace ‘preventing’ with ‘minimising’ as it would be more appropriate when applied to slaughter.

Article 7.5.12.

In the second paragraph of point 1, the Code Commission agreed with the proposal to replace ‘increased’ with ‘prolonged’, as the term ‘prolonged’ is more time based and therefore more appropriate.

In the second paragraph of point 2, the Commission did not agree to replace ‘emergency’ with ‘emergently’ when referring to emergency killing, as it was deemed unnecessary.

In point 3, fourth paragraph, the Code Commission did not agree to add ‘providing access to food’ as this paragraph refers to the timeframe immediately after unloading. Also, in this point 3, fifth paragraph, the Commission did not agree with the proposal to add ‘isolated’ here as it is implied from ‘appropriate care’.

In point 4, the Code Commission did not agree with a comment to keep the last sentence which was proposed to be deleted as it did not provide added value.

Article 7.5.13.

In point 1, the Commission agreed with a proposal to replace 'will' with 'may', as in other parts of the code, when it is not a sure fact.

In point 3, the last sentence, the Code Commission agreed with a comment to remove 'voluntarily' and include 'as to prevent' earlier in the sentence instead for clarity.

In the sixth paragraph, the Code Commission did not agree to replace 'rise' with 'move independently', as these words do not have the same meaning in this sentence.

In the thirteenth paragraph, the Commission did not agree with comments to add 'animals known to be' before 'pregnant' as this addition did not add clarity.

Article 7.5.14.

In point 2(d), the Commission discussed a comment to remove 'carcass bruising' and instead add 'bruising' to point 4(d). The Commission agreed that as carcass refers to an animal post-slaughter, this should be kept as a separate point, exclusive to carcasses. Therefore, 'bruised carcass' was added as a new point for clarity.

In Point 3, the second paragraph, the Code Commission did not agree to change 12 hours to 24 hours. The Commission noted that it is important to consider the planning of slaughter operations and agreed that normally animals should not stay more 24 hours in the slaughterhouse.

In point 3, the ninth paragraph, the Code Commission rearranged the first part of the paragraph for improved clarity and agreed with a comment to add 'without delay' to emphasise the urgency of conducting euthanasia in downed animals.

Article 7.5.15.

In point 2(b), the Code Commission did not agree with the addition of 'of conscious animals', as struggling is a conscious behaviour only.

In point 2(f), the Code Commission agreed with a comment to delete 'frequency of' for consistency as this has also been removed in Article 7.5.13.

Article 7.5.16.

The Code Commission did not agree to replace 'render' with 'caused' in the second paragraph as the word 'render' is widely used in the context of the stunning operations.

In the first paragraph, the Code Commission did not agree with a comment to add 'except when multiple animals are placed in the restrainer simultaneously. In such cases, all the animals shall be stunned as quickly as possible.' The Commission agreed that animals should always be stunned as quickly as possible and that the proposed sentence does not provide added value to the paragraph.

Article 7.5.17.

The Code Commission did not agree with comments to modify the text of point 1, as the sentence was too long and confusing. Instead, the Commission deleted the first three sentences of the paragraph, rearranged the rest of the paragraph, including by adding a new sentence to address skull fractures in young calves.

In point 1, second paragraph, the Code Commission did not agree with a comment to add 'ideally a single shot,' or a proposal to use a silencer as a single shot should always be the goal. However, the Commission agreed with a comment to add 'as well as certain extensively reared animals.' As captive wild animals

should be included since they can be slaughtered in slaughterhouses, the Commission further amended the text to read ‘certain extensively reared domestic and captive wild animals.’

Article 7.5.18.

Regarding the recommended electrical parameters, the Code Commission reminded Members that these correspond to minimum recommendations that need to be adapted to each situation, considering the different species and types of animals. It is important to use the appropriate electrical parameters that give a satisfactory outcome for the welfare of animals by primarily using animal-based measures.

In point 4, paragraph 2, second indent, the Code Commission agreed to delete ‘slaughter’ for consistency with the rest of point 4. The Code Commission did not agree with the comment to change the figures in the last two indents as it was deemed unjustified.

Article 7.5.19.

The Code Commission did not agree with a comment to add ‘Where aversive gases are used, the period before loss of consciousness should be minimised’ at the end of the first paragraph of point 4, due to the risk of an incomplete stunning. The Code Commission highlighted the need to balance welfare concerns when stunning pigs in a group and amended the sentence to reflect this.

Article 7.5.20.

The Code Commission did not agree with a comment to add ‘The restraining should be maintained until the animal is unconscious’ as it was deemed too prescriptive and not in line with the language used in the *Terrestrial Code*.

Article 7.5.21.

In point 1, the first paragraph, the Code Commission did not agree with a comment to replace ‘not’ with ‘unlikely,’ ‘may’ with ‘is more likely to’ and ‘impacts’ with ‘affect’. The Commission considered the sentence clear as written and the proposed amendments were not in line with the style of the *Code*. Instead, the Commission replaced ‘impacts’ with ‘effects’ for ease of translation. In the same paragraph the *Code* Commission did not agree with a comment to replace ‘considered not to achieve consciousness’ with ‘considered unconsciousness’ as it did not improve the clarity of the sentence.

Article 7.5.23.

In point 2(a), the Code Commission agreed with a comment to add ‘restraint’ to this paragraph for the additional clarity.

Article 7.5.25.

In point 2(a), the Code Commission agreed with a comment to delete ‘strike against the facilities’ as ‘collide with facility’ was deemed more appropriate.

Article 7.5.26.

In point 1(b) the Code Commission did not agree with a comment to add ‘leading to thermal stress as poor ventilation would cause additional problems beyond thermal stress.

Article 7.5.27©n point 1(c), the Code Commission did not agree with a comment to add ‘shackling or’ before ‘stunning’. After consideration, the Commission deleted ‘before stunning’ and added the word ‘inappropriate’ at the beginning of the phrase, as the hazard is inappropriate handling and removal of animals from contain©.

In point 1(e), the Code Commission agreed to include ‘or are not properly aligned’ regarding conveyor belts as the belt alignment is also important.

The Commission agreed with the comment to remove ‘animals’ from the list, for consistency with the rest of the items on the list provided in point 2(a).

In the fourth paragraph of point 3, the Code Commission agreed with a comment to replace ‘birds’ with ‘animals’ as there could also be animals other than birds such as rabbits.

Article 7.5.28.

In point 1(b) instead of adding ‘and rabbits’, the Code Commission agreed to replace ‘birds’ with ‘animals’ for consistency where this has been applied throughout the c©ter.

In point 2(e), the Code Commission did not agree with a comment to include ‘rabbits’ after ‘respiratory distress’, as the recommendation was not deemed only applicable to rabbits.

The Code Commission, in the third paragraph of point 3, did not agree to add ‘conveyance’ as it was already considered part of the shackling process.

The Code Commission did not agree with a comment to remove a reference to the shackling of heavy birds as there is a greater welfare concern with the shackling of heavy birds and it should be avoided when possible.

Article 7.5.29.

The Code Commission agreed with a comment to add ‘of animals in containers’ in the heading of this article for consistency with the category of animals covered by this section.

In the first paragraph of point 1 the Commission did not agree with a comment to reinstate ‘wool’, as this part of the text corresponds to animals arriving in containers at the slaughterhouse.

The Code Commission did not agree with a comment to modify the first paragraph of point 3 as it did not add value to the current text.

In point 4 on species-specific recommendations, the Code Commission did not agree to add a new text at the end of the recommended minimum electrical parameter. However, the Commission reworded the text to include a reference to Chapter 7.1. ‘Introduction to the recommendations for animal welfare’, to clarify the first sentence of this point.

Article 7.5.30.

In point 1, the second paragraph, the Code Commission agreed with a comment to indicate that the entry of the ramp leading to the electrical water-bath stun equipment should not be electrically charged to avoid pre-stun shocks.

In point 1, the third paragraph, the Code Commission did not agree with a comment to add other examples of factors that could affect the individual bird electrical resistance, as the list of factors provided are already implicit in the current text.

In point 3, the fifth paragraph, the Commission agreed with a comment to clarify the purpose of water level adjustments, and added ‘to minimise overflow’ at the end of the paragraph.

In point 3, the sixth paragraph, the Code Commission agreed with a comment to replace ‘and’ with ‘or,’ to be consistent with Article 7.5.29.

In point 3, the eighth paragraph, the Code Commission did not agree to delete the entire paragraph regarding the use of constant current stunners, as this recommendation is based on expert opinions that this is a better option on animal welfare grounds. However, the Commission deleted 'always' for clarity.

Regarding comments on the twelfth paragraph of point 3, the Code Commission did not agree to delete the entire paragraph. However, it amended the text to highlight the potential negative animal welfare consequences, and to encourage Members to seek alternative methods.

In point 4, the Code Commission did not agree with a comment to delete the species-specific recommendation on use of high frequencies regarding the electrical parameter for ducks, geese, chicken and turkeys, as these recommendations are supported by scientific data.

The Code Commission agreed with a comment to modify the second paragraph of point 4 to emphasise how to select the effective electrical parameters.

Article 7.5.31.

In point 1, the first paragraph, the Code Commission did not agree with a comment to add references regarding the misapplication of mechanical stunning methods as it did not add further value to the section.

Regarding some comments on the use of cervical dislocation and decapitation in point 1, the Code Commission agreed to delete both methods, as they are not methods recommended for the purpose of stunning animals.

In point 2, the Code Commission did not agree with comments to modify the use of palpebral and corneal reflexes as the animal-based measures to assess effective and ineffective stunning, as both reflexes are used at the same time.

Article 7.5.32.

In point 1, the first paragraph, the Code Commission partially agreed with a comment to add high stocking density as another aspect to consider for the efficient stunning by controlled atmosphere.

Article 7.5.33.

In point 2, the third paragraph, the Code Commission did not agree with a comment to add a mention to the ineffectiveness of bleeding duration process regarding the presence of 'red skin,' as the birds would already be dead.

The Code Commission agreed that decapitation should not be used as a bleeding method in conscious animals in the last paragraph of point 3.

The revised Chapter 7.5. 'Slaughter of animals' is presented as Annex 10 (in track changes) and Annex 11 (cleaned text), and will be proposed f^{or} adoption at the 91st General Session in May 2024.

5.7. Infection with foot and mouth disease virus (Chapter 8.8.) and Application for official recognition by WOAH of free status for foot and mouth disease (Chapter 1.11.)

Comments on Chapter 8.8 were received from Argentina, Australia, Brazil, Canada, China (People's Republic of), Japan, New Caledonia, New Zealand, Switzerland, Thailand, the USA, the WOAH Americas Region, the EU and the WRO.

Comments on Chapter 1.11 were received from New Caledonia, New Zealand, Switzerland and the EU.

Background

The most recent updates to Chapter 8.8. 'Infection with foot and mouth disease virus' were adopted in 2015. Since then, the chapter has undergone a comprehensive revision to address requests from Members and to align with other chapters, and has been circulated five times, the first time in September 2015.

The *ad hoc* Group on foot and mouth disease (FMD) contributed to the development of the revised chapter (see its June 2016 and June 2020 reports for details). The revised chapter has been reviewed by the Code Commission and the Scientific Commission throughout the revision process, and inputs have also been sought from the Biological Standards Commission, as relevant.

The revised chapter was proposed for adoption at the 90th General Session in May 2023. At the General Session, the President of the Code Commission acknowledged irreconcilable diverging views expressed by Members on the proposed text and some inconsistencies within it, and decided to withdraw the proposed chapter to continue working towards building a clearer and consensual version. He informed that the Commission would continue working on the draft chapter with solid scientific rationales and expertise to develop a new proposal together with a revised Chapter 1.11. 'Application for official recognition by WOAH of free status for FMD' with the aim of proposing them for adoption in 2024.

At its September 2023 meeting, the Code Commission considered comments received, together with the inputs from the Biological Standards Commission, the Scientific Commission, and experts who were requested to address specific points. The Code Commission agreed to circulate the revised chapter using the version proposed for adoption at the 90th General Session in May 2023, highlighting only the amendments introduced in this meeting. The Code Commission also considered a draft revised Chapter 1.11. with input by the Scientific Commission to ensure alignment with the revised Chapter 8.8. The Commission agreed to circulate the revised Chapter 1.11. for comments.

Discussion

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

The Code Commission considered comments received, together with the inputs from the Biological Standards Commission, the Scientific Commission, and experts who were requested to address specific points.

General comments

The Code Commission noted comments expressing support for the proposed amendments.

The Commission noted that a comment to simplify the requirements for maintenance of official FMD status was outside of its scope and requested that the Secretariat forward the comment to the Scientific Commission for its consideration. The Commission also forwarded to the Scientific Commission some comments that referred to the interpretation of some points of Chapter 1.11.

Article 8.8.1

In point 6, the Code Commission did not agree with a comment to change the risk of FMD virus (FMDV) transmission from African Buffalo to domestic livestock from 'rare' to 'not negligible'. The Commission agreed that there was no added clarity with this change and referred to prior considerations received from the Scientific Commission.

Article 8.8.1bis

The Code Commission did not agree with a comment to add processing requirements to the safe commodities 'UHT milk and derivatives thereof' and 'protein meal'. Adding such processing requirement to specifically address FMD risk would mean that they are not safe commodities. The Code Commission also did not agree to add a specification that 'extruded dry pet food' cannot be processed 'using cold

extrusion method', as this was not used for this commodity. The Commission stressed that these commodities have already been evaluated and determined to meet the criteria for safe commodities.

The Code Commission did not agree with a comment to delete 'protein meal' and 'extruded dry pet food' from the list of safe commodities. Experts have confirmed that the production of 'protein meal' according to the definition in the Glossary involved a standard processing that includes a minimum time and temperature treatment that inactivates pathogenic agents such as FMDV. Likewise, experts have established that processing for extruded dry pet food is adequate to inactivate FMDV.

The Code Commission acknowledged a comment proposing to add 'rendered fats' to the list of safe commodities. The Commission considered that the supporting documentation had some valuable information but noted that more data on the standardised processes for production of different categories of rendered fats were needed to propose them as 'safe commodities'.

Article 8.8.2

The Code Commission did not agree with a comment that vaccinated animals should not be imported into countries or zones that are recognised as free from FMD where vaccination is not practised. The Code Commission considered that the import conditions proposed provide adequate risk mitigation measures for rendering those vaccinated animals safe to be imported. Therefore, there would be no need to limit the number of imported vaccinated animals nor specify purpose of such imports.

The Code Commission did not agree with a comment that import requirements in Article 8.8.11. for vaccinated animals should be more stringent in line with requirements outlined in this article for emergency vaccination of zoo animals, notably in terms of post-import monitoring. The Commission highlighted that the provisions in Article 8.8.2. referring to the emergency vaccination of zoo animals, refer to an exceptional situation where vaccination is done in response to an imminent threat of FMDVcirculation. The Commission highlighted that considering the risk mitigations have been applied before the animals are imported, they should be considered safe and thus do not need post-import measures.

In point 1, the Code Commission amended the text for consistency with previous changes made to Article 8.8.3 point 1(b).

The Code Commission acknowledged a comment about the potential need for additional surveillance if a country or zone recognised as free from FMD where vaccination is not practised imports vaccinated animals. However, it noted that in accordance with the relevant articles of the chapter, the surveillance strategies are to be chosen by the Members' Veterinary Authority for a country or zone depending on the structure and vaccination status of the target populations, and that would include any type of situation where vaccinated animals are present. This would be part of the dossier sent to WOAH for recognition or annual reconfirmation of status.

The Code Commission amended point 5 in response to several comments to clarify that movements of all commodities between zones of different animal health status within a country will be permitted if they comply with the same requirements as for importation between countries of different animal health status. The added sentence implied that there was no need of repeating in different articles similar conditions for transfer between zones as were in articles for importation. Thus, the Code Commission agreed to delete the Article 8.8.9bis, which became superfluous and potentially misleading.

In response to a question regarding the deleted text in point 5, the Code Commission confirmed that vaccinated animals may be imported into a country or zone recognised as free from FMD where vaccination is not practised without affecting its free status, regardless of the status of the exporting country. The Commission stressed that the import or movement should be carried out in accordance with this chapter to be considered safe.

The Code Commission did not agree with a comment to restore Article 8.8.5bis to its previous location as part of Article 8.8.2, as it is more clearly defined in its current location.

Article 8.8.9bis

The Commission noted that the sentence added in Article 2 point 5 implied that there was no need of repeating in different articles similar conditions for transfer between zones as were in articles for importation. Thus, the Code Commission agreed to delete the Article 8.8.9bis, which became superfluous and potentially misleading.

Article 8.8.11

The Code Commission noted comments that were already addressed by the changes proposed to Article 8.8.2.

In point 3, the Code Commission, in agreement with the opinion of the Scientific Commission, amended the text to request a virological test to be performed instead of a serological test, recognizing that virological testing was more appropriate to detect recently sub-clinically infected animals, which is the risk to be mitigated in that situation.

Article 8.8.11bis

The Code Commission noted comments that were already addressed by the changes proposed to Article 8.8.2., and made no change to that article.

Article 8.8.12

In point 5(b), the Code Commission amended the text for consistency with other Articles.

Article 8.8.25

In point 1(a), the Code Commission replaced ‘establishments’ with ‘herds’ for consistency with *Terrestrial Code* conventions, and ‘FMD’ was amended to ‘FMDV’ for clarity.

The Code Commission agreed with a comment to allow for an option of single high-temperature short-time HTST treatment for milk originating from herds not infected or suspected of being infected with FMDV and added the option to point 1(a). The Commission noted that in general in the *Terrestrial Code*, there was a difference in terms of risk mitigation between articles describing requirements and conditions for safe trade of commodities, and articles only describing treatments that inactivate the pathogenic agent in commodities, and that it explained why treatments required for trade may be different from those required for inactivation.

Article 8.8.31

The Code Commission noted a comment suggesting that pH testing of meat could be done prior to maturation of the meat, and that muscle groups other than the longissimus dorsi be selected for pH testing. The Code Commission requested that appropriate data be provided to justify alternate options to consider amending the provision, that could be taken into consideration in a future revision.

In point 3, the Code Commission agreed with a comment regarding the proper notation for water activity and amended the text to use lowercase italic ‘a’ and subscript ‘w’, in all places of the chapter where it was used.

Article 8.8.40

In response to a comment suggesting the development of guidelines for surveillance for countries or zones that are free without vaccination and import FMD vaccinated animals, the Code Commission commented that this item was discussed in the February 2023 report and highlighted that any such guidelines intended to support Members in implementing adopted standards are not part of the WOAH standard setting process. The Commission referred the matter to the Secretariat for further consideration.

The Code Commission did not agree with an editorial comment to change 'surveillance for FMD' to 'surveillance for FMDV.' The Commission noted that the current language is consistent with the conventions of the *Terrestrial Code*.

In Point 2, the fourth paragraph, the Code Commission agreed to replace 'animals' with 'animal populations', for clarity and consistency with the rest of the chapter and other relevant chapters.

b) Application for official recognition by WOAH of free status for foot and mouth disease (Chapter 1.11.)

General comments

The Code Commission noted comments expressing support for the proposed amendments.

The Commission forwarded some comments received to the Scientific Commission for its consideration.

The Code Commission, in agreement with the Scientific Commission, concurred with a general comment that changes proposed in Article 1.11.3 should also be replicated in other articles for consistency.

Article 1.11.1

In the eighth paragraph, the Code Commission added the time frame required for the declaration of freedom from FMD to 12 months to be consistent with the revised four points that follow, and with Article 1.11.3, which was circulated in Septe©r 2023.

In point 1(c), the Code Commission added a summary description of wildlife habitat to the information to be provided for wildlife demographics. This is consistent with changes made to point 3 of Article 8.8.2, and the change that was made to Ar©le 1.11.3.

In point 5(c), the Code Commission added a requirement to describe how previously vaccinated or newly introduced vaccinated animal populations are considered in the strategy and design of the surveillance programme.

In point 6(d), the Code Commission included vaccination status as an item to be considered when implementing import control procedures.

In point 8, the Code Commission made editorial changes for consistency in numbering the points referenced in the sentence.

Article 1.11.2

In the eighth paragraph, the Code Commission added the time frame required for the declaration of freedom from FMD to 12 months to be consistent with revisions to the four points that follow, and with Article 1.11.3, which was circulated in September 2023.

The Code Commission added a paragraph after point 5 to require 24 months of surveillance in accordance with Chapter 8.8, as well as regulatory measures for the prevention and control of FMD.

In point 8, the Code Commission made editorial changes for consistency in numbering the points referenced in the sentence©**rticle 1.11.3**

In point 1(c), the Code Commission agreed with a comment to add a summary description of wildlife habitat to the information to be provided for wildlife demographics, and to reflect this change in other relevant articles of the chapter. This is consistent with changes made to point 3 of Article 8.8.2.

In point 5(c), the Code Commission added 'populations' after animal for clarity and consistency with Chapter 8.8. The Code Commission agreed with a comment that this point should be conditional to changes in corresponding information in Chapter 8.8.

In point 8, the Code Commission did not agree with a comment to remove reference to point 6, as there is a point 6.

Article 1.11.4.

The Commission amended the text for consistency with the changes proposed to other articles.

The revised Chapter 8.8. 'Infection with foot and mouth disease virus', and Chapter 1.11. 'Application for official recognition by WOAH of free status for foot and mouth disease' are presented as Annex 12 and Annex 13, respectively, and will be proposed for adoption at the 91st General Session in May 2024.

5.8. Infection with Rift Valley fever virus (Chapter 8.16.)

Comments were received from Switzerland and the EU.

Background

At its September 2023 meeting, the Code Commission was informed that the revised Chapter 3.1.19. 'Rift Valley fever (Infection with Rift Valley fever virus)' of the *Terrestrial Manual* was adopted at the 90th General Session in May 2023.

Following the recommendations of the Biological Standards Commission, the Commission noted that the *Terrestrial Manual* chapter had been amended to include diagnostic tests suitable for trade in live animals and proceeded to review relevant articles of Chapter 8.16. 'Infection with Rift Valley fever virus' to ensure alignment, and circulated the revised Article 8.16.8. for comments.

Discussion

General comments

The Code Commission noted comments expressing support for the proposed amendments.

The Code Commission did not agree with a comment to add 'Rift Valley fever virus' before the abbreviation, RVFV, as the first use was already addressed with the Article 8.16.1.

The revised Article 8.16.8. of Chapter 8.16. 'Infection with Rift Valley fever virus' is presented as Annex 14 and will be proposed for adoption at the 91st General Session in May 2024.

5.9. Infection with *Trichinella* spp. (Chapter 8.18.)

Comments were received from Switzerland, Thailand and the EU.

Background

At its September 2023 meeting, the Code Commission was informed that the revised Chapter 3.1.22. 'Trichinellosis (Infection with *Trichinella* spp.)' of the *Terrestrial Manual* was adopted at the 90th General Session in May 2023.

Following the recommendations of the Biological Standards Commission, the Commission noted that the *Terrestrial Manual* chapter had been amended and included a change to the number of taxon of the pathogenic agent, and proceeded to review relevant articles Chapter 8.18. 'Infection with *Trichinella* spp.' to ensure alignment, and circulated the revised Article 8.18.1 for comments.

Discussion

General comments

The Code Commission noted comments expressing support for the proposed amendments.

Article 8.18.1.

In the second paragraph, the Code Commission agreed with a comment to add a reference to the specific 'L1 larval stage' because this is the only larval stage that lives in the muscles. The Commission made editorial amendments for clarity.

In the sixth paragraph, the Code Commission considered a comment on the appropriate way of referring to Codex Alimentarius Standards and requested the Secretariat to consult with the Codex Secretariat. The Commission agreed not to introduce any change to the text at this stage.

The revised Article 8.18.1. of Chapter 8.18. 'Infection with *Trichinella* spp.' is presented as Annex 15, and will be proposed for adoption at the 91st General Session in May 2024.

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

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

Background

In September 2022, the Code Commission agreed to add the development of a new chapter for Infection with *Coxiella burneti* (Q fever) in the *Terrestrial Code* to its work programme and drafted a new chapter, consisting of one single article for the general provisions, including the definition of its occurrence, based on a case definition endorsed by the Scientific Commission.

The Code Commission also agreed to amend the name of the listed disease in Article 1.3.1. to 'Infection with *Coxiella burneti* (Q fever)' but to circulate this amendment closer to adoption, after considering the comments on the proposed new disease-specific chapter.

The proposed new Chapter 8.X. 'Infection with *Coxiella burnetii* (Q fever)', was circulated three times, the last time in the September 2023 Code Commission meeting report.

Discussion

The Commission noted comments supporting the proposed new chapter.

Article 8.X.1.

In the first paragraph, the Code Commission did not agree with a comment to add 'in relation to the species defined for the purpose of the *Terrestrial Code* or for human infection' at the end of the sentence, but amended the text for clarity.

In the same paragraph, in response to a question about the necessity of reporting of Q fever detected in free roaming dogs and cats, the Code Commission answered that it should be reported because if animals are domesticated, even if free-roaming they would play a role in the cycle of transmission. Similarly, in response to a question about the evidence of the epidemiologically significant role of wild and feral animals, the Code Commission reiterated that this evidence was provided in the *Terrestrial Manual* Chapter 3.1.17.'Q fever' and described in previous reports of the Commission.

The new Chapter 8.X. 'Infection with *Coxiella burnetii* (Q fever)' is presented as Annex 16, and will be proposed for adoption at the 91st General Session in May 2024.

5.11. Infection with *Trypanosoma evansi* (Surra) (New Chapter 8.Z.)

Comments were received from Argentina, Brazil, China (People's Republic of), Switzerland, the UK, the WOAH Americas Region, the EU and the WRO.

Background

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

Between 2015 and 2018, a draft new Chapter 8.Z. 'Infection with *Trypanosoma evansi* (Surra)', and a revised Chapter 12.3. 'Dourine', were developed, circulated for comments and extensively discussed but due to the need to clarify the scope of these chapters in terms of animal hosts and pathogenic agents, in February 2018, both Commissions agreed to put Chapters 8.Z. and 12.3. on hold and to progress work on Chapter 8.18. 'Infection with *Trypanosoma brucei, T. congolense, T. simiae* and *T. vivax'*, which was adopted in May 2021. Both Commissions had also agreed that, notwithstanding diagnostic issues, the scope of the new Chapter 8.Z. should address surra of multiple species including equids and that the scope of Chapter 12.3. should remain as dourine of equids. The Commissions agreed that work on these two chapters should recommence after the adoption of the new Chapter 8.18.

At its February 2021 meeting, the Code Commission requested that the *ad hoc* Group also consider relevant comments that had been received in 2018.

In June 2021, a meeting of the *ad hoc* Group was convened to draft a new Chapter 8.Z. 'Infection with *Trypanosoma evansi* (Surra)'.

In September 2022, the Code Commission reviewed the draft new Chapter 8.Z. and the *ad hoc* Group report, together with the opinion of the Scientific Commission at its September 2021 meeting. The Code Commission identified a number of critical points that were not clearly explained in the supporting reports, and agreed not to circulate the proposed draft chapter for comments until it clarified these points.

At its February 2023 meeting, the Code Commission considered information provided by the Secretariat to address the points that it had requested clarification on, made amendments and circulated the draft chapter for comments.

At its September 2023 meeting, the Code Commission considered the comments together with the inputs from the *ad hoc* Group, made amendments and circulated for comments.

Discussion

Article 8.Z.1.

The Code Commission reminded Members that the *ad hoc* Group noted that *T. evansi* can infect a large range of domestic and wild mammals, but it proposed that for the purposes of the *Terrestrial Code*, surra can be defined as an infection of susceptible animals with *T. evansi*. The *ad hoc* Group also noted that 'susceptible animals' in this chapter means domestic and wild animals from the Equidae, Camelidae, Bovidae, Suidae, Canidae, Felidae families, the orders Rodentia and Lagomorpha, and non-human primates.

Article 8.Z.2.

The Code Commission noted a comment to reconsider the reinstatement of meat as a safe commodity or elimination of the maturation of meat in Article 8.Z.11bis 'Recommendations for importation of fresh meat from susceptible animals from countries or zones infected with *T. evansi*,'. In agreement with experts and the Scientific Commission, the Code Commission considered that meat of susceptible animals having been slaughtered in a slaughterhouse/abattoir and subjected to ante- and post-mortem inspections with

favourable results did comply with the requirements of Chapter 2.2. It therefore added this commodity in the list and deleted Article 8.Z.11bis.

The Code Commission acknowledged a comment to add 'rendered fats' into the list of safe commodities. The Commission noted that a clear definition of the commodity, including standardised processing or treatment, notably the steps considered critical in the inactivation of the pathogenic agent of concern, supported by sound scientific evidence and data, is needed. The Commission noted that this may be discussed in the future if the data is provided.

Article 8.Z.6.

The Code Commission modified the title of the article to be consistent with the animal species described in the disease definition in Article 8.Z.1., while considering the risks at international trade of those animals, and the risk mitigation methods available to guarantee safe trade.

Article 8.Z.7.

As for Article 8.Z.6., the Code Commission modified the title of the article to be consistent with the animal species described in the disease definition in Article 8.Z.1., while considering the risks at international trade of those animals, and the risk mitigation methods available to guarantee safe trade.

In this regard, the Code Commission agreed with the opinion of the Scientific Commission at its February 2024 meeting, to exclude 'camelids' from the scope of recommendations for importation from countries or zones infected with *T. evansi* because of the lack of evidence regarding the pathogenesis and dynamics of the immune response in camels, and the consequent impossibility to guarantee the health status of the imported animals with the current recommendations.

The Commission reminded Members that the absence of articles on import recommendations for particular commodities does not preclude the application of appropriate sanitary measures, and noted that in that case the measures for the importation of animals of relevant species other than those for which recommendations for trade are provided in this chapter, should be based on a risk analysis according to Chapter 2.1. 'Import risk analysis' of the *Terrestrial Code* and Chapter 3.1.21. of the *Terrestrial Manual.*

In point 2, the Code Commission did not agree with a comment to add 'agent identification (microscope or molecular)' due to the lack of sensitivity of this test. This applied to similar comments to Article 8.Z.8. and Article 8.Z.11.

The Commission reminded Members that the *ad hoc* Group considered that lack of sensitivity and impracticality of employing agent identification test (i.e. molecular and microscopic techniques) for these purposes, and therefore recommended that diagnostic testing should be conducted using antibody detection test, such as the card agglutination test (CATT) or ELISA test which are described in the *Terrestrial Manual*.

Article 8.Z.9.

The Code Commission considered a comment to clarify the scope of the recommendations, and made editorial amendments for clarity and consistency with other chapters.

The new Chapter 8.Z. 'Infection with *Trypanosoma evansi* (Surra)' is presented as Annex 17, and will be proposed for adoption at the 91st General Session in May 2024.

5.12. Revision of Articles 13.2.1. and 13.2.2. of Rabbit haemorrhagic disease (Chapter 13.2.)

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

Background

At its February 2022 meeting, the Code Commission agreed to add the revision of Chapter 13.2. to its work programme in response to a Member comment.

At its February 2023 meeting, the Code Commission considered a case definition that had been endorsed by the Scientific Commission in its September 2022 meeting and agreed to revise Article 13.2.1. accordingly. The Commission, in agreement with a recommendation of the Scientific Commission, also amended Article 13.2.2. to reflect the expanded animal host range of the case definition.

The revised Articles 13.2.1. and 13.2.2. of Chapter 13.2. were circulated twice for comments.

At its September 2023 meeting, the Code Commission agreed to amend the disease name in Article 1.3.7. of Chapter 1.3. from 'Rabbit haemorrhagic disease' to 'Infection with pathogenic rabbit lagoviruses (Rabbit haemorrhagic disease)' and decided to circulate the proposed amendment for comments.

Discussion

General Comments

The Code Commission noted comments expressing support for the proposed amendments.

The Commission acknowledged comments on the need to further revise the chapter and requested the Secretariat to record these points for future work.

Article 13.2.1.

In the first paragraph, the Code Commission did not agree with comments to replace 'RHDV' in the parenthesis with 'RHDV 1' as it is consistent with the corresponding chapter of the *Terrestrial Manual*.

The revised Articles 13.2.1. and 13.2.2. of Chapter 13.2. 'Rabbit haemorrhagic disease' is presented as Annex 18, and will be proposed for adoption at the 91st General Session in May 2024.

5.13. Revision of Chapter 15.1. Infection with African swine fever virus

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

Background

At its February 2023 meeting, in response to a comment from a Member to add 'extruded dry pet food' as a safe commodity to Chapter 15.1. Infection with African swine fever virus, the Code Commission agreed to add this item to its work programme.

At its September 2023 meeting, the Code Commission reviewed the information on the production process and heat treatments provided by the GAPFA, against the criteria described in Article 2.2.2., and agreed that 'extruded dry pet food' meets the criteria for a safe commodity for this disease and should therefore be added to the list of safe commodities in Article 15.1.2. The Code Commission also agreed to amend point 1 of Article 15.1.2., following the terminology agreed by the Commission in February 2022 for this commodity, i.e., 'heat-treated *meat products* in a hermetically sealed container with a F_0 value of 3 or above' for consistency.

Discussion

The Code Commission considered the comments received.

In point 1, the Code Commission did not agree with a comment to clarify the timing of heat treatment in relation to the packaging. The Commission explained that the text was clear as written that heat treatment is conducted after the hermetical sealing.

In response to comments on point 3 requesting clarification on the standards for processing that were taken into consideration in assessing 'extruded dry pet food' as a 'safe commodity' at its last meeting, the Code Commission reminded Members that the assessment was based on the description of the standardised industry production processes and heat treatments provided by GAPFA. According to those data, 'extruded dry pet food' is an extruded dry kibble coated with a palatant, wherein ingredients of animal and plant origin are combined with micronutrients and pre-conditioned with water and heat for 120 to 180 seconds prior to extrusion under pressure at a minimum temperature of 80°C throughout its substance. The kibble is further dried under heat following a time/temperature regimen sufficient to reduce moisture of the kibble from around 22 – 28% moisture to around 8 – 10% moisture. The kibble is coated with a palatant which has been treated to a minimum process of 70°C for 30 minutes. The finished product is shelf stable with water activity that will not support microbial growth. These elements will allow the Code Commission to consider the inclusion of 'extruded dry pet food' in the list of safe commodities each time a disease-specific chapter will be reviewed.

The Code Commission agreed with a comment to include 'protein meal' in the list of safe commodities, for the same reasons discussed in the item 5.7. of this report.

The Commission acknowledged a comment to add 'rendered fats' to the list of safe commodities. The Commission noted that a clear definition of the commodity, including a standardised processing or treatment, notably the steps considered critical in the inactivation of the pathogenic agent of concern, supported by sound scientific evidence is needed. The Commission noted that this may be discussed if the data is provided in the future.

The revised Article 15.1.2. is presented as Annex 19 and will be proposed for adoption at the 91st General Session in May 2024.

5.14. New chapter Infection with *Camelpox* virus (Chapter 16.Z.)

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

Background

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

In September 2022, the Code Commission considered the case definition that was endorsed by the Scientific Commission in February 2022, the experts' inputs, opinions of the Biological Standards Commission and Chapter 3.5.1. *'Camelpox'* of the *Terrestrial Manual* adopted in 2021. The Commission drafted a new Chapter X.Z. 'Infection with *Camelpox* virus', consisting of a single article for the general provisions, including the definition of its occurrence.

At its September 2023 meeting, in view of the progress of the proposed amendments, the Code Commission agreed to amend the disease name in Article 1.3.9. from '*Camelpox*' to 'Infection with *Camelpox* virus' and to circulate the text for comments.

The proposed new Chapter 16.Z. 'Infection with *Camelpox* virus' was circulated for comments three times.

Discussion

The Code Commission noted comments expressing support for the proposed amendments.

Article 16.Z.1.

In the first paragraph, the Code Commission agreed with comments that 'camelpox' should be capitalised as well as italicised and amended the text following the recommendations of the ICTV.

In the same paragraph, the Code Commission did not agree with a comment to add 'New World camelids' as animal hosts and reiterated the explanation provided in its previous reports that, based on the advice provided by experts, these animals are not considered to play a significant role in the epidemiology of the disease.

In point 2, the Code Commission agreed with a comment that the first letter of the word 'orthopox' should be capitalised and amended the text for consistency.

In point 4, the Code Commission did not agree with a comment to add 'that was or is' before 'showing' and 'which is' before 'epidemiologically' as it considered the text was clear as written. The Commission responded that it was not required that clinical signs and antibodies be present at the same time to confirm a case.

The new Chapter 16.Z. 'Infection with *Camelpox* virus' is presented as Annex 20, and will be proposed for adoption at the 91st General Session in May 2024.

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

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

Background

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

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

In February 2023, both the Code Commission and the Aquatic Animals Commission proposed some amendments and circulated them in their respective February 2023 reports to allow Members to consider them at the same time. The Code Commission also agreed to propose amendments for the use of these terms in the User's Guide.

The proposed amendments have been circulated four times.

Discussion

The Code Commission noted that a comment for '*animal for slaughter*' should be discussed along with the revision of Chapter 7.5. 'Slaughter of animals' and associated Glossary definitions (see item 5.6. of this report).

In response to a comment for Article 8.3.15. to replace '*Veterinary Services*' with '*Veterinary Authority*', the Code Commission did not agree as it considered that it is more accurate to use Veterinary Services in reference to surveillance activities.

In response to a comment for Article 12.2.8. and Article 12.7.8. to avoid using twice the term '*Veterinary Services*' in the same sentence at the beginning and at the end, the Code Commission agreed to amend the text to avoid that repetition.

The revised texts are presented as Annex 21, and will be proposed for adoption at the 91st General Session in May 2024.

6. Texts circulated for comments

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

6.1. User's Guide

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

Background

At its September 2023 meeting, the Code Commission agreed to revise the User's Guide, following a discussion at the 90th General Session in May 2023. The Commission proposed several amendments to part B *Terrestrial Code* content, to incorporate a more detailed explanation of the disease-specific chapters, in line with the newly developed 'Framework for *Terrestrial Code* standards' (see item 7.3.), and to develop a new point to explain the use of terms referring to animals (hosts) used in the *Terrestrial Code*. The Code Commission highlighted its commitment to continuing working on the User's Guide and circulated the proposed amendments for comments.

Discussion

B. *Terrestrial Code* content

In point 10, second indent, the Code Commission did not agree with a comment to refer solely to 'case definition'. The Commission highlighted that there was a difference, for the purposes of the *Terrestrial Code*, between the 'definition of the disease' and the definition of its 'occurrence', which could also be referred to as 'case definition'. The Commission explained that the 'definition of the disease' describes and defines the disease by naming the pathogenic agent(s) and the animal host(s) that are covered by a disease-specific chapter (such as notification, animal health status, safe trade, surveillance etc.) and other relevant provisions in the *Terrestrial Code*. The definition of the 'occurrence' of the disease provides the criteria and different options to confirm a 'case' of the disease (as defined in the Glossary: an animal infected by a pathogenic agent), with the primary objective of enabling Members to comply with their notification obligations to WOAH. The Commission amended the text for clarity.

The Code Commission also introduced amendments to different bullet points, for clarity.

In the second paragraph, the Code Commission amended the text to clarify that the first article of a disease-specific chapter is not limited to providing the definition of occurrence for the purpose of notification to WOAH, but that it may include other provisions.

C. Specific issues

In point 3, the Commission agreed with a comment to amend the text for clarity.

D. Name of animal species

The Commission acknowledged a comment from the WGW to review the genus referred to as 'ducks'. The Commission noted that this should be taken into consideration in future work on Section 10 of the *Terrestrial Code*, and requested the Secretariat to seek further advice from the WGW on the matter.

The Commission acknowledged a comment from the WGW querying whether the term 'Suidae' would include peccaries and agreed that they are included. The Commission noted that the family 'Tayassuidae' is not mentioned in the table because they are not included in the *Terrestrial Code*.

The Commission agreed with a comment from the WGW and amended the taxonomy listed for 'new world camelids' to include vicuña and guanaco.

The revised User's Guide is presented as Annex 22 for comments.

6.2. Introduction to the recommendations for animal welfare (Chapter 7.1)

Comments were received from Canada, Colombia, Japan, Norway, Singapore, South Africa, Switzerland, the UK, the USA, the AU-IBAR, the EU and the ICFAW.

Background

In February 2022, the Code Commission agreed to consider a comment to include the 'five domains' concept in Chapter 7.7. Dog population management and requested that the Secretariat and the WOAH Animal Welfare Collaborating Centres (AWCC) prepare a background document for its consideration.

In September 2022, the Commission reviewed the background document and noted that the 'five domains' as an animal welfare concept is recognised internationally, and it may be relevant to include it in Chapter 7.1. 'Introduction to the recommendations for animal welfare' rather than Chapter 7.7. The Commission agreed that given this was still a relatively new concept, it should develop a document to explain the concept to Members and how it is linked to the concept of 'five freedoms' currently used in the Code. The Commission requested the Secretariat to prepare a draft text for inclusion in Chapter 7.1. in consultation with the AWCC.

At the September 2023 meeting, the Code Commission discussed an explanatory note prepared by the WOAH AWCC (Annex 27) and proposed some modifications to Chapter 7.1. to Members and circulated the revised chapter for comments.

Discussion

General comments

The Code Commission noted comments expressing support for the proposed amendments.

In response to a comment requesting information regarding the rationale for the proposed amendments in the chapter and access to the explanatory document discussed at the September 2023 meeting, the Commission agreed to provide the relevant content from that document as Annex 27 for information.

Article 7.1.1.

In the second paragraph, the Code Commission agreed with several comments to delete 'severely or for a long time' as brief but severe suffering should be also considered as an important welfare problem. In the same paragraph the Code Commission agreed to add the word "avoidable" to reinforce the idea of minimising any negative experience.

The Commission did not agree to include a sentence regarding an opportunity to experience positive states as this is addressed in the last paragraph of this article.

Article 7.1.2.

In point 2, the Code Commission did not agree to add text to explain the concept of 'five freedoms' and 'five domains', and agreed to include an extract of the explanatory note on five domains mode (see Annex 27).

Also, the Code Commission did not agree to develop a definition for 'mental state', as the term is consistently used in the chapter and not widely used in the *Terrestrial Code*.

In the same point, the Code Commission did not agree with a comment to reword the whole paragraph as it is not the intention to take out the 'five freedoms' concept and replace it with the 'five domains' concept, but to add the five domains for a more complete view of existing tools for the assessment of animal welfare.

The Commission agreed to replace 'behavioural interaction' with 'behaviour' for clarity.

In point 4, the Code Commission did not agree with the rewording of this point as the proposal did not add clarity.

In point 5, the Commission did not agree to delete the reference to animals used for recreation and entertainment, as these animals need to be covered in the guiding principles mentioned in this chapter. In the same point, the Commission did not agree to include a reference to the use of animals collected from wildlife, as the proposed text was deemed as a recommendation and not a guiding principle. The relevant recommendations can be found in the specific chapters in Section 7.

In point 6, the Commission did not agree with a comment to add a provision regarding the environment that animals could share as it is not within the scope of this chapter.

In point 7, the Commission agreed to delete 'often', as it does not add value to the sentence and animal welfare does not necessarily improve productivity or food safety.

Article 7.1.3.

Regarding comments in point 1, the Code Commission did not agree to modify the title of the article as all articles in this chapter are implicitly applicable to the rest of Section 7 of the *Terrestrial Code*. Also in point 1, the Commission did not agree to add an additional explanation regarding the assessment of the welfare of animals. Instead, the Commission agreed to include a new text at the end of point 2.

In point 3, the Code Commission did not agree to include some terms such as pleasure, contentment or distress, but agreed to include 'negative and positive' before 'affective states', and to delete the examples.

The Code Commission did not agree to include details on how to measure or determine the strength of animal preferences, as those details can be found in other chapters in Section 7 by species or operations.

The Code Commission did not agree to add text to explain the assessment of different management methods, as this is covered in Articles 7.1.4 and 7.1.5.

Article 7.1.4.

In point 1, the Code Commission did not agree to delete the sentence concerning the consequences of a treatment and its applicability. However, the text was modified to make it clearer that the recommendation of the *Terrestrial Code* may include some specific aspects depending on the environment, the resources, and management of the production systems under which the animals are kept.

In point 4, the Commission noted a comment to provide a clearer wording and amended the text accordingly.

The Commission agreed in part with a comment in point 5 to clarify the end users of the standards when choosing relevant measures. Therefore, to avoid being too prescriptive it modified the wording to make it more generic.

In point 6 the Commission amended the text to clarify the fact that changes in practices are needed and should be applied when animal welfare outcomes are unsatisfactory.

Article 7.1.5.

In point 1, the Code Commission did not agree to include ‘prioritise’ when using genetic selection, as prioritisation is not the intention of the guiding principles. This recommendation can be found in the different species-specific chapters on animal welfare and animal production systems.

The Commission did not agree to reinstate ‘parasites’ in point 2, as this risk related to local conditions is included in the term ‘disease.’ On the other hand, the Commission agreed to reword the text to take into account the adaptability to local conditions.

For consistency with point 2, the Commission also deleted 'parasites' from point 3.

In point 4, the Commission agreed with a comment that resting and movement should be both comfortable and safe, and amended the text accordingly.

The Commission agreed partially in point 5 with a comment to include the concept of promoting positive social behaviour, but only replaced ‘allow’ with ‘promote’ to keep the text concise.

In point 6, the Commission agreed with a comment to improve clarity regarding the environmental conditions for housed animals and amended the text accordingly.

The Commission did not agree with comments on Point 7 regarding the provision of feed and water ‘at all times,’ as this is a recommendation that contradicts e.g. with Chapter 7.5 ‘Animal welfare during slaughter’. The Commission considered this can be challenging in some agroecological conditions. Also, the Commission did not agree to change the last part of this point as the intention is to prevent hunger and thirst as well as malnutrition and dehydration.

In point 9, the Code Commission agreed with comments to include a new text at the beginning of this point to highlight the importance of using alternatives to some painful procedures as a general principle.

The Commission did not agree with some comments on point 10 as they did not add clarity. In addition, some of the suggestions are already addressed in the other chapters of Section 7 of the *Terrestrial Code*.

In point 11, the Code Commission agreed to add ‘training’ to complement the competencies that owners and handlers should have to treat animals with which they are in contact.

The revised Chapter 7.1. ‘Introduction to the recommendations on animal welfare’ is presented as Annex 23, for comments.

The extract of the explanatory notes on five domains prepared by the WOAH Animal Welfare Collaborating Centres, is presented as Annex 27 for information.

6.3. Killing for disease control purposes (Chapter 7.6.)

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 as well as the revision of related Glossary definitions.

At its June 2023 meeting, the *ad hoc* Group started work on Chapter 7.6. and developed a draft revised chapter and submitted its report together with the draft chapter to the Code Commission for consideration at its September 2023 meeting.

At its September 2023 meeting, the Code Commission considered the *ad hoc* Group report and the draft revised Chapter 7.6., provided feedback on the proposed text, and requested that the *ad hoc* Group be reconvened to continue working on the draft chapter.

Discussion

The Code Commission acknowledged the work of the *ad hoc* Group and considered a draft revised Chapter 7.6., together with some comments made by the members of the Code Commission in preparation of this meeting.

The Code Commission noted a proposal from the *ad hoc* Group to amend the title of the revised chapter to 'Animal welfare at the time of killing'. The Commission agreed in principle with this proposal taking into account the expanded scope of the revised chapter, which is not only about the killing of animals for disease control purposes but also under other circumstances, such as natural and man-made disasters. Also, the Commission noted that the revised chapter appeared to focus on the welfare issues related to mass killing of animals and that the text in the articles should reflect that.

The Code Commission reviewed the draft chapter and agreed to circulate for comments the first eight articles of the draft revised chapter, which include general recommendations.

The Code Commission agreed to continue working in the intersession and discuss the rest of the chapter during their September 2024 meeting.

The Articles 7.6.1 to 7.6.8 of the draft revised Chapter 7.6. Killing for disease control purposes, are presented as Annex 24, for comments.

6.4. New chapter on infection with Nipah virus (Chapter 8.Y.)

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

Background

At its February 2022 meeting, the Code Commission was informed that in September 2021 the Scientific Commission had endorsed the draft case definition developed by subject matter experts for Nipah virus encephalitis. The Code Commission reviewed the experts' reports and the Scientific Commission's opinion and agreed that the rationale provided for the case definition was not sufficient to support commencing the work to develop a single-article chapter. The Code Commission highlighted that if a change was considered for either in pathogenic agents or in its animal hosts, that this should be done through an assessment against the listing criteria in accordance with Chapter 1.2.

In February 2023, following the Code Commission request, and after consultation between the Biological Standards Commission and the Scientific Commission, the Scientific Commission amended the draft case definition, and forwarded it the Code Commission for consideration.

At its September 2023 meeting, the Code Commission agreed to draft a new Chapter 8.Y. 'Infection with Nipah virus', consisting of a single article for the general provisions, including the definition of its occurrence. The Code Commission also agreed to include an option for seroconversion only (i.e., without any further conditions) in the proposed point 3 of Article 8.Y.1., based on the opinions of the Scientific Commission and the Biological Standards Commission.

Regarding the name of the listed disease in Chapter 1.3., the Code Commission agreed to amend it from 'Nipah virus encephalitis' to 'Infection with Nipah virus' and moved from Article 1.3.5. (diseases of suidae) to Article 1.3.1. (diseases of multiple species), and to propose these amendments to Chapter 1.3. closer to the adoption of the new draft Chapter 8.Y.

Discussion

In the first paragraph, the Code Commission considered comments to add other species as animal hosts or as carriers. The Commission noted that the pigs and horses are the species considered to play a significant role in the epidemiology of the disease, which was aligned with *Terrestrial Manual*. However, the Commission added a text to clarify that the Nipah virus can infect a wide range of species but pigs and horses are the only species that play a significant role in the epidemiology of the disease.

In the same paragraph, the Code Commission agreed with a comment to change the order of 'horses' and 'pigs' as it considered that the infection of Nipah virus of pigs is highly contagious.

The Code Commission did not agree with a comment to delete point 3 as it considered that for that disease, evidence of active infection detected by seroconversion, as defined in the *Terrestrial Manual*, would constitute a confirmed case.

In points 3 and 4, the Code Commission did not agree with a comment to add 'infection with a cross-reactive virus' as it is inconsistent with the language mentioned at the start of the sentence 'antibodies specific to Nipah virus'.

In point 4, the Commission disagreed to a comment to delete 'suspected' but noted that it would work on a Glossary definition for 'suspected' case in the future.

The Code Commission reminded Members that the amendment of 'Nipah virus encephalitis' in Chapter 1.3. Diseases, infections and infestations listed by WOAH will be proposed when the new draft Chapter 8.Y. will be proposed for adoption.

The new Chapter 8.Y. 'Infection with Nipah virus' is presented as Annex 25, for comments.

6.5. Revision of Chapter 12.3 Dourine

Background

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

Between 2015 and 2018, a draft new Chapter 8.Z. 'Infection with *Trypanosoma evansi* (Surra)' and a revised Chapter 12.3. 'Dourine' were developed, circulated for comments and extensively discussed, but due to the need to clarify the scope of these chapters in terms of host species and pathogenic agents, in February 2018, both Commissions agreed to put Chapters 8.Z. and 12.3. on hold and to progress work on Chapter 8.19. 'Infection with *Trypanosoma brucei*, *T. congolense*, *T. simiae* and *T. vivax'*, which was adopted in May 2021. Both Commissions had also agreed that, notwithstanding diagnostic issues, the scope of the new Chapter 8.Z. should address surra of multiple species including horses and that the scope of Chapter 12.3. should remain as dourine of equids. The Commissions agreed that work on these two chapters should recommence after the adoption of the new Chapter 8.19.

The *ad hoc* Group was convened in July 2023 to draft a revised Chapter 12.3, in line with the approach used for the draft Chapter 8.Z. 'Infection with *Trypanosoma evansi* (Surra) for comments, that was circulated for comments in February 2023

In September 2023, the Scientific Commission reviewed the *ad hoc* Group's report and the draft revised Chapter 12.3. and forwarded it to the Code Commission.

Discussion

The Code Commission considered the *ad hoc* Group report and opinions of the Scientific Commission together with the draft revised Chapter 12.3. 'Dourine'.

The Code Commission reviewed the draft revised Chapter 12.3. and made amendments to the draft text for clarity and consistency. The Code Commission reminded Members to refer to the *ad hoc* Group report and the Scientific Commission's September 2023 report in conjunction with this report, and noted that the explanations provided in the previous reports are not repeated in this report.

In Article 12.3.1., point 1, the Code Commission agreed to include a reference to 'surra'. The Commission acknowledged that it was not conventional to refer to other diseases in a disease-specific chapter, but agreed to the opinion of the *ad hoc* Group to justify this:

"In the first part of the case definition on the observation of trypanosomes with *Trypanozoon* morphology, the Group discussed that having an epidemiological link to a confirmed case of dourine would unequivocally render the equid a case. However, if the same equid had only a 'suspected previous association or contact', it would not be sufficient, regardless of the molecular techniques used, to definitively classify the equid as infected with *T. equiperdum*. Therefore, to be classified as a case, the equid should also show clinical signs consistent with dourine as proposed by the *ad hoc* Group. Notwithstanding, if neither an epidemiological link to a confirmed case nor suspected case may be established, to avoid misclassification with surra, the Group proposed to add that the case should be from an area where surra is not known to occur."

The Commission noted that due to the large number of amendments proposed, the revised chapter is only presented as clean text.

The revised Chapter 12.3 'Dourine' is presented as Annex 26, for comments.

7. Updates on WOAH initiatives relevant to the Code Commission

7.1. WOAH Standards Online Navigation Tool

The Code Commission was updated on the WOAH Standards Online navigation tool project, which is an innovative project aimed at providing users with streamlined access and navigation of WOAH Standards.

The project will deliver three new user interfaces, on the WOAH Website:

- Navigation and search tool; this interface will provide a guided navigation experience that will allow users to navigate through the WOAH Codes and Manuals.
- Recommendations for safe international trade, by commodity; this interface will enable users to easily visualise recommendations for safe international trade by commodity through a comprehensive filtering system.
- Management of Standards; this interface will enable WOAH staff to efficiently manage and update WOAH International Standards, following adoption of new or revised text at the WOAH General Assembly.

The tool will be demonstrated at a kiosk at the 91st General Session in May 2024 and is projected to go 'live' in July 2024.

This project represents a significant milestone in WOAH's commitment to enhance access and utilisation of WOAH standards and contributes to the objectives of the 7th Strategic Plan to implement digital transformation, respond to Members' needs and improve WOAHs efficiency and agility.

7.2. WOAH Global Animal Welfare Strategy

Background

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

Discussion

The Secretariat provided an update of the Global Animal Welfare Forum, which is one of the relevant activities of the GAWS work plan.

The 2023 forum, 'Developing national animal welfare legislation; Different paths for the same destination', focused on presentations and discussions to bring knowledge, shared experience and support for the development of national animal welfare legislation. The topic was selected given that national veterinary legislation is the foundation for the implementation of WOAH international standards and for achieving good governance in animal health and welfare.

Key outcomes from the discussions during the forum were the need to agree on a common language and terms when developing legislation and regulations and the importance of monitoring and evaluating policies, alongside the need to influence human behaviour to improve animal welfare. The complex relationship between sustainability and animal welfare featured in discussions throughout the forum. The participants also noted the potential for policymaking to be more creative and less prescriptive, which may make policies easier to enforce.

Also, participants agreed that collaboration amongst WOAH Members was important and that those more advanced in the development and implementation of legislation could support those less advanced, and share lessons learned. WOAH capacity building tools such as the WOAH PVS Pathway and Veterinary Legislation Support Programme, were identified as key tools to be used by WOAH Members to improve their animal welfare regulatory framework.

The Code Commission acknowledged the information provided and noted that WOAH standards are not regulations *per se*, but serve as guidance to develop national regulations.

The Secretariat informed the Commission that the full report of the forum is available on the WOAH website.

7.3. Framework for *Terrestrial Code* Standards

Background

At the February 2021 Code Commission meeting, the Secretariat proposed developing a framework for *Terrestrial Code* Standards that would serve as a useful guide to ensure a consistent approach when undertaking work on the development or revision of a chapter. Noting the differences in the objectives and structure of the chapters within Volume I and Volume II of the *Terrestrial Code*, and within the different sections of Volume I, the Commission requested the Secretariat to begin by working on the content of disease-specific chapters, i.e. Volume II.

Since then, the Code Commission has worked closely with the Secretariat, in consultation with the Scientific Commission, and based on previous discussions and agreements between the Code Commission, the Scientific Commission and, where relevant, with the Biological Standards Commission, to develop a document that provides a detailed description of the structure and content of a disease-specific chapter, including the key references to other parts of the *Terrestrial Code* and other WOAH Standards, and conventions regarding the use of terms, wording and structure.

The Code Commission acknowledged that the framework is a living document and should be used as the reference for those undertaking work on the development of new or revised chapters. The Commission also agreed that the framework would help Members gain a better understanding of disease-specific chapters in the *Terrestrial Code* and could eventually be made available to Members at a later stage.

In September 2023, the Code Commission reviewed the document and requested the Secretariat to finalise a first edition as of February 2024 and requested that it be shared at the same time with the Scientific Commission and the Biological Standards Commission. Moreover, the Code Commission requested the Secretariat to use the framework in upcoming disease-specific chapter revisions and provide feedback with the Commission.

Discussion

The Secretariat presented to the Code Commission a consolidated framework document which had been also shared with the Scientific Commission and the Biological Standards Commission at their February

2024 meeting, as well as a list of identified issues by the Commission at its September 2023 meeting to be addressed in the future.

The Commission commended the work done and agreed to close this as a first edition of the document, to be used initially for internal purposes, and requested the Secretariat to use it in the upcoming work to review or develop disease-specific chapters. The Commission emphasised that this should be a living document that, while striving for harmonisation and consistency, should allow for evolution.

The commission reviewed the list of issues to be further discussed and agreed to continue working to progressively address them, together with other items that may arise. The Commission noted that some of the priority items identified were already being considered in the upcoming works on 'animal hosts' (see item 4.2.1 of this report), 'zoning' (see item 4.2.6. of this report), the User's guide (see item 6.1. of this report) and on 'commodity' (see item 7.4. of this report).

Noting the progress in the development of the new tool to visualise the recommendations for international trade by commodity (see item 7.1. of this report), and the progress on the work on 'commodity' (see item 7.4. of this report), the Commission agreed to initiate, when possible, a discussion to improve the structure of the articles containing trade recommendations.

The Commission requested the Secretariat to report back at its next meeting and to incorporate the maintenance of the 'framework' as a standing item for every Code Commission meeting.

7.4. Commodities

Background

At its September 2021 meeting, the Code Commission agreed on an internal procedure to manage commodities' names and their listing as safe commodities in *Terrestrial Code* chapters. Since then, the Commission has been working with the Secretariat to develop a consolidated approach to managing commodities' names.

In September 2023, the Code Commission discussed a set of rules and a categorised tree, considering the WCO HS, to achieve consistency in the naming of commodities in the context of the WOAH internal SOP. The Commission agreed with the proposed approach, provided feedback to the Secretariat and noted that this would be a continuous work aiming at progressively developing a standardised approach and requested the Secretariat to consolidate this work with the framework for *Terrestrial Code* Standards.

The Code Commission noted that there was a need to consider some groups of commodities such as 'dairy commodities', 'egg commodities' or commodities associated with 'rendering' to clarify the standard terminology and associated industrial process and requested the Secretariat to continue developing a standardised approach in collaboration with relevant partner organisations and report back at a future meeting.

Discussion

The Secretariat updated the Commission on the progress of this work based on the Code Commission's feedback on the proposed set of rules and categorised tree discussed at its September meeting. The Secretariat informed that these had been taken into consideration for the development of the new WOAH Standards online navigation tool (See items 7.1. of this report), and that the project will provide additional insights and tools to progress this work on commodities.

With regards to the clarification of some commodity groups, the Secretariat reported that it has been working with partner organisations, particularly with the World Renderers Organisation, that had established a working group dedicated to standardizing definitions for the most significant and commonly traded rendered products.

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

7.5. Transparency of the WOAH process for the elaboration of Standards

The Secretariat updated the Code Commission on progress that had been made to improve the transparency of the WOAH process for the elaboration of Standards, in particular the publication of comments submitted by Members and partners.

The Secretariat informed the Commission that the Director General communicated this initiative to Members in December 2023 and that a Standard Operating Procedure (SOP) had been developed for the submission of comments during the process for the elaboration of WOAH international standards, as well as a guide on how to submit and present comments, and that these documents have been published on the WOAH website and on the Delegates' website.

The Secretariat reminded the Commission that this is a progressive process, that will start in March/April 2024 with the publication on the Delegates' website of comments considered on new and revised standards during February 2024 Commission meetings, at the same time as the publication of the respective February 2024 Commission report. This process takes a step-wise approach and includes an evolution of the Commission reports towards transparency of comments considered and Commission responses, which will result in better documentation and traceability of the WOAH process for the elaboration of Standards.

7.6. WAHIAD and WAHIS Platform updates

The Code Commission was updated on the development and evolution of the WAHIS platform during 2023 which included the optimisation of the early warning, biannual report modules, and the development of the annual report module. The Commission was reminded that sessions were organised with members of all the Specialist Commissions to demonstrate how to use WAHIS functionalities and to gather feedback on needs. Similar sessions will be convened in 2024 and all Commissions are encouraged to participate.

The Commission was briefed on the relevant updates of the WAHIS Reference Tables made in December 2023. The objective of this work was to align with the changes adopted in the WOAH International Standards at the 2023 General Session.

The Commission commended this work and encouraged the communication between the Secretariat and WOAH World Animal Health Information and Analysis Department (WAHIAD) to continue evaluating changes to the WOAH Standards that may need to be reflected in WAHIS.

7.7. New WOAH Emerging Diseases *ad hoc* Group

The Code Commission was updated on the establishment of a 'WOAH *ad hoc* Group on Emerging Diseases (including re-emerging diseases) and Drivers of Disease Emergence in Animals', presented as "WOAH's Emerging Diseases Group (EDG)", which met for the first time in December 2023. The Secretariat reported that this Group was an evolution of the *ad hoc* Group on COVID-19 and would be proposed to work permanently with specific Working Group Terms of Reference (ToR).

The Secretariat reported that the Group discussed their dual role of supporting WOAH, that is in a response function and in a business-as-usual operational function, and that the experts deliberated and identified existing gaps in the current framework for addressing emerging diseases in WOAH and formulated a set of deliverables and a work plan for the first year of operation.

The Code Commission noted the update from this Group and its ToR. The Commission regretted that it had not seen the ToR previously, as this group will have potential work on some aspects of the *Terrestrial Code*. It provided feedback and expressed concerns on some points covered in the first meeting report, especially a biased understanding of the term 'emerging disease', which is defined in the Glossary of the *Terrestrial Code* (not only 'for the purposes of trade'). The Commission highlighted the importance of maintaining a close alignment with the existing mechanisms for the assessment of 'emerging diseases' and coordination with the Scientific Commission who oversees that process. While acknowledging the importance of some of the topics discussed by the Group, especially the possible role of hazard identification by WOAH, the Commission stressed that it was critical to respect the principles of notification

of emerging disease to WOAH, and the existing related standards. The Commission reminded that notification to WOAH of 'emerging diseases' as defined in the Glossary was an obligation for Members and it was aimed 'to minimise the spread of important animal diseases, and their pathogenic agents, and to assist in achieving better worldwide control of these diseases' as described in Article 1.1.2. of the *Code*, and that going beyond this could imply unjustified burden to Members. On the other hand, the Commission considered that, in the case of apparently emerging events and findings of importance yet to be evaluated, the WOAH Scientific Network, notably the WOAH Reference laboratories and Collaborating Centres, would be best placed to help in defining the actual and potential impacts of each of these events.

The Commission thanked the Secretariat for the information provided and expressed its willingness to contribute to this work, as relevant.

7.8. Publication of the Observatory thematic study on zoning

A representative of the WOAH Observatory informed the Code Commission about the Thematic Study on Zoning Report (Part 1), which was published in January 2024. They explained that it is a descriptive report on the use, challenges and impact of zones established due to infection with avian influenza (AI), African swine fever (ASF) and foot and mouth disease (FMD) in WOAH Members from 2018-2022. Members were asked to complete three questionnaires to provide information on their use of zoning for AI, ASF and FMD. They had good response rates with 50-60% of Members having responded to the different disease questionnaires. Members responded that zoning had a positive impact on the control of the three diseases (81%-91%). The top challenges for implementation of zoning were staffing and availability of other resources of Veterinary Services, enforcement of biosecurity and animal identification and traceability. Members reported that recognition of zones by trading partners can take more than two years, and is mainly driven by transparency and trust in certification systems.

The Code Commission supported one of the recommendations of the report that WOAH organise an inter-regional forum where Members from different parts of the world could share experiences in establishing disease-free zones and discuss practical approaches, solutions, and tools to be considered for creating and successfully maintaining a disease-free zone. The Commission also noted that, besides the conclusions of the referred report, if such activity was organised, the outcomes could provide valuable inputs that could be considered for the development of the new Chapter 4.X. on implementation of zoning (see item 4.2.6. of this report).

8. Updates on the other standard-setting bodies and international organisations

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

8.1. One Heath Global Coordination

The Code Commission was updated on the ongoing activities undertaken at WOAH to ensure global coordination of One Health activities.

The Code Commission was informed of the current activities conducted under the 'Quadripartite", coordination action between the Food and Agriculture Organization of the United Nations (FAO), United Nations Environment Programme (UNEP), World Health Organization (WHO) and WOAH.

Also, the Commission was provided with an update of the ongoing works at WHO to negotiate a new international agreement to strengthen global pandemic prevention, and if necessary to review the International Health Regulations (IHR), which WOAH has been following closely as an observer.

The Commission discussed different aspects of this work, and agreed with the importance of ensuring good coordination of these activities between international organisations, as well as promoting the practical implementation of the 'One Health approach'.

The Commission noted that the ongoing discussions should be an opportunity to reinforce for the coordination between the human and animal health sectors. The Commission noted that Veterinary Services play a critical role in surveillance, detection, prevention, and control of animal diseases, including zoonoses and emerging pathogenic agents. The Commission reminded that the 'One Health approach' is deeply incorporated into the *Terrestrial Code*, not only because it addresses directly animal diseases and zoonoses, but also because the impact in human health is at the core of many of the recommended measures, as it is part of the vital role of Veterinary Services. In addition to disease specific measures, the Commission also noted that the *Terrestrial Code* contains one whole section dedicated to veterinary public health (Section 6), including areas like food safety systems and antimicrobial resistance. The Commission stressed that it would be important to ensure that key aspects of these standards for both organisations are well coordinated and expressed interest in supporting this effort.

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…/Annexes

Annex 1. Adopted Agenda

MEETING OF THE WOAH TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 6 to 16 February 2024

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1. **Welcome**
   - **1.1.** Director General and Deputy Director General
2. **Adoption of agenda**
3. **Cooperation with other Specialist Commissions**
   - **3.1.** Scientific Commission for Animal Diseases
     - **3.1.1.** SOP for listing decision for pathogenic agents
     - **3.1.2.** SOP for determining whether a disease should be considered as emerging
       - **3.1.2.1.** Ongoing assessments and new requests
     - **3.1.3.** Case definitions
     - **3.1.4.** Animal hosts to be targeted by WOAH Standards for a listed disease
     - **3.1.5.** Notification obligations
     - **3.1.6.** Removal of questionnaire chapters (Chapters 1.7. to 1.12.)
     - **3.1.7.** Revision of Chapter 4.4. Zoning and compartmentalisation
   - **3.2.** Biological Standards Commission
     - **3.2.1.** Biological Standards Commission's recommendations to the *Terrestrial Code*
   - **3.3.** Aquatic Animals Commission
     - **3.3.1.** Aquatic Animals Commission work on chapter on implementation of compartmentalisation
4. **Code Commission's work programme not including texts proposed for comments or adoption**
   - **4.1. Ongoing work items (not in order of priority)**
     - **4.1.1.** Animal hosts to be targeted by WOAH Standards for a listed disease
     - **4.1.2.** Wildlife health
     - **4.1.3.** Emergency Management
     - **4.1.4.** Revision of Chapter 4.4. Zoning and compartmentalisation
     - **4.1.5.** Revision of Chapter 4.7. Collection and processing of bovine, small ruminant and porcine semen
     - **4.1.6.** Revision of Chapter 7.2. Transport of animals by sea, 7.3. Transport of animals by land and 7.4. Transport of animals by air
     - **4.1.7.** Revision of Chapter 7.6. Killing of animals for disease control purposes
     - **4.1.8.** Revision of Chapter 12.3. Dourine
     - **4.1.9.** Revision of chapters on equine encephalitides (Chapters 8.10. Japanese encephalitis, 12.4. Equine encephalitis (Eastern and Western) and 12.11. Venezuelan equine encephalomyelitis)
     - **4.1.10.** Revision of Chapter 14.8. Scrapie

4.1.11. Revision of Chapters 5.5. and 5.7. and associated glossary

4.1.12. Revision of Chapter 1.6. Procedures for official recognition of animal health status, endorsement of an official control programme, and publication of a self-declaration of animal health status, by WOAH

4.1.13. New Chapter Crimean-Congo Hemorrhagic Fever

4.2. Items under consideration for inclusion in work programme

4.3. New proposals and requests for inclusion in work programme

4.3.1. New World screwworm and Old World screwworm

4.3.2. Comment on EHD

4.3.3. New requests

4.4. Prioritisation of items in work programme

5. Texts circulated for comments

5.1. Glossary: 'animal product', 'biological products', 'commodity', 'death', 'euthanasia', 'germinal products', 'greaves', 'semen collection centre', 'slaughter' and 'stunning'

5.2. Disease, infections and infestations listed by WOAH (Chapter 1.3.)

5.3. General hygiene in semen collection and processing centre (Chapter 4.6.)

5.4. Revision of Chapter 4.7. Collection and processing of bovine, small ruminant and porcine semen

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

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

5.7. Infection with foot and mouth disease virus (Chapter 8.8.) and Application of official recognition by WOAH of free status for foot and mouth disease (Chapter 1.11.)

5.8. Infection with Rift Valley fever virus (Chapter 8.16.)

5.9. Infection with Trichinella spp. (Chapter 8.18.)

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

5.11. Infection with Trypanosoma evansi (New Chapter 8.Z.)

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

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

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

5.15. Revision of Articles 13.2.1. and 13.2.2. of Rabbit haemorrhagic disease (Chapter 13.2.)

5.16. Revision of Chapter 15.1. Infection with African swine fever virus

5.17. New chapter Infection with Camelpox virus (Chapter 16.Z.)

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

6. Updates on WOAH initiatives relevant to the Code Commission

6.1. User's Guide

6.2. Glossary: 'biosecurity', 'biosecurity plan', 'border post', 'container', 'point of exit', 'quarantine station', 'swill' and 'vehicle/vessel'

6.3. New Chapter on biosecurity (Chapter 4. X.)

6.4. Revision of Chapters 5.4.

6.5. Revision of Chapters 5.6.

6.6. Revision of Chapter 7.1. Introduction to the recommendations for animal welfare

6.7. New Chapter Infection with Nipah virus (Chapter 8.Y.)

6.8. Revision of Chapter 14.8. Scrapie

7. Updates on the other standard-setting bodies and international organisations

7.1. WOAH standards navigation tool

7.2. WOAH Global Animal welfare strategy (Forum)

7.3. Framework

7.4. Commodities

7.5. Publication of Member comments

7.6. WAHIAD and WAHIS Platform updates

7.7. New WOAH Emerging Diseases *Ad hoc* Group (EDG)

7.8. Publication of the Observatory thematic study on zoning

8. Updates on the other standard-setting bodies and international organisations

8.1. Updates of WOAH and IHR

9. Meeting review

10. Date of next meeting

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Annex 2. List of Participants

MEETING OF THE WOAH TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 6 to 16 February 2024

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MEMBERS OF THE COMMISSION

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

Prof Salah Hammami
(Vice-President)
Epidemiologist and virologist,
National School of Veterinary Medicine,
Sidi Thabet,
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Dr Gaston Maria Funes
(Vice-President)
Counsellor for Agricultural Affairs,
Embassy of Argentina to the EU,
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Dr Bernardo Todeschini
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Federal Agricultural Officer
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Dr Kiyokazu Murai
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Annex 4

G L O S S A R Y

EU	**The EU supports the adoption of this revised Glossary. The EU has one more comment.**

ANIMAL PRODUCTS

means any parts of an *animal*, and or a raw or manufactured products containing any material derived from *animals*, excluding *germinal products*, *biological products* and *pathological material*.

BIOLOGICAL PRODUCTS

means a products of animal or microorganism origin, used as reagents in the diagnosis of diseases, for treatment, control and prevention of diseases, and or in the collection and processing of *germinal products*.

COMMODITY

means a live *animals*, an *animal products* of animal origin, animal genetic material *germinal products*, a *biological products* and or *pathological material*.

~~*DEATH*~~

~~means the irreversible permanent loss of all vital functions brain activity demonstrable by the loss of brain stem reflexes. This may be confirmed through a combination of criteria such as dilated pupil and absence of corneal reflex, cardiac activity and breathing.~~

EUTHANASIA

means the killing of an animal ~~act of inducing death~~ for welfare purposes using a method that causes a rapid and irreversible loss of consciousness with minimum pain and distress ~~to animal~~.

EU	**The EU suggests keeping "for welfare purposes" in the definition of euthanasia:** **"means the killing of an animal for welfare purposes using a method that causes a rapid and irreversible loss of consciousness with minimum pain and distress to animal."** **Justification:** **Considering that very often healthy animals are killed (e.g. for disease control or scientific purposes) the EU believes that it is important to keep "for welfare purposes" in order to not include such killings in the term "Euthanasia".**

GERMINAL PRODUCTS

means animal semen, oocytes, embryos ~~and~~ or *hatching eggs*.

~~*GREAVES*~~

~~means the protein-containing residue obtained after the partial separation of fat and water during the process of rendering.~~

~~*ARTIFICIAL INSEMINATION CENTRE*~~*SEMEN COLLECTION CENTRE*

means an *approved* facility ~~*approved* by the *Veterinary Authority* and which~~ that meets the conditions set out in the *Terrestrial Code* for the collection, processing and~~/or~~ storage of semen.

SLAUGHTER

means the ~~any~~ killing ~~procedure that causes the death of an animal by bleeding~~ of an animal~~s~~ primarily intended for human consumption.

STUNNING

means any ~~mechanical, electrical, chemical or other~~ procedure that causes ~~rapid~~ ~~immediate~~ loss of consciousness for the purpose of killing without ~~minimal~~ avoidable *distress*, fear and *pain* ~~and other types of and suffering for the purpose of killing; when used before slaughter, the loss of consciousness lasts until death from the slaughter process.; in the absence of slaughter, the procedure would allow the animal to recover consciousness.~~

Annex 5

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY WOAH

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

Preamble

The diseases, *infections* and *infestations* in this chapter have been assessed in accordance with Chapter 1.2. and constitute the WOAH list of terrestrial animal diseases.

In case of modifications of this list adopted by the World Assembly of WOAH Delegates, the new list comes into force on 1 January of the following year.

Article 1.3.1.

The following are included within the category of ~~multiple species~~ diseases, *infections* and *infestations* of multiple species:

– Anthrax

– Crimean Congo hemorrhagic fever

– Equine encephalomyelitis (Eastern)

– Heartwater

– Infection with Aujeszky's disease virus

– Infection with bluetongue virus

– Infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*

– Infection with *Coxiella burnetii* (Q fever)

– Infection with *Echinococcus granulosus*

– Infection with *Echinococcus multilocularis*

– Infection with epizootic hemorrhagic disease virus

– Infection with foot and mouth disease virus

– Infection with *Leishmania* spp. (Leishmaniosis)

– Infection with *Mycobacterium tuberculosis* complex

– Infection with rabies virus

– Infection with Rift Valley fever virus

– Infection with rinderpest virus

– Infection with *Trichinella* spp.

– Infection with *Trypanosoma brucei*, *Trypanosoma congolense*, *Trypanosoma simiae* and *Trypanosoma vivax*

– Infection with *Trypanosoma evansi* (Surra)

– Japanese encephalitis

– New World screwworm *(Cochliomyia hominivorax)*

– Old World screwworm *(Chrysomya bezziana)*

– Paratuberculosis

~~– Q fever~~

~~– Surra *(Trypanosoma evansi)*~~

– Tularemia

– West Nile fever.

Article 1.3.~~2~~4.

The following are included within the category of ~~bovine~~ diseases and *infections* of bovinae:

– Bovine anaplasmosis

– Bovine babesiosis

– Bovine genital campylobacteriosis

– Bovine spongiform encephalopathy

~~– Bovine viral diarrhoea~~

– Enzootic bovine leukosis

– Haemorrhagic septicaemia (*Pasteurella multocida* serotypes 6:b and 6:e)

– Infection with bovine pestiviruses (Bovine viral diarrhoea)

– Infection with lumpy skin disease virus

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

– Infection with *Theileria annulata*, *Theileria orientalis* and *Theileria parva*

– Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

– Trichomonosis.

Article 1.3.~~3~~7.

The following are included within the category of ~~sheep and goat~~ diseases and *infections* of caprinae:

– Caprine arthritis/encephalitis

– Contagious agalactia

– Contagious caprine pleuropneumonia

– Infection with *Chlamydia abortus* (Enzootic abortion of ewes, ovine chlamydiosis)

– Infection with peste des petits ruminants virus

– Infection with *Theileria lestoquardi*, *Theileria luwenshuni* and *Theileria uilenbergi*

– Maedi–visna

– Nairobi sheep disease

– Ovine epididymitis *(Brucella ovis)*

– Salmonellosis (*S.* abortusovis)

– Scrapie

– Sheep pox and goat pox.

Article 1.3.4~~5~~5.

The following are included within the category of ~~equine~~ diseases and *infections* of equidae:

~~– Contagious equine metritis~~

– Dourine

– Equine encephalomyelitis (Western)

– Equine infectious anaemia

~~– Equine piroplasmosis~~

– Infection with African horse sickness virus

– Infection with *Burkholderia mallei* (Glanders)

– Infection with equid herpesvirus-1 (Equine rhinopneumonitis)

– Infection with equine arteritis virus

– Infection with equine influenza virus

– Infection with *Taylorella equigenitalis* (Contagious equine metritis)

– Infection with *Theileria equi* and *Babesia caballi* (Equine piroplasmosis)

– Venezuelan equine encephalomyelitis.

Article 1.3.~~5~~8.

The following are included within the category of ~~swine~~ diseases and *infections* of suidae:

– Infection with African swine fever virus

– Infection with classical swine fever virus

– Infection with porcine reproductive and respiratory syndrome virus

– Infection with *Taenia solium* (Porcine cysticercosis)

– Nipah virus encephalitis

– Transmissible gastroenteritis.

Article 1.3.~~6~~3.

The following are included within the category of ~~avian~~ diseases and *infections* of aves:

– Avian chlamydiosis

– Avian infectious bronchitis

– Avian infectious laryngotracheitis

– Duck virus hepatitis

– Fowl typhoid

– Infection with high pathogenicity avian influenza viruses

– Infection of birds other than *poultry*, including *wild* birds, with influenza A viruses of high pathogenicity

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

– Infection with *Mycoplasma gallisepticum* (Avian mycoplasmosis)

– Infection with *Mycoplasma synoviae* (Avian mycoplasmosis)

– Infection with Newcastle disease virus

– Infectious bursal disease (Gumboro disease)

– Pullorum disease

– Turkey rhinotracheitis.

Article 1.3.~~7~~6.

The following are included within the category of ~~leporids~~ diseases and *infections* of leporidae:

– Infection with pathogenic rabbit lagoviruses (Rabbit haemorrhagic disease)

– Myxomatosis.

~~– Rabbit haemorrhagic disease.~~

Article 1.3.~~8~~2.

The following are included within the category of ~~bee~~ diseases, *infections* and *infestations* of apinae:

– Infection of honey bees with *Melissococcus plutonius* (European foulbrood)

– Infection of honey bees with *Paenibacillus larvae* (American foulbrood)

– Infestation of honey bees with *Acarapis woodi*

– Infestation of honey bees with *Tropilaelaps* spp.

– Infestation of honey bees with *Varroa* spp. (Varroosis)

– Infestation with *Aethina tumida* (Small hive beetle).

Article 1.3.9.

The following are included within the category of ~~camelids~~ diseases and *infections* of camelidae:

– Infection with ~~C~~camelpox virus

– Infection of with Middle East respiratory syndrome coronavirus.

Annex 7

CHAPTER 4.6.

~~GENERAL HYGIENE IN~~ SEMEN COLLECTION, PROCESSING AND STORAGE

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

Article 4.6.1.

General provisions

The objective of this chapter is to provide recommendations that ~~will~~ aim at reduc~~e~~ing~~e~~ the likelihood of introduction and spread of *listed diseases* and contamination of fresh, chilled~~,~~ or frozen semen ~~of~~ from various species of donor animals with ~~potentially~~ pathogenic agents in a *semen collection centre*.

1) This chapter provides recommendations on:

~~1~~a) procedures for the collection, processing~~,~~ and storage of semen ~~of~~ from bovine, ovine, caprine, porcine, equine, and cervid donor animals;

~~2~~b) *biosecurity* ~~measures~~ for ~~the operation of~~ *semen collection centres*;

~~3~~c) conditions applicable to the management and housing of semen donor animals and teasers.

~~This chapter provides a comprehensive framework for processes that can be applied to reduce the likelihood of transmission of *listed diseases* in through semen.~~ *Veterinary Services* play a key role in identifying, assessing~~,~~ and managing disease *risk* posed by the collection, processing~~,~~ and storage of semen from various species of donor animals in a *semen collection centre* and establishing appropriate measures to minimi~~z~~se this risk. The *Veterinary Authority* should provide the regulatory standards and~~/or~~ oversight to ensure that the recommendations in this chapter, as appropriate, are complied with.

~~Although this chapter is focused on reducing the probability of transmitting *listed diseases* through international trade of semen, t~~The recommendations in this chapter ~~may also be appropriately~~ apply~~ied when~~ to semen ~~is~~ collected, processed~~,~~ and stored for international trade or for domestic distribution.

Recommendations on *animal welfare* in accordance with the principles in Chapter 7.1. of the *Terrestrial Code* ~~are applicable~~ should be applied to the animals kept within the *semen collection centre*~~, in accordance with relevant articles in Chapter 7.1. of the *Terrestrial Code*~~.

Recommendations regarding specific animal health requirements for donor animals to provide assurance of the absence of selected *listed diseases*, *infections* and *infestations* are found in Chapter 4.7. and ~~other~~ relevant disease-specific chapters.

2) For the purposes of the *Terrestrial Code,* the *semen collection centre* ~~is~~ comprise~~d of~~:

~~1~~a) animal accommodation facilities;

~~2~~b) semen collection facilities;

~~3~~c) semen processing facilities, including mobile ~~laboratories~~ processing units;

~~4~~d) semen storage facilities;

~~5~~e) administration offices.

The listed facilities may be ~~on~~ in one location or consist of single or multiple ~~facility~~ entities ~~on~~ in several locations.

3) For the purposes of this chapter~~,~~:

~~1~~a) 'biosecure' refers to the state of a place or facility, in which *biosecurity* is ~~effectively~~ implemented effectively;

~~2~~b) 'resident facility' means a biosecure animal accommodation facility where donor and teaser animals are kept for the purpose of semen collection;

~~3~~c) 'pre-entry isolation facility' means a biosecure animal accommodation facility where donor and teaser animals are subjected to testing prior to entering the resident facility;

~~4~~d) '~~germplasm~~ cryogenic ~~storage~~ tank' means a sealable ~~canister~~ tank for storage and transport of frozen semen, embryos or oocytes.

Article 4.6.2.

General conditions applicable to semen collection centres

~~For the approval of T~~the *semen collection centre* ~~should be approved by the *Veterinary Authority*.~~

~~For that purpose, the *Veterinary Services* should conduct regular audits of *biosecurity plans*, protocols, procedures and records on the health of the animals in the *semen collection centre* and on the hygienic production, storage and dispatch of semen, at least annually, and request~~ and verify ~~appropriate corrective actions, if needed.~~

Each facility in the *semen collection centre* should be under the direct supervision of a *veterinarian* who is responsible for ensuring that, in the facilities under ~~its~~ their supervision, the health~~,~~ and welfare of animals are monitored, ~~and~~ the *biosecurity plan* ~~in the facilities under his/her supervision are~~ is implemented, and all documentation including records of procedures is kept current and accessible. The supervising *veterinarian* should communicate directly with the *Veterinary Services* in the event of a disease incursion or serious adverse hygiene event.

Animal identification, animal traceability~~,~~ and movement *registration* should be in accordance with Chapter 4.2. and Chapter 4.3.

The *semen collection centre* should implement and document processes that ensure identification and traceability of semen from collection to processing ~~and~~, storage and final dispatch from the semen storage facility. Fresh, chilled, or frozen semen products ~~stored and/or~~ dispatched from the semen storage facility should be identified ~~in accordance with the national regulation~~ to allow accurate and transparent identification of the donor animal, where the semen was collected and~~/or~~ processed, and when it was collected.

Donor and teaser animals should be ~~maintained~~ kept in animal accommodation facilities separately from animals not associated with the *semen collection centre* ~~or maintained in separate animal accommodation facilities that may have a different *animal health status*~~.

Biosecurity plans should be developed for the *semen collection centre* in accordance with a *risk analysis* and should, at a minimum, address the following ~~for each facility~~:

1) Personnel ~~on~~ at the *semen collection centre* should be technically competent and apply ~~high standards of~~ personal hygiene~~,~~ to prevent the introduction of pathogenic agents. Personnel should receive regular training and demonstrate competency ~~of~~ in skills applicable to the *semen collection centre* and covering ~~his/her~~ their specific responsibilities at the centre, which are documented.

2) In general, only donor and teaser animals of the same species should be permitted ~~to~~ at the *semen collection centre*. All donor and teaser animals should meet the ~~animal health status~~ health requirements as determined by the *semen collection centre* and comply with the regulations set out by the *Veterinary Authority*. If other animals are needed ~~on~~ at the *semen collection centre*, such as dogs for herding purposes, these should be kept ~~on~~ at the *semen collection centre* and not transferred from one establishment to another, and measures to prevent their contact~~s~~ with *wildlife* should be implemented. If ~~O~~other species are

needed ~~may be resident on~~ at the *semen collection centre*, ~~provided that~~ appropriate pre-entry tests should have been conducted and *biosecurity* ~~is~~ should be in place to ensure they meet the ~~animal health status~~ health requirements as determined by the *semen collection centre* prior to entry. ~~These animals should be kept in separate biosecure animal accommodation facilities that are physically separate from animals associated with semen production.~~

3) Isolation facilities should be washed and disinfected prior to the admittance of each new group of animals. Animals exhibiting any signs of illness upon arrival or during the isolation period should be removed to a separate area.

4~~3~~) Natural mating should be avoided for at least ~~four weeks~~ 30 days prior to entry into the pre-entry isolation facility and ~~avoided~~ should not occur after entry into the animal accommodation facility or semen collection facility.

5~~4~~) Measures should be in place to prevent the entry of ~~*wildlife*~~ *wild* or *feral* ~~animals~~ *animals* (including rodents, ~~and~~ arthropods~~)~~ or other domestic animals susceptible to pathogenic agents transmissible to the animals in the *semen collection centre*.

6~~5~~) In accordance with a *biosecurity plan*~~,~~:

~~i~~a) ~~T~~the entry of visitors to any part of the *semen collection centre* where *biosecurity* is required should only be allowed if authorised and controlled~~.~~;

~~ii~~b) ~~A~~appropriate protective clothing and footwear only for use within the *semen collection centre* facilities should be provided~~.~~;

~~iii~~c) ~~F~~footbaths should be provided, where necessary, and regularly cleaned and the disinfectant renewed based on the manufacturer's recommendations~~.~~;

~~iv~~d) any additional measures such as complete change of clothing or shower may be required depending on the risks; and

~~v~~e) ~~R~~records should be kept of the daily movements of all staff and visitors that enter the *semen collection centre*.

7~~6~~) Appropriate *disinfection* of work areas and equipment should be implemented and documented regularly by trained and competent staff.

~~7) Control measures should be in place to minimise the entry of insects and rodents.~~

8~~87~~) *Vehicles* for the transport of animals, *feed*~~,~~ and waste and manure removal should be used in a manner which minimises health risks to animals in the *semen collection centre*.

9~~8~~) Up-to-date and accessible records should be kept of all movements of animals and *germinal products* associated with the *semen collection centre* to ensure *traceability*.

For the approval of the *semen collection centre* by the *Veterinary Authority*, the *Veterinary Services* should conduct regular audits of *biosecurity plans*, protocols, procedures and records on the health of the animals in the *semen collection centre* and on the hygienic production, storage and dispatch of semen, at least annually, and request and verify appropriate corrective actions, if needed.

Article 4.6.3.

Recommendations applicable to animal accommodation facilities

Animal accommodation facilities should be designed so that cleaning and *disinfection* measures ~~are easy and efficient to~~ can be implemented efficiently. Individual and group housing pens should be kept clean ~~and the bedding renewed as often as necessary to ensure it is dry and clean~~.

The animal accommodation facilities should include dedicated areas for *feed* storage, ~~for~~ manure storage, bedding storage, and for the isolation of any sick animals. Animal accommodation facilities should be species~~-~~ specific, where relevant.

There should be a separate pre-entry isolation facility that is managed as a separate biosecure facility for holding animals that are required to complete testing and isolation prior to entry to the resident facility. Procedures for animal identification, blood sampling and vaccination of animals within the *semen collection centre* should be conducted in accordance with relevant recommendations in the *Terrestrial Code*. In the instance where the *Veterinary Authority* has determined that a pre-entry isolation facility is not required,

such as for the collection of equine semen, pre-entry conditions ~~to~~ for entering the resident facility or semen collection facility should be included in the *biosecurity plan* of the *semen collection centre.*

The decision to house animals indoors or outdoors will be determined by the *semen collection centre* in accordance with the *biosecurity plan*. Donor animals and teasers that are housed outdoors, or allowed access outdoors, should be accommodated to minimise *vector* attacks and adequately protected from adverse weather conditions. ~~Donor animals and teasers that are housed indoors, should be accommodated to allow for adequate ventilation and proper footing and bedding.~~

All donor and teaser animal accommodations should be adapted to the needs of the species of donor ~~being collected~~. Watering and feeding systems should be constructed so that ~~it~~ they provide~~s~~ minimum contact between donor animals and can be easily cleaned.

Bedding should be clean and dry, soft, and easy to spread and remove. Bedding should be removed regularly and replaced, following thorough cleaning and *disinfection* of relevant surfaces.

Feed and bedding material should be kept in a dry place ~~and~~, stored in a manner to prevent access by *wildlife* or pests, and stored in conditions that are well monitored.

Manure, litter, and bedding material should be disposed of in such a way as to prevent the transmission of diseases ~~and be in compliance with all relevant health and environmental legislation~~.

Article 4.6.4.

Recommendations applicable to semen collection and semen collection facilities

The semen collection facility can be co-located with the resident facility and share *biosecurity* to accommodate the same designated *animal health status* ~~of~~ as the resident facility. If the semen collection facility is co-located with a resident facility, the semen collection facility should not be used to collect from other donor animals not housed in the resident facility. If the semen collection facility is a separate facility, *biosecurity* should be in place to allow only animals ~~of~~ that meet the same ~~*animal health status*~~ health requirements to be permitted entry into that facility.

Donors and teaser animals should be kept and prepared in such a way as to facilitate the hygienic collection of semen. Donor animals should be dry and clean when arriving in the semen collection area.

~~Donor animals~~ Semen should be collected from donor animals in the semen collection facility and not ~~collected~~ in the resident facility. Any exception should be justified and adequately managed by the *biosecurity plan*.

In addition to point 5 of Article 4.6.2., ~~P~~personnel and visitors ~~should~~ may be provided with specific protective clothing and footwear for use only at the semen collection facilities and worn at all times, and waiting periods before re-entering the centre can be required.

Equipment used for the animals should be dedicated to the semen collection facility and ~~or~~, if not new, disinfected before being introduced to the *semen collection centre*. All other equipment and tools brought ~~on~~ to the ~~premises~~ semen collection facility should be examined and *disinfected*, if necessary, to minimise the introduction of pathogenic agents.

The semen collection facility and associated equipment should be designed in such a way as to allow for effective cleaning and *disinfection*, where applicable.

The floor of the mounting area should be clean and provide safe footing. When rubber mats are used, they should be cleaned after each collection.

Preputial orifices of donor animals should be clean and free of excessive hair or wool to avoid contamination of the semen. Hair or wool at the preputial orifice should be regularly trimmed as needed but not completely removed to avoid excessive irritation of the preputial mucosa while urinating.

Hair or wool on the hindquarters of teaser animals should be kept short to avoid contamination during the collection process. A teaser animal should have its hindquarters thoroughly cleaned before each collection session. A plastic apron can be used to cover the hindquarters of the teaser animal, but the apron should be replaced with a clean apron or thoroughly cleaned and *disinfected* between donor animals.

A dummy mount, if used, should be made of a material that is easy to clean and disinfect and should be thoroughly cleaned after each collection. Disposable plastic covers may be used.

When used, ~~the~~ an artificial vagina should be cleaned completely after each collection. It should be dismantled, washed, rinsed, dried~~,~~ and protected from dust. The inside of the body of the device and the cone should be *disinfected* before re-assembly using *disinfection* procedures approved by the *Veterinary Authority.*

Lubricant used in the artificial vagina should be new and the equipment used to spread the lubricant should be clean and free of dust.

The artificial vagina should be handled in a manner to prevent dirt and debris from entering.

When successive ejaculates are being collected from the same donor, a new artificial vagina should be used for each collection to prevent any contamination. The artificial vagina should also be changed when the animal has inserted its penis without ejaculating.

All semen should be collected into a labelled sterile receptacle, either disposable or sterilised by autoclaving or heating and kept clean prior to use.

After semen collection, the receptacle should be left attached to the cone within its sleeve or sheath until it has been ~~re~~moved from the semen collection ~~area~~ facility to the ~~laboratory~~ semen processing facility.

During collection, the technician should wear disposable gloves and change them between donor animals.

Article 4.6.5.

General principles applicable to semen processing and semen processing facilities

The semen processing facility should be physically separated from the ~~other~~ semen collection facilities and may include separate areas for the preparation and cleaning of artificial vaginas, semen evaluation and processing, semen pre-storage and storage.

The semen processing facility should be constructed with materials that permit effective cleaning and *disinfection*, in accordance with Chapter 4.14.

Entry to the facility should be restricted to authorised personnel only.

Protective clothing for use only in the semen processing facility should be provided and worn at all times.

The facility and its equipment should be regularly cleaned and well maintained. Work surfaces for semen evaluation and processing should be regularly cleaned and disinfected.

Only semen from the same species and from donors that meet~~with~~ the same health requirements~~*animal health status*~~ should be processed at the same time. Semen from donors that do not meet~~with a different~~ the same health requirements ~~*animal health status*~~ or from different species may be processed consecutively if appropriate hygienic measures in accordance with the *biosecurity plan* have been implemented.

Semen should be collected and processed in a manner that ensures accurate identification and traceability of collecting tubes from the time of semen collection until storage.

All containers and instruments used for the collection, processing, preservation or freezing of semen should be single-use or be cleaned and disinfected or sterilised before use, depending on the manufacturer's instructions.

If not immediately processed, t~~T~~he receptacle containing freshly collected semen should be ~~stoppered or~~ covered ~~in a way~~ to prevent contamination as soon as possible after collection, until processing. During processing, containers containing the semen should be ~~stoppered or~~ covered during times when diluent or other components are not being added.

Equipment used for gender-sorting of sperm should be clean and disinfected between ejaculates in accordance with the recommendations of the manufacturer. Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from animals ~~of~~ that meet the same health requirements ~~*animal health status*~~.

Recommendations regarding the use of diluents for processing semen:

1) Buffer solutions used in diluents prepared on the premises should be sterilised ~~by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes)~~ or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additives, or antibiotics.

2) In the case of ready-to-use commercial extenders, the manufacturer's recommendations should be followed.

3) If the constituents of a diluent are supplied in commercially available powder form, the water used for preparing the semen diluent should have been distilled or demineralised, sterilised ~~(121°C for 30 minutes or equivalent)~~, stored correctly and allowed to cool before use.

4) Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product should be free from pathogenic agents or sterilised~~; milk heat-treated at 92°C for 3–5 minutes, eggs from SPF flocks when available~~. When ~~an~~ egg yolk only is used as the extender, it should be separated from the egg white using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption may be used, or egg yolk treated ~~by, for example, pasteurisation or irradiation~~ to reduce bacterial contamination. Commercial ~~UHT~~ ultra-high temperature (UHT) milk or powdered skimmed milk for human consumption may be used. Other additives should be sterilised before use.

5) Diluent should be stored according to the manufacturer's instructions. Storage vessels should be ~~stoppered~~ closed.

6) Antibiotics may be added to the diluent to minimise the growth of bacterial contaminants or control specific venereal pathogens that may be present in semen. The names of the antibiotics and their concentration should be recorded.

Article 4.6.6.

General principles applicable to semen storage and storage facilities

Semen storage facilities and cryogenic ~~germplasm storage~~ tanks should allow for easy cleaning and *disinfection*.

Cryogenic tanks, if not new, should be disinfected before being introduced to the semen collection centre.

The manufacturer's instructions for the safe *disinfection* of cryogenic ~~germplasm storage~~ tanks should be complied with.

Movement of cryogenic ~~germplasm storage~~ tanks from one semen storage facility to another should be completed under controlled conditions subject to the *biosecurity plan* of the *semen collection centre.*

Measures should be in place to ensure that ~~A~~access to the semen storage facility ~~should be~~ is restricted to authorised personnel ~~and the storage room should be locked when not in use~~.

Accurate records should be maintained that identify semen being transferred into, stored~~,~~ and transferred out of the semen storage facility. Semen straws should be clearly and permanently identified.

Only semen from the same species and from donors that meet the same health requirements should be stored in the same liquid nitrogen.

Only new liquid nitrogen should be used to fill or top up cryogenic ~~germplasm storage~~ tanks.

Annex 8

CHAPTER 4.7.

COLLECTION AND PROCESSING OF BOVINE, SMALL RUMINANT AND PORCINE SEMEN

EU	**The EU supports the adoption of this revised chapter.**

Article 4.7.1.

General considerations

The purposes of official sanitary control of semen production are to:

1) maintain the health of animals on ~~an *artificial insemination centre*~~ a *semen collection centre* at a level which permits the international distribution of semen with a negligible risk of infecting other animals or humans with pathogenic agents transmissible by semen;

2) ensure that semen is hygienically collected, processed and stored.

~~*Artificial insemination centres*~~ *Semen collection centres* should comply with recommendations in Chapter 4.6.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 4.7.2.

Conditions applicable to testing of bulls and teaser animals

Bulls and teaser animals should enter ~~an *artificial insemination centre*~~ a *semen collection centre* only when they fulfil the following requirements.

1. Prior to entering pre-entry isolation facility

   The animals should comply with the following requirements prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the diseases in question.

   a) Brucellosis – Chapter 8.4.

   b) Bovine tuberculosis – ~~Point 3 or 4 of~~ Article 8.12~~1~~.7~~5~~.

   c) Bovine viral diarrhoea (BVD)

      The animals should be subjected to:

      i) a virus isolation test or a test for virus antigen, with negative results; and

      ii) a serological test to determine the serological status of every animal.

   d) Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

      If the ~~*artificial insemination centre*~~ *semen collection centre* is to be considered as infectious bovine rhinotracheitis/infectious pustular vulvovaginitis free (IBR/IPV), the animals should either:

i) come from an IBR/IPV free *herd* as defined in Article 11.8.3.; or

ii) be subjected, with negative results, to a serological test for IBR/IPV on a blood sample.

e) Bluetongue

The animals should comply with Articles 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* of origin of the animals.

2. Testing in the pre-entry isolation facility prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the ~~*artificial insemination centre*~~ *semen collection centre*, bulls and teaser animals should be kept in a pre-entry isolation facility for at least 28 days. The animals should be tested as described below a minimum of 21 days after entering the pre-entry isolation facility, except for *Campylobacter fetus* subsp. *venerealis* and *Tritrichomonasfoetus*, for which testing may commence after 7 days in pre-entry isolation. All the results should be negative except in the case of BVD antibody serological testing (see point 2 b) i) below).

A) Brucellosis

The animals should be subjected to a serological test with negative results.

b) BVD

i) The animals should be subjected to a virus isolation test or a test for virus antigen, with negative results. Only when all the animals in pre-entry isolation have had negative results, may the animals enter the semen collection facilities.

ii) All animals should be subjected to a serological test to determine the presence or absence of BVD antibodies.

iii) Only if no seroconversion occurs in the animals which tested seronegative before entry into the pre-entry isolation facility, may any animal (seronegative or seropositive) be allowed entry into the semen collection facilities.

iv) If seroconversion occurs, all the animals that remain seronegative should be kept in pre-entry isolation until there is no more seroconversion in the group for a period of three weeks. Serologically positive animals may be allowed entry into the semen collection facilities.

c) *Campylobacterfetus* subsp. *venerealis*

i) Animals less than six months old or kept since that age only in a single sex group prior to pre-entry isolation should be tested once on a preputial specimen, with a negative result.

ii) Animals aged six months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

d) *Tritrichomonas foetus*

i) Animals less than six months old or kept since that age only in a single sex group prior to pre-entry isolation, should be tested once on a preputial specimen, with a negative result.

ii) Animals aged six months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

e) IBR/IPV

If the ~~*artificial insemination centre*~~ *semen collection centre* is to be considered as IBR/IPV free, the animals should be subjected, with negative results, to a diagnostic test for IBR/IPV on a blood sample. If any animal tests positive, the animal should be removed immediately from the pre-entry isolation facility and the other animals of the same group should remain in pre-entry isolation and be retested, with negative results, not less than 21 days after removal of the positive animal.

f) Bluetongue

The animals should comply with the provisions referred to in Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* where the pre-entry isolation facility is located.

3. Testing programme for bulls and teasers resident in the semen collection facilities

All bulls and teasers resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the country or *zone* where the semen collection facilities are located is not free:

a) Brucellosis

b) Bovine tuberculosis

c) BVD

Animals negative to previous serological tests should be retested to confirm absence of antibodies.

Should an animal become serologically positive, every ejaculate of that animal collected since the last negative test should be either discarded or tested for virus with negative results.

d) *Campylobacterfetus* subsp. *venerealis*

i) A preputial specimen should be tested.

ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay-off of more than six months should be tested not more than 30 days prior to resuming production.

e) Bluetongue

The animals should comply with the provisions referred to in Article 8.3.9. or Article 8.3.10.

f) *Tritrichomonas foetus*

i) A preputial specimen should be cultured.

ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay-off of more than six months should be tested not more than 30 days prior to resuming production.

g) IBR/IPV

If the ~~*artificial insemination centre*~~ *semen collection centre* is to be considered as IBR/IPV free, the animals should comply with the provisions in point 2 c) of Article 11.8.3.

4. Testing for BVD prior to the initial dispatch of semen from each serologically positive bull

Prior to the initial dispatch of semen from BVD serologically positive bulls, a semen sample from each animal should be subjected to a virus isolation or virus antigen test for BVD. In the event of a positive result, the bull should be removed from the centre and all of its semen destroyed.

5. Testing of frozen semen for IBR/IPV in ~~artificial insemination centres~~ semen collection centres not considered as IBR/IPV free

Each aliquot of frozen semen should be tested as per Article 11.8.7.

Article 4.7.3.

Conditions applicable to testing of rams/bucks and teaser animals

Rams/bucks and teaser animals should only enter ~~*an artificial insemination centre*~~ *a semen collection centre* if they fulfil the following requirements.

1. Prior to entering pre-entry isolation facility

   The animals should comply with the following requirements prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the diseases in question.

   a) Brucellosis – Chapter 8.4.

   b) Ovine epididymitis – Article 14.6.3.

   c) Contagious agalactia – Points 1 and 2 of Article 14.2.1.

   d) Peste des petits ruminants – Points 1, 2 a) or 3 of Article 14.7.10.

   e) Contagious caprine pleuropneumonia – Article 14.3.7., depending on the CCPP status of the country or *zone* of origin of the animals.

   f) Paratuberculosis – Free from clinical signs for the past two years.

   g) Scrapie – Comply with Article 14.8.8. if the animals do not originate from a scrapie free country or *zone* as defined in Article 14.8.3.

   h) Maedi-visna – Article 14.5.2.

   i) Caprine arthritis/encephalitis – Article 14.1.2. in the case of goats.

   j) Bluetongue

      The animals should comply with Articles 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* of origin of the animals.

   k) Tuberculosis – In the case of goats, a single or comparative tuberculin test, with negative results.

2. Testing in the pre-entry isolation facility prior to entering the semen collection facilities

   Prior to entering the semen collection facilities of the ~~*artificial insemination centre*~~ *semen collection centre*, rams/bucks and teasers should be kept in a pre-entry isolation facility for at least 28 days. The animals should be tested as described below a minimum of 21 days after entering the pre-entry isolation facility, with negative results.

   a) Brucellosis – Chapter 8.4.

   b) Ovine epididymitis – Point 1 d) of Article 14.6.4.

   c) Maedi-visna and caprine arthritis/encephalitis – Test on animals.

   d) Bluetongue

      The animals should comply with the provisions referred to in Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* where the pre-entry isolation facility is located.

3. Testing programme for rams/bucks and teasers resident in the semen collection facilities

   All rams/bucks and teasers resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the country or *zone* where the semen collection facilities are located is not free:

a) Brucellosis;

b) ovine epididymitis;

c) Maedi-visna and caprine arthritis/encephalitis;

d) tuberculosis (for goats only);

e) bluetongue.

The animals should comply with the provisions referred to in Article 8.3.9. or Article 8.3.10.

Article 4.7.4.

Conditions applicable to testing of boars

Boars should only enter ~~an *artificial insemination centre*~~ a *semen collection centre* if they fulfil the following requirements.

1. Prior to entering pre-entry isolation facility

The animals should be clinically healthy, physiologically normal and comply with the following requirements within 30 days prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the diseases in question.

a) Brucellosis – Chapter 8.4.

b) Foot and mouth disease – Articles 8.8.10., 8.8.11. or 8.8.12.

c) Aujeszky's disease – Article 8.2.9. or Article 8.2.10.

d) Transmissible gastroenteritis – Article 15.5.2.

e) African swine fever – Article 15.1.6. or Article 15.1.7.

f) Classical swine fever – Article 15.2.9. or Article 15.2.10.

g) Porcine reproductive and respiratory syndrome – Test complying with the standards in the *Terrestrial Manual*.

2. Testing in the pre-entry isolation facility prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the ~~*artificial insemination centre*~~ *semen collection centre*, boars should be kept in a pre-entry isolation facility for at least 28 days. The animals should be subjected to diagnostic tests as described below a minimum of 21 days after entering the pre-entry isolation facility, with negative results.

a) Brucellosis – Chapter 8.4.

b) Foot and mouth disease – Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16.

c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.

d) Transmissible gastroenteritis – Article 15.5.4.

e) African swine fever – Article 15.1.9. or Article 15.1.10.

f) Classical swine fever – Article 15.2.11. or Article 15.2.12.

g) Porcine reproductive and respiratory syndrome – The test complying with the standards in the *Terrestrial Manual*.

3. Testing programme for boars resident in the semen collection facilities

All boars resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the country or *zone* where the semen collection facilities are located is not free:

a) Brucellosis – Chapter 8.4.

b) Foot and mouth disease – Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16.

c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.

d) Transmissible gastroenteritis – Article 15.5.4.

e) African swine fever – Article 15.1.9. or Article 15.1.10.

f) Classical swine fever – Article 15.2.11. or Article 15.2.12.

g) Porcine reproductive and respiratory syndrome – The test complying with the standards in the *Terrestrial Manual*.

~~**Article 4.7.5.**~~

~~General considerations for hygienic collection and handling of semen~~

~~Observation of the recommendations described in the articles below will very significantly reduce the likelihood of the semen being contaminated with common bacteria which are potentially pathogenic.~~

~~**Article 4.7.6.**~~

~~Conditions applicable to the collection of semen~~

~~1) The floor of the mounting area should be clean and provide safe footing. A dusty floor should be avoided.~~

~~2) The hindquarters of the teaser, whether a dummy or a live teaser animal, should be kept clean. A dummy should be cleaned completely after each period of collection. A teaser animal should have its hindquarters cleaned carefully before each collecting session. The dummy or hindquarters of the teaser animals should be sanitized after the collection of each ejaculate. Disposable plastic covers may be used.~~

~~3) The hand of the person collecting the semen should not come into contact with the animal's penis. Disposable gloves should be worn by the collector and changed for each collection.~~

~~4) The artificial vagina should be cleaned completely after each collection where relevant. It should be dismantled, its various parts washed, rinsed and dried, and kept protected from dust. The inside of the body of the device and the cone should be disinfected before re-assembly using approved *disinfection* techniques such as those involving the use of alcohol, ethylene oxide or steam. Once re-assembled, it should be kept in a cupboard which is regularly cleaned and disinfected.~~

~~5) The lubricant used should be clean. The rod used to spread the lubricant should be clean and should not be exposed to dust between successive collections.~~

~~6) The artificial vagina should not be shaken after ejaculation, otherwise lubricant and debris may pass down the cone to join the contents of the collecting tube.~~

~~7) When successive ejaculates are being collected, a new artificial vagina should be used for each mounting. The vagina should also be changed when the animal has inserted its penis without ejaculating.~~

~~8) The collecting tubes should be sterile, and either disposable or sterilised by autoclaving or heating in an oven at 180°C for at least 30 minutes. They should be kept sealed to prevent exposure to the environment while awaiting use.~~

~~9) After semen collection, the tube should be left attached to the cone and within its sleeve until it has been removed from the collection room for transfer to the laboratory.~~

Article 4.7.7.

Conditions applicable to the handling of semen and preparation of semen samples in the laboratory

1. Diluents

a) All receptacles used should have been sterilised.

b) Buffer solutions employed in diluents prepared on the premises should be sterilised by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additive and antibiotics.

c) If the constituents of a diluent are supplied in commercially available powder form, the water used should have been distilled or demineralised, sterilised (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.

d) Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product should be free from pathogenic agents or sterilised; milk heat-treated at 92°C for 3–5 minutes, eggs from SPF flocks when available. When egg yolk is used, it should be separated from eggs using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination, may be used. Other additives should also be sterilised before use.

e) Diluent should not be stored for more than 72 hours at +5°C before use. A longer storage period is permissible for storage at –20°C. Storage vessels should be stoppered.

f) A mixture of antibiotics should be included with a bactericidal activity at least equivalent to that of the following mixtures in each ml of frozen semen: gentamicin (250 µg), tylosin (50 µg), lincomycin–spectinomycin (150/300 µg); penicillin (500 IU), streptomycin (500 µg), lincomycin-spectinomycin (150/300 µg); or amikacin (75 µg), divekacin (25 µg).

The names of the antibiotics added and their concentration should be stated in the *international veterinary certificate*.

2. Procedure for dilution and packing

a) The tube containing freshly collected semen should be sealed as soon as possible after collection, and kept sealed until processed.

b) After dilution and during refrigeration, the semen should also be kept in a stoppered container.

c) During the course of filling receptacles for dispatch (such as insemination straws), the receptacles and other disposable items should be used immediately after being unpacked. Materials for repeated use should be disinfected with alcohol, ethylene oxide, steam or other approved *disinfection* techniques.

d) If sealing powder is used, care should be taken to avoid its being contaminated.

3. Conditions applicable to the storage and identification of frozen semen

Semen for export should be stored in straws separately from other genetic material not meeting the requirements of this chapter with fresh liquid nitrogen in sterilised/sanitised flasks before being exported.

Semen straws should be sealed and code-marked in line with the international standards of the International Committee for Animal Recording (ICAR).

Prior to export, semen straws should clearly and permanently be identified and placed into new liquid nitrogen in a new or sterilised flask or container under the supervision of an *Official Veterinarian*. The contents of the container or flask should be verified by the *Official Veterinarian* prior to sealing with an official numbered seal before export and accompanied by an *international veterinary certificate* listing the contents and the number of the official seal.

4. Sperm sorting

~~Equipment used for sex-sorting sperm should be clean and disinfected between animals in accordance with the recommendations of the licencer of the system. Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from animals of same or better health status.~~

~~Semen straws containing sex-sorted sperm should be permanently identified as such.~~

Annex 9

CHAPTER 6.10.

RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE

EU	**The EU thanks the Code Commission and in general supports the adoption of this revised chapter. Important comments are inserted in the text below.**

Article 6.10.1.

Purpose and scope

This document provides guidance for the responsible and prudent use of *antimicrobial agents* in veterinary medicine for treatment, control and prevention of diseases in food- and non-food-producing *animals*, with the aim of protecting both *animal* and human health as well as minimising and containing antimicrobial resistance risks in the relevant animal ~~the~~ environment, as part of a One Health approach.

It defines the respective responsibilities of the *Competent Authorities*~~y~~ and stakeholders such as the veterinary pharmaceutical industry, *veterinarians*, animal feed manufacturers, distributors, and ~~food~~ animal ~~producers~~ breeders, owners and keepers, who are involved in any or all of the following activities:~~the authorization~~ regulatory approval, production, control, importation, exportation, sales, advertising, distribution, prescription and use of *veterinary medicinal products* ~~(*VMPs*)~~ containing *antimicrobial agents*.

Responsible and prudent use is determined by taking into account the importance of the *antimicrobial agent* to veterinary and human medicine, the risk of development of antimicrobial resistance, the specifications detailed in the relevant regulatory approval and the indications for use, including off-label use, ~~marketing authorization and their implementation~~ when *antimicrobial agents* are administered to *animals*. ~~and~~ It is part of good veterinary ~~and good agricultural good *animal* husbandry~~ practices. All measures to keep *animals* healthy, such as preventing infectious ~~*animal*~~ diseases through vaccination, *biosecurity*, good agricultural practices and animal husbandry practices and adequate nutrition contribute to a decreased need of using *antimicrobial agents* in *animals*, thus reducing the risk for development and spread of antimicrobial resistance.

EU	**Editorial comment to the last sentence above to clarify we refer to good husbandry practices:** **"All measures to keep animals healthy, such as preventing infectious diseases through vaccination, biosecurity, good agricultural practices and good animal husbandry practices and adequate nutrition contribute to a decreased need of using antimicrobial agents in animals, thus reducing the risk for development and spread of antimicrobial resistance."**

Activities associated with the responsible and prudent use of *antimicrobial agents* should involve all relevant stakeholders.

Coordination of these activities at the national or regional level is recommended and may support the implementation of targeted actions

by the stakeholders involved and enable clear and transparent communications.

Article 6.10.2.

Objectives of responsible and prudent use

~~Responsible and prudent~~ veterinary medical ~~use~~ of ~~*antimicrobial agents*~~ ~~includes implementing~~ ~~practical measures and recommendations intended to improve *animal* health and *animal welfare* while preventing or reducing the selection, emergence and spread of antimicrobial resistant bacteria~~ and resistance determinants in ~~*animals*, humans and the relevant *animal* environment;~~ in *animals* and humans. ~~Such measures include:~~ The objectives of responsible and prudent veterinary medical use of *antimicrobial agents* are to:

1) ~~ensuring the responsible and prudent~~ rational ~~use of *antimicrobial agents* in *animals* with the purpose of optimising~~ preserve the ~~both their~~ effectiveness of *antimicrobial agents* used in veterinary and human medicine ~~efficacy~~ and their safety in *animals*;

EU	**Article 6.10.2, point 1,** **Safety is an attribute of veterinary medicinal products whereas antimicrobial agents have intrinsic properties. This point is about agents.** **Therefore, the EU proposes to reword point 1 as follows:** **Point 1: "~~ensuring the responsible and prudent rational use of antimicrobial agents in animals with the purpose of optimising~~ preserve the ~~both their~~ effectiveness of antimicrobial agents used in veterinary and human medicine ~~efficacy~~ and ~~their~~ safety ~~in animals~~ensure safe use of antimicrobial medicines in animals.**

2) comply~~ing~~ with the ethical obligation and economic need to keep *animals* in good health;

3) prevent~~ing~~ or reduce~~ing~~ ~~the~~ transfer of resistant micro-organisms or resistance determinants within animal *populations*, between *animals*, humans, and the ~~relevant animal~~ environment ~~the environment and between *animals* and humans~~;

~~4) contributeing to the maintenance maintaining of the effectiveness efficacy and usefulness of *antimicrobial agents* used in *animal* veterinary and human medicine;~~

5) protect~~ing~~ ~~consumer~~ human health by ensuring the safety of food of *animal* origin with respect to residues of *antimicrobial agents*.

In order to achieve the objectives of responsible and prudent veterinary medical use of *antimicrobial agents,* a range of measures intended to improve animal health and *animal welfare* while preventing or reducing the selection, emergence and spread of antimicrobial resistant microorganisms and resistance determinants in *animals*, humans and ~~the relevant animal~~ environment should be implemented. These measures include promotion of good animal husbandry practices, hygiene procedures, *biosecurity*, ~~and~~ *vaccination* strategies, access to laboratory testing, and alternatives to the use of antimicrobials, which can help to minimise the need for antimicrobial use in *animals*.

Article 6.10.3.

Responsibilities of the Competent Authorities~~y~~

1. National Action Plan for Antimicrobial Resistance

The *Competent Authorities~~y~~* should design and oversee the implementation of the relevant part of their National Action Plan considering the findings of the situational analysis of the country, the objectives of the WOAH, WHO, FAO and UNEP Global Action Plan (GAP) for Antimicrobial Resistance and existing guidance for developing National Action Plans for antimicrobial resistance. The

Competent Authorities~~y~~ in cooperation with animal health, plant health, environment and public health professionals, and other relevant stakeholders should adopt a One Health approach to promote the responsible and prudent use of *antimicrobial agents* as an element of a national strategy to minimise and contain antimicrobial resistance. Furthermore, the *Competent Authorities~~y~~* should allocate budgetary resources for the design and implementation of the relevant part of their National Action Plan including communication strategies and professional training programmes. The *Competent Authorities~~y~~* should also conduct regular monitoring and evaluation of the National Action Plan.

National Action Plans should incorporate~~,~~ and ~~educate~~ inform on~~,~~ best management practices, including disease prevention and control measures, implementation of *biosecurity* ~~policies~~ and development of animal health programmes to reduce the burden of animal disease thereby reducing the need for antimicrobial use. As part of National Action Plans for antimicrobial resistance, the *Competent Authorities~~y~~* should ensure that surveillance for antimicrobial use and antimicrobial resistance in the animal health sector are in place and should work closely together with human, plant and environmental sectors on the harmonisation, analysis and integration of *surveillance* across sectors. The *Competent Authorities* should implement a programme in accordance with Chapters 1.4. and 6.8.

National Action Plans should include recommendations to relevant professional organisations ~~as appropriate~~ to develop evidence-based~~,~~ species or sector-specific antimicrobial use guidelines.

~~1~~2. Regulatory approval~~Marketing authorisation~~

~~All Member Countries should combat the unauthorised manufacture, compounding, importation, advertisement, trade, distribution, storage and use of unlicensed, adulterated and counterfeit products, including bulk active ingredients, through appropriate regulatory controls and other measures.~~

The *Competent Authority* is responsible for granting relevant regulatory approval ~~marketing authorisation~~ which should be done in accordance with the provisions of the *Terrestrial Code*. The *Competent Authority* ~~It~~ has a significant role in specifying the terms of this ~~authorisation~~ approval and in providing the appropriate information to *veterinarians* and all other relevant stakeholders.

The *Competent Authority* should establish and implement efficient statutory registration procedures that evaluate the quality, safety and efficacy and ~~proposed~~ post-marketing surveillance programmes for ~~of VMP~~ *veterinary medicinal products* containing *antimicrobial agents*. According to Article 3.2.2., the *Competent Authority* should be free from any commercial, financial, hierarchical, political or other pressures which might influence ~~affect~~ its judgement or decisions.

Member Countries lacking the necessary resources to implement an efficient registration procedure for ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents*, and which are importing them, should undertake the following measures:

a) evaluate the effectiveness ~~efficacy~~ of administrative controls on the import of these ~~VMP~~ *veterinary medicinal products*;

b) evaluate the validity of the registration procedures of the exporting ~~and~~ or manufacturing country as appropriate;

c) develop the necessary technical co-operation with an experienced ~~relevant authorities~~ *Competent Authority* to check the quality of imported ~~VMP~~ *veterinary medicinal products* as well as the validity of the recommended conditions of use.

The *Competent Authority~~ies~~* of *importing countries* should request the veterinary pharmaceutical industry to provide ~~quality~~ certificates of quality prepared by the *Competent Authority* of the exporting or ~~and~~ manufacturing country as appropriate.

Regulatory approval ~~Marketing authorisation~~ is granted for ~~treatment, control and prevention of diseases and~~veterinary medical use, which excludes growth promotion, on the basis of the data submitted by a ~~the~~ pharmaceutical company ~~industry~~ or other applicant and only if the criteria of quality, safety~~, quality~~ and efficacy are met.

~~Member countries~~ The *Competent Authority* ~~are~~ is encouraged to consult and apply, as appropriate, ~~or require the use of~~ the ~~existing~~ guidelines based on the technical requirements for veterinary product registration established by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

An evaluation of the ~~potential~~ risks and benefits to both *animals* and humans resulting from the use of *antimicrobial agents* in ~~with~~

~~particular focus on use in food producing~~ *animals*~~,~~ should be carried out. The evaluation may ~~should~~ focus on each individual *antimicrobial agent*~~;and~~ the findings from one agent should not be generalised to the antimicrobial class to which the particular active ingredient belongs. Guidance on use ~~usage~~ should be provided for all target species, route of administration, dosage regimen~~s~~, (dose, dosing interval and duration of the ~~treatment~~administration), and withdrawal period as relevant~~ and different durations of treatment that are proposed~~.

The *Competent Authority* should ~~expedite~~ implement timely ~~the~~ regulatory approval processes for new *antimicrobial agents* or ~~treatment~~ other options, including alternatives to the use of antimicrobials, in order to address ~~a~~ specific needs for the treatment of animal diseases and should take into account recommendations included in the WOAH List of Antimicrobials of Veterinary Importance.

~~2~~3. Quality ~~control~~ of antimicrobial agents and ~~VMP~~ veterinary medicinal products containing antimicrobial agents

The *Competent Authority* should make sure that the quality of the *veterinary medicinal products* was determined by the applicant in accordance with national and international guidance to ensure that:

~~Quality controls should be performed:~~

a) the specifications of *antimicrobial agents*~~in compliance with the provisions of *good manufacturing practices;*~~

~~b)~~ ~~to ensure that analysis specifications of *antimicrobial agents*~~ used as active ingredients comply with the provisions of registration documentations (such as monographs) approved by the relevant *Competent Authority;*

~~c~~b) ~~to ensure that~~ the quality of *antimicrobial agents* in the marketed dosage forms is maintained until the expiry date, established under the recommended storage conditions;

~~d~~c) ~~to ensure the stability and compatibility of~~ *antimicrobial agents* are stable and compatible when mixed with *feed* or ~~drinking~~ water;

~~e~~d) ~~to ensure that~~ all *antimicrobial agents* and the ~~VMP~~ *veterinary medicinal products* containing them are manufactured to the appropriate quality and in compliance with the provisions of *good manufacturing practices* ~~purity in order to guarantee their safety and efficacy~~.

~~3~~4. Assessment of ~~therapeutic~~ efficacy

The *Competent Authority* should conduct an assessment of the ~~therapeutic~~ efficacy based on data provided in the relevant regulatory approval application submitted by the applicant to enable marketing:

a) Preclinical trials

i) Preclinical trials should:

– establish the spectrum of activity of *antimicrobial agents* against relevant pathogenic agents and non-pathogenic agents (commensals);

– assess the capacity of the *antimicrobial agents* to select for resistance *in vitro* and *in vivo*, taking into consideration intrinsically resistant ~~and pre-existing resistant~~ strains and strains with acquired resistance;

– establish an appropriate dosage regimen ~~(dose, dosing interval and duration of the treatment)~~ and route of administration necessary to ensure the ~~therapeutic~~ efficacy of the *antimicrobial agents* and limit the selection of antimicrobial resistance. Pharmacokinetic and pharmacodynamic data and models can assist in this appraisal. Such data together with clinical data could be used by independent experts to establish clinical breakpoints per animal species, *antimicrobial agent* and pathogen combination.

ii) The activity of *antimicrobial agents* towards the targeted microorganism should be established by pharmacodynamics investigations. The following characteristics ~~criteria~~ should be taken into account, as appropriate:

– spectrum of activity and mode of action;

– minimum inhibitory concentration (MIC) and minimum bactericidal concentrations (MBC) against recent isolates;

– time-kill kinetics ~~when appropriate~~;

– time-dependent or concentration-dependent activity, or co-dependency;

– activity and concentration at the site of *infection*.

iii) The dosage regimens allowing maintenance of effective antimicrobial concentrations ~~levels~~ should be ~~established~~ informed by pharmacokinetics and pharmacodynamics investigations~~. The following criteria~~ and should ~~be~~ taken into account:

– ~~bio-availability in accordance with the route of administration;~~

– any potential routes of administration proposed by the applicant;

– absorption, distribution, metabolism and elimination, and ~~of the *antimicrobial agents* in the treated *animal*~~ and concentration at the site of *infection*~~, metabolism and elimination;~~.

– ~~metabolism;~~

– ~~excretion routes.~~

– ~~any potential routes of administration proposed by the applicant.~~

Further dose determination studies may be conducted to examine the microbiological and clinical response to several dose levels or dosing intervals.

Any proposed u~~U~~se of combinations of *antimicrobial agents* should be scientifically supported.

b) Clinical trials

Clinical trials in the target animal species should be performed to confirm the validity of the claimed ~~therapeutic~~ indications and dosage regimens established during the preclinical phase. The following criteria should be taken into account:

– diversity of the clinical cases encountered when performing multi-centre trials;

– compliance of protocols with good clinical practice;

– eligibility of studied clinical cases, based on appropriate criteria of clinical and bacteriological diagnoses;

– parameters for qualitatively and quantitatively assessing the efficacy of the treatment.

45. Assessment of the potential of antimicrobial agents to select for resistance

Other studies may be requested in support of the assessment of the potential of *antimicrobial agents* to select for resistance. The applicant for regulatory approval ~~The party applying for market authorisation~~ should, where possible, supply data derived in target animal species under the intended conditions of use.

For this assessment the following may be considered:

a) the concentration of ~~either~~ active *antimicrobial agents* ~~or~~ and, where appropriate, active metabolites in the gut of the *animal* (where the majority of ~~potential foodborne~~ pathogenic and commensal bacteria ~~agents~~ reside) at the defined dosage level;

b) the antimicrobial activity of the *antimicrobial agents* and metabolites in the intestinal environment;

~~b~~c) the pathway for ~~the~~ human exposure to antimicrobial resistant microorganisms, antimicrobial resistance determinants and antimicrobial residues in the relevant animal environment;

~~c~~d) the presence of and potential ~~degree~~ for co-selection, co-resistance and cross-resistance;

~~d~~e) the ~~intrinsic and pre-existing,~~ baseline level of resistance, including intrinsic and acquired resistance, in the pathogenic ~~agents,~~ commensal and food-borne bacteria of human health relevance ~~concern~~ in both *animals* and humans.

6. Assessment of the impact on the relevant animal environment

The *Competent Authority* should consider the results of an antimicrobial resistance environmental risk assessment in accordance with Chapter 6.11. For both food- and non-food producing *animals* the following risk factors should be taken into consideration as appropriate: reuse of wastewater for irrigation, use of manure, other waste-based fertilisers for soil fertilisation, transfer of antimicrobial resistant microorganisms and determinants in veterinary practice. When a significant antimicrobial resistance risk is determined the need for monitoring and proportionate risk management measures should be discussed.

~~6. Establishment of clinical breakpoints~~

~~In order to interpret the result of a susceptibility test, there is a need for clinical breakpoints for each bacteria-antimicrobial-*animal* species combination. Those clinical breakpoints should be established by independent experts.~~

~~5~~7. Establishment of acceptable daily intake (ADI), maximum residue limit (MRL) and withdrawal periods in food-producing *animals*

a) The establishment of an ADI for each *antimicrobial agent*, and an MRL for each animal-derived food, should be undertaken before a *veterinary medicinal product* containing it is granted regulatory approval.

~~a~~b) When setting the ADI and MRL for an *antimicrobial agent*, the safety evaluation should also include the potential microbiological ~~biological~~ effects on the intestinal ~~flora~~ ~~microbiome~~ microbiota of humans to derive ADI.

~~b) The establishment of an ADI for each *antimicrobial agent*, and an MRL for each *animal* derived food, should be undertaken before a VMP *veterinary medicinal product* containing it is granted marketing authorization regulatory approval.~~

c) For all ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* for use in food-producing *animals*, withdrawal periods should be established for each animal species in order to ensure compliance with the MRLs, taking into account:

– the MRLs established for the *antimicrobial agent* in the target animal edible tissues;

– the composition of the product and the pharmaceutical form;

– the dosage regimen;

– the route of administration.

d) ~~The applicant should describe~~ Methods used for regulatory testing of residues in food should be described and based on the established marker residues.

~~6~~8. ~~Assessment~~ Protection ~~of the impact on the relevant animal environment~~

~~An assessment of the impact of the proposed antimicrobial use on risks to the relevant environment should be conducted in accordance with national or international guidelines.~~

~~The *Competent Authority* should consider the results of an antimicrobial resistance environmental risk assessment. For both food and non-food producing *animals* the following risk factors should be taken into consideration as appropriate: reuse of wastewater for irrigation, use of manure, other waste-based fertilizers for soil fertilization, transfer of antimicrobial resistant genes or bacteria in veterinary practice. When a significant antimicrobial resistance risk is determined the need for monitoring and proportionate risk management measures should be discussed.~~

~~7~~98. Establishment of a summary of product characteristics or equivalent for each ~~VMP~~ veterinary medicinal product containing antimicrobial agents

~~The summary of product characteristics contains~~ The *Competent Authority* should ensure that the Summary of Product Characteristics (SPC) or equivalent, the package insert, and labelling includes the information necessary for the appropriate use of ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents.* ~~and constitutes the official reference for their labelling and package insert. This~~ The SPC or equivalent summary should contain the following items as appropriate:

a) name of the *veterinary medicinal product*;

~~a~~b) active ingredient and class;

c) pharmaceutical form;

d) quantitative composition;

~~b~~e) pharmacological properties;

~~c~~f) any potential adverse effects;

~~d~~g) target animal species and, as appropriate, age or production category;

~~e~~h) therapeutic indications;

~~f~~i) target micro-organisms;

~~g~~j) dosage regimen (i.e. dose, frequency of dosing, and route and duration of administration) ~~and route of administration~~;

~~h~~k) withdrawal periods;

~~i~~l) incompatibilities and interactions;

~~j~~m) storage conditions and shelf-life;

~~k~~n) operator safety;

~~l~~o) particular precautions before use;

p) precautions for the protection of the environment;

q) use during pregnancy, lactation or lay;

~~m~~r) particular precautions for the proper disposal of unused ~~un-used~~ or expired products;

~~n~~s) information on conditions of use relevant to ~~responsible and prudent use of antimicrobials and~~ minimis~~e~~ing the development

~~the potential for selection~~ of resistance;

~~o~~t) ~~C~~contraindications~~.~~;

u) known signs of overdosage and information about its treatment.

~~8~~109. Post-marketing antimicrobial resistance surveillance

The *Competent Authority* should assess ~~T~~the information collected through existing pharmacovigilance and surveillance programmes, including reporting of lack of response ~~efficacy~~, and any other relevant scientific data. These information sources should form part of the comprehensive strategy to detect and minimise antimicrobial resistance.

In addition, ~~to this, the following~~ specific surveillance should be considered~~:~~

~~a) General epidemiological surveillance~~

~~The *surveillance* of *animal* microorganisms resistant to ***antimicrobial agents*** is essential. The *Competent Authority* relevant authorities should implement a programme in accordance with Chapter 1.4.~~

~~b) Specific surveillance~~

~~***Specific surveillance***~~ to assess the impact of the use of a specific ~~*antimicrobial agent*~~ *veterinary medicinal product*, where scientific evidence indicates a specific risk and may be implemented after the granting of the relevant regulatory approval ~~marketing authorisation~~. The *surveillance* programme should evaluate not only resistance in target animal pathogens ~~pathogenic agents~~, but also in foodborne and other relevant zoonotic pathogens ~~pathogenic agents~~, and commensals if relevant and possible. This will also contribute to general epidemiological *surveillance* of antimicrobial resistance.

~~9~~1~~1~~10. Distribution ~~Supply~~ and administration of ~~the~~ antimicrobial agents or ~~VMP~~ veterinary medicinal products containing antimicrobial agents

~~The relevant authorities~~ The *Competent Authority* should ensure that all the *antimicrobial agents* and *veterinary medicinal products* containing *antimicrobial agents* used in *animals* including through *feed* and water are:

~~a) prescribed by a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agents* in accordance with the national legislation and under the supervision of a *veterinarian*;~~

~~b~~a) supplied only through licensed or authorised distribution systems;

b) not illegal, substandard, falsified medicines or unapproved formulations and that these are prevented from entering distribution systems;

c) prescribed by a *veterinarian* or other suitably trained person authorised to prescribe *veterinary medicinal products* containing *antimicrobial agents* in accordance with the national legislation;

~~c~~d) administered to *animals* by a *veterinarian* or under the supervision or by direction of a *veterinarian*, ~~or~~ by other ~~authorised~~ suitably trained persons, animal breeders, owners or keepers as appropriate.

The *Competent Authority* should encourage the availability of authorised products on the market and in collaboration with the veterinary pharmaceutical industry follow-up any potential drug shortages.

~~The relevant authorities~~~~The *Competent Authority*~~ *Veterinary Services* should develop and implement effective procedures for the safe collection and disposal or destruction of unused or expired ~~VMPs~~ *veterinary medicinal products* containing *antimicrobial agents*. Their labels should have appropriate instructions for disposal and destruction.

EU	**Article 6.10.3. Point 10, 3rd paragraph** **The development and implementation of effective procedures for the safe collection and disposal or destruction of unused or expired veterinary medicinal products containing antimicrobial agents might not be dealt with by the Veterinary Services in every country. Therefore, to foster greater flexibility, the EU propose to change the wording "Veterinary Services" to "Member Countries". It is at the discretion of the Member Countries how to organise themselves in a manner that best suits their needs for the development and implementation of these procedures:** **"~~The relevant authorities~~ The Member Countries ~~Veterinary Services~~ should develop and implement effective procedures for the safe collection and disposal or destruction of unused or expired ~~VMPs~~ veterinary medicinal products containing *antimicrobial agents*. Their labels should have appropriate instructions for disposal and destruction"**

~~10~~12~~11~~. Control of advertising

All advertising of *antimicrobial agents* should be compatible with the principles of responsible and prudent use and should be controlled by codes of advertising standards. The *Competent Authority* ~~relevant authorities must~~ should ensure that:

a) the advertising of these products complies with the regulatory approval ~~marketing authorisation~~ granted, in particular regarding the content of the summary of product characteristics or equivalent;

b) ~~it~~ advertising is restricted to a *veterinarian* or other suitably trained person authorised to prescribe ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents*, or to persons permitted to supply *veterinary medicinal products* in accordance with the national legislation ~~and under the supervision of a *veterinarian*.~~; and

c) their promotion is done in a manner consistent with specific regulatory recommendations for the product.

12. Establishment of clinical breakpoints

The *Competent Authority* should encourage and support the development of clinical breakpoints for each bacteria-antimicrobial-animal species combination to interpret the results of susceptibility tests. Those clinical breakpoints should be established in accordance with the *Terrestrial Manual*.

~~11~~13. Training related to the use ~~on the usage~~ of antimicrobial agents and antimicrobial resistance

The *Competent Authority* should take a key role in promoting targeted training for responsible and prudent use of antimicrobials and on antimicrobial resistance. The target audiences for t~~T~~he training on the ~~usage~~ use of *antimicrobial agents* should include all the relevant stakeholders and organisations, such as the ~~*Competent Authority*,~~ veterinary pharmaceutical industry, veterinary ~~schools~~ and paraprofessional education establishments, research institutes, veterinary professional and paraprofessional organisations and other approved users such as breeders, owners and keepers of food ~~-~~producing *animals* ~~owners~~ and manufacturers of medicated animal *feed*. The~~This~~ training may ~~should focus on preserving the effectiveness of *antimicrobial agents* and~~ include:

~~a)~~ ~~information on disease prevention, management and mitigation strategies;~~

~~b~~a) the ability of *antimicrobial agents* to select for resistant microorganisms in *animals* and the ~~relative~~ importance of that resistance to public and animal health and the relevant animal environment;

~~c~~b) the need to observe responsible and prudent use principles ~~recommendations~~ for the use of *antimicrobial agents* in animal husbandry in agreement with the provisions of the ~~marketing authorisations~~ regulatory approval, national and international guidelines and recommendations from the WOAH List of Antimicrobial Agents of Veterinary Importance

~~d~~c) information on the appropriate storage conditions before and during use and proper disposal of unused or expired ~~VMP~~ *veterinary medicinal products*;

~~e) record keeping;~~

d) training in existing and new methodologies for target pathogen identification, susceptibility testing, molecular detection of resistance and risk assessment models, understanding methods and results of antimicrobial susceptibility testing and molecular analysis and their use in risk assessment;

e) interpretation of relevant risk assessment outputs of antimicrobial resistance derived from the use of *veterinary medicinal products* containing *antimicrobial agents* in *animals* and how to use these outputs to inform the development of *risk ~~communication~~ management* and *risk communication ~~management~~* strategies;

f) the collection and reporting of antimicrobial resistance and antimicrobial use data to the *Competent Authority* to complement existing national and international surveillance programmes;

g) information on disease prevention, management and mitigation strategies that can contribute to reducing the need to use *antimicrobial agents* in *animal*s.

14. Monitoring of antimicrobial use

In accordance with Chapter 6.9., ~~T~~the *Competent Authority* should collate data on antimicrobial use in a harmonised manner to improve the understanding of the extent and trends of antimicrobial use and antimicrobial resistance in animal *populations* at national level and identify areas for further research. The data collected on antimicrobial use at country level should:

a) give an indication of the trends in the use of *antimicrobial agents* in *animals* over time and potential associations with antimicrobial resistance in *animals;*

b) help in the interpretation of antimicrobial resistance *surveillance* data and assist in responding to problems of antimicrobial resistance in a precise and targeted way;

c) assist in *risk management* to evaluate the effectiveness of efforts and mitigation strategies;

d) inform *risk communication* strategies~~.~~;

e) foster improved antimicrobial stewardship, ensuring continued availability of safe and effective antimicrobial agents for both animal and human health.

The *Competent Authority* should provide the ~~antimicrobial use~~ data to the 'Animal Antimicrobial Use Global database of the World Organisation for Animal Health' on a yearly basis.

~~12~~15. Knowledge gaps and r~~R~~esearch

The *Competent Authority* ~~relevant authorities~~ should encourage coordination of public- and ~~industry~~private-funded research, including in the following areas ~~but not limited to~~: ~~for example on methods to identify and mitigate the public health risks associated with specific *antimicrobial agent* uses, or on the ecology of antimicrobial resistance.~~

a) improve the knowledge about the mechanisms of action, pharmacokinetics and pharmacodynamics of *antimicrobial agents* to optimize the dosage regimens for veterinary medical use and their effectiveness;

b) improve the knowledge about the mechanisms of ~~transmission,~~ selection, co-selection, emergence and ~~dissemination~~ transmission of resistance determinants and resistant microorganisms in animal *populations*, and between *animals*, humans and the relevant animal environment, ~~and~~ including along the food chain;

c) develop practical models for applying the concept of *risk analysis* to assess the animal and public health concerns linked to the development of antimicrobial resistance in *animal*s and animal-derived foods;

d) further develop protocols to predict, during the ~~authorization~~ regulatory approval process, the impact of the proposed use of the *antimicrobial agents* in *animals* on the rate and extent of antimicrobial resistance development and spread to *animals*, humans, plants and the relevant animal environment, following a One Health approach;

e) assess the primary drivers leading to use of *antimicrobial agents* in *animals*, and the effectiveness of different interventions to change behaviour and reduce the need to use *antimicrobial agents* in *animals*;

f) develop safe and effective alternatives to *antimicrobial agents*, new *antimicrobial agents*, rapid diagnostics, and vaccines for infectious diseases to reduce the need for antimicrobial use in *animals*;

EU	**Article 6.10.3.Point 15(f),** **For consistency reasons and in line with previous EU comment (which has already been reflected in the text) that there is no agreed definition of the term 'alternatives to antimicrobials' and no specific regulatory requirements for such products exist, the EU proposes to insert the wording 'the use of' as follows:** **"(f) develop safe and effective alternatives to the use of antimicrobial agents, new antimicrobial agents, rapid diagnostics, and vaccines for infectious diseases to reduce the need for antimicrobial use in animals"**

g) improve knowledge on the role of the environment on the persistence of *antimicrobial agents*, and the emergence, transfer and persistence of antimicrobial resistance determinants and resistant microorganisms ~~resulting from antimicrobial use~~ in the relevant animal~~s~~ environment.

16. *Competent Authorities* should implement appropriate regulatory measures to control the unauthorised manufacture, compounding, importation, advertisement, trade, distribution, storage and use of unlicensed, adulterated and counterfeit *veterinary medicinal products* containing *antimicrobial agents*, including bulk active ingredients.

Article 6.10.4.

Responsibilities of the veterinary pharmaceutical industry with regards to ~~VMP~~ veterinary medicinal products containing antimicrobial agents

1. Regulatory approval~~Marketing authorisation~~

The veterinary pharmaceutical industry has responsibilities to:

a) ~~Supply~~ provide all the information requested by the national *Competent Authority* as specified in Article 6.10.3;

b) guarantee the quality of this information in compliance with the provisions of good manufacturing, laboratory and clinical practices;

c) implement, and ~~regularly timely~~ report in a timely manner ~~on~~, a pharmacovigilance programme, and on request, *specific surveillance* for bacterial susceptibility and resistance data~~;~~. For the latter, the veterinary pharmaceutical industry should

~~d)~~ isolate and identify bacteria, and collect relevant data and submit them to the *Competent Authority*. ~~The~~ These data ~~will~~ may enable independent experts to establish clinical breakpoints for use in the laboratory to guide antimicrobial therapy.

2. Marketing and export

For the marketing and export of ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents*:

a) only licensed and officially approved ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* should be sold and supplied, and then only through ~~licensed/~~authorised distribution systems;

b) the veterinary pharmaceutical industry should provide ~~quality~~ certificates of quality prepared by the *Competent Authority* of the exporting or ~~and~~ manufacturing countries to the *importing country*;

c) the veterinary pharmaceutical industry should endeavour to ~~guarantee~~ ensure the availability of authorised products and cooperate with the *Competent Authority* to forecast and avoid any drug shortage;

~~c~~d) the veterinary pharmaceutical industry should provide the *Competent Authority* ~~national regulatory authority should be provided~~ with the information necessary to evaluate the amount of *antimicrobial agents* marketed.

3. Advertising

The veterinary pharmaceutical industry should respect principles of responsible and prudent use and should comply with established codes of advertising practices ~~standards~~, including to:

a) distribute information in compliance with the provisions of the granted ~~authorization~~ approval;

b) not advertise ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* directly to the food animal ~~producer~~ breeder, owner and keeper or to the general public.

4. Training

The veterinary pharmaceutical industry should participate in training programmes as defined in point 13~~1~~ of Article 6.10.3.

5. Research

The veterinary pharmaceutical industry should contribute to research as defined in point 12~~5~~ of Article 6.10.3.

Article 6.10.5.

Responsibilities of wholesale and retail distributors

1) Distributors ~~of VMP containing *antimicrobial agents*~~ should only distribute *veterinary medicinal products* containing *antimicrobial agents* ~~do so~~ in accordance with the national legislation ~~on the prescription of~~ as prescribed by a *veterinarian* or other suitably trained person authorised to prescribe ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* ~~in accordance with the national legislation and under the supervision of a *veterinarian*~~. All products should be appropriately labelled.

2) The recommendations on the responsible and prudent use of ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* should be reinforced by retail distributors who should keep for an appropriate period detailed sales records of:

   a) date of ~~supply~~sale;

   b) name and contact information of the prescriber;

   c) name of user;

   d) name of product;

   e) batch number;

   f) expiration date;

   g) quantity supplied;

   h) copy of prescription~~.~~;

   i) other information as required by national legislation.

3) Distributors should also be involved in training programmes on the responsible and prudent use of ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents*, as defined in point 13~~1~~ of Article 6.10.3.

Article 6.10.6.

Responsibilities of veterinarians

The *veterinarian*'s responsibility is to promote ~~public health, antimicrobial stewardship,~~ animal health and *animal welfare*, as well as public health, through antimicrobial stewardship, ~~including~~ prevention, detection, diagnosis ~~identification~~, ~~prevention~~ control and treatment of animal diseases. The promotion of sound animal husbandry methods, hygiene procedures, *biosecurity* and *vaccination* strategies can help to minimise the need for antimicrobial use in ~~food-producing~~ *animal*s.

The *veterinarian~~s~~* should only prescribe *antimicrobial agents* for *animals* under their care. The v*eterinarian* should consider safe and effective ~~non-antimicrobial options or~~ alternatives to the use of antimicrobials before prescribing *antimicrobial agents.*

Some of the responsibilities described in this article may be applicable to *veterinary paraprofessionals* or other suitably trained persons according to the national legislation.

1. ~~Use of antimicrobial agents~~Pre-requisites for using antimicrobial agents

   The responsibilities of *veterinarians* are to obtain a detailed history and carry out a proper clinical examination of the *animal(s)* ~~and then~~, taking appropriate samples for further testing as necessary. If the provisional or definitive diagnosis is a microbial infection, then the *veterinarian* should:

   a) ~~administer, or~~ prescribe, dispense or administer *antimicrobial agents* only when necessary ~~and taking into consideration the WOAH list of *antimicrobial agents* of veterinary importance~~ to treat, control or prevent infectious diseases in *animals*;

b) avoid ~~using~~ the use of *antimicrobial agents* ~~routinely~~ to compensate for inadequate animal husbandry practices;

c) take into consideration the WOAH List of Antimicrobial Agents of Veterinary Importance and follow science-based species or sector-specific antimicrobial use guidelines for responsible and prudent use when available and follow the principles of antimicrobial stewardship;

~~b~~d) make an appropriate choice of *antimicrobial agent* based on clinical experience and available diagnostic laboratory information (pathogenic agent isolation, identification and ~~antibiogram~~ antimicrobial susceptibility testing) ~~where possible~~;

~~c~~e) provide a detailed treatment protocol, including precautions and withdrawal period ~~times~~ (if applicable), especially when prescribing extra-label or off-label use~~.~~;

f) provide ~~appropriate~~ adequate supportive therapy, if appropriate~~, which may, for example, include fluid therapy, segregation from other *animals*, administration of anti-inflammatory or analgesic agents~~.

2. Choosing antimicrobial agents

~~a.~~ The choice of an ~~effectiveness~~ effective ~~expected efficacy of the~~ treatment is based on:

~~i~~a) the clinical experience of the *veterinarians*, their diagnostic insight and therapeutic judgement;

~~ii~~b) diagnostic laboratory information (pathogenic agent isolation, identification and ~~antibiogram~~ antimicrobial susceptibility testing);

~~iii~~c) pharmacodynamic~~s~~ properties of the selected antimicrobial agent, including the activity towards the pathogenic agents involved;

~~iv~~d) the appropriate dosage regimen (i.e. dose, frequency of dosing, and route and duration of administration) ~~and route of administration~~;

~~v~~e) pharmacokinetics and tissue distribution to ensure that the selected therapeutic agent is effective at the site of *infection*;

~~vi~~f) the epidemiological history relevant to ~~of~~ the *animal* or *animals* being treated ~~rearing unit~~, particularly in relation to the antimicrobial resistance profiles of the pathogens ~~pathogenic agents~~ involved.

Should a first-line antimicrobial treatment fail or should the disease recur, an investigation ~~a second line treatment~~ should be undertaken ~~based on the results of diagnostic tests. In the absence of such results, an appropriate *antimicrobial agent* belonging to a different class or sub-class should be used~~ to reassess the circumstances including reviewing the diagnosis, conducting additional diagnostic testing as needed, and then formulate and implement a new treatment plan, which may or may not include another *antimicrobial agent*.

~~In emergencies~~In particular situations, a *veterinarian* may treat *animals* empirically, before ~~without recourse to~~ an accurate diagnosis and antimicrobial susceptibility testing results are available, to prevent the development of clinical disease ~~and for reasons of *animal welfare*~~.

~~b. Use of combinations of *antimicrobial agents* should be scientifically supported.~~ Combinations of *antimicrobial agents* may be used ~~for their synergistic effect~~ to increase ~~therapeutic~~ effectiveness ~~efficacy or to broaden the spectrum of activity~~, but only when scientifically supported.

When prescribing, dispensing or administering a *veterinary medicinal product* containing *antimicrobial agents* intended for veterinary medical use to an individual or a group of *animal*s to treat, control or prevent an infectious disease as defined in Chapter 6.9, the *veterinarian* should give specific consideration to their categorisation in the WOAH List of Antimicrobial Agents of Veterinary Importance or national lists. Preference should be given to the least important *antimicrobial agent* as categorised by WHO that is appropriate for use.

3. Appropriate veterinary medical use of the selected ~~VMP veterinary medicinal~~ product containing antimicrobial agents ~~chosen~~

The ~~A~~ prescription of a ~~for VMP~~ *veterinary medicinal product* containing *antimicrobial agents* should exclude growth promotion and indicate ~~precisely~~ the dosage regimen, the withdrawal period where applicable, and when considering group treatments, the total amount of ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* to be provided, which will depend ~~depending~~ on the dosage, duration of treatment, and the number of *animals* to be treated.

~~When prescribing, dispensing or administering a *veterinary medicinal product* containing *antimicrobial agents* intended for veterinary medical use to an individual or a group of *animals* to treat, control or prevent infectious disease as defined in Chapter 6.9, the *veterinarian* should give specific consideration to their categorisation in the WOAH List of Antimicrobial Agents of Veterinary Importance as well as to the WHO List of Critically Important Antimicrobials. Preference should be given to the least important *antimicrobial agent* as categorised by WHO that is appropriate for use.~~

The *veterinarian* should ensure that instructions for the administration of the product are clearly explained and understood by ~~the food *animal*~~ breeders, owners, ~~or~~ keepers or any other person responsible for administering the product.

The extra-label or off-label use of a ~~VMP~~ *veterinary medicinal product* and of a compounded product containing *antimicrobial agents* may be permitted in certain appropriate circumstances and should be for treatment, control and prevention of diseases, in agreement with the national legislation in force including the withdrawal period~~s to be used~~, as applicable. It is the *veterinarian*'s responsibility to define the conditions of responsible and prudent use in such a case including the dosage regimen, the route of administration and the withdrawal period.

The use of compounded ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* and extra-label or off-label use of registered ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* should be limited to circumstances where an appropriate registered product is not available and should take into account recommendations provided in the WOAH List of Antimicrobial Agents of Veterinary Importance.

4. Recording of data

Records of~~n~~ ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* should be kept in conformity with the national legislation. ~~Information r~~Records should include the following, as appropriate:

a) commercial name of the *veterinary medicinal products*;

b) name of the *antimicrobial agents* in the *veterinary medicinal products*;

~~ab~~c) quantities ~~of VMP~~ used ~~per *animal* species~~ in *animals* or supplied to each *establishment* or animal breeder, owner or keeper;

~~b) a list of all VMP supplied to each food-producing animal holding;~~

~~c~~d) route of administration;

~~d~~e) animal species;

~~e~~f) number of *animal*s treated;

~~f~~g) clinical condition treated;

~~cg~~h) treatment schedules including *animal* identification and length of the withdrawal period;

~~dh~~i) antimicrobial susceptibility data, including laboratory records of pathogenic agent isolation, identification and susceptibility testing obtained from isolates;

~~ei~~j) comments concerning the response of the *animal* or *animals* to treatment;

~~f~~k) the investigation of adverse reactions associated with ~~to~~ antimicrobial treatment, including lack of effectiveness ~~response due to possible antimicrobial resistance~~. Suspected adverse reactions should be reported to the holder of the regulatory approval or appropriate *Competent Authority*~~regulatory authorities~~ in accordance with national legislation.

Veterinarians should also periodically review farm records on the use of ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* to ensure compliance with their directions or prescriptions and use these records to evaluate the effectiveness ~~efficacy~~ of treatments.

5. Labelling

All ~~VMP~~ *veterinary medicinal products* supplied by a *veterinarian* should be labelled in accordance with the national legislation.

6. Training and ~~continued~~ continuing professional development

Veterinary professional and paraprofessional organisations should participate in the training programmes as defined in point 13~~1~~) of Article 6.10.3. It is recommended that veterinary professional and paraprofessional organisations develop for their members species-specific clinical practice recommendations on the responsible and prudent use of ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents*.

Article 6.10.~~8~~7.

Responsibilities of animal feed manufacturers

1. The manufacturing and supply of medicated *feed* containing *antimicrobial agents* to farmers keeping food-producing *animals* by animal feed manufacturers should be allowed only on the prescription of a *veterinarian*. Alternatively, such medicated *feed* may be prescribed by other suitably trained persons authorised to prescribe ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* in accordance with the national legislation ~~and under the supervision of a veterinarian~~. Animal feed manufacturers preparing medicated *feed* should do so following rules put in place by the *Competent Authority* in accordance with the national legislation. All medicated *feed* and medicated premixes should be appropriately labelled.

2. Keep detailed records for medicated feed and premixes for a suitable period of time according to national legislation.

~~2. The regulations and recommendations on the responsible and prudent use of VMP containing *antimicrobial agents* should be reinforced by *animal feed* manufacturers who should keep detailed records.~~

3. Use only approved sources of pharmaceutical products ~~medications~~: Animal feed manufacturers preparing medicated *feed* should ensure that only approved sources of medications are added to *feed* at a level, and for a species and purpose as permitted by the medicated ~~drug~~ premix label or a veterinary prescription.

4. Ensure appropriate labelling with product identification, direction for use and withdrawal ~~time~~ period: animal feed manufacturers preparing medicated feed should ensure that medicated animal *feed* are labelled with the appropriate information (e.g., level of medication, approved claim, target ~~intended~~ species, directions for use, warning, cautions) ~~so as~~ to ensure effective and safe use by the producer.

EU	**Article 6.10.7.Point 4,** **For consistency and clarity reasons the EU proposes to replace the word 'producer' with the following: 'breeders, owners and keepers of food-producing animals'.** **"4. Ensure appropriate labelling with product identification, direction for use and withdrawal ~~time~~ period: animal feed manufacturers preparing medicated feed should ensure that medicated animal *feed* are labelled with**

	the appropriate information (e.g., level of medication, approved claim, target ~~intended~~ species, directions for use, warning, cautions) ~~so as~~ to ensure effective and safe use by the ~~producer~~ breeders, owners and keepers of food-producing animals.”

5. Implement appropriate production practices to prevent contamination of other *feed*: animal feed manufacturers preparing medicated *feed* should implement *good manufacturing* ~~appropriate production~~ *practices* to avoid unnecessary carry over and ~~unsafe~~ cross contamination of unmedicated *feed*.

6. Feed manufacturers should participate in training programmes as defined in point 13 of Article 6.10.3.

Article 6.10.~~7~~8.

Responsibilities of ~~food animal producers~~ breeders, owners and keepers of food-producing animals

1. ~~Food *animal* producers~~ ~~b~~Breeders, owners and keepers~~,~~ of food-producing *animals* with the assistance and guidance of a *veterinarian*, are responsible for implementing animal health and *animal welfare* programmes, including *biosecurity* and good animal husbandry practices on their farms in order to reduce the need for the use of *antimicrobial agents* in *animals*, and to promote animal health and food safety.

2. ~~Food *animal* producers~~ ~~b~~Breeders, owners and keepers of food-producing *animals* should:

   a) draw up a health plan with the attending *veterinarian* that outlines preventive and control measures ~~(e.g., feedlot health plans, mastitis control plans, endo- and ectoparasite control, *vaccination* programmes and other *biosecurity* measures)~~;

   b) ~~address~~ implement on-farm *biosecurity* ~~measures~~ and take appropriate hygiene precautions ~~as appropriate~~;

   ~~d~~c) isolate sick *animals*, when appropriate, to avoid the transfer of pathogenic agents;

   d) dispose of dead or dying *animals* promptly under conditions approved by the ~~relevant authorities~~ *Competent Authorities*;

   ~~e) address on-farm biosecurity measures and take basic hygiene precautions as appropriate;~~

   ~~b~~e) use *veterinary medicinal products* ~~VMP~~ containing *antimicrobial agents* only on the prescription and under the supervision of a *veterinarian, veterinary paraprofessional* or other suitably trained person ~~authorised to prescribe *VMP* containing *antimicrobial agents*~~ in accordance with the national legislation ~~and under the supervision of a *veterinarian*~~;

   ~~c~~f) use *veterinary medicinal products* ~~VMP~~ containing *antimicrobial agents* in accordance with product label instructions, including storage conditions, and ~~or~~ the instructions of the ~~attending~~ prescribing *veterinarian*; extra-label/off-label use of *veterinary medicinal products* containing *antimicrobial agents* should be in line with the relevant national legislation and the instructions of the prescribing *veterinarian;*

   ~~f~~g) comply with ~~and record~~ the recommended withdrawal periods to ensure that residue levels in animal-derived food do not present a *risk* for the consumer;

   ~~g~~h) use ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* within the expiry date and dispose of unused and expired surplus ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* under conditions safe for the relevant animal environment according to the summary of product characteristics (SPC) or equivalent, or relevant national legislation;

i) ensure that only medicated premixes containing *antimicrobial agents* from authorised sources are added to feed at a dose and duration appropriate for the target animal species and purpose of use as permitted by the medicated premix label or a veterinary prescription when preparing medicated *feed* on-farm;

~~h~~i) maintain all the laboratory records of bacteriological and susceptibility tests; these data should be made available to the *veterinarian* responsible for treating the *animals*;

~~i~~k) keep adequate records of all ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* used, including the following:

i) name of the product or the active pharmaceutical ingredient ~~and active substance,~~ and batch number ~~and expiry date~~;

ii) name and contact details of prescriber and the supplier;

iii) date of administration;

iv) identification of the *animal* or group of *animals*, and the number of *animals* to which the *antimicrobial agent* was administered;

v) ~~clinical conditions~~ disease treated;

vi) ~~dosage~~dose regimen (including dose, dosing interval and duration of treatment);

vii) withdrawal periods including the end-date of the withdrawal periods;

~~viii) results of laboratory tests;~~

~~ix) effectiveness of therapy;~~

~~x) suspected adverse events;~~

~~j~~l) inform the responsible *veterinarian* of recurrent disease problems.

3. Training

Food animal ~~producers~~ breeders, owners and keepers should participate in the training programmes as defined in in point 13~~1~~ of Article 6.10.3.

It is recommended that food animal ~~producer~~ organisations work in cooperation with the veterinary professional organisations to implement existing guidelines for the responsible and prudent use of ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents*.

Article 6.10.9.

Responsibilities of breeders, owners and keepers of non-food producing animals

Animal breeders, owners and keepers, with the assistance and guidance of a *veterinarian*, are responsible for the health and welfare of their *animal*s and should:

1) implement the wellness plans and preventative health plans recommended by their *veterinarian*;

2) strictly follow their *veterinarian*'s recommendations and ensure that if any, the administration of *veterinary medicinal products* containing *antimicrobial agents* follows the veterinary prescription;

3) avoid administering over the counter~~,~~ ~~leftover and expired~~ human and ~~*animal*~~ veterinary *antimicrobials agents* to their *animals*;

4) not administer remaining or expired human and veterinary *antimicrobials agents* to their *animals*;

~~4~~5) inform their *veterinarian* or *veterinary paraprofessional* of the administration of any additional medicinal products than those prescribed by the *veterinarian* during the consultation;

~~5~~6) inform their *veterinarian* of any observed lack of ~~response~~ effectiveness or ~~other~~ adverse effect.

7) ensure that only *antimicrobial agents* from authorised sources are administered in accordance with national legislation.

Annex 10

DRAFT CHAPTER 7.5.

ANIMAL WELFARE DURING SLAUGHTER

EU position

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

There are still two comments inserted in the text below.

Introduction

Providing good welfare to ~~the~~ animals at *slaughter* is ethically and economically beneficial. The implementation of *animal welfare* measures, in addition to giving value to the product directly for ethical reasons, contributes to the improvement of workers' wellbeing, health and safety. This will also contribute to food safety and product quality, ~~and product quality, and is essential for (including food safety)~~ and consequently to the improvement of economic~~al~~ returns [Blokhuis *et al.*, 2008; Lara and Rostagno, 2018].

Article 7.5.2.

Scope

This chapter identifies ~~potential~~ *hazards* to *animal welfare* ~~*hazards*~~ during *slaughter* and provides recommendations for arrival and *unloading*, *lairage*, handling, *restraint*, *stunning* and bleeding of animals in *slaughterhouses/abattoirs*. It provides animal-based measures to assess the level of welfare and recommends remedial and corrective actions to be applied, when necessary.

This chapter applies to the *slaughter* in *slaughterhouses/abattoirs* of free-moving animals ~~the following domestic animals~~, ~~e.g.~~such as ~~cattle, buffalo, bison, sheep, goats, horses, donkeys, mules,~~ruminants, camelids, equids and pigs, and animals in *containers* ~~(e.g.~~such as rabbits and most *poultry* species~~)~~. ~~hereafter referred as "animals." Recommendations consider whether animals arrive at the *slaughterhouse/abattoir* in *containers* or are free-moving.~~

~~The principles underpinning these recommendations should also be applied to the *slaughter* of other species and those slaughtered in other places.~~

This chapter should be read in conjunction with the guiding principles for *animal welfare* provided in Chapter 7.1., Chapter 7.14. ~~killing of reptiles for their skins, meat and other products~~ and with relevant provisions of Chapters 6.2. and 6.3.

~~The principles underpinning these recommendations may should also be applied apply to the *slaughter* of other species and those slaughtered in other places.~~

Article 7.5.3.

Definitions ~~for the purpose of this chapter~~

For the purposes of this chapter:

Bleeding means the act of severing major blood vessels that supply the brain, to ensure *death*.

Article 7.5.4.

Hazards to a~~A~~nimal welfare ~~hazards~~

Hazards to *animal welfare* during each of the pre-slaughter stages have a~~n additive~~ cumulative effect on the stress of the animals [Moberg and Mench, 2000].

At ~~the~~ *slaughterhouses/abattoirs*, animals are exposed to *hazards* to *animal welfare* ~~*hazards*~~ including ~~fasting~~ *feed* and water deprivation, mixing of unfamiliar *animals*, handling by humans, exposure to a novel environment (e.g. noise, lighting, flooring and smells), forced movement ~~physical exercise~~, limited space allowance, ~~extreme~~ adverse weather conditions and ineffective ~~inadequate~~ *stunning* and bleeding. These *hazards* can have negative impacts on the welfare of the animals that can be assessed through animal-based measures. In the absence of feasible animal-based measures, ~~In addition~~ resource-based measures and management-based measures may be used as a ~~substitute~~ proxy. *Hazards* to a~~*Animal welfare* *hazards*~~ can be minimised by appropriate design of premises and choice of equipment, and through good management, training and competency of personnel.

Article 7.5.5.

~~Criteria (or m~~ Measures~~)~~

The welfare of animals at *slaughter* should be assessed using ~~outcome~~ animal-based measures. Although consideration should be given to the resources provided as well as the design and management of the system, animal-based ~~criteria~~ measures are preferential. However, key *stunning* parameters ~~need to~~ should be ~~considered~~ selected, taking into account ~~alongside~~ animal-based measures.

The routine use of these ~~outcome~~ animal-based measures and the appropriate thresholds should be adapted to the different situations in which animals are managed at a *slaughterhouse/abattoir*. It is recommended that target values or thresholds for animal-based measures ~~*welfare* measurables~~ be based on current scientific ~~knowledge~~ evidence and appropriate national, sectorial or regional standards.

Article 7.5.6.

Management

The *slaughterhouse/abattoir* operator is responsible for the development and ~~enforcement~~ implementation of an ~~dedicated~~ operating plan that should consider the following:

- training and competency of personnel;
- design of premises and choice of equipment;
- standard operating procedure ~~and corrective actions~~;
- recording, reporting adverse incidents and taking corrective actions;
- ~~training and competency of personnel;~~
- throughput (number of animals slaughtered per hour);
- maintenance and cleaning procedures of equipment and premises;
- ~~contingency~~ emergency plans.
- ~~operating procedure and corrective actions.~~

Article 7.5.7.

Training and competency of personnel

Animal handlers and other personnel have a crucial role to play in ensuring good *animal welfare* conditions from the time of arrival of the animals at the *slaughterhouse/abattoir* through to their *death*. Training for all personnel should emphasise the importance of *animal welfare* and their responsibility in contributing to the welfare of the animals that come through the *slaughterhouse/abattoir*.

Animal handlers should understand the species-specific behavioural patterns of the animals they are working with and the~~ir~~ underlying principles ~~to~~ for carrying out the required tasks whilst ensuring good *animal welfare*. They should be experienced and competent in handling and moving the animals with knowledge ~~about animal behaviour and physiology and able~~ that allows them to identify signs of *distress*, fear, and *pain* ~~and suffering~~ and take preventive and corrective actions. Personnel in charge of *restraint* (including pre-stun shackling) and of *stunning* and bleeding operations should be familiar with the relevant equipment, ~~their~~ and its

key working parameters and procedures. Personnel in charge of *stunning*, post-stun shackling and bleeding animals should be able to identify and take corrective actions in case of: ~~in~~effective ~~*stunning* of the animal and signs of recovery of consciousness, should be able to detect if an animal is still alive prior to dressing or scalding and should be able to take corrective actions, if necessary~~ [EFSA, 2013a; EFSA 2013b]

a) ineffective *stunning* of the animal;

b) recovery of consciousness;

c) ~~animal is still alive~~ signs of life prior to dressing or scalding.

Competencies may be gained through a combination of formal training and practical experience. These competencies should be assessed by the *Competent Authority* or by an independent body recognised by the *Competent Authority*.

Only the personnel actively working ~~on the slaughter line~~in areas where live animals are handled should be present in these areas ~~where animals are handled~~. The presence of visitors or other personnel should be limited in ~~those~~ these areas in order to prevent unnecessary noise, shouting~~, or~~ and movement ~~or~~ and to reduce risk of accidents.

Article 7.5.8.

Design of premises and choice of equipment

The design of premises and the choice of equipment used in a *slaughterhouse/abattoir* have ~~an~~ important impacts on the welfare of animals. The~~y should consider the~~ animals' needs should be considered~~, in terms of their physical comfort~~ including:

– thermal comfort ~~conditions~~,;

– ease of movement~~,~~ ;

– protection from injury ~~protection from sudden or excessive noise~~;

– protection from visual, auditory and olfactory overstimulation;

– minimising fear and avoiding *distress* and *pain* ~~,~~;

– ~~and~~ ability to perform natural and social behaviours~~,~~ ;~~as well as~~

– water~~ing~~ and feed~~ing~~ ~~needs, including the need of sick or injured animals~~;

– needs arising from illness or injury;

– needs arising from other vulnerabilities (e.g. pregnant, lactating or neonatal animals).

Premises should be designed to eliminate distractions that may cause approaching animals to stop, baulk or turn back.

Flooring should be non-slip to prevent injury and stress due to slipping or falling. There should be ~~A~~adequate quality and quantity of lighting to allow ~~allowing adequate~~ appropriate ante-mortem inspection of animals and to enable ~~assist~~ the moving of animals utilising low-stress handling techniques.

The design of the *slaughterhouse/abattoir* and choice of equipment should take into consideration the species, categories, quantities, ~~and~~ size or weight and age of the animals. *Restraint*, *stunning* and bleeding equipment is critical for the welfare of an animal at the time of *slaughte*r. Appropriate back-up equipment should be available for immediate use in case of failure of the primary *stunning* equipment ~~initially used~~.

Article 7.5.9.

~~The t~~Throughput ~~is (number of animals slaughtered per hour)~~

The throughput of the *slaughterhouse/abattoir* is the number of animals slaughtered per hour. It **s**hould never exceed the maximum ~~specification~~ capacity of the design of the facilities or equipment. ~~and may~~ The *slaughterhouse/abattoir* operators should continuously monitor throughput and adjust it to any operational changes, such as staff numbers and experience or line breakdowns. ~~It~~Throughput may ~~also~~ need to be reduced ~~depending on the~~if welfare ~~outcomes are~~ is negatively impacted.

Personnel allocation should be adequate for the anticipated throughput and be sufficient to implement the *slaughterhouse/abattoir* operating plan as well as ante- and post-mortem inspections.

Article 7.5.10.

Maintenance and cleaning procedures

All equipment should be clean~~and~~, well maintained~~,~~ and ~~including~~ calibrated~~ion~~, in accordance with the manufacturer's instructions in order to ensure positive outcomes for *animal welfare* ~~and safety of personnel~~.

Maintenance and cleaning of handling, *unloading*, *lairage* and moving facilities and equipment contribute to ensuring that animals are handled smoothly, ~~preventing~~ minimising *pain* and fear.

Maintenance and cleaning of handling, *restraining*, *stunning* and bleeding equipment are essential to ensure reliable and ~~efficient~~ effective *stunning* and *slaughter*, thereby minimising *pain*, fear and suffering.

Article 7.5.11.

~~Contingency~~ Emergency plans

~~Contingency~~ Emergency plans should be in place at the *slaughterhouse/abattoir* to protect the welfare of the animals in the event of an emergency. The ~~contingency~~ plans should consider the most likely emergency situations given the species slaughtered and the location of the *slaughterhouse/abattoir.*

~~Contingency~~ Emergency plans should be documented and communicated to all responsible parties~~;~~ and these plans should be tested regularly.

~~Each p~~Personnel who ~~has~~have a role to play in implementing ~~contingency~~ the plans should be well trained on the tasks they have to perform ~~in case of emergency~~.

Article 7.5.12.

Arrival of free-moving animals

On arrival at the *slaughterhouse/abattoir*, animals ~~will~~ would already have been exposed to *hazards* that may have negative impacts on their welfare. Any previous *hazards* will have a cumulative effect that may affect the welfare of the animals throughout the *slaughter* process. Therefore, animals should be transported to the *slaughterhouse/abattoir* in a manner that minimises adverse animal health and welfare ~~outcomes~~, and in accordance with Chapters 7.2. and 7.3.

1~~.~~) Animal welfare concerns:

Delay in *unloading* of animals is a major ~~the main~~ *animal welfare* concern at arrival [NAMI, ~~2017~~2021].

Animals in *vehicles* have smaller space allowances than on farm, undergo water and *feed* deprivation, may have suffered from an injury, ~~and~~ and may be exposed to ~~thermal stress due to~~ adverse weather conditions and to stress and discomfort from social disturbance, noise, vehicle vibration and motion. In addition, stationary *vehicles* may have insufficient ventilation. Delays in *unloading* animals will prolong or exacerbate the impact of these *hazards*. Under these circumstances, injured or sick animals requiring urgent attention ~~will~~ may not be identified or dealt with appropriately and therefore the duration of their suffering will be ~~increased~~ prolonged.

2~~.~~) Animal-based and other ~~measurables~~ measures ~~include~~:

It can be difficult to assess animal-based measures while animals are in the *vehicle*. Some ~~measurables~~ measures that may be assessed include animals with injuries, lameness ~~and /~~ or poor body condition or those that are sick or have died. Panting, shivering and huddling may indicate thermal stress. Drooling and licking may indicate prolonged thirst.

Animals dead or emergency killed (see Article 7.5.19.) on arrival ~~or condemned on arrival~~ should be recorded and monitored as an indicator of *animal welfare* prior to and during transport.

Time from arrival to *unloading* and the environmental temperature and humidity can be used to establish relevant thresholds for corrective action.

3~~.~~) Recommendations:

Animals should be unloaded promptly on arrival. This is facilitated by scheduling the arrival of the animals at the *slaughterhouse/abattoir* to ensure that there are sufficient personnel and adequate space in the *unloading* or *lairage* area.

Consignments of animals ~~assessed~~ whose welfare is ~~to be~~ at greater risk of being compromised ~~*animal welfare hazards*~~ should be unloaded first. When no space is immediately available, creating space should be a priority. Provision~~s~~ should be made to provide shelter, shade or additional ventilation during waiting periods, or animals should be transported to an alternative nearby location where such provision ~~is~~ available.

Animals should not be isolated throughout the *slaughter* process, except under specific conditions, such as for aggressive or sick animals.

Animals should be provided with drinking water as soon as possible after *unloading*.

~~Special consideration should be given to a~~Animals that have undergone long or arduous journeys ~~times~~, are sick or injured ~~animals~~, are lactating or pregnant ~~animals~~ and ~~young~~ neonatal animals~~. These animals~~ should be slaughtered as a priority and without delay~~. If this is not possible, animals should be given appropriate care. arrangements should be made to mitigate or prevent suffering, in particular by: milking dairy animals at intervals of not more than 12 hours and providing appropriate conditions for suckling and the welfare of the newborn neonatal animal in the case of a female having given birth. Mortalities and injuries should be reported to the competent authority.~~

4~~.~~) Species-specific recommendations:

Some species such as ~~P~~pigs and shorn sheep are especially sensitive to extreme temperatures and therefore special attention should be ~~taken~~ paid when dealing with delays in *unloading* ~~this species~~sensitive animals. This may include careful consideration of transport plans to time arrival and processing, provision of additional means of temperature and humidity control ~~ventilation / heating, etc~~.

~~Shorn sheep might be especially sensitive to extreme temperatures and therefore special attention should be taken when dealing with delays in *unloading*.~~

~~Lactating animals should be given special attention and given priority when *unloading* and processing.~~

~~Unweaned animals are especially sensitive to extreme temperatures and can find it difficult to regulate their body temperature. They are verymore susceptible to dehydration, illness and stress after transportation and handling. These animals must be given special attention and be given priority when *unloading* and processing.~~

Article 7.5.13.

~~Displacements~~ Handling of free-moving animals

This article addresses the handling of animals during *unloading* and *lairage,* and in the *killing* area.

1~~.~~) Animal welfare concerns:

During *unloading,* animals are exposed to similar *hazards* to those encountered when being loaded (see Chapters 7.2. and 7.3.). Inappropriate equipment in the *vehicle* or the *slaughterhouse/abattoir*, such as a lack of lateral protection when *unloading*, excessively steep ramps, slippery surfaces~~,~~ or an absence of foot battens, may result in animals slipping, falling or being

trampled, causing injuries. The absence of ramps, ~~or~~ lifts or an *unloading* bay or dock could ~~can~~ result in animals being pushed or thrown off the *vehicle*. These *hazards* can also be associated with inappropriate handling and forced physical movement of animals that are unable to move independently as a result of weakness or injuries. Exposure to novel environments (e.g. noise, lighting, flooring, smell) ~~will~~ may cause fear and reluctance to move, or turning back. Poorly designed facilities will increase the risk of such fear and injuries.

2~~.~~) Animal-based and other ~~measurables~~ measures ~~include~~:

a) animals ~~running~~ slipping~~and~~, falling and piling up;

b) animals with broken or otherwise injured limbs;

c) animals turning-back, attempting to escape ~~and~~ or reluctant to move;

d) animal vocalisation referring to *distress* ~~and frequency of (e.g. high-pitched vocalisation for in pigs) especially for pigs and cattle~~;

~~d~~ e) animals that are unable to move by themselves due to reasons other than ~~those with~~ broken or injured limbs;

~~e~~ f) animals that ~~strike against the facilities~~ collide with facility structures;

~~f~~ g) ~~frequency of~~ use of ~~excessive~~ force by personnel;

~~g~~ h*)* ~~frequency of~~ use of electrical ~~prods~~ goads.

Animals are safely handled when these measures are below an acceptable threshold.

3~~.~~) Recommendations:

Ramps or lifts should be provided and used except when the *vehicle* and the *unloading* dock are at the same height. ~~Ramps or lifts should be positioned so that the animals can be handled safely~~. There should be no gap between the *vehicle* and ~~the ramp~~ *unloading* dock.~~,~~ Ramps or lifts should be positioned so that the animals can be handled safely. T~~t~~he gradient should not be ~~too~~ so steep as to prevent~~ing~~ animals from moving voluntarily~~moving~~, and solid side barriers should be in place.

EU comment:

The EU proposes the following change of the last sentence on the above paragraph:

"The gradient should not be so steep as to prevent animals from moving forward ~~voluntarily~~ and solid side barriers should be in place."

Justification:

Linguistic suggestion agreed according to the report of the meeting of the Commission in February 2024.

Design of the facilities should promote the natural movements of animals, and, as far as possible, ~~with a minimal~~ minimise human interaction.

Preventive ~~measures~~ equipment such as foot battens, rubber mats and deep-groove flooring can help animals to avoid slipping.

The *unloading* area and raceways should be well lit so that animals can see where they are going.

The design of areas and raceways should aim to minimise the potential for distractions that may cause animals to stop, baulk or turn back when being unloaded (e.g. shadows, changes in flooring, moving objects, loud or sudden noises). For details refer to Chapters 7.2. and 7.3.

Animals that are injured, sick or unable to rise require immediate action and, when necessary, emergency *killing* should be performed ~~euthanised~~ without moving them and without delay. Refer to Articles 7.5.19. and 7.5.2~~0~~1. Such animals should never be dragged, nor should they be lifted or handled in a way that might cause further *pain*~~,~~ and suffering or exacerbate injuries.

Personnel should be calm and patient, assisting ~~the~~ animals to move using a soft voice and slow movements. They should not shout, kick, or use any other means that is likely to cause *distress*, fear or *pain* to the animals. Under no circumstances should *animal handlers* resort to violent acts to move animals (see Article 7.5.20.).

Personnel should not stand between an animal and where they want it to move to as this may cause the animal to baulk. They should keep in mind the flight distance and point of balance of the animal when positioning themselves to encourage movement.

Animals should be moved in small groups as this decreases fear and makes use of their natural tendency to follow other animals.

Mechanical handling aids ~~and electric goads~~ should be used in a manner to encourage and direct movement of the animals without causing *distress*, fear ~~and or~~ or *pain*. Preferred mechanical aids include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and ~~metallic~~ rattles.

Other handling aids should not be used as a substitute for good facility design and handling. They should not be used repeatedly if an animal fails to respond or move. In such cases it should be determined whether some physical or other impediment is preventing the animal from moving.

Electric goads should ~~only~~ not be used on a routine basis to move animals. ~~in extreme cases and not on a routine basis to move animals.~~ Electric goads may only be used when other measures have been ineffective, the animal has no injury or other condition that is impeding mobility and there is room for the animal to move forward without obstruction (e.g. obstacles or other animals).

The use of electric goads should be limited to ~~battery-powered~~ low-voltage goads applied to the hindquarters of adult pigs and large ruminants, and never to sensitive areas such as the eyes, mouth, ears, ano-genital region, udders or belly. Such instruments should not be used on equids, camelids, ratites, sheep and goats ~~of any age~~, pregnant animals or on calves or piglets. Shocks ~~shall~~ should not be used repeatedly if the animal fails to respond and should not last longer than one second [Ritter *et al.*, 2008].

~~Mechanical Other Hhandling aids and electric goads should not be used as a substitute for good facility design and handling. They should not be used repeatedly if an animal fails to respond or move. In such cases it should be determined whether some physical or other impediment is preventing the animal from moving.~~

~~Electric goads should only be used in extreme cases and not on a routine basis to move animals.~~

~~The use of electric goads should be limited to battery-powered goads applied to the hindquarters of adult pigs and large ruminants, and never to sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.~~

The manual lifting of animals should be avoided; if it is necessary, animals should not be grasped or lifted in a manner which causes *pain* or suffering and physical damage (e.g. bruising, fractures, dislocations). (See Article 7.5.20.).

Animals should not be forced to move at a speed greater than their normal walking pace to minimise injury through slipping or falling. Facilities should be designed, constructed and staffed with competent animal handlers, so that less than 1% of the animals fall.

~~4. Species-specific recommendations:~~

~~None identified~~.

Article 7.5.14.

Lairage of free-moving animals

1.) Animal welfare concerns:

Animals during *lairage* may be exposed to several *hazards* to *animal welfare* *hazards* during lairage including:

a) food *feed* and water deprivation leading to prolonged hunger and thirst;

b) absence of protection against extremes adverse in weather or climate conditions, leading to thermal stress;

c) sudden or excessive noises, including from personnel, machinery, metal yards and gates facilities, and equipment and gates, leading to fear;

d) insufficient space to lie down and move freely leading to fatigue and aggressive behaviour;

e) poor design and maintenance leading to *distress* and injuries;

f) mixing of unfamiliar animals leading to aggressive behaviour; or social stress;

g) limited access to resources (e.g. drinkers, bedding) leading to aggressive behaviour;

h) exposure to hard, sharp or abrasive surfaces leading to injury or lameness (e.g. sharp, abrasive).

2.) Animal-based and other measurables measures include:

a) thermal stress (e.g. panting, sweating, shivering, huddling behaviour);

b) space allowance;

c) excessive soiling with faeces (e.g. coat cleanliness, dag score for sheep);

d) injuries (e.g. lameness, open wounds, fractures);

e) illness (e.g. limping, diarrhoea, coughing);

f) aggressive behaviours (e.g. mounting, fighting);

g) frequency of animal vocalisation referring to *distress* especially for pigs and cattle (e.g. hitch high-pitched vocalisation in pigs; loud moos or bellows in bovines);

h) restlessness (e.g. pacing, walking with continuous ear movements and frequency of snorts – especially for in horses) [Micera *et al.*, 2010 and Visser *et al.*, 2008];

i) bruised carcass bruising.

3.) Recommendations:

Animals should have constant access to clean drinking water. Water supply points should be designed according to the species and age of the animal, with environmental conditions that allow for effective consumption. The number and location of the water supply points should minimise competition.

Animals should be provided with *feed* in *lairage* if the duration between loading and expected time for *slaughter* exceeds 24 hours. Animals should be provided with *feed* in *lairage* if the duration between loading their last meal and expected time for *slaughter* exceeds a period appropriate for the species and age of animals. In the absence of information on the transport duration in any case, Aanimals which that are not expected to be slaughtered afterwithin 12 hours of arrival should be fed as appropriate for the age and speciesand should be given moderate amounts of food at appropriate intervals.

The *lairage* should provide animals with protection against adverse weather conditions including shade and shelter.

Animals should be protected from excessive and sudden noise (e.g. ventilation fans, alarms, or other indoor or outdoor equipment).

Lairage areas should be free from sharp edges and other *hazards* that may cause injury to animals.

The *lairage* should provide enough space for all animals to lie down at the same time, to move freely and to move away in case of aggressive behaviours.

Lairage areas should have adequate lighting levels to allow inspection of the animals.

Animals from different categories (e.g. sexes, sizes, horned or not, species) ~~groups (or different species)~~ should not be mixed except if they are already familiar to each other.

Animals that ~~can move freely but~~ are injured, sick, ~~very young~~ pregnant or are neonates ~~or pregnant~~ should be slaughtered with priority or ~~isolated~~ separated to protect them from other animals ~~and be slaughtered with priority~~. Animals that are very ill or down or have ~~catastrophic~~ severe injuries should be euthanized without delay (see Article 7.5.~~19~~22.).

4~~.~~) Species-specific recommendations:

~~None identified.~~ Pigs should be ~~kept~~ moved in ~~small~~ groups ~~(~~up to 15~~)~~ [Barton-Gade and Christensen ,1998]~~when resting in lairage, when moving to the stunner and when stunned~~.

Bison and cervids need specific design and construction standards for ~~the~~ unloading and holding prior to *slaughter*.

Article 7.5.15.

Restraint for stunning or bleeding (free-moving animals)

1~~.~~) Animal welfare concerns:

The purpose of *restraint* is to facilitate the correct application of the *stunning* or bleeding equipment. Incorrect *restraint* may not only lead to ineffective *stunning* or bleeding, but also cause *distress*, fear and *pain*~~and *distress*~~.

Other *hazards* include:

a) slippery ~~ing or falling of animals entering the~~ restraining area;

b) ~~struggling or escape attempts caused by~~ insecure *restraint*;

c) ~~injuries and *pain* caused by~~ excessive force of *restraint*;

d) a restraint box that is not appropriate to the size of the animal;

~~d~~e) ~~fear caused by~~ prolonged *restraint*, which may exacerbate insecure or excessive *restraint*.

~~In addition, s~~*Slaughter* without *stunning* increases the risk of *pain* and fear due to the need for robust *restraint* of conscious animals for neck cutting, especially if animals are turned on their sides or backs [von Holleben *et al.*, 2010; Pleiter, 2010].

2~~.~~) Animal-based and other ~~measurables~~ measures ~~include~~:

a) animal slipping or falling;

b) struggling;

c) escape attempts;

d) animal vocalisation referring to *distress* ~~(cattle and pigs)(e.g. high-pitched vocalisation in pigs)~~;

e) reluctance to enter the restrainer;

f) ~~frequency of~~ use of electric goads.

3~~.~~) Recommendations:

Where individual restraint is used, ~~T~~the restrainer should be narrow enough that the animals cannot move ~~either~~ backward~~s~~ ~~or~~, forward~~s~~ or turn around.

The restrainer being used should be appropriate to the size of the animals and the restrainer should not be loaded beyond its design capacity.

In case of *slaughter* without *stunning*, the restrainer should restrain the head ~~appropriately~~ and should support the body of the animal ~~appropriately~~.

The restraint~~ing~~ should be maintained until the animal is unconscious.

When restrainers ~~are used~~ that hold an animal with its feet off the floor are used, the animal ~~must~~ should be held in a balanced, comfortable, upright position.

When a restrainer is used to rotate an animal from an upright position, the body and head ~~must~~ should be securely held and supported to prevent struggling and slipping within the device.

Restrainers should not have sharp edges and should be well maintained to minimise risk of injury.

Non-slip flooring should be used to prevent animals from slipping or falling.

Flooring design and handling methods that~~intentionally~~ cause loss of balance, slipping or falling, i.e. a box with a floor that rises on one side upon entry to the box, should not be used ~~intentionally~~.

Distractions (e.g. movements of equipment or people, loose chains or objects, shadows, shiny surfaces or floors) should be minimised to prevent baulking ~~balking~~ and improve ease of entry into the restrainer.

No animal~~s~~ should enter the restrainer until equipment and personnel are ready to stun and slaughter that animal.

No animal~~s~~ should be released from the restrainer until the operator has confirmed loss of consciousness.

Animals should not be left in ~~conveyor style~~ single file races or restrainers during work breaks, and in the event of a breakdown animals should be removed from the ~~conveyor~~ restrainer promptly.

The restrainer should be in a clean and non-slip condition.

Animals should not be able to pile on top of each other in the restrainer, nor receive pre-stun shocks from contact with the animal in front, in the case of electrical *stunning*.

Animals subject to specific methods of *stunning* should be individually restrained to ensure precise positioning of the *stunning* equipment. However, this should not apply when restraining is likely to cause additional *distress* or *pain* as well as excessive and unpredictable movements (e.g. animals that cannot move normally due to injuries or sickness, *wild* animals or horses).

4~~.~~) Species-specific recommendations:

Gondolas for gas *stunning* of pigs should not be overloaded and ~~pigs~~ should allow pigs ~~be able~~ to stand without being on top of each other.

Head *restraint* is recommended for ~~cattle~~ bovines.

Specialised restraining equipment and methods are required for ~~B~~bison and cervids. ~~as well as any species which may be processed with or without stunning.~~

Article 7.5.16.

General principles for ~~S~~stunning of free-moving animals and animals in containers

~~1. Animal welfare concerns:~~

~~The main *animal welfare* concern associated with *stunning* is 'ineffective *stunning*' which results in *pain*, *distress* or fear during induction of unconsciousness and possible recovery before *death*.~~

~~The most common methods for *stunning* are mechanical, electrical and exposure to controlled atmosphere.~~

~~*Stunning* prior to *slaughter* decreases or avoidprevents *pain* and suffering to animals and also improves workers' safety.~~

~~Mechanical *stunning* is divided into penetrativeng *stunning* and non-penetrating non-penetrative percussive *stunning* applications. Both applications use different types of devices aimed to induce immediate loss of consciousness as the impact of the bolt on the skull results in concussion and disruption of normal brain function [Daly *et al.*, 1987; EFSA, 2004]. Penetrative *stunning* devices propel a bolt which penetrates the skull and enters the cranium damaging the brain. Non-penetrative percussive *stunning* devices propel a blunt bolt which does not penetrate the skull, but results in rapid loss of consciousness from impact. The main *hazards* preventing effective mechanical *stunning* are incorrect shooting position and incorrect direction of the impact. These may cause ineffective *stunning* and *pain* or short lasting unconsciousness. Poor maintenance of the equipment or inadequate cartridge power or air line pressure (in pneumatic stunners) can result in low bolt velocity., Llow bolt velocity, misuseInappropriate use of cartridge Low bolt velocity, narrow bolt diameter or short length of bolt leading to shallow penetration, may also affect the effectiveness of *stunning*. In older animals with a thicker skull, low bolt velocity may result inthere is an increase risk of an ineffective stun., especially with In non-penetrating non-penetrative percussive *stunning* applications, high bolt velocity may cause fracture of the skull and ineffective *stunning* [Gibson *et al.*, 2014]. If not applied correctly, fracture of the skull and ineffective *stunning* are more likely to occur with young animals such as calves, when a higher bolt velocity is used. Absence of or incorrect restraint can lead to an incorrect shooting position.~~

~~Electrical *stunning* involves application of an electric current to the brain of sufficient magnitude to induce immediate unconsciousness [EFSA, 2004; Grandin, 1980]. The main *hazards* preventing effective electrical *stunning* are: incorrect electrode placement, poor contact, electrical arcing, high contact resistance caused by wool or dirt on the animal surface, dirty or corroded electrode, low voltage/current or high frequency [EFSA, 2004].~~

~~Controlled atmosphere *stunning* methods involve the exposure to high concentrations of carbon dioxide (hypercapnia), low concentration of oxygen (hypoxia) or a combination of the two (hypercapnic hypoxia). Loss of consciousness is not immediate following exposure of animals to controlled atmosphere *stunning*. The main *hazards* causing increased *distress* during induction of unconsciousness are irritant or aversive gas mixtures (e.g. CO_2 in high concentrations), low gas temperature and humidity. The main *hazards* causing ineffective controlled atmosphere *stunning* are incorrect gas concentration and too short gas exposure time [Anon, 2018; EFSA, 2004; Velarde *et al.*, 2007].~~

~~Gases or gas mixtures that are *pain*ful to inhale should preferably not be used to stun or kill pigs.~~

~~2. Animal-based and other measurables include.:~~

~~Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, just before and during bleeding until death occursis confirmed neck cutting, and during bleed-out [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].~~

~~No single indicator should be relied upon alone. Multiple indicators should be used to determine whether a stun is effective and the animal is unconscious.~~

~~Mechanical *stunning:*~~

~~An effective stun is characterised by the presence of all the following signs: immediate collapse; apnoea; tonic seizure; absence of corneal reflex; absence of eye movements.~~

The presence of any of the following signs may indicates an a high risk of ineffective stun or recovery of consciousness: rapid eye movement or nystagmus, vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

Electrical *stunning:*

An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex.

The presence of any of the following signs may indicates an high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

Gas *stunning*:

An effective stun is characterised by the presence of all the following signs: loss of posture; apnoea; absence of corneal reflex; absence of muscle tone.

The presence of any of the following signs may indicates an high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

3. Recommendations:

Animals should always be stunned as soon as they are restrained.

When a two-step electrical stun-kill method is used, the electrical current must reachbe applied to the brain before it reaches the heart otherwise the animal will experience cardiac arrest while still conscious.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system method. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be used, cleaned, maintained and stored following manufacturer's recommendations.

Regular calibration of the equipment according to the manufacturer's procedure areis recommended. Effectiveness of the *stunning* should be monitored regularly.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters or and follow the manufacturer's recommendations for *stunning*, such as:

a) Mechanical:

- position and direction of the shot [AVMA, 2016];
- grain of the cartridge or air pressure appropriate to the type of animal (captive bolt) [Gibson *et al.*, 20152014];
- length and diameter of the bolt (captive bolt);
- calibre and type of gun and ammunition (free bullet).

b) Electrical:

- shape, size and placement of the electrodes [AVMA, 2016];
- pressure contact between electrode and head;
- wetting point of contact;
- minimum exposure time;

- electrical parameters (current intensity(A), waveform type (AC and DC), voltage(V) and frequency(Hz));
- visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors and displays duration of exposure, voltage and applied current.

c) Controlled atmosphere:

- gas concentrations and exposure time;
- temperature and humidity;
- rate of decompression (law atmospheric pressure system for *stunning*);
- animal based measure should be monitored during the induction phase, if possible, because this can be a point of highest welfare risk for animals.
- visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors gas concentration and temperature.
- gases or gas mixtures that are *pain*ful to inhale should preferably not be used to stun or kill pigs

4. Species specific recommendations:

Non-penetrativeng captive bolt should not be used in animals with thick skull (e.g. bison, water buffalo)mature cattle and pigs [Finnie, 1993 and Finnie *et al.*, 2003].

The *Competent Authority* should determine effective electrical parameters, based on scientific evidence for different types of animals.

Where high electrical frequencies is used, the amperage should also be increased.

Gases or gas mixtures that are *pain*ful to inhale should preferably not be used to stun or kill pigs.

1.) Animal welfare concerns:

The main *animal welfare* concern associated with *stunning* is 'ineffective *stunning*' which results in *distress*, fear and *pain*, *distress* or fear during induction of unconsciousness and possible recovery before *death*.

Animals should only be stunned using *stunning* methods that have been scientifically validated as effective for *stunning* that species. The most common methods for *stunning* are mechanical, electrical and exposure to controlled atmosphere. Animals should only be stunned using *stunning* methods that have been scientifically validated as effective for *stunning* that species.

EU comment

The EU suggests deleting the first sentence of the paragraph above:

"Animals should only be stunned using *stunning* methods that have been scientifically validated as effective for *stunning* that species. The most common methods for *stunning* are mechanical, electrical and exposure to controlled atmosphere. Animals should only be stunned using *stunning* methods that have been scientifically validated as effective for *stunning* that species."

Justification:

Editorial because the sentence is identical to the third sentence of the paragraph.

Stunning prior to *slaughter* ~~decreases or avoid~~ prevents *distress*, fear and *pain* ~~and suffering~~ to animals during neck cutting and bleeding ~~and also improves workers' safety~~.

2~~.~~) Animal-based and other ~~measurables~~ measures ~~include.~~:

~~Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, just before and during bleeding until death occursis confirmed neck cutting, and during bleed-out [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].~~

~~No single indicator should be relied upon alone~~. Multiple indicators should be used to determine whether a stun is effective and the animal is unconscious.

After *stunning*, the state of consciousness is assessed to identify if animals are successfully rendered unconscious or if they are conscious (e.g. *stunning* was ineffective or they recovered consciousness) and therefore at risk of experiencing *distress*, fear and *pain*. For each animal-based measures of state of consciousness, outcomes either suggesting unconsciousness (e.g. presence of tonic seizures) or suggesting consciousness (e.g. absence of tonic seizures) have been identified for each *stunning* method.

3~~.~~) Recommendations:

Animals should always be stunned as soon as they are restrained.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup ~~system~~ method. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Effectiveness of *stunning* should be monitored using multiple animal-based measures at different stages: immediately after *stunning*, just before and during bleeding until *death* ~~occurs~~ is confirmed ~~neck cutting, and during bleed-out~~ [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

Stunning equipment should be used, cleaned, maintained and stored following manufacturer's recommendations.

Regular calibration of the equipment according to the manufacturer's procedure ~~are~~is recommended. ~~Effectiveness of the *stunning* should be monitored regularly.~~

*Slaughterhouses/abattoir*s should have standard operating procedures that define key operating parameters ~~or~~ and follow the manufacturer's recommendations for *stunning* the species and age group concerned.~~, such as:~~

~~4.~~) ~~Species-specific recommendations:~~

Article 7.5.17.

Mechanical stunning of free-moving animals

1~~.~~) Animal welfare concerns:

~~Mechanical *stunning* is divided into penetrativeng *stunning* and non-penetrating non-penetrative percussive *stunning* applications. Both applications use different types of devices aimed to induce immediate loss of consciousness as the impact of the bolt on the skull results in concussion and disruption of normal brain function [Daly *et al.*, 1987; EFSA, 2004]. In addition to the concussive effect, Ppenetrative *stunning* devices propel a bolt which penetrates the skull and enters the cranium causing additional damageing to the brain. Non-penetrative percussive *stunning* devices propel a blunt bolt which does not penetrate the skull, but results in rapid loss of consciousness from impact (concussive effect).~~ The main *hazards* preventing effective mechanical *stunning* are incorrect shooting position and incorrect direction of the impact. These may cause ineffective *stunning* ~~and *pain*~~ or short-lasting unconsciousness. Absence of or incorrect restraint can lead to an incorrect shooting position. Poor maintenance of the equipment or inadequate cartridge power or air line pressure ~~(in pneumatic stunners)~~ can result in ~~low bolt velocity which delivers~~ less concussive impact to the skull. ~~Llow bolt velocity, misuse~~ Inappropriate use of cartridge ~~Low bolt velocity~~, narrow bolt diameter or short length of bolt ~~leading to shallow penetration,~~ may also affect the effectiveness of *stunning*. In ~~older~~ animals with a thicker skull, ~~low bolt velocity may result in~~ there is an increased risk of an ineffective stun~~.~~, especially with ~~In non-penetrating~~ non-penetrative percussive *stunning* ~~applications, high bolt velocity may cause fracture of the skull and ineffective *stunning* [Gibson *et al.*, 2014]~~. ~~If not applied correctly,~~Ffracture of the skull which

may cause ~~and~~ ineffective *stunning* are more likely to occur ~~with~~ in young animals such as calves~~, when a higher bolt velocity is used~~.

For ~~*wild*~~ certain extensively reared domestic and *captive wild* animals ~~*or feral animals*~~, on-site shooting with a free bullet in the brain can be an alternative to prevent stressful handling and transport. Under such circumstances, the main objective ~~animal welfare concern~~ is a shot that kills the animal immediately.

2~~.~~) Animal-based and other ~~measurables~~ measures ~~include~~:

~~Mechanical *stunning:*~~

Animal-based measures of a~~A~~n effective stun are ~~is characterised by the presence of all the following signs~~: immediate collapse; apnoea; tonic-clonic seizure; absence of corneal ~~reflex~~ or palpebral reflex ~~and~~; absence of eye movements.

Animal-based measures ~~The presence of any of the following signs may indicates an~~ a ~~high risk~~ of ineffective stun or recovery of consciousness are: absence of collapse or attempts to regain posture rapid eye movement or nystagmus, vocalisation; spontaneous blinking; righting reflex; presence of corneal ~~reflex~~ or palpebral reflex~~and~~; rhythmic breathing.

3~~.~~) Recommendations:

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters ~~or~~ and follow the manufacturer's recommendations for *stunning* the species and age group concerned, such as*:*

~~Mechanical:~~

~~– position and direction of the shot [AVMA, 2016];~~

– grain of the cartridge or air pressure ~~appropriate to the type of animal~~ (captive bolt) [Gibson *et al.*, 2015~~2014~~];

– calibre and type of gun and ammunition (free bullet);

– length and diameter of the penetrating bolt ~~(captive bolt)~~;

– shape and diameter of the non-penetrating bolt;

– position and direction of the shot [AVMA, 2016].

~~– calibre and type of gun and ammunition (free bullet).~~

4~~.~~) Species-specific recommendations:

Non-penetrative~~ng~~ captive bolt should not be used in animals with thick skull (e.g. bison, water buffalo)~~mature cattle and pigs [Finnie, 1993 and Finnie *et al.*, 2003]~~.

Water buffaloes should be stunned with penetrative captive bolt in the occipital position using a heavy-duty contact-fired captive bolt gun directed at the nose or using large-calibre firearms and deformation ammunition (e.g. 0.357 Magnum).

Article 7.5.18.

Electrical stunning in free-moving animals

1~~.~~) Animal welfare concerns:

Electrical *stunning* involves application of an electric current across ~~to~~ the brain of sufficient magnitude to induce immediate unconsciousness [EFSA, 2004; Grandin, 1980]. The main *hazards* preventing effective electrical *stunning* are: incorrect electrode placement, poor contact, electrical arcing, high contact resistance caused by wool or dirt on the animal surface, dirty or corroded electrode, low voltage/current or high electrical frequency [EFSA, 2004]. Excessively wet hides or fleeces may result in ineffective *stunning* due to electrical current taking the path of least resistance and flowing around the outside of the

body rather than through the skull. This may paralyse the animal, or cause pre-stun shocks, rather than *stunning* the animal. If electrodes are energised prior to ensuring they have good contact with the animal, this results in *pain* from the shock.

2.) Animal-based and other measures:

Electrical *stunning:*

Animal-based measures of an effective stun are: An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex; or palpebral reflex.

Animal-based measures of ineffective stun or recovery of consciousness are: The presence of any of the following signs may indicates an high risk of ineffective stun or recovery of consciousness: absence of tonic-clonic seizures; vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; or palpebral reflex; rhythmic breathing.

3.) Recommendations:

When a two-step head to body electrical stun-kill method is used, the electrical current should reach be applied to the brain before it reaches the heart otherwise the animal will experience cardiac arrest while still conscious.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters and follow the manufacturer's recommendations for *stunning* the species and age group concerned, such as*:*

When a two-step electrical stun-kill method is used, the electrical current must reachbe applied to the brain before it reaches the heart otherwise the animal will experience cardiac arrest while still conscious.

Electrical:

- shape, size and placement of the electrodes [AVMA, 2016];
- pressure contact between electrode and head;
- wetting moisten point of contact;
- minimum exposure time;
- electrical parameters (current intensity [A], waveform type [AC and DC], voltage [V] and frequency [Hz]);
- maximum stun to stick interval;
- visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors and displays duration of exposure, voltage and applied current.

4.) Species-specific recommendations:

The *Competent Authority* should determine eEffective electrical parameters, should be determined based on scientific evidence for different types of animals.

For head-only *stunning*, minimum parameters are recommended for the following species:

- 1.15 [AVMA] to 1.28 A for bovines [EFSA 2020b],
- 1.25 A for slaughter (finished) pigs [AVMA],
- 1.8 A for sows and boars [AVMA],
- 1 A for small ruminants [EFSA 2013c, and EFSA 2015, AVMA].

The minimum parameters above are recommended to be used with an electrical frequency of 50Hz. Where higher ~~electrical~~ frequencies ~~is~~ are used, the amperage should also be increased.

Article 7.5.19.

Controlled atmosphere stunning in free-moving animals

1~~.~~) Animal welfare concerns:

Controlled atmosphere *stunning* methods involve the exposure to high concentrations of carbon dioxide (hypercapnia), low concentration of oxygen (hypoxia) or a combination of the two (hypercapnic hypoxia). Loss of consciousness is not immediate following exposure of animals to controlled atmosphere *stunning*. The main *hazards* causing increased *distress* during induction of unconsciousness are irritant or aversive gas mixtures (e.g. CO_2 in high concentrations), low gas temperature and humidity, and overloading of the gondola or restraint. The main *hazards* causing ineffective controlled atmosphere *stunning* are incorrect gas concentration and too short gas exposure time [Anon, 2018; EFSA, 2004; Velarde *et al.*, 2007].

~~Gases or gas mixtures that are *pain*ful to inhale should preferably not be used to stun or kill pigs.~~

2~~.~~) Animal-based and other ~~measurables~~ measures ~~include.~~:

~~Gas *stunning*:~~

Animal-based measures of an effective stun are:~~An effective stun is characterised by the presence of all the following signs:~~ loss of posture; apnoea; absence of corneal ~~reflex~~ or palpebral reflex; absence of muscle tone.

Animal-based measures of an ineffective stun or recovery of consciousness are:~~The presence of any of the following signs may indicates an high risk of ineffective stun or recovery of consciousness:~~ vocalisation; spontaneous blinking; righting reflex; presence of corneal ~~reflex~~ or palpebral reflex; rhythmic breathing.

3~~.~~) Recommendations:

~~c) Controlled atmosphere:~~

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters and follow the manufacturer's recommendations for *stunning* the species and age group concerned, such as*:*

– gas concentrations and exposure time;

– temperature and humidity;

– ~~rate of decompression (law atmospheric pressure system for *stunning*);~~

– stocking density of the gondola or restraint for pigs;

– ~~animal-based measures should be monitored during the induction phase, if possible, because this can be a point of highest welfare risk for animals;~~

– ~~since animal-based measures are difficult to monitor and adapt during the induction phase, resource-based measures should be used such as monitoring of gas concentration(s) and exposure time. Gas concentrations and exposure time, temperature and humidity must should be monitored continuously at the level of the animal inside the chamber;~~

– visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors gas concentration and temperature.

– ~~gases or gas mixtures that are *pain*ful to inhale should preferably not be used to stun or kill pigs~~

Animal-based measures should be monitored during the induction phase~~,~~ because this can be a point of highest welfare risk for animals. Since animal-based measures are difficult to monitor and adapt during the induction phase, resource-based

measures should be used such as monitoring of gas concentration(s) and exposure time. Gas concentrations and exposure time, temperature and humidity should be monitored continuously at the level of the animal inside the chamber.

4.) Species-specific recommendations:

Pigs:

Gases or gas mixtures that are painful to inhale should preferably not be used to stun or kill pigs. However except, if such methods allow animals pigs to be stunned in groups and it has a short induction phase, as they could can present a certain animal welfare benefits compared to methods requiring individual *restraint*.

Article 7.5.20.17

Bleeding of free-moving animals

1.) Animal welfare concerns:

The main *animal welfare* concern at the time of bleeding following *stunning* is the recovery of consciousness due to prolonged stun-to-stick interval or due to incomplete severance of the main blood vessels.

Bleeding without prior *stunning* increases the causes risk of animal suffering because the incision to sever blood vessels results in substantial tissue damage in areas well supplied with nociceptors. The activation of these nociceptors causes the animal to experience *pain* [Gregory, 2004; Gibson *et al.*, 2009]. Loss of consciousness due to bleeding is not immediate and there is a period during which the animals can feel experience fear, *pain* and *distress* [Gregory, 2004; Johnson *et al.*, 2015]. This period will be reduced by applying *stunning* immediately after neck cutting.

Absence of or ineffective *stunning* may result in animals being released from the *restraint*, shackled, and bled and/or further processed while they are still conscious or have the potential to recover consciousness.

2.) Animal-based and other measurables measures include:

The main animal-based measureable is the blood flow (rate and duration). For animal-based and other measurables measures of return of consciousness after *stunning*, see Article 7.5.16.

In cases of bleeding without *stunning* the animal-based and other measurables measures that indicate loss of consciousness include all the following: absence of muscle tone; absence of corneal reflex or and palpebral reflex; absence of rhythmic breathing. Unconsciousness should be reassessed until *death* is confirmed. In addition, cessation of bleeding after a continuous and rapid blood flow can be used as an indicator of *death*.

3.) Recommendations:

a) both carotid arteries or the blood vessels from which they arise should be severed;

a b) continuous and rapid blood flow should be assured after bleeding;

b c) cessation of blood flow *death* should be assured before further processing;

c d) bleeding knives should be sharpened for each animal as necessary to fulfil recommendations a) and b).

In addition, the following should be considered:

Slaughter with *stunning*:

a) the stun-to-stick interval should be short enough to ensure that the animal will die beforenot recovering consciousness before it dies;

b) unconsciousness should be confirmed before bleeding;

c) animals who are stunned with a reversible method should be bled without delay to avoid them regaining consciousness during bleeding.

Slaughter without *stunning*:

a) bleeding should be carried out by a single incision; any second intervention should be recorded and analysed to improve procedures.

b) further processing may only be carried out when the *death* of the animal has been ascertained ~~and no movement can be detected~~.

4) Species-specific recommendations:

~~None identified.~~

~~Cattle~~ Bovines are at risk of prolonged bleed out times and regaining consciousness as the bilateral vertebral arteries are not cut during a neck cut. ~~If As they are not cut, t~~The vertebral arteries will continue to provide blood to the brain. Furthermore ~~and can cause~~ any occlusion of the cut major arteries~~,~~ will slow~~ing~~ exsanguination. Therefore, bleeding with a cut of the brachiocephalic trunk should ~~always~~ be preferred in ~~cattle~~ bovines.

Article 7.5.21~~18~~.

Slaughter of pregnant free-moving animals

1~~.~~) Animal welfare concerns:

Fetuses in the uterus are considered not to ~~cannot~~ achieve consciousness [EFSA, 2017; Mellor, D. J. *et al.*, 2005~~Diesch *et al.*, 2005~~]. However, if removed from the uterus the fetus may perceive *pain* or other negative ~~impacts~~ effects.

2~~.~~) Animal-based and other ~~measurables~~ measures ~~include~~:

~~None identified.~~ Signs of consciousness in the ~~foetus~~ neonate after removal from the uterus, such as breathing [Mellor, 2003; Mellor, 2010; EFSA, 2017].

3~~.~~) Recommendations:

Under ~~normal circumstances~~ WOAH recommendations (Chapter 7.3. Animal transport by land), pregnant animals that would be in the final 10% of their gestation period at the planned time of *unloading* at the *slaughterhouse/abattoir* should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that pregnant females are handled separately.

The fetus should be left undisturbed in utero for at least 30 minutes after the *death* of the dam [EFSA, 2017; Anon, 2017]. The uterus could be removed as a whole, clamped and kept intact such that there is no possibility for the fetus to breathe.

In cases where the fetus is removed before 30 minutes has elapsed *euthanasia* ~~(captive bolt followed by bleeding)~~ should be carried out immediately.

~~4.) Species-specific recommendations:~~

~~None identified.~~

Article 7.5.22~~19~~.

Emergency killing of free-moving animals

This article addresses animals that show signs of severe *pain* or other types of severe suffering before being unloaded or within the *slaughterhouse/abattoir*. These animals may correspond to animals unfit to travel as listed in Article 7.3.7. Principles described below should be described in the emergency plan and may also apply to animals that are not suitable for *slaughter* for commercial reasons, even if they do not present signs of *distress, pain* or suffering.

1.) Animal welfare concerns:

Some animals can arrive at *slaughterhouses/abattoirs* with injuries or severe illnesses that can cause undue *distress* and *pain* and suffering. This is more likely in animals of low economic value.

2.) Animal-based and other measurables measures include:

Animals requiring emergency *killing* are unable to walk independently or present severe injuries such as fractures, large open wounds, or prolapses. They may also present clinical signs of serious illness or being in a state of extreme weakness. New-born animals or animals that gave birth within the last 48 hours may also belong to this category.

3.) Recommendations:

Animals should not be moved unless it can be done without causing further *distress, pain* or suffering.

Animal handlers should euthanise the animal as soon as possible.

Emergency *killing* should be systematically recorded and analysed in order to improve procedures and prevent recurrences.

~~4.) Species-specific recommendations:~~

~~None identified.~~

Article 7.5.2320.

Methods, procedures or practices that should not be used ~~unacceptable on animal welfare grounds~~ for free-moving animals

1) ~~None of t~~The following practices for handling animals ~~are un~~acceptable ~~and~~ should not be used under any circumstances:

a) crushing, twisting or breaking tails of animals;

b) applying pressure using an injurious object or applying an irritant substance to any part of an animal ~~to sensitive areas such as eyes, mouth, ears, anogenital region or belly~~;

c) hitting animals with instruments such as large sticks, sticks with sharp ends, ~~metal~~ piping, stones, fencing wire or leather belts;

d) kicking, throwing or dropping animals;

e) grasping, lifting or dragging animals only by ~~some~~ body parts such as their tail, head, horns, ears, limbs, wool or hair;

f) dragging animals by any body part, by any means, including ~~with~~ chains, ~~or~~ ropes or by hand;

g) forcing animals to walk over other animals;

h) interfering with any sensitive area (e.g. eyes, mouth, ears, anogenital region, udder or belly).

2) ~~None of t~~The following practices for restraining conscious animals are unacceptable and should not be used under any circumstances:

a) mechanical clamping of the legs or feet of the animals as the sole method of *restraint*, including tying limbs together or lifting one or more limbs off the ground;

b) breaking legs, cutting leg tendons or blinding animals;

c) severing the spinal cord, by using for example a puntilla or dagger;

d) applying electrical current that does not span the brain;

e) suspending or hoisting ~~conscious animals~~them by the feet or legs;

f) severing brain stem by piercing through the eye socket or skull bone;

g) forcing animals to ~~the ground~~sit or lay down by one or more handlers jumping on and lying across the animal's back~~.~~;

h) trip floor boxes that are designed to make animals fall.

3) Breaking the neck while the animal is still conscious during bleeding is also an unacceptable practice.

Article 7.5.24~~21~~.

Arrival of animals in containers

On arrival at the *slaughterhouse/abattoir*, animals ~~will~~ would already have been exposed to *hazards* that may have negative impacts on their welfare. Any previous *hazards* will have a cumulative effect that may impair the welfare of the animals throughout the *slaughter* process. Therefore, animals should be transported to the *slaughterhouse/abattoir* in a manner that minimises adverse animal health and welfare outcomes, and in accordance with Chapters 7.2. and 7.3.

1~~.~~) Animal welfare concerns:

Animals in *containers* have smaller space allowances than on farm, undergo water and *feed* deprivation, may have suffered from injury and may be exposed to thermal stress due to adverse weather conditions and stress from social disturbance, noise, *vehicle* vibration and motion. In addition, stationary *vehicles* may have insufficient ventilation. Delays in *unloading containers* will prolong or exacerbate the impact of these *hazards*. Under these circumstances, injured or sick animals requiring urgent attention will not be identified and therefore the duration of their suffering will be increased.

2~~.~~) Animal-based and other ~~measurables~~ measures ~~include~~:

It can be difficult to assess animal-based measures while animals are in the *containers* and especially when the *containers* are on the *vehicle* or when many *containers* are stacked on top of each other. Some ~~measurables~~ measures that may be assessed include animals with injuries, or those that are sick or have died. Panting, reddening of the ears (heat stress in rabbits), shivering and huddling may indicate thermal stress. In rabbits drooling and licking may indicate prolonged thirst.

Time from arrival to *unloading* and *slaughter*, the environmental temperature and humidity (e.g. ambient, inside the *vehicle*) can be used to establish relevant thresholds for corrective action.

3~~.~~) Recommendations:

Animals should be slaughtered as soon as they arrive at the *slaughterhouse/abattoir*. If not possible, *containers* should be unloaded, or *vehicles* should be placed in *lairage* or in sheltered and adequately ventilated area, promptly on arrival. This is facilitated by scheduling the arrival of the animals at the *slaughterhouse/abattoir* to ensure that there are sufficient personnel and adequate space in the *lairage* area. Time at *lairage* should be kept ~~at~~ to a minimum.

Consignments of animals assessed to be at greater risk of compromised *animal welfare* ~~*hazards*~~ (e.g. from long journeys, prolonged lairage, end-of-lay hens) should be unloaded first or should be considered for prioritised *slaughter*. When no available space is immediately available, creating space should be a priority. Provisions should be made to provide shelter, shade, cooling or heating systems or additional ventilation during waiting periods, or animals should be transported to an alternative nearby location where such provisions are ~~is~~ available. ~~Mortalities and injuries should be reported to the competent authority.~~

4~~.~~) Species-specific recommendations:

~~Poultry is especially sensitive to extreme temperatures and therefore special attention should be taken when dealing with delays in *unloading* this species in extreme temperatures.~~

Birds may get trapped or their wings or claws may get caught in the fixtures, mesh or holes in poorly designed, constructed or maintained transport systems. Similarly, rabbits may trap their paws in the fixtures mesh or holes in poorly designed,

constructed or maintained transport systems. Under these situations, operators *unloading* birds or rabbits should ensure gentle release of trapped animals.

Article 7.5.2522.

Moving of animals in containers

This article addresses the handling of ~~containerised~~ animals in *containers* during *unloading* and *lairage,* and into the *killing* area.

1.) Animal welfare concerns:

During *unloading* and moving *containers,* animals can be exposed to *pain*, stress and fear due to tilting, dropping or shaking of the *containers*.

During *unloading* and moving *containers,* animals can be exposed to adverse weather ~~or climate~~ conditions and experience *pain* and *distress* ~~face heat stress, frost bite, or death.~~[EFSA, 2019].

2.) Animal-based and other ~~measurables~~ measures ~~include~~:

a) animals with broken limbs or dislocated joints;

b) animals that ~~strike against the facilities~~ collide with facility structures ~~strike against the facilities~~;

c) animal~~s~~ ~~vocalizsing~~ vocalisations referring to *distress*;

d) body parts (i.e. wings, limbs, feet, paws or heads) stuck between *containers*;

e) animals injured by sharp projections inside *containers.*

3.) Recommendations:

Containers in which animals are transported should be handled with care, moved slowly, and should not be thrown, dropped or knocked over. Where possible, they should be horizontal while being loaded or unloaded mechanically and stacked to ensure ventilation and prevent animals piling on one another. In any case, *containers* should be moved and stored in an upright position as indicated by specific marks.

Animals delivered in *containers* with perforated or flexible bottoms should be unloaded with particular care to avoid injury by crushing or jamming of body parts.

Animals that are injured, jammed or sick require immediate action and, when necessary, should be taken from the *containers* and euthanised without delay. Refer to Article~~s~~ 7.5.34 ~~7.5.8, 7.5.9., 7.6.8 and 7.6.1724~~.

Staff should routinely inspect the *containers* and remove the broken *containers* that should not be re-used.

~~4.) Species-specific recommendations:~~

~~None identified.~~

Article 7.5.2623.

Lairage of animals in containers

1.) Animal welfare concerns:

Animals ~~during *lairage*~~ may be exposed to several *hazards* to *animal welfare* ~~*hazards*~~ during *lairage* including:

a) ~~food~~ *feed* and water deprivation leading to prolonged hunger and thirst~~,~~;

b) poor ventilation;

c~~b~~) absence of protection against adverse weather ~~or climate~~ conditions ~~extremes in climate~~ leading to thermal stress~~,~~;

d~~c~~) sudden or excessive noises, including from personnel, leading to fear~~,~~;

e~~d~~) insufficient space to lie down and move freely leading to fatigue and aggressive behaviour~~,~~;

f~~e~~) not being inspected or accessible for emergency *killing* when necessary.

2~~.~~) Animal-based and other ~~measurables~~ measures ~~include~~:

a) thermal stress (e.g. panting, shivering, huddling behaviour, reddening of the ears)~~,~~;

b) space allowance~~,~~;

c) excessive soiling with faeces~~,~~;

d) injuries (e.g. splay leg, open wounds, fractures, dislocations)~~,~~;

e) sick or dead animals.

3~~.~~) Recommendations:

Animals should be slaughtered upon arrival at the *slaughterhouse/abattoir*.

Staff should routinely inspect and monitor *containers* while in the *lairage* to observe animals for signs of *distress*, fear and *pain* ~~suffering and *distress*~~ and take appropriate corrective action to address any concerns.

The *lairage* should provide animals with protection against adverse weather conditions.

Animals should be protected from sudden and excessive noise (e.g. ventilation fans, alarms, or other indoor or outdoor equipment).

~~4.) Species-specific recommendations:~~

~~None identified.~~

Article 7.5.27~~24~~.

Unloading animals from containers before stunning

1~~.~~) Animal welfare concerns:

Animals are removed manually or ~~automatically~~ mechanically by tilting ~~(poultry) from~~ the transport *containers*.

When the *containers* with ~~birds~~ animals are manually or mechanically emptied by tipping, animals fall on to conveyors. Dumping, piling up and shock ~~might happen~~ may occur, especially for the last ~~birds~~animals, which are often removed by manual or mechanical shaking of the *containers*.

Other *hazards* include:

a) narrow openings or doors of the *containers*;

b) *containers* placed too far away from the place of shackling or *stunning*;

c) inappropriate handling and removal of animals from *containers* ~~before *stunning*~~;

~~c~~d) incorrect design of manual or mechanical tipping ~~manually or using mechanical~~ equipment that cause animals to fall~~ing~~ from a height ~~and conveyor belts that are running too fast or too slow resulting in piling or injured animals~~;

e) conveyor belts that are running too fast or too slowly or are not properly aligned resulting in piling or injury.

2.~~.~~) Animal-based and other ~~measurables~~ measures ~~include~~:

a) ~~animals~~ falling;

b) struggling, including wing flapping;

c) escape attempts;

d) vocalisation referring to *distress*;

e) injuries, dislocations, fractures;

f) pi~~l~~ling~~-off~~up of animals.

3.~~.~~) Recommendations:

Removal of animals from ~~the~~ *containers* in a way that causes *pain*, e.g. by one leg, wings, neck or ears, should be avoided.

Animals should be removed from *containers* by the body or by both legs using both hands and one animal at a time. Animals should not be grabbed and lifted by one leg, the ears, wings or fur and they should not be thrown, sw~~i~~ung or dropped.

Animals should not be mistreated in the process of *unloading* and shackling prior to *stunning* ~~(e.g. excessive force used when shackling, punching, kicking, or otherwise hurting).~~

Modular systems that involve tipping of live ~~birds~~ animals are not conducive to maintaining good animal welfare. These systems, when used, should ~~be~~ have an incorporated ~~with a~~ mechanism to facilitate ~~birds~~ animals sliding out of the transport system, rather than being dropped or dumped on top of each other ~~from heights of more than a metre~~.

It should be ensured that every animal is removed from the *containers* ~~before they are returned~~.

~~4.) Species specific recommendations:~~

~~Any animal~~ Birds with broken bones and/or dislocated joints should be humanely~~emergency killed before being hung on shackles for processing.~~

Article 7.5.28~~25~~.

Restraint for stunning animals from containers

1.~~.~~) Animal welfare concerns:

The purpose of *restraint* is to facilitate the correct application of the *stunning* and ~~or~~ bleeding procedures ~~equipment~~. Incorrect *restraint* ~~and~~ or handling cause *distress*, fear and *pain* ~~fear and *distress*~~ and may lead to ineffective *stunning* and ~~or~~ bleeding.

Other *hazards* include:

a) Inversion can provoke compression of the heart and lungs or air sacs by the viscera and might compromise breathing and cardiac activity. This ~~might~~ will cause *distress*, fear and *pain* ~~and fear~~ in conscious birds and rabbits.

b) Shackling ~~hanging~~ ~~birds~~ animals upside down by inserting both legs into ~~metal~~ shackles. During shackling, the ~~birds~~ animals are also subjected to compression of their legs and wing flapping by their neighbour(s), leading to *distress*, *pain* and fear.

c) Inappropriate shackling (e.g. shackles are too narrow or too wide, ~~birds~~ animals are ~~hung~~ shackled by one leg, or when one ~~bird~~ animals is shackled on two different adjacent shackles) leads to *distress*, *pain* and fear ~~when shackles are too narrow or too wide, when the birds are hung by one leg, or when one bird is shackled on two different adjacent shackles~~. Line speed, without a concomitant increase in workforce, can contribute to poor shackling outcomes.

d) Drops, curves and inclination of the shackle line or high speed of the shackle line create fear and possible *pain* due to the sudden changes in position as well as increased effects of inversion.

2.) Animal-based and other ~~measurables~~ measures ~~include~~:

a) ~~struggling (~~wing flapping for birds;

b) escape attempts;

c) ~~high frequency~~ vocalisations referring to ~~(*distress* calls) of high frequency (poultry)~~;

d) injuries ~~and *pain* caused by excessive force of restraint or shackling;~~.

e) respiratory distress.

~~e) fear caused by prolonged restraint, which may exacerbate insecure or excessive restraint.~~

3.) Recommendations:

Stunning methods that avoid handling, shackling and inversion of conscious animals should always be preferred.

Where, this is not possible, ~~A~~animals should be handled and restrained to minimise ~~without provoking~~ struggleing or attempts to escape.

~~Avoid inversion of conscious animals.~~

~~Avoid shackling of conscious animals but there is no real way to prevent or correct shackling, however, as it is a part of some of the *stunning* methods most commonly used in slaughter plants.~~

Shackle lines ~~must~~ should be constructed and maintained so they do not jolt ~~birds~~animals ~~as~~ because this is likely to stimulate wing flapping ~~(poultry)~~ or struggleing. Shackle line speeds ~~must~~ should be optimised so that they do not cause the ~~birds~~animals to struggle. Shackling duration prior to *stunning* should be kept to a minimum.

To minimise wing flapping ~~(poultry)~~ or struggleing, breast support should be provided to the birds from the shackling point up to the stunner.

~~Inappropriate shackling, such as shackles that are too narrow or too wide shackles, birds~~animals ~~being pushed into the shackles with force, birds~~animals ~~shackled by one leg, or shackled on two different adjacent shackles, should be avoided.~~

Inappropriate shackling can be prevented by the appropriate training of ~~the~~ relevant staff, by rotating the staff to avoid boredom and fatigue ~~training staff to handle birds~~animals ~~with care and compassion, by an competent professional, shackleing birds~~animals ~~gently by both legs and killing injured birds~~animals ~~before shackling, by rotating staff at regular intervals to avoid boredom and fatigue~~ and by using shackles that are appropriate and adjustable for ~~to~~ the species and size of the ~~birds~~animals.

4.) Species-specific recommendations:

Rabbits:

Restraining for head-only electrical *stunning* is manual and involves holding the rabbit with one hand supporting its belly, and the other hand guiding the head into the *stunning* tongs or electrodes.

Rabbits should not be lifted or carried by the ears, head, hair or, one leg, or by the skin at the back of the neck without supporting the body.

Poultry:

Shackling should not be used with heavy birds ~~like~~ such as parent *flocks,* turkeys or with birds that are more susceptible to fractures ~~like~~ (e.g. end-of-lay hens).

Poultry should not be lifted or carried by the head, neck, wings or one leg.

Article 7.5.29~~26~~.

Head-only electrical stunning of animals in containers

1~~.~~) Animal welfare concerns:

Electrical *stunning* involves application of an electric current ~~to~~across the brain of sufficient magnitude ~~magnitude current and intensity~~ to induce immediate unconsciousness [EFSA, 2004; Grandin, 1980]. The main *hazards* preventing effective electrical *stunning* are: incorrect electrode placement, poor contact, dirty or corroded electrode, electrical arcing, high contact resistance caused by hair and feathers ~~wool~~ or dirt on the animal surface~~,~~ and inappropriate electrical parameters (low voltage/current or high frequency [EFSA, 2004]).

2~~.~~) Animal-based and other ~~measurables~~ measures ~~include~~:

~~Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, and just before and during bleeding until death occurs is confirmed [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].~~

~~No indicator should be relied upon alone.~~ Multiple indicators should be used to determine whether a stun is effective and the animal is unconscious.

Animal-based measures of an effective stun are: ~~An effective stun is characterised by the presence of all the following signs:~~ tonic-clonic seizures; ~~loss of posture;~~ apnoea; ~~and~~ absence of corneal or ~~reflex; absence of and~~ palpebral reflex.

Animal-based measures of ineffective stun or recovery of consciousness are:~~The presence of any of the following signs indicate a high risk of ineffective stun or recovery of consciousness:~~ vocalisation; spontaneous blinking; righting reflex; presence of corneal ~~reflex;~~or palpebral reflex; rhythmic breathing~~.~~; spontaneous swallowing and head shaking.

3~~.~~) Recommendations:

Animals should be stunned as soon as they are restrained.

~~To minimise any disturbance to birds during shackling, where shackles are wet to improve conductivity, they should be wet only prior to birds' legs being placed in them.~~

In the case of ineffective *stunning* or recovery, animals should be re-stunned ~~immediately~~ using a backup system ~~or and~~ or be ~~immediately~~ killed immediately. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be used, cleaned, maintained and stored following the manufacturer's recommendations.

Constant current stunners ensure that the minimum current is provided to the animal independently from individual impedance and should always be preferred to constant voltage stunners ~~since because the first ones former ensure that the minimum current is provided to the animal independently from individual impedance~~.

Regular calibration of the equipment according to the manufacturer's procedure ~~are~~ is recommended. Effectiveness of the *stunning* should be monitored regularly.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters and~~or~~ follow the manufacturer's recommendations for *stunning*, such as:

– shape, size and placement of the electrodes [AVMA, 2016];

– contact between electrode and head;

– electrical parameters (current intensity [A], waveform type [AC and DC], voltage [V] and frequency [Hz]);

– visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors and displays voltage and applied current.

4.) Species-specific recommendations:

The *Competent Authority* should determine Eeffective electrical parameters, should be determined based on scientific evidence data on the welfare outcomes for different types of animals in accordance with point 5 of Article 7.1.4.

For head-only *stunning*, minimum parameters are recommended for the following species:

– 240 mA for hens and broiler chicken [EFSA, 2019],

– 400 mA for turkeys [EFSA, 2019],

– 600 mA for geese and ducks [EFSA, 2019],

– 140 mA for rabbits (100V of a 50 Hz sine wave AC) [EFSA, 2020a].

Article 7.5.3027.

Electrical water-bath stunning for poultry

1.) Animal welfare concerns:

In electrical water-bath *stunning* poultry are inverted and hung shackled by the legs from a shackle line. The bird's head has direct contact with the water-bath, and an electric current is passed from the water through the bird to the leg shackle. *Hazards* that may prevent effective electrical *stunning* are: lack of contact between head and water, differences in individual bird resistance, improper system grounding, pre-stun shocks due to wings contacting water before the head, and the use of inappropriate electrical parameters (low voltage/current or high frequency [AVMA 2016]).

Hazards that increase the likelihood of animals experiencing pre-stun shocks are: poor handling at shackling, inappropriate line speed, physical contact between birds, incorrect angle of entry ramp, wet entry ramp wetted by charged water, incorrect water-bath height, and shallow immersion.

Factors affecting individual bird resistance include the resistance between the shackle and the leg (leg/shackle interface), shackling on top of a severed foot, shackling by one leg, poor shackle position, incorrect shackle size, dry shackles, scale on the shackle surface, and keratinised skin on the legs (e.g. older birds).

Where inappropriateinsufficient electrical *stunning* parameters (e.g. high frequency) are used, conscious animals are at risk of being electro-immobilised or paralysed causing *pain* and suffering.

2.) Animal-based and other measurables measures include:

Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, and just before and during bleeding until death occurs is confirmed [EFSA, 2019; EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

No indicator should be relied upon alone. Multiple indicators should be used to determine whether a stun is effective and the animal is unconscious.

Animal-based measures of an effective stun are An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex; absence of or palpebral reflex.

Animal-based measures of ineffective stun or recovery of consciousness are The presence of any of the following signs indicate a high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex or palpebral reflex; rhythmic breathing; spontaneous swallowing; and head shaking.

3.) Recommendations:

The height of the water-bath stunner must should be adjusted so that the birds' heads are completely immersed in the water cannot pull themselves up and avoid the stunner. Avoid distractions such as people walking under the birds as because this can cause birds to pull up.

Personnel should watch for short or stunted birds as these birds will not be able to make contact with the water and will not be stunned. These birds should be stunned in the slaughter line (e.g. penetrative captive bolt) or removed and euthanised.

The rail of the shackle line should run smoothly. Sudden movement such as jolts, drops or sharp curves in the line may cause birds to flap and avoid the stunner.

To minimise any disturbance to birds during shackling, where shackles are wet to improve conductivity, they could should be wetted only prior to birds' legs being placed in them.

Pre-stun shocks should be avoided and can be reduced by having a smooth shackle line and entry in to the water-bath and by adjusting the water level of the bath to minimise overflow.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system and or be killed immediately. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be used, cleaned, maintained and stored following the manufacturer's recommendations.

Constant current stunners should always be preferred to constant voltage stunners since the first ones because the former ensure that the minimum current is provided to the animals independently from individual their impedance.

Regular calibration of the equipment according to the manufacturer's procedure are is recommended. Effectiveness of the *stunning* should be monitored regularly.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters or follow the manufacturer's recommendations for *stunning*, such as:

– water level;

– number of birds in the water-bath;

– contact between water and head, as well as between the legs and the leg shackle;

– electrical parameters (current intensity [A], waveform type [AC and DC], voltage [V] and frequency [Hz]);

– visual or auditory warning system to alert the operator to proper or improper function, such as a device that monitors and displays voltage and applied current.

Ensure an optimum combination of voltage and frequency during electrical water-bath *stunning* practices, to maximise the effectiveness of *stunning*.

Hazards to *animal welfare* hazards such as inversion of conscious inversion of birds, pre-stun shocks, and variability in electrical current delivered to each bird are inherent risks of electrical water-bath *stunning*. The use of electrical water-bath *stunning* should be avoided and replaced by Thus, alternative *stunning* systems which avoid these associated animal welfare *hazards* should be preferred.

4.) Species-specific recommendations:

The *Competent Authority* should determine effective Effective electrical parameters, should be based on scientific evidence for different types and species of birds.

~~The *Competent Authority* should determine~~ Effective electrical parameters should be based on scientific ~~evidence~~ data on the welfare outcomes for different types ~~and species~~ of animals ~~birds~~ in accordance with point 5 of Article 7.1.4.

For water-bath *stunning* depending on the frequency, minimum parameters are recommended for the following species [EFSA, 2019]:

- For f~~F~~requency below 200 Hz:
  - 100 mA for chicken,
  - 250 mA for turkeys,
  - 130 mA for ducks and geese,
  - 45 mA for quails.
- For frequency from 200 to 400 Hz:
  - 150 mA for chicken,
  - 400 mA for turkeys.
- For frequency from 400-600 Hz:
  - 200 mA for chicken,
  - 400 mA for turkeys.

Birds should receive the current for at least 4 seconds.

Ducks, geese and quails should not be stunned at frequencies higher than 200 Hz [EFSA, 2019].

Chicken and turkeys should not be stunned at frequencies higher than 600 Hz [EFSA, 2019].

Article 7.5.31~~28~~.

Mechanical stunning of animals arriving in containers

The mechanical methods described here are penetrative and non-penetrative captive bolt systems~~percussive blow to the head, cervical dislocation and decapitation~~. Effective mechanical *stunning* requires a severe and immediate damage to the brain caused by the application of mechanical force. For that reason, cervical dislocation and decapitation cannot be considered as *stunning* methods.

1~~.~~) Animal welfare concerns:

Mechanical methods require~~d~~ precision and often physical strength to restrain and stun the animals. ~~A c~~Common causes ~~for~~ of the misapplication of these methods ~~is~~ are ~~the~~ a lack of proper skill and ~~the~~ operator fatigue.

Penetrative and non-penetrative c~~C~~*aptive bolt*

An incorrect shooting position or incorrect captive bolt parameters (not hitting the skull with sufficient force) will mis-stun~~ned~~ the animal, leaving it conscious and leading to serious wounds and consequently *distress*, fear and *pain*~~, suffering, and fear~~.

Improper captive bolt parameters may be linked to: the use of an inappropriate~~improper~~ gun (bolt diameter); inappropriate~~improper~~ cartridges~~,~~; or an overheated or badly maintained gun.

~~*Percussive blow to the head*~~

~~An incorrect application of the blow, by not hitting the brain with sufficient force will also mis-stunned the animals leading to serious wounds and consequently *pain* and fear.~~

~~In addition, the blow might not be consistently effective when delivered to an animal held upside down by its legs (part of the energy is dissipated by the movement of the body instead of damaging the brain).~~

~~*Cervical dislocation and decapitation*~~

~~Because neither method applyies to the brain, t~~The loss of consciousness ~~may be delayed. is not immediate and, in some cases,W when the method is not properly applied there.There is a risk of neck crushing and the *distress*, fear and *pain* and fear of the animal might be prolonged.~~

~~Decapitation~~

~~In addition, d~~Decapitation ~~is associated with an open wound leading to intense *pain* and delayed loss of consciousness, leading to intense *distress*, fear and *pain* [EFSA, 2019].~~

2~~.~~) Animal-based and other ~~measurables~~ measures ~~include~~:

Penetrative and non-penetrative ~~C~~captive bolt: ~~and percussive blow to the head~~

~~With birds, s~~Severe convulsions (wing flapping ~~[poultry]~~ and leg kicking i.e. uncontrolled muscular movements) occur immediately after ~~shooting or percussive blow~~ the mechanical *stunning* intervention. This is due to the loss of control of the brain over the spinal cord. Since mechanical *stunning* is applied ~~on~~ to individual animals, its efficacy can be assessed immediately after the stun [Nielsen *et al.*, 2018].

~~Effectiveness of stunning should be monitored at different stages: immediately after stunning, and just before and during bleeding until death is confirmed occurs [EFSA, 2019; EFSA, 2013a; EFSA, 2013b; AVMA, 2016].~~

Animal-based measures of an effective stun are:~~An effective stun is characterised the following signs:~~ the absence of corneal ~~reflex;or~~ or palpebral reflex; apnoea~~,~~; ~~the absence of rhythmic breathing and the presence of immediate collapse~~ loss of posture; presence of tonic-clonic seizure.

Animal-based measures of ineffective stun or recovery of consciousness are:~~The presence of any of the following signs indicates a high risk of ineffective stun or recovery of consciousness:~~ vocalisations; spontaneous blinking; righting reflex; presence of corneal reflex~~or~~ or palpebral reflex; rhythmic breathing.

~~*Cervical dislocation and decapitation*~~

~~Death can be confirmed from several indicators: complete severance between the brain and the spinal cord (i.e. gap between neck vertebrae and base of skull), permanent absence of breathing, absence of corneal or palpebral reflex, dilated pupil, or relaxed carcass [EFSA, 2013a].~~

~~*Decapitation*~~

~~ABM for death by decapitation: dDeath can be confirmed by complete severance between the head and the body~~

3~~.~~) Recommendations:

Penetrative and non-penetrative ~~C~~captive bolt ~~and percussive blow to the head~~ should only be used as backup or for small-~~scale~~ throughput slaughtering as in small *slaughterhouses/abattoirs* or on-farm slaughter or for emergency *killing*.

Penetrative and non-penetrative ~~C~~captive bolt:

The captive bolt gun should be used, cleaned, maintained and stored following the manufacturer's recommendations.

The power of the cartridge, compressed air line pressure or spring should be appropriate for the species and size of birds. Cartridges should be kept dry and the gun regularly inspected and maintained.

Effectiveness of the *stunning* should be monitored ~~regularly~~.

Because it requires precision, this method should only be applied with proper restraint of the head of the animals~~.~~ In addition, in the case of birds, they should be restrained in a bleeding cone to contain wing flapping.

The captive bolt should be pointing perpendicularly on the parietal bones of birds.

Placement is different for birds with ~~or~~ and without combs:

Without comb:

The placement of the device should be directly on the midline of the skull and at the highest/widest point of the head with the captive bolt aimed directly down towards the brain [AVMA, 2020].

With comb:

~~As far as captive bolt i~~In chickens (and ~~other poultry with comb development) is concerned, the~~ The placement of the device should be directly behind the comb and on the midline of the skull with the captive bolt aimed directly down towards the brain of the bird [AVMA, 2020].

~~The power of the cartridge, compressed air line pressure or spring should be appropriate for the species and size of birds. Cartridges should be kept dry and the gun regularly inspected and maintained.~~

~~This method should be dealt with a single sufficiently strong hit the frontoparietal region of the head and should resulted in loss of auditory evoked potentials when using an EEG in broilers and broiler breeders.~~

~~Fatigue of the operator can lead to inconsistency in application, creating concern that the technique may be difficult to apply humanely to large numbers of birds. It should not be done with the animal's head hanging down since inversion is stressful and part of the energy of the blow will be dissipated by the movement of the body.~~

~~It should not be used as a routine method and should be limited as a back-up method limited to small animals (e.g. up to 3kg liveweight manually and up to 5 kg mechanical).~~

Rabbits:

The device should be placed in the centre of the forehead, with the barrel in front of the ears and behind the eyes. The device should be discharged twice in rapid succession at the pressure recommended for the age and size of the rabbit [Walsh *et al.,* 2017].

~~The power of the cartridge, compressed air line pressure or spring should be appropriate for the animal species and size of birds. Cartridges should be kept dry and the gun regularly inspected and maintained.~~

~~As an indication for broiler chickens, the appropriate specifications for captive bolt *stunning* are a minimum of 6-mm bolt diameter driven at an air pressure of 827 kPa to a penetration depth of 10 mm [Raj and O'Callaghan, 2001].~~

There should be a sufficient ~~bolt~~ number of bolt guns such that they are allowed to cool between operations~~, and they should be cleaned and maintained according to manufacturer's instructions~~.

~~*Percussive blow to the head*~~

~~This method~~ The blow ~~should be dealt with a single sufficiently strong hit placed in the frontoparietal region of the head resulted in loss of auditory evoked potentials in broilers and broiler breeders.~~

~~Fatigue of the operator can lead to inconsistency in application, creating concern that the technique may be difficult to apply humanely to large numbers of birds. It should not be done with the animal's head hanging down since inversion is stressful and part of the energy of the blow will be dissipated by the movement of the body.~~

~~Considering that the application of this method is entirely manual and prone to error, percussive blow might be used only when no other *stunning* method is available and, by establishing a maximum number of animals per operator in time to avoid errors due to operator fatigue.~~

~~It should not be used as a routine method and should be limited as a back-up method limited to small size animals (e.g. up to 3kg liveweight manually and up to 5 kg mechanical).~~

~~This method should not be used in rabbits because of the difficulties to apply this method efficiently.~~

~~*Cervical dislocation*~~

~~Cervical dislocation is not recommended in conscious animals and should only be used when there are no other options available.should not be used in conscious birds under any circumstances. avoided since it does not render the animal unconscious immediately.~~

~~It should not be used as a routine method and should be limited to use as a back-up method limited to for small size animals (e.g. up to 3kg liveweight manually and up to 5 kg mechanically).~~

~~Mechanical dislocation should be preferred to manual dislocation as because the efficiency of the firstformer is less dependent on the operator's strength than the latter.~~

~~Cervical dislocation should not be undertakenperformed with tools such as pliers as they cause neck crushing tools (e.g. pliers),rather than concussion, and consequently *pain* and fear. These tools may not cause complete severance between the brain and the spinal cord.~~

~~*Decapitation*~~

~~Decapitation should not be used in conscious rabbits because it does not render the animal unconscious immediately.~~

4.) Species-specific recommendations:

~~Because of their size, heavy animals such as turkeys, geese or mature rabbits should not be stunned through percussive blow to the head or cervical dislocation.~~

Turkeys, ducks ~~and~~, geese and chickens may be also properly stunned by non-penetrative captive bolt [Walsh *et al.*, 2017; Woolcott *et al.*, 2018; Gibson *et al.*, 2019, Stiewert *et al.* 2021; HSA, 2023].

Article 7.5.32~~29~~.

Controlled atmosphere stunning for animals in containers ~~poultry~~

Animals may be exposed to controlled atmosphere *stunning* methods either directly in crates or after being unloaded on a conveyor belt. Animals are not subject to restraint. Controlled atmosphere *stunning* includes exposure to carbon dioxide, inert gases, mixtures of carbon dioxide with inert gases or low atmosphere pressure (LAPS). ~~The effectiveness and animal welfare impacts of LAPS are still being evaluatedas it is a newer form of controlled atmosphere stunning in comparison with other methods, ; so far it has only been demonstrated to be effective for the stunning of chickens been studied in poultry and therefore is not suitable for use in rabbits or other animals without further study.~~

1.) Animal welfare concerns:

A common concern of all controlled atmosphere *stunning* methods is the risk of insufficient exposure of animals to the modified atmosphere, which can result in animals recovering ~~returning to~~ consciousness before or during bleeding and ~~cause~~causing

respiratory distress ~~respiratory~~, fear and *pain*~~and fear~~. The insufficient exposure to the modified atmosphere may be due to either ~~a~~ too short exposure time, a too low concentration of gas, too high stocking density or a combination of these variables.

These variables are critical because animals being stunned in large groups need special attention to ensure unconsciousness prior to neck cutting. For this reason, the duration of unconsciousness induced needs to be longer than required by other *stunning* methods to ensure that animals do not recover consciousness prior to being killed.

Furthermore, *hazards* causing increased *distress* during induction of unconsciousness are irritant or aversive gas mixtures, low gas temperature and humidity. In the case of exposure to carbon dioxide, there is a risk that animals are exposed to ~~a~~ too high a concentration of this gas, leading to *pain* and *distress*. Exposure of conscious animals to more than 40% carbon dioxide (CO_2) will cause painful stimulation of the nasal mucosa and aversive reactions.

Low atmospheric pressure systems (LAPS) should not be confused with decompression~~.~~ : LAPS utilise a slow removal of air where animals exhibit minimal to no aversive behaviours. Decompression is a fast process that is associated with ~~induction of~~ *pain* and respiratory distress.

2~~.~~) Animal-based and other ~~measurables~~ measures ~~include~~:

It may be difficult to monitor the effectiveness of controlled atmosphere *stunning* ~~due to~~ because of limited access to ~~observation~~ observe ~~of~~ animals during the *stunning* process. All chamber-type systems should have either windows or video cameras so that problems with induction can be observed. If problems are observed, there is a need to take immediate~~ly any~~ corrective measure~~s~~ that could alleviate the suffering of the animals concerned.

Therefore, it is essential that the unconsciousness ~~death~~ of animals is confirmed at the end of the exposure to the controlled atmosphere.

~~Death~~ Unconsciousness can be confirmed ~~from~~ by ~~permanent absence of breathing~~ apnoea, absence of corneal ~~reflex~~ or palpebral reflex, dilated pupils and relaxed carcass.

Since animal-based measures are difficult to monitor, resource-based measures should also be used such as monitoring of gas concentration(s), exposure time, gas displacement rate, and ~~decompression~~ rate of air removal (for LAPS ~~low atmosphere pressure~~).

3~~.~~) Recommendations:

Conscious animals should not be exposed to carbon dioxide concentrations exceeding 40%. Any compressed gas should also be vaporised prior to administration and humidified at room temperature to prevent the risk of animals experiencing thermal shock.

The duration of exposure and the gas concentration should be designed and implemented in such a way that all animals are rendered unconscious until *death* ~~dead before being shackled~~.

Gas concentrations and exposure time, temperature and humidity ~~must~~ should be monitored continuously at the level of the animal inside the chamber.

Stunning systems should have visual and auditory warning system to alert the operator to improper function, such as inappropriate gas concentration or decompression rate.

In the case of low atmosphere pressure *stunning* ~~decompression~~ the rate of air removal should be monitored continuously. The decompression rate should not be greater than or equivalent to a reduction in pressure from standard sea level atmospheric pressure (760 Torr) to 250 Torr in not less than 50 s. During ~~a~~ the second phase, a minimum atmospheric pressure of 160 Torr ~~shall~~ should be reached within the following 210 s.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

4.) Species-specific recommendations:

The use of Low aAtmosphere pPressure *stunning* should be restricted to broilers and newly hatched chicks. has only been scientifically studied on commercial broilers chickens [Gurung *et al.*, 2018; Jongman and Fisher, 2021] and therefore should not be used for other animals until further information is available.

The recommended CO_2 displacement rate for rabbits is 50-60% of the chamber or cage volume/min as this results in a significantly shorter time to insensibility and death [Walsh *et al.*, 2016, AVMA 2020]. Exposure to CO_2 at high concentrations can reduce pre-stun handling and produce irreversible *stunning* in rabbits. With a stun-to-stick interval of up to 2 min, 200 s of exposure at 80%, 150 s at 90% and 110 s at 98% are recommended [Dalmau *et al.*, 2016]. While there are advantages to high CO_2 exposure in rabbits, it is not without welfare concerns (aversion, vocalisation).

Article 7.5.3330.

Bleeding in of animals arriving in containers

1.) Animal welfare concerns

In poultry, tThe most common animal welfare concern at the time of bleeding is recovery of consciousness due to ineffective electric water bath *stunning* practices or an ineffective bleeding. There are a lot many of factors that determine the efficacy of a *stunning* procedure such as type of chicken animal (broiler, breeder, layer), animal weight, voltage, frequency, impedance and duration of *stunning* or gas (mixture) concentration and exposure [Zulkifli *et al.*, 2013; Raj, 2006; Wotton & Wilkins, 2004].

Improper *stunning* practice leads to the risk of animals suffering experiencing *distress*, fear and *pain* fear, *distress*, and *pain*, during and after *slaughter* if they regain consciousness. There is also an additional risk of injury on to bones (coracoid and scapula), wings and joints due to flapping struggling if birds animals regain consciousness.

Bleeding without prior *stunning* increases the risk ofcauses animal suffering because the incision to sever blood vessels results in substantial tissue damage in areas well supplied with nociceptors. The activation of these nociceptors causes the animal to experience *pain* [Gregory, 2004; Gibson *et al.*, 2009]. Loss of consciousness due to bleeding is not immediate and there is a period during which the animals can feel experience *distress*, fear, and *pain* and *distress* [Gregory, 2004; Johnson *et al.*, 2015].

In case of bleeding without *stunning*, higher more cases of injury, bruisesing, haemorrhage and broken body parts are expected to occur due to wing flapping and violent muscular contractions [McNeal *et al.*, 2003).

Bleeding duration also plays an integral part in processing, where animals that have not undergone a sufficient bleeding period (a minimum 40 sec), may still be alive upon reaching the scalding tank. Live and conscious birds, if not removed prior to scalding, will then be subjected to additional *pain* stimulators from the heat inside the scalding tank and *death* by drowning.

2.) Animal-based and other measurables measures include:

The main animal-based measurables measure is the blood flow (rate and duration). For animal-based and other measurables measures of return of consciousness after *stunning* (see Article 7.5.16Article 7.5.26. to Article 7.5.29).

One of the most common parameters in determining bleeding efficiency is the percentage of blood loss, where the amount of blood loss is estimated through from the difference between pre-slaughter weight and post-slaughter weight [Velarde *et al.*, 2003; Sabow *et al.*, 2015].

For poultry birds, the presence of 'red-skin' carcasses may be the result of ineffective *killing* and with live birds entering the scalding tank.

The effectiveness of a *stunning* procedure on birds can be seen through the following signs: absence of corneal reflex, loss of posture tonic-clonic seizures and apnoea. Presence of one or more signs during bleeding may be the result of ineffective *stunning* procedure.

3.) Recommendations:

The *slaughterhouse/abattoir* operators should ensure that:

- both carotid arteries ~~should be~~ are severed;
- qualified personnel take random samples of ~~birds~~ animals ~~between~~ after the end of *stunning* and before bleeding to ensure ~~birds~~ animals are not showing signs of consciousness;
- immediately after bleeding, qualified personnel ~~right after bleeding~~ check that the jugular veins, carotid arteries~~y~~ and trachea ~~windpipe~~ were cut thoroughly, guaranteeing ~~a well~~ an efficient bleeding process ~~afterwards~~.
- ~~the slaughter line speed allows a minimum bleeding period of 90 seconds (for chickens) so that there is minimum blood loss of 60 % percent before reaching the scalding tank or other potentially *pain*ful operation;~~
- ~~qualified personnel check that at the bleeding line, especially before scalding, birds are completely dead. Birds that are still alive need to be euthanised immediately removed from shackle.~~

Decapitation should ~~not~~ be applied as bleeding method only ~~in~~ to unconscious ~~birds~~ animals.~~used as a bleeding technique because it does not allow monitoring possible return of consciousness.~~

4.) Species-specific recommendations:

- for chicken, the slaughter line speed should allow a minimum bleeding period of 90 seconds ~~(for chickens)~~ so that there is minimum blood loss of 60 % before reaching the scalding tank or other potentially painful operation;
- qualified personnel should check that at the bleeding line, especially before scalding, birds are completely dead. Birds that are still alive need to be euthanised immediately and removed from shackle.

~~None identified.~~

Article 7.5.34.~~31~~

Emergency killing of~~n~~ animals arriving in containers

This article addresses animals that show signs of severe *distress* or *pain* ~~or other types of severe~~ ~~suffering~~ before being unloaded or within the *slaughterhouse/abattoir*. These animals may correspond to animals unfit to travel as listed in Article 7.3.7. Principles described may also apply to animals that are not suitable for *slaughter* for commercial reasons, even if they do not present signs of *pain* or suffering.

1.) Animal welfare concerns:

Some animals can arrive at *slaughterhouses/abattoirs* with injuries or severe illnesses that can cause undue *distress, pain* ~~and suffering~~ suffering.

2.) Animal-based and other ~~measurables~~ measures ~~include~~:

Animals requiring emergency *killing* are those~~, among others that present with~~ with severe injuries such as fractures, bone dislocations, and large open wounds.

They may also present clinical signs of serious illness or be~~ing~~ in a state of extreme weakness.

3.) Recommendations:

Animal handlers should euthanise the animals as soon as they are identified at arrival, during lairage or at the time of shackling.

Emergency *killing* should be systematically recorded and analysed to improve procedures and prevent recurrences.

~~4.) Species-specific recommendations:~~

~~None identified yet.~~

Article 7.5.3532.

Methods, procedures or practices that should not be used ~~unacceptable on animal welfare grounds~~ for animals arriving in containers

1) ~~None of t~~The following practices for handling animals ~~are unacceptable and they~~ should not be used under any circumstances:

   a) applying pressure using an injurious object or applying an irritant substance to any part of the body of ~~the~~ an animal;

   b) hitting animals including with instruments such as ~~large~~ sticks, notably sticks with sharp ends, ~~metal~~ piping, stones, fencing wire or leather belts;

   c) kicking, throwing or dropping animals;

   d) stepping on or crushing animals;

   ~~d~~e) grasping, lifting or dragging animals only by ~~some~~ body parts such as their tail, head, ears, limbs, hair or feathers.

   ~~e) dragging animals by any body parts.~~

2) ~~None of t~~The following practices for restraining animals ~~are unacceptable and~~ should not be used:

   a) mechanical clamping of the legs or feet of the animals as the sole method of *restraint*;

   b) breaking legs, cutting leg tendons or blinding animals;

   c) applying electrical current that does not span the brain; ~~such as the use of the electrical *stunning* method with a single application leg-to-leg~~

   d) severing the brain stem by piercing through the eye socket or skull bone;

   e) crushing the neck ~~crushing~~.

   In ~~poultry~~ birds, electro-immobilisation for neck-cutting or preventing wing flapping during bleeding, or the method of brain piercing through the skull without prior *stunning* should not be used under any circumstances ~~are unacceptable~~.

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Annex 12

CHAPTER 8.8.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

EU	**The EU supports the adoption of this revised chapter.** **The EU takes this opportunity to thank the Code Commission and the Scientific Commission for assessing EU comments on the importation of vaccinated animals and for the clarifications provided.** **The EU takes note that the request to review and simplify the requirements for maintenance of official FMD status is being assessed by both Commissions and we look forward to it. The EU remains open to support this work in any way possible.**

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 the following animals (hereafter 'susceptible animals') with FMDV:

– animals of the ~~families~~ family *Suidae* ~~and *Cervidae*,~~;

– animals of the subfamilies *bovinae*, *caprinae* and *antilopinae* of the family *Bovidae* and family *Cervidae* (hereafter 'ruminants')~~,~~; and

– *Camelus bactrianus* ~~with FMDV (hereafter 'susceptible animals')~~.

~~2bis) For the purposes of this chapter, a 'bovine' means an animal of the species *Bos taurus* or *Bos indicus*.~~

3) The following defines the occurrence of *infection* with FMDV:

a) FMDV has been isolated and identified as such from a sample from a~~n~~ susceptible animal ~~listed in point 2~~; or

b) antigen or nucleic acid specific to FMDV has been detected in a sample from a~~n~~ susceptible animal ~~listed in point 2~~, showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *case* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or

c) antibodies to structural proteins (SP) or non-structural proteins (NSP) of FMDV, that are not a consequence of *vaccination*, have been detected in a sample from a~~n~~ susceptible animal ~~listed in point 2~~, showing clinical signs consistent with FMD,

or epidemiologically linked to a confirmed or suspected *case* of FMD, or giving cause for suspicion of previous association or contact with FMDV.

4) Transmission of FMDV in a vaccinated *population* is demonstrated by change in virological or serological evidence indicative of recent *infection*, even in the absence of clinical signs or any cause for suspicion of previous association or contact with FMDV. Transmission of FMDV shall be notified to WOAH as occurrence of *infection*.

5) For the purposes of the *Terrestrial Code*, the *incubation period* of FMD shall be 14 days.

6) ~~*Infection* with FMDV can give rise to disease of variable severity and to transmission of FMDV.~~ FMDV may persist in the pharynx and associated lymph nodes of some ruminants ~~for a variable but limited period of time~~ beyond 28 days after *infection*, but not indefinitely. Such animals have been termed carriers. However, ~~T~~the only species for which transmission of FMDV has been proven from ~~persistently infected individuals~~ carriers is the African buffalo *(Syncerus caffer)*. ~~However,~~ and transmission of FMDV from African buffalo to domestic livestock is rare.

7) Standards for ~~diagnostic tests~~ diagnosis and vaccines, as well as information on the epidemiology, are described in the *Terrestrial Manual*.

Article 8.8.1bis.

Safe commodities

When authorising the importation or transit of the following *commodities, Veterinary Authorities* should not require any type of FMD-related conditions, regardless of the *animal health status* of the *exporting country* or *zone*:

1) UHT *milk* and derivatives thereof;

2) heat-treated *meat products* in hermetically sealed container with a F_0 value of 3 or above;

3) *protein meal*;

4) gelatine;

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

6) limed hides, pickled pelts, and semi-processed leather;

7) extruded dry pet food.

Other *commodities* of susceptible animals can be traded safely if in accordance with the relevant articles in this chapter.

Article 8.8.2.

Country or zone free from FMD where vaccination is not practised

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:

1) there has been no ~~*case* of~~ *infection* with FMDV;

2) the *Veterinary Authority* has current knowledge of, and authority over, all *herds* of domestic and *captive wild* susceptible animals in the country or *zone*;

3) the *Veterinary Authority* has current knowledge of the distribution and habitat of *wild* and *feral* susceptible animals in the country or *zone*;

4) appropriate *surveillance* has been implemented in accordance with:

a) Article 1.4.6. where historical freedom can be demonstrated; or

b) Articles 8.8.40. to 8.8.42. where historical freedom cannot be demonstrated, which includes the detection of clinical signs of FMD and demonstrates:

i) no *infection* with FMDV in unvaccinated animals;

ii) no transmission of FMDV in previously vaccinated animals;

5) measures to prevent the introduction of the *infection* have been in place; in particular, the importations or movements of *commodities* into the country or *zone* have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*. Unless otherwise specified in this chapter, movements of *commodities* within a country between *zones* of different *animal health status* should comply with the same requirements as for importation; ~~Introduction of vaccinated animals have only been carried out either:~~

~~a) from countries or *zones* free from FMD where *vaccination* is practised in accordance with Articles 8.8.11. or 8.8.11bis., or~~

~~b) for *slaughter* in accordance with Articles 8.8.8. and 8.8.9.bis.; For ruminants, the head, including the pharynx, tongue and associated lymph nodes, was either destroyed or treated in accordance with Article 8.8.31.;~~

6) *vaccination* against FMD is prohibited and the prohibition has been effectively implemented and supervised.

The country or *zone* will be included in the list of countries or *zones* free from FMD, where *vaccination* is not practised in accordance with Chapter 1.6.

Retention on the list requires annual reconfirmation of compliance with all points above and provisions under point 4 of Article 1.4.6. Documented evidence should be resubmitted annually for all points above. Any changes in the epidemiological situation or other significant events should be notified to WOAH in accordance with Chapter 1.1.

Provided the conditions of point 4 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~~ is in place, including effective separation from other susceptible domestic *population*s or *wildlife*;

– the susceptible 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*.

A country or *zone* free from FMD where *vaccination* is not practised may maintain its free status despite an incursion of African buffaloes from a neighbouring infected country or *zone* provided that it is demonstrated that the provisions in this article continue to be met and documented evidence has been submitted to and accepted by WOAH.

Article 8.8.3.

Country or zone free from FMD where vaccination is practised

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*:

1) for at least the past 12 months:

   a) there has been no transmission of FMDV;

   b) there has been no *infection* ~~of~~ with FMDV ~~in the unvaccinated subpopulations~~;

   c) the *Veterinary Authority* has current knowledge of, and authority over, all *herds* of domestic and *captive wild* susceptible animals in the country or *zone*;

   d) the *Veterinary Authority* has current knowledge of the distribution and habitat of *wild* and *feral* susceptible animals in the country or *zone*;

   e) compulsory systematic *vaccination* in the target *population* has been carried out to achieve adequate *vaccination* coverage and population immunity; based on the epidemiology of FMD in the country or *zone*, ~~it may be decided to vaccinate only a defined *subpopulation* comprised of certain species or other subsets of the total susceptible population~~ the target *population* should be defined in accordance with Chapter 4.18.

   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) for the past 24 months:

   appropriate *surveillance* has been implemented in accordance with Articles 8.8.40. to 8.8.42. and demonstrates points 1 a) and 1 b) above.

The country or *zone* will be included in the list of countries or *zones* free from FMD where *vaccination* is practised in accordance with Chapter 1.6.

Retention on the list requires annual reconfirmation of compliance with all points above and relevant provisions under point 4 of Article 1.4.6. Documented evidence should be resubmitted annually for all points above. Any changes in the epidemiological situation or other significant events should be notified to WOAH in accordance with Chapter 1.1.

Article 8.8.3bis.

Transition of vaccination status in a country or zone free from FMD

As recommended in Article 4.18.10., *vaccination* programmes may include an exit strategy.

If a Member Country that meets the requirements of a country or *zone* free from FMD where *vaccination* is practised and is recognised by WOAH as such, wishes to change its status to country or *zone* free from FMD where *vaccination* is not practised, it should notify WOAH in advance of the intended date of cessation of *vaccination* and apply for the new status within 24 months of the cessation. The status of this country or *zone* remains unchanged until compliance with Article 8.8.2. is approved by WOAH. If the application for the new status is not provided within 24 months of the cessation or if the compliance is not approved by WOAH, then evidence should be provided that it complies with Article 8.8.3. Otherwise, the status of the country or *zone* as being free from FMD where *vaccination* is practised ~~will be~~ is suspended. ~~If the country or *zone* does not comply with requirements of Article 8.8.2., evidence should be provided that it complies with Article 8.8.3. Otherwise the status will be suspended.~~

If a Member Country that meets the requirements of a country or *zone* free from FMD where *vaccination* is not practised and is recognised by WOAH as such, wishes to change its status to country or *zone* free from FMD where *vaccination* is practised, it should provide WOAH with an application ~~and a plan following the structure of the Questionnaire~~ in accordance with Chapter 1.11. The status ~~as~~ of the country or *zone* as free from FMD where *vaccination* is not practised remains unchanged until the application and plan are approved by WOAH. As soon as it is recognised as free from FMD where *vaccination* is practi~~c~~ised, the country or *zone* ~~will~~ should begin the *vaccination*. Then ~~T~~the Member Country should provide evidence within six months that it has complied~~s~~ with Article 8.8.3. ~~for this time period.~~ Otherwise, the status ~~will be~~ is suspended.

Article 8.8.4.

Compartment free from FMD where vaccination is not practised

A *compartment* free from FMD where *vaccination* is not practised can be established in any country or *zone*. In defining such a *compartment* the principles of Chapters 4.4. and 4.5. should be followed. Susceptible animals in the free *compartment* should be separated from any other susceptible animals by the effective application of a *biosecurity plan*.

A Member Country wishing to establish a *compartment* free from FMD where *vaccination* is not 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* that:

   a) no *infection* with FMDV has occurred during the past 12 months;

   b) *vaccination* against FMD is prohibited;

   c) no animal vaccinated against FMD within the past 12 months is in the *compartment*;

   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 *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation;

   f) an *animal identification* and *traceability* system in accordance with Chapters 4.2. and 4.3. 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 in accordance with point 1.

The *compartment* should be approved by the *Veterinary Authority*. The approval should only be granted when no *infection* with, or transmission of, FMDV has occurred within a 10-kilometre radius of the *compartment* during the three months prior to the ~~effective establishment~~ application 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 4.4. and 4.5. should be followed. Susceptible animals in the free *compartment* should be separated from any other susceptible animals by the application of an effective *biosecurity plan*.

A Member Country wishing to establish a *compartment* free from FMD where *vaccination* is practised should:

1) have a record of regular and prompt animal disease reporting and, if not free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;

2) declare for the free *compartment* where *vaccination* is practised that:

   a) no *infection* or transmission of FMDV has occurred during the past 12 months;

b) compulsory systematic *vaccination* is carried out using a vaccine that complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection. The *vaccination* coverage and population immunity are closely monitored;

c) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;

d) 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* or transmission at an early stage with a high level of confidence;

e) an *animal identification* and *traceability* system in accordance with Chapters 4.2. and 4.3. is in place;

3) describe in detail:

a) the animal *subpopulation* in the *compartment*;

b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out according to point 1 and the *vaccination* plan;

c) implementation of points 2 b), 2 d) and 2 e).

The *compartment* should be approved by the *Veterinary Authority*. The approval should only be granted when no *infection* or transmission of FMDV has occurred within a 10-kilometre radius of the *compartment* during the three months prior to the ~~effective establishment~~ application of the *biosecurity plan*.

Article 8.8.5.

Country or zone infected with FMDV

A country or *zone* shall be considered as infected with FMDV when the requirements for acceptance as a country or *zone* free from FMD either where *vaccination* is not practised or where *vaccination* is practised are not fulfilled.

Article 8.8.5bis.

Establishment of a protection zone within a country or zone free from FMD

Susceptible animals in a country or *zone* free from FMD should be protected by the application of *biosecurity* that prevents the entry of FMDV into the free country or *zone*. Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*.

A *protection zone* may be established, in response to an increased risk of FMD, in accordance with Article 4.4.6. The *Veterinary Authority* should submit as soon as possible an application to WOAH, ~~in~~ supported ~~of the application,~~ by documented evidence that, in addition to the requirements of Article 4.4.6.:

1) the susceptible animal *populations* within the *protection zone* are clearly identified as belonging to the *protection zone;*

2) strict movement control of susceptible animals and their products is in place in line with the relevant provisions of this chapter;

3) ~~enhanced~~ increased *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in place in the *protection zone* and enhanced awareness in the rest of the country or *zone*;

4) intensified *biosecurity* in the *protection zone* is in place;

5) awareness campaigns aimed at the general public, breeders, traders, *veterinarians* and other relevant stakeholders are implemented;

6) a *biosecurity plan* is in place, which may include~~ing~~ the implementation of emergency *vaccination* ~~is in place~~, in particular when the *protection zone* is established in a country or *zone* free from FMD where *vaccination* is not practised.

The *protection zone* is considered as effectively established when the conditions described in this article and in Article 4.4.6. have been applied and documented evidence is submitted to and has been accepted by WOAH.

If *vaccination* is implemented in the *protection zone* established within a country or *zone* free from FMD where *vaccination* is not practised, the free status of the *protection zone* is suspended and the free status of the rest of the country or *zone* is not affected. The status of the *protection zone* can be recovered following point 1 of Article 8.8.7. Alternatively, should the Member Country wish to maintain *vaccination* in the *protection zone,* Article 8.8.3bis applies.

In the event of an *outbreak* within a previously free *protection zone*, the free status of the *protection zone* is suspended and the status of the *protection zone* can be recovered following Article 8.8.7., while the free status of the rest of the country or *zone* is not affected. Alternatively, if the *Veterinary Authority* establishes a *containment zone* after an *outbreak* in the *protection zone*, an application in accordance with Articles 4.4.7. and 8.8.6. should be submitted as soon as possible. In particular, when applying for a *containment zone*, it should be stated whether the boundaries would be the same as the boundaries of the *protection zone* or within the boundaries of the *protection zone*.

A *protection zone*, in which the free status has remained unchanged, should ~~be limited to less than~~ not last more than 24 months from the date of its approval by WOAH. During this period, ~~T~~the Member Country should either ~~apply for~~ inform WOAH of the ~~removal~~ lifting of the *protection zone* or apply for its official recognition of the *protection zone* as a ~~separate *zone* within 24 months from the date of its approval by WOAH~~ in accordance with either Article 8.8.2. or 8.8.3.

Article 8.8.6.

Establishment of a containment zone within a country or zone previously free from FMD

In the event of *outbreaks* within a country or *zone* previously free from FMD where *vaccination* is either practised or not, including within a *protection zone*, 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 WOAH, in addition to the requirements of Article 4.4.7. documented evidence that:

1) on suspicion, a standstill has been imposed on the suspected *establishments* and effective controls on the movement of animals and other *commodities* are in place in the country or *zone*;

2) on confirmation, the standstill and movement controls described in point 1 have been reinforced;

3) epidemiological investigations into the likely source of the *outbreaks* have been carried out;

4) *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) 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 these areas may be reinstated irrespective of the provisions of Article 8.8.7., once the *containment zone* has been approved by WOAH as complying with points 1 to 5 above.

In the event of recurrence of *infection* with FMDV in unvaccinated animals or 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 free status of the whole country or *zone* is suspended until the relevant requirements of Article 8.8.7. are fulfilled.

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

The recovery of the free status of the *containment zone* should be achieved within 24 months of its approval and follow the provisions of Article 8.8.7., otherwise the status of the rest of the country or *zone* is suspended.

Article 8.8.7.

Recovery of free status

1) When *infection* with FMDV occurs in a 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 NSP of FMDV to demonstrate no transmission of FMDV in the 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.

   The country or *zone* will regain its free status only after the submitted evidence, based on the provisions of Chapter 1.11., has been accepted by WOAH.

   The time periods in points 1 a) to 1 c) are not affected if official emergency *vaccination* of zoological collections has been carried out following the relevant provisions of Article 8.8.2.

   Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.8.2. applies.

2) When *infection* with FMDV occurs in a country or *zone* previously free from FMD where *vaccination* is not practised, the following waiting period is required to gain the status of 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 NSP of FMDV demonstrates no transmission of FMDV.

   The country or *zone* can gain the status of free from FMD where *vaccination* is practised only after the submitted evidence, based on the provisions of Chapter 1.11. has been accepted by WOAH.

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

3) When *infection* with FMDV or transmission of FMDV occurs in a country or *zone* previously free from FMD where *vaccination* is practised, one of the following waiting periods is required to regain this free status:

   a) six months after the disposal of the last animal killed where a *stamping-out policy*, with emergency *vaccination*, and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological *surveillance* based on the detection of antibodies to NSP of FMDV demonstrates no transmission of FMDV. This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of *infection* in the non-vaccinated *population* and absence of transmission of FMDV in the vaccinated *population* based on the provisions of points 7 and 8 of Article 8.8.40. as appropriate; or

   b) 12 months after the detection of the last *case* where a *stamping-out policy* is not applied, but where emergency *vaccination* and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological *surveillance* based on the detection of antibodies to NSP of FMDV demonstrates no evidence of transmission of FMDV.

   The country or *zone* will regain its free status only after the submitted evidence, based on the provisions of Chapter 1.11., has been accepted by WOAH.

   When emergency *vaccination* is not applied, the above waiting periods do not apply, and Article 8.8.3. applies.

4) When *infection* with FMDV occurs in a *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 only when FMD has been successfully eradicated within the *containment zone* and status has been regained following the provisions in this article.

For Member Countries not applying for recovery within 24 months after suspension of status, the provisions of Article 8.8.2., Article 8.8.3., Article 8.8.4. or Article 8.8.4bis. apply.

Article 8.8.8.

Direct transfer within a country of ~~FMD~~ susceptible animals from an infected zone, including containment zone, for slaughter in a free zone (whether vaccination is practised or not)

In order not to jeopardise the status of a free *zone*, ~~FMD~~ susceptible animals should only leave the infected *zone* if transported directly 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 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) the *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the infected *zone*;

6) *vehicles* and the *slaughterhouse/abattoir* 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. For ruminants, the head, including the pharynx, tongue and associated lymph nodes, was either destroyed or treated in accordance with Article 8.8.31. 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~~ inactivate any FMDV potentially present.

~~Article 8.8.9bis.~~

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

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

~~1) no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;~~

~~2) the animals were kept in the *zone* of origin for at least three months prior to movement;~~

~~3) the animals are transported under the supervision of the *Veterinary Authority* in a *vehicle*, directly from the *establishment* of origin to the *slaughterhouse/abattoir*;~~

~~4) if transiting an infected *zone*, the animals were not exposed to any source of FMDV during transportation to the *place of shipment*.~~

Article 8.8.10.

Recommendations for importation of susceptible animals from countries, zones or compartments free from FMD where vaccination is not practised

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 country, *zone* or *compartment* free from FMD where *vaccination* is not practised;

3) if transiting an infected *zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*;

4) if previously vaccinated, comply with point 4 of Article 8.8.11.

Article 8.8.11.

Recommendations for importation of susceptible animals ~~domestic ruminants and pigs~~ from countries, zones or compartments free from FMD where vaccination is practised

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 country, *zone* or *compartment* free from FMD where *vaccination* is practised;

3) if not vaccinated were subjected to ~~virological~~ a virological ~~and serological~~ test~~s~~ for FMD with negative result~~s~~ on a sample~~s~~ collected not earlier than 14 days before 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 shipment;

5) if transiting an infected *zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*.

Article 8.8.11bis.

Recommendations for the importation of vaccinated susceptible animals destined for slaughter from a country, zone or compartment free from FMD where vaccination is practised

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

1) no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to shipment;

2) the animals were kept in the country, *zone* or *compartment* of origin since birth or for at least three months prior to shipment;

3) the animals were transported under the supervision of the *Veterinary Authority* directly from the *establishment* of origin in sealed *vehicles/vessels*;

4) if transiting an *infected zone*, the animals were not exposed to any source of FMDV during transportation to the *place of shipment*.

Article 8.8.12.

Recommendations for importation of susceptible animals ~~domestic ruminants and pigs~~ from countries or zones infected with FMDV, where an official control programme exists

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) if pigs, they have not been fed swill not complying with Article 8.8.31bis.;

3) prior to isolation, the animals were kept in the *establishment* of origin:

   a) for 30 days, or since birth if younger than 30 days, if a *stamping-out policy* is applied to control FMD in the *exporting country* or *zone*, or

   b) for three months, or since birth if younger than three months if a *stamping-out policy* is not applied to control FMD in the *exporting country* or *zone*;

4) the *establishment* of origin is covered by the *official control programme* and FMD has not occurred within it for the relevant period as defined in points 3 a) and 3 b) above;

5) the animals were isolated for the 30 days prior to shipment:

   a) in a *quarantine station*, and all animals in isolation were subjected to diagnostic virological and serological tests for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period, or

   b) in an establishment that is not a *quarantine station*, *infection* with FMDV did not occur within a 10-kilometre radius of the *establishment* during that period, and all animals in isolation were subjected to diagnostic virological and serological tests for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period;

6) the animals were not exposed to any source of FMDV during their transportation from the *establishment* to the *place of shipment*.

Article 8.8.14.

Recommendations for importation of fresh and frozen semen of domestic ruminants and pigs from countries, zones or compartments free from FMD where vaccination is not practised

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 country, *zone* or *compartment* free from FMD where *vaccination* is not practised;

   ~~c) were kept in an *artificial insemination centre*;~~

2) the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.

Article 8.8.15.

Recommendations for importation of frozen semen of domestic ruminants and pigs from countries, zones or compartments free from FMD where vaccination is practised

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 country, *zone* or *compartment* free from FMD where *vaccination* is practised;

c) either

i) 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 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 4.6. and 4.7.;

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 males were kept showed any clinical sign of FMD.

Article 8.8.16.

Recommendations for importation of frozen semen of domestic ruminants and pigs from countries or zones infected with FMDV

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* to which no animal had been added in the 30 days before collection, and within a 10-kilometre radius of which, FMD has not occurred in the 30 days before and after collection;

c) either

i) 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 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 4.6. and 4.7.;

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 8.8.18.

Recommendations for importation of *in vitro* produced bovine embryos from countries, zones or compartments free from FMD where vaccination is not practised

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 country, *zone* or *compartment* free from FMD where *vaccination* is not practised;

2) fertilisation was achieved with semen meeting the conditions referred to in Articles 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., 4.9., and 4.10. as relevant.

Article 8.8.19.

Recommendations for importation of *in vitro* produced bovine embryos from countries, zones or compartments free from FMD where vaccination is practised

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 country, *zone* or *compartment* free from FMD where *vaccination* is practised;

   c) either

      i) 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 collection;

      or

      ii) were subjected, not less than 21 days and not more than 60 days after collection, to tests for antibodies against FMDV, with negative results;

2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.8.14., 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., 4.9., and 4.10. as relevant.

Article 8.8.20.

Recommendations for importation of fresh meat or meat products of susceptible animals from countries, zones or compartments free from FMD where vaccination is not practised

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 country, *zone* or *compartment* free from FMD where *vaccination* is not practised or have been imported in accordance with Article 8.8.10., Article 8.8.11., Article 8.8.11bis. or Article 8.8.12.;

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

Article 8.8.21.

Recommendations for importation of fresh meat and meat products of susceptible animals ~~ruminants and pigs~~ from countries, zones or compartments free from FMD where vaccination is practised

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

1) ~~ruminants or pigs~~ that have been kept in the country, *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., Article 8.8.11bis. or Article 8.8.12.;

2) ~~ruminants or pigs~~ that have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results;

3) if ruminants, from which the head, including the pharynx, tongue and associated lymph nodes, has been excluded from the shipment.

Article 8.8.22.

Recommendations for importation of fresh meat of bovines ~~and water buffaloes *(Bubalus bubalis)* (excluding feet, head and viscera)~~ from countries or zones infected with FMDV, where an official control programme exists

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

EITHER

b) comes from bovines that comply with Article 8.8.10., 8.8.11., 8.8.11bis. or 8.8.12.; and the carcasses were not released earlier than 24 hours after *slaughter* and not before *Veterinary Authorities* have confirmed that FMD has not occurred in the *establishment* of origin;

OR

2) a) comes from ~~animals~~ bovines which:

~~a~~i) have remained, for at least three months prior to *slaughter*, in a *zone* of the *exporting country* where bovines ~~and water buffaloes~~ are regularly vaccinated against FMD and where an *official control programme* is in operation;

~~b~~ii) 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~~iii) were kept for the past 30 days in:

– a *quarantine station*; or

– an *establishment*, within a 10-kilometre radius of which FMD has not occurred during that period;

~~d~~iv) have been transported, in a *vehicle* which was cleaned ~~cleansed~~ and disinfected before ~~the bovines and water buffaloes were~~ loadinged, 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~~v) 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~~vi) were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., with favourable results;

~~2~~b) comes from deboned carcasses:

~~a~~i) from which feet, head, viscera and the major lymphatic nodes have been removed;

~~b~~ii) which, prior to deboning, have been submitted to maturation at a temperature greater than + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was less than 6.0 when tested in the middle of both the longissimus dorsi muscle.

Article 8.8.22bis.

Recommendations for importation of fresh meat of ~~domestic~~ pigs from countries or zones infected with FMDV, where an official control programme exists

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

1) the *meat* comes from ~~animals~~ pigs complying with Article 8.8.10., 8.8.11., 8.8.11bis. or 8.8.12.;

2) the ~~animals~~ pigs were transported, in a *vehicle* which was cleaned and disinfected before ~~the pigs were~~ *loading~~ed~~*, 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~~ pigs 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~~ pigs were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., with favourable results;

5) the carcasses were not released earlier than 24 hours after *slaughter* and not before *Veterinary Authorities* have confirmed that FMD has not occurred in the *establishment* of origin.

Article 8.8.22ter.

Recommendations for importation of fresh meat of ~~domestic~~ sheep and goats ~~(excluding feet, head and viscera)~~ from FMD infected countries or zones where an official control programme exists

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

1) sheep and goats ~~animals~~ that were transported, in a *vehicle* which was cleaned and disinfected before the domestic sheep and goats were loaded, directly from the *establishment* of origin or *quarantine station* to the approved *slaughterhouse/abattoir* without coming into contact with other FMD susceptible animals that do not fulfil the conditions required for export, either during transport or at the *slaughterhouse/abattoir*;

2) sheep and goats ~~animals~~ that were slaughtered in an approved *slaughterhouse/abattoir*:

   a) which is officially designated for export;

   b) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;

3) sheep and goats ~~animals~~ that were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., with favourable results; and

EITHER,

4) sheep and goats ~~animals~~ that comply with Article 8.8.10., 8.8.11., 8.8.11bis. or 8.8.12.; and the carcasses were not released earlier than 24 hours after *slaughter* and not before *Veterinary Authorities* have confirmed that FMD has not occurred in the *establishment* of origin;

OR

5) sheep and goats ~~animals~~ that:

a) have remained, for at least three months prior to *slaughter*, in a *zone* of the *exporting country* where bovines ~~and water buffaloes~~ are regularly vaccinated against FMD and where an *official control programme* is in operation;

b) were kept for the past 30 days in:

- a *quarantine station*; or

- an *establishment*, within a ten-kilometre radius of which FMD has not occurred during that period, and no susceptible animals were introduced into the *establishment* during that period;

c) had their carcasses deboned:

i) from which feet, head, viscera and the major lymphatic nodes have been removed;

ii) which, prior to deboning, have been submitted to maturation at a temperature greater than + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was less than 6.0 when tested in the middle of both the longissimus dorsi muscle.

Article 8.8.23.

Recommendations for importation of meat products of susceptible animals from countries or zones infected with FMDV

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

1) the entire consignment of *meat products* comes from animals which have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results;

2) the *meat products* come from *meat* that complies with Articles 8.8.22., 8.8.22bis. or 8.8.22ter., or they have been processed to ensure the ~~destruction~~ inactivation of FMDV in accordance with one of the procedures in Article 8.8.31.;

3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMDV.

Article 8.8.24.

Recommendations for importation of ~~products of~~ animal products ~~origin~~ (other than those covered by other articles) from countries, zones or compartments free from FMD whether vaccination is practised or not

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a country, *zone* or *compartment* free from FMD, or which have been imported in accordance with Article 8.8.10., Article 8.8.11., Article 8.8.11bis. or Article 8.8.12.

Article 8.8.25.

Recommendations for importation of milk and milk products (other than those listed in Article 8.8.1bis.) from countries or zones infected with FMDV

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

1) these products:

a) originate from ~~*establishments*~~ *herds* which at the time of *milk* collection were not infected or suspected of being infected with FMDV,~~;~~ and comes from *milk* that:

~~b) i) have been processed to ensure the destruction~~ inactivation ~~of FMDV in accordance with one of the procedures in Article 8.8.35.; or~~

~~i~~ii) ~~comes from milk that~~ has a pH less than 7 or has been tested for FMDV with negative results~~,~~ and~~heated at a minimum temperature of 72 C for at least 15 seconds;~~

ii) has been heated at a minimum temperature of 72 C for at least 15 seconds;

or

b) have been processed to ensure the inactivation of FMDV in accordance with one of the procedures in Article 8.8.35.

2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

Article 8.8.27.

Recommendations for importation of wool, hair, bristles, raw hides and skins from domestic susceptible animals from countries or zones infected with FMDV

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

1) these products have been processed to ensure the ~~destruction~~ inactivation 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 and processing to avoid contact of the products with any potential source of FMDV.

Article 8.8.28.

Recommendations for importation of straw and forage from countries or zones infected with FMDV

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 10 minutes,

b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35-40% in a chamber kept closed for at least eight hours and at a minimum temperature of 19°C;

OR

3) have been kept in bond for at least four months before being released for export.

Article 8.8.29.

Recommendations for importation of skins and trophies derived from susceptible animals (other than those listed in Article 8.8.1bis.) from countries, zones or compartments free from FMD, whether vaccination is practised or not

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products are derived from animals that have been killed in a country or *zone* free from FMD or which had~~ve~~ been imported from a country, *zone* or *compartment* free from FMD.

Article 8.8.30.

Recommendations for importation of skins and trophies derived from susceptible animals (other than those listed in Article 8.8.1bis.) from countries or zones infected with FMDV

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

Article 8.8.31.

Procedures for the inactivation of FMDV in meat and meat products of susceptible animals

For the inactivation of FMDV present in *meat* and *meat products* of susceptible animals, 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', so that the moisture protein ratio is not greater than 2.25:1 or the water activity (a~~A~~$_w$) is not greater than 0.85. ~~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.~~

4. Any equivalent treatment which has been demonstrated to inactivate FMDV in *meat* and *meat products*

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, one of the following procedures should be used:

1) for wool, industrial washing, which consists of the immersion in a series of baths of water, soap and sodium hydroxide (NaOH) or potassium hydroxide (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 in a water-soluble detergent held at 60-70°C;

5) for wool, storage 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, 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, the following procedure should be used: treatment for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na_2CO_3).

Article 8.8.35.

Procedures for the inactivation of FMDV in milk and milk products

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

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]) applied twice; or

2) ~~if the *milk* has a pH of 7.0 or greater, the HTST process applied twice; or~~

~~3)~~ any equivalent treatment that has been demonstrated to inactivate FMDV in *milk*.

Article 8.8.37.

Procedures for the inactivation of FMDV in skins and trophies from susceptible animals

For the inactivation of FMDV present in skins and trophies from susceptible *animals*, one of the following procedures should be used prior to complete taxidermal treatment:

1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed; or

2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher); or

3) soaking, with agitation, in a 4% (weight/volume) solution of sodium carbonate (Na_2CO_3) maintained at pH 11.5 or greater for at least 48 hours; or

4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at pH less than 3.0 for at least 48 hours; wetting and dressing agents may be added; or

5) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na_2CO_3).

Article 8.8.38.

Procedures for the inactivation of FMDV in casings of ruminants and pigs

For the inactivation of FMDV present in casings of ruminants and pigs, the following procedures should be used: treating for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl, $a_w < 0.80$), or with phosphate supplemented salt containing 86.5% NaCl, 10.7% Na_2HPO_4 and 2.8% Na_3PO_4 (weight/weight/weight), either dry or as a saturated brine ($a_w < 0.80$), and kept at a temperature of greater than 12°C during this entire period.

Article 8.8.39.

WOAH endorsed official control programme for FMD

A Member Country may, on a voluntary basis, apply for endorsement of its *official control programme* for FMD in accordance with Chapter 1.6., when it has implemented measures in accordance with this article.

For a Member Country's *official control programme* for FMD to be endorsed by WOAH, the Member Country should provide a description of an *official control programme* for the control and eventual eradication of FMD in the country or *zone*. This document should address and provide documented evidence on the following:

1) epidemiology:

   a) the detailed epidemiological situation of FMD in the country, highlighting the current knowledge and gaps;

   b) the main production systems and movement patterns of susceptible animals and their products within and into the country and, where applicable, the specific *zone*;

2) surveillance and diagnostic capabilities:

   a) FMD *surveillance* in place, in accordance with Chapter 1.4. and Articles 8.8.40. to 8.8.42.;

   b) diagnostic capability and procedures, including regular submission of samples to a *laboratory* that performs diagnostic testing and further characterisation of strains;

   c) serosurveillance conducted in susceptible species, including *wildlife,* to serve as sentinels for FMDV circulation in the country;

3) *vaccination*:

   a) *vaccination* is compulsory in the target *population* and is practised in accordance with Chapter 4.18.;

   b) detailed information on *vaccination* campaigns, in particular:

      i) the strategy that is adopted for the *vaccination* campaign;

      ii) target *populations* for *vaccination*;

      iii) target geographical area for *vaccination*;

      iv) monitoring of *vaccination* coverage, including serological monitoring of population immunity;

      v) the strategy to identify vaccinated animals;

vi) technical specification of the vaccines used, including matching with the circulating FMDV strains and description of the vaccine licensing procedures in place;

vii) if relevant, proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;

viii) the proposed strategy and work plan including the timeline for transition to the cessation of *vaccination*;

4) the measures implemented to prevent the introduction of the pathogenic agent and to ensure the rapid detection of all FMD *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.

The country will be included in the list of countries having a WOAH endorsed *official control programme* for FMD in accordance with Chapter 1.6.

Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above.

Article 8.8.40.

General principles of surveillance

Articles 8.8.40. to 8.8.42. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Member Countries seeking establishment, maintenance or recovery of freedom from FMD at the country, *zone* or *compartment* level or seeking endorsement by WOAH of their *official control programme* for FMD, in accordance with Article 8.8.39. *Surveillance* aimed at identifying disease and *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, and transmission of, FMDV should be carefully designed and implemented to avoid producing results that are insufficient to be accepted by WOAH or trading partners, or being excessively costly and logistically complicated.

The strategy and design of the *surveillance* programme will depend on the historical epidemiological circumstances including whether *vaccination* has been 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 animal~~s~~ *populations* should be considered in the strategy and design of the *surveillance* programme.

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 transmission of FMDV should target animals that are less likely to show vaccine-derived antibodies to NSP, such as young animals vaccinated a limited number of times, or unvaccinated animals. In any unvaccinated *subpopulation*, *surveillance* should demonstrate no evidence of *infection* with FMDV.

Surveillance strategies employed for establishing and maintaining a *compartment* should identify the prevalence, distribution and characteristics of FMD outside the *compartment*.

3. WOAH endorsed official control programme

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

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

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

4. Surveillance strategies

The strategy employed to establish the prevalence of *infection* with FMDV or to substantiate freedom from *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 and pigs). The Member Country should justify the *surveillance* strategy chosen and the frequency of sampling as adequate to detect *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 *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 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. 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 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 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 status free from FMD where vaccination is not practised or early recovery of status free from FMD where vaccination is practised in the area(s) where emergency vaccination has been applied but not followed by the slaughtering of all vaccinated animals

In addition to the general conditions described in this chapter, a Member Country seeking either recovery of status of a country or *zone* previously free from FMD where *vaccination* is not practised, including a *containment zone*, or recovery of status of a country or *zone* previously free from FMD where *vaccination* is practised, earlier than the six months as specified respectively under point 1 c) of Article 8.8.7. or under point 3 a) of Article 8.8.7. should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved when answering the relevant questionnaire in Chapter 1.11. by demonstrating compliance with either a) or b) and c) below, in the area(s) where emergency *vaccination* has been applied. It is advisable that the *Veterinary Authority* consider the different options for the recovery of a free status when control measures are first implemented at the onset of the *outbreak* in order to plan for the applicable requirements to be met.

a) The following serological surveys have been conducted in the area where emergency *vaccination* has been applied and have demonstrated the absence of *infection* in unvaccinated *animals* and the absence of transmission in emergency vaccinated *animals*:

   i) for vaccinated ruminants, serological surveys using 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 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 movements 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 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 status free from FMD where vaccination is practised in the area outside of the area(s) where emergency vaccination has been applied

In addition to the general conditions described in this chapter, a Member Country seeking recovery of status of a country or *zone* previously free from FMD where *vaccination* is practised in the area outside of the area(s) where emergency *vaccination* has been applied, earlier than six months as specified under point 3 a) of Article 8.8.7. should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved either by meeting the requirements listed in a) below or by demonstrating compliance with the requirements listed in b) and c) below, when answering the questionnaire in Article 1.11.2. or Article 1.11.4.

With regard to the *surveillance* requirements listed in b), it should be noted that clinical signs may not be apparent in the routinely vaccinated *population*. The expression of clinical signs would depend on the relationship between the virus strain used in the routine *vaccination* to the virus that caused the *outbreak*. For example, following an incursion of a new serotype it would be expected that the routinely vaccinated animals would show clinical signs if infected. In contrast, following an incursion of a serotype or strain covered by the vaccine it would be expected that most of the routinely vaccinated animals would be protected and therefore less likely to be infected and to show clinical signs if infected. Other factors such as *vaccination* coverage and timing of *vaccination* could influence the likelihood of *infection* and expression of clinical signs.

It is advisable that the *Veterinary Authority* consider the different options for the recovery of a free status when control measures are first implemented at the onset of the *outbreak* in order to plan for the applicable requirements to be met.

a) Establishment of a containment zone

A *containment zone* that includes all emergency *vaccination* area(s) has been established based on the provisions of Article 8.8.6. to provide assurance that FMD has not occurred in the area outside the emergency *vaccination* area(s).

b) The following *surveillance* components have been implemented in the area outside of the area(s) where emergency *vaccination* has been applied and have demonstrated the absence of *infection* in unvaccinated *animals* and the absence of transmission in vaccinated *animals*:

i) risk-based serological *surveillance* in vaccinated *herds* with stratification according to relevant factors such as proximity to the emergency *vaccination* area, region/*establishment* with numerous movements 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 movements 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* 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 species that usually do not show clinical signs or husbandry systems that do not permit sufficient observations. In such situations, serological *surveillance* should be used. However, recognising the difficulty in sampling *wildlife*, *surveillance* of domestic species in close contact with susceptible *wildlife* can provide supportive evidence of the *animal health status* of these *wildlife* populations. Hunting, capture and non-invasive sampling and observation methods can also be used to obtain information and diagnostic samples from *wildlife* species.

2. Virological surveillance

Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is mostly dependent upon clinical *surveillance* to provide samples. FMDV isolates should be sent regularly to a WOAH Reference Laboratory.

Virological *surveillance* aims to:

a) confirm clinically suspected *cases*;

b) follow up positive serological results;

c) characterise isolates for epidemiological studies and vaccine matching;

d) monitor *population*s at risk for the presence and transmission of the virus.

3. Serological surveillance

Serological *surveillance* aims to detect antibodies resulting from *infection* or *vaccination* using NSP tests or SP tests.

Serological *surveillance* may be used to:

a) estimate the prevalence or substantiate freedom from *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

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 SP and the NSP of the virus. Vaccinated *animals* produce antibodies mainly or entirely to the SP of the virus depending upon vaccine purity. In unvaccinated *population*s, SP tests may be used to screen sera for evidence of *infection* with, FMDV or to detect the introduction of vaccinated *animals*. In vaccinated *population*s, SP tests may be used to monitor the serological response to the *vaccination*. The SP tests are serotype specific. For optimal sensitivity an antigen or virus closely related to the field strain expected should be selected.

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 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 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 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 reactor that has been confirmed in a *laboratory* should be investigated. The investigation should examine all evidence, which may include the results of any further serological tests used to confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to transmission of FMDV, as well as of virological tests. This investigation should document the status for each positive *herd*. Epidemiological investigation should be continued concurrently.

Clustering of seropositive results within *herds* or within a region should be investigated as it may reflect any of a series of factors or events, including the demographics of the *population* sampled, vaccinal exposure or the presence of *infection* or transmission. As clustering may signal *infection* or transmission, the investigation of all instances should be incorporated in the survey design.

Paired serology can be used to identify 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 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.* If there is no transmission of FMDV, they will remain serologically negative.

2. Follow-up of field and laboratory findings

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

It is difficult to determine the significance of small numbers of seropositive *animals* in the absence of current FMDV transmission. 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 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 *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.

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CHAPTER 1.11.

APPLICATION FOR OFFICIAL RECOGNITION BY WOAH OF FREE STATUS FOR FOOT AND MOUTH DISEASE

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

Article 1.11.1.

Country free from infection with foot and mouth disease virus where vaccination is not practised

The following information should be provided by WOAH Member Countries to support applications for official recognition of status as a country where *vaccination* is not practised that is free from *infection* with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*.

The dossier provided to WOAH should address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the WOAH *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the WOAH official languages. Weblinks to supporting documents in one of the official languages of WOAH may also be provided, where they exist.

All annexes should be provided in one of the WOAH official languages.

The Delegate of the Member Country applying for recognition of FMD freedom for a country where *vaccination* is not practised must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.2. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating ~~that~~ for at least the past 12 months:

1) there has been no ~~*case* of~~*infection* with FMDV ~~during the past 12 months~~;

2) there has been no ~~evidence of FMDV~~ transmission of FMDV in previously vaccinated animal *populations;*

3) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;

~~2~~4) ~~no~~ *vaccination* against FMD has been prohibited and the prohibition has been effectively implemented and supervised ~~carried out during the past 12 months.~~

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions in Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and, where relevant, of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of the *infection*. Provide maps identifying the

features above. Specify whether the application includes any noncontiguous territories.

b) Livestock demographics. Describe the composition of the livestock industry in the country. In particular, describe:

i) the susceptible animal *population* by species and types of production systems;

ii) the number of *herds* or *flocks*, etc. of each susceptible species;

iii) their geographical distribution;

iv) *herd* or *flock* density;

v) the degree of integration and role of producer organisations in the different production systems;

vi) any recent significant changes observed in the production (attach relevant documents if available).
Provide tables and maps.

c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country? Provide estimates of *population* sizes, ~~and~~ geographic distribution and a summary description of their habitat. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?

d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.2. and 3.3. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.

c) Provide information on any PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.

d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.

e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are movements of all susceptible species controlled in the country? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in

the past 24 months and the action taken.

3. FMD eradication

a) History. If *infection* has never occurred in the country, or has not occurred within the past 25 years, state explicitly whether or not the country is applying for recognition of historical freedom according to Article 1.4.6. of the *Terrestrial Code*.

If *infection* has occurred in the country within the past 25 years, provide a description of the FMD history in the country, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last *case* or *eradication*, and the types and strains in the country.

b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of FMD in response to any past incursions of FMD virus.

c) Vaccines and *vaccination*. Briefly answer the following:

i) Is there any legislation that prohibits *vaccination*? If so:

– Provide the date when *vaccination* was formally prohibited;

– Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.

ii) Was *vaccination* ever used in the country? If so:

– Provide the date when the last *vaccination* was carried out;

– What type of vaccine was used?

– What species were vaccinated?

– How were vaccinated animals identified?

– What was the fate of those animals?

iii) In addition, if *vaccination* was applied during the past 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following:

– the vaccine strains;

– potency and formulation, purity, details of any vaccine matching performed;

– the species vaccinated;

– identification of vaccinated animals;

– the way in which the *vaccination* of animals was certified or reported and the records maintained;

– evidence that the vaccine used complies with Chapter 3.1.8. of the *Terrestrial Manual*.

d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 3.1.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

a) Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country, including the following:

   i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;

   ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;

   iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

   iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

   v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;

   vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

b) If FMD *laboratory* diagnosis is not carried out in 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.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*, and Chapter 3.1.8. of the *Terrestrial Manual*. The following information should be included:

a) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

b) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

   Provide a summary table indicating, for the past 24 months, the number of suspected *cases*, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.

c) Serological or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are surveys conducted? Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale. Describe how previously vaccinated or newly introduced vaccinated animal *populations* are considered in the strategy and design of the *surveillance* programme, if applicable.

   Provide a summary table indicating, for the past 24 months, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and on how these findings are acted upon. Provide criteria for selection of *populations* for targeted surveillance based on the risk and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.

e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, including details of:

a) Coordination with other countries. Describe any relevant factors in neighbouring countries that should be taken into account (e.g. size, distance from the border to affected *herds*, *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

Are *protection zones* in place? If so, provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

c) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

d) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species, vaccination status, and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.

ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?

iii) Cite the regulations and describe procedures, type and frequency of checks, and management of

noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:

– animals;

– genetic material (semen, oocytes and embryos);

– animal products;

– *veterinary medicinal products*;

– other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.

7. Control measures and contingency planning

a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the WOAH official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.

b) In the event of a suspected or confirmed FMD *outbreak*:

i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. livestock standstills)?

ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;

iii) Describe the actions that would be taken to control the disease situation in and around the

establishments where the *outbreak* is confirmed;

iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;

vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 8.8.7. and points 4, 5 and 6 ~~1, 3 and 4~~ of Article 8.8.2. of the *Terrestrial Code* and provide detailed information as specified in Sections 3, 5 and 6 ~~1-7 (inclusive)~~ of this questionnaire.

Article 1.11.2.

Country free from infection with foot and mouth disease virus where vaccination is practised

The following information should be provided by WOAH Member Countries to support applications for official recognition

of status as a country where *vaccination* is practised that is free from *infection* with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*.

The dossier provided to WOAH should address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the WOAH *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the WOAH official languages. Weblinks to supporting documents in one of the official languages of WOAH may also be provided, where they exist.

All annexes should be provided in one of the WOAH official languages.

The Delegate of the Member Country applying for recognition of FMD freedom for a country where *vaccination* is practised must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating ~~that~~ for at least the past 12 months:

1) there has been no ~~case of~~*infection* with FMDV ~~for the past 24 months~~;

2) no ~~evidence of FMDV~~ transmission of FMDV ~~for the past 12 months~~;

~~3) *surveillance* for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. and is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;~~

~~4~~3) ~~routine~~ compulsory systematic *vaccination* is carried out in the target population ~~for the purposes of the prevention of FMD~~;

~~5~~4) the vaccine used complies with the standards described in the *Terrestrial Manual*.

And, for at least the past 24 months, *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation, and regulatory measures for the prevention and control of FMD have been implemented.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions in Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

   a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and, where relevant, of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of the *infection*. Provide maps identifying the features above. Specify whether the application includes any noncontiguous territories.

   b) Livestock demographics. Describe the composition of the livestock industry in the country. In particular, describe:

      i) the susceptible animal *population* by species and types of production systems;

      ii) the number of *herds* or *flocks*, etc. of each susceptible species;

      iii) their geographical distribution;

      iv) *herd* or *flock* density;

v) the degree of integration and role of producer organisations in the different production systems;

vi) any recent significant changes observed in the production (attach relevant documents if available). Provide tables and maps.

c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country? Provide estimates of *population* sizes, ~~and~~ geographic distribution and a summary description of their habitat. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?

d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.2. and

3.3. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.

c) Provide information on any PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.

d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.

e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are movements of all susceptible species controlled in the country? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

a) History. Provide a description of the FMD history in the country, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last *case* or *eradication*, and the types and strains in the country.

b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, modified stamping-out policy, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of FMD in response to any

past incursions of FMD virus.

c) Vaccines and *vaccination*. Describe any legislation regulating *vaccination*. Provide a description and justification of the *vaccination* strategy and programme, including the following:

i) the vaccine strains;

ii) potency and formulation, purity, details of any vaccine matching performed;

iii) the species vaccinated;

iv) identification of vaccinated animals;

v) the way in which the *vaccination* of animals was certified or reported and the records maintained;

vi) the date on which the last *vaccination* was performed;

vii) evidence that the vaccine used complies with Chapter 3.1.8. of the *Terrestrial Manual*.

d) Provide detailed evidence of *vaccination* coverage and population immunity as follows:

Describe how the number of animals intended for *vaccination* and the number of vaccinated animals are estimated.

For serological surveys to estimate population immunity, provide detailed information on the sampling frame (target population, age, species and *vaccination* status) and survey design (expected prevalence, acceptable error, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How long after *vaccination* are samples collected? Describe how the threshold for protective immunity has been established.

Provide the results of the *vaccination* coverage and population immunity by year, serotype, species, as relevant.

Provide details of any additional methods applied for monitoring the performance of *vaccination*.

e) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 3.1.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

a) Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved

laboratories in the country, including the following:

i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;

ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;

iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent

results and, if applicable, the corrective measures applied;

v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;

vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

b) If FMD *laboratory* diagnosis is not carried out in 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.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*, and Chapter 3.1.8. of the *Terrestrial Manual*. The following information should be included:

a) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

b) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months, the number of suspected *cases*, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.

c) Serological or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are surveys conducted? Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past 24 months, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted surveillance based on the risk and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.

e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

f) Provide evidence that surveys are carried out to assess *vaccination* coverage and population immunity of the target *populations*, show laboratory evidence that the vaccine strains used is appropriate.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, including details of:

a) Coordination with other countries. Describe any relevant factors in neighbouring countries that should be taken into account (e.g. size, distance from the border to affected *herds*, *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or

ecosystem.

Are *protection zones* in place? If so, provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

c) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

d) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.

ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?

iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:

- animals;
- genetic material (semen, oocytes and embryos);
- animal products;
- *veterinary medicinal products*;
- other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.

7. Control measures and contingency planning

a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the

WOAH official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.

b) In the event of a suspected or confirmed FMD *outbreak*:

i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. livestockstandstills)?

ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;

iii) Describe the actions that would be taken to control the disease situation in and around the

establishments where the *outbreak* is confirmed;

iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;

vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 8.8.7. and points 1 e), f), g) and 2~~, 3 and 4~~ of Article 8.8.3. of the *Terrestrial Code* and provide detailed information as specified in Sections 3, 5 and 6~~ 1-7 (inclusive)~~ of this questionnaire.

Article 1.11.3.

Zone free from infection with foot and mouth disease virus where vaccination is not practised

The following information should be provided by WOAH Member Countries to support applications for official recognition of status as a *zone* where *vaccination* is not practised that is free from *infection* with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*.

The dossier provided to WOAH should address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the WOAH *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the WOAH official languages. Weblinks to supporting documents in one of the official languages of WOAH may also be provided, where they exist.

All annexes should be provided in one of the WOAH official languages.

The Delegate of the Member Country applying for recognition of FMD zonal freedom must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.2. have

been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating ~~that~~ for at least the past 12 months:

1) there has been no ~~*case* of~~ *infection* with FMDV ~~during the past 12 months~~;

2) there has been no ~~evidence of FMDV~~ transmission of FMDV in previously vaccinated animal~~s~~ *populations*;

3) *surveillance* ~~for FMD and FMDV transmission~~ in accordance with Articles 8.8.40. to 8.8.42. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;

4) ~~no~~ *vaccination* against FMD has been prohibited and the prohibition has been effectively implemented and supervised ~~carried out during the past 12 months~~.

In addition, the Delegate of the Member Country applying for recognition of historical zonal freedom must also submit documentary evidence that the provisions in Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of the *infection*.

The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide maps identifying the features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

b) Livestock demographics. Describe the composition of the livestock industry in the country and the *zone*. In particular, describe:

i) the susceptible animal *population* by species and types of production systems in the country and the *zone*;

ii) the number of *herds* or *flocks*, etc. of each susceptible species;

iii) their geographical distribution;

iv) *herd* or *flock* density;

v) the degree of integration and role of producer organisations in the different production systems;

vi) any recent significant changes observed in the production (attach relevant documents if available).

Provide tables and maps.

c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country and the *zone*? Provide estimates of *population* sizes, ~~and~~ geographic distribution and a summary description of their habitat. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?

d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country or *zone*, and between *zones* of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations

and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.2. and 3.3. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.

c) Provide information on any PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.

d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.

e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are movements of all susceptible species controlled in and between *zones* of the same or different status for all production systems? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

a) History. If *infection* has never occurred in the country, or has not occurred within the last 25 years, state explicitly whether or not the *zone* is applying for recognition of historical freedom according to Article 1.4.6. of the *Terrestrial Code*.

If *infection* has occurred in the *zone* within the past 25 years, provide a description of the FMD history in the country and *zone*, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last *case* or *eradication* and the types and strains in the country.

b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. *stamping-out policy*, modified stamping-out policy, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of FMD in response to any past incursions of FMD virus.

c) Vaccines and *vaccination*. Briefly answer the following:

i) Is there any legislation that prohibits *vaccination*? If so:

– Provide the date when *vaccination* was formally prohibited;

– Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.

ii) Was *vaccination* ever used in the *zone*? If so:

- Provide the date when the last *vaccination* was carried out;
- What type of vaccine was used?
- What species were vaccinated?
- How were vaccinated animals identified?
- What was the fate of those animals?

iii) In addition, if *vaccination* was applied during the past 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following:

- the vaccine strains;
- potency and formulation, purity, details of any vaccine matching performed;
- the species vaccinated;
- identification of vaccinated animals;
- the way in which the *vaccination* of animals was certified or reported and the records maintained;
- evidence that the vaccine used complies with Chapter 3.1.8. of the *Terrestrial Manual*.

iv) If *vaccination* continues to be used in the rest of the country, give details of the species vaccinated and on the post-*vaccination* monitoring programme.

d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 3.1.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

a) Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country. Indicate the *laboratories* where samples originating from the *zone* are diagnosed. Address the following points:

i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;

ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;

iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;

vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

b) If FMD *laboratory* diagnosis is not carried out in 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.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with Articles 8.8.40. to 8.8.42. of the

Terrestrial Code, and Chapter 3.1.8. of the *Terrestrial Manual*. The following information should be included:

a) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

b) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months, the number of suspected *cases*, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.

c) Serological or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are surveys conducted? Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale. Describe how previously vaccinated or newly introduced vaccinated animal~~s~~ *populations* are considered in the strategy and design of the surveillance programme, if applicable.

Provide a summary table indicating, for the past 24 months, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted surveillance based on the risk and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.

e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country or *zone*, including details of:

a) Coordination with other countries. Describe any relevant factors in neighbouring countries and *zones* that should be taken into account (e.g. size, distance from the border to affected *herds*, *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem. If the FMD free *zone* without *vaccination* is established in a FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Are *protection zones* in place? If so, indicate whether or not the *protection zone* are included in the proposed FMD free *zones*. Provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the

spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

c) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

d) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the *zone*. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species, vaccination status, and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.

ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?

iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and follow-up of the following:

- animals;
- genetic material (semen, oocytes and embryos);
- animal products;
- *veterinary medicinal products*;
- other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.

7. Control measures and contingency planning

a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the WOAH official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.

b) In the event of a suspected or confirmed FMD *outbreak*:

i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. livestockstandstills)?

ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;

iii) Describe the actions that would be taken to control the disease situation in and around the

establishments where the *outbreak* is confirmed;

iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;

vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a *zone* where *vaccination* is not practised should comply with the provisions of Article 8.8.7. and points 4, 5 and 6 ~~1, 3 and 4~~ of Article 8.8.2. of the *Terrestrial Code* and provide detailed information as specified in Sections 3, 5 and 6 ~~1-7 (inclusive)~~ of this questionnaire.

Article 1.11.4.

Zone free from infection with foot and mouth disease virus where vaccination is practised

The following information should be provided by WOAH Member Countries to support applications for official recognition of status as a *zone* where *vaccination* is practised that is free from *infection* with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*.

The dossier provided to WOAH should address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the WOAH *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the WOAH official languages. Weblinks to supporting documents in one of the official languages of WOAH may also be provided, where they exist.

All annexes should be provided in one of the WOAH official languages.

The Delegate of the Member Country applying for recognition of FMD zonal freedom must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating ~~that~~ for at least the past 12 months:

1) there has been no ~~case of~~*infection* with FMDV ~~for the past 24 months~~;

2) no ~~evidence of FMDV~~ transmission of FMDV ~~for the past 12 months~~;

~~3)~~ ~~*surveillance* for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. and is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;~~

~~4~~3) ~~routine~~ compulsory systematic *vaccination* is carried out in the target population ~~for the purposes of the prevention of FMD~~;

~~5~~4) the vaccine used complies with the standards described in the *Terrestrial Manual*.

And, for at least the past 24 months, *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation, and regulatory measures for the prevention and control of FMD have been implemented.

In addition, the Delegate of the Member Country applying for recognition of historical zonal freedom must also submit documentary evidence that the provisions in Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of the *infection*.

The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide maps identifying the features above, including a digitalised, geo-referenced map with a description of the geographical boundaries of the *zone*.

b) Livestock demographics. Describe the composition of the livestock industry in the country and the *zone*. In particular, describe:

i) the susceptible animal *population* by species and types of production systems in the country and the *zone*;

ii) the number of *herds* or *flocks*, etc. of each susceptible species;

iii) their geographical distribution;

iv) *herd* or *flock* density;

v) the degree of integration and role of producer organisations in the different production systems;

vi) any recent significant changes observed in the production (attach relevant documents if available).

Provide tables and maps.

c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country and the *zone*? Provide estimates of *population* sizes, ~~and~~ geographic distribution and a summary description of their habitat. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?

d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country or *zone*, and between *zones* of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.2. and 3.3. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.

c) Provide information on any PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.

d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.

e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are movements of all susceptible species controlled in and between *zones* of the same or different status? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

a) History. Provide a description of the FMD history in the country and *zone*, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last *case* or *eradication* and the types and strains in the country.

b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. *stamping-out policy*, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of FMD in response to any past incursions of FMD virus.

c) Vaccines and *vaccination*. Describe any legislation regulating *vaccination*. Provide a description and justification of the *vaccination* strategy and programme, including the following:

i) the vaccine strains;

ii) potency and formulation, purity, details of any vaccine matching performed;

iii) the species vaccinated;

iv) identification of vaccinated animals;

v) the way in which the *vaccination* of animals was certified or reported and the records maintained;

vi) the date on which the last *vaccination* was performed;

vii) evidence that the vaccine used complies with Chapter 3.1.8. of the *Terrestrial Manual*.

d) Provide detailed evidence of *vaccination* coverage and population immunity as follows:

Describe how the number of animals intended for *vaccination* and the number of vaccinated animals are estimated.

For serological surveys to estimate population immunity, provide detailed information on the sampling frame (target population, age, species and *vaccination* status) and survey design (expected prevalence, acceptable error, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How long after *vaccination* are samples collected? Describe how the threshold for protective immunity has been established.

Provide the results of the *vaccination* coverage and population immunity by year, serotype, species, as relevant.

Provide details of any additional methods applied for monitoring the performance of *vaccination*.

e) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 3.1.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

a) Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country. Indicate the *laboratories* where samples originating from the *zone* are diagnosed. Address the following points:

i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;

ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;

iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;

vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

b) If FMD *laboratory* diagnosis is not carried out in 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.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*, and Chapter 3.1.8. of the *Terrestrial Manual*. The following information should be included:

a) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

b) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months, the number of suspected *cases*, the number of

samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.

c) Serological or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are surveys conducted? Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past 24 months, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted surveillance based on the risk and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.

e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

f) Provide evidence that surveys are carried out to assess *vaccination* coverage and population immunity of the target *populations*, show laboratory evidence that the vaccine strains used is appropriate.

6. <u>FMD prevention</u>

Describe the procedures in place to prevent the introduction of FMD into the country, including details of:

a) Coordination with other countries. Describe any relevant factors in neighbouring countries and *zones* that should be taken into account (e.g. size, distance from the border to affected *herds* or *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

If the FMD free *zone* with *vaccination* is established in a FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

Are *protection zones* in place? If so, indicate whether or not the *protection zone* are included in the proposed FMD free *zones*. Provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species) and provide a geo-referenced map of the *zones*.

b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

c) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

d) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of

susceptible animals or their products into the country or *zone*. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and if so, the duration and location of quarantine. Advise whether import permits and *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.

ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?

iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and follow-up of the following:

- animals;
- genetic material (semen, oocytes and embryos);
- animal products;
- *veterinary medicinal products*;
- other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.

7. Control measures and contingency planning

a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the WOAH official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.

b) In the event of a suspected or confirmed FMD *outbreak*:

i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. livestock standstills)?

ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;

iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;

iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;

vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a *zone* where *vaccination* is practised should comply with the provisions of Article 8.8.7. and points 1 e), f), g) and 2~~, 3 and 4~~ of Article 8.8.3. of the *Terrestrial Code* and provide detailed information as specified in Sections 3, 5 and 6~~ 1 7 (inclusive)~~ of this questionnaire.

Article 1.11.5.

Application for endorsement by WOAH of an official control programme for foot and mouth disease

The following information should be provided by WOAH Member Countries to support applications for endorsement by WOAH of an *official control programme* for foot and mouth disease (FMD) in accordance with Chapter 8.8. of the *Terrestrial Code*.

The dossier provided to WOAH should address concisely all the topics under the headings provided in Sections 1 to 4 to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

In Sections 3 f) to 3 i) describe concisely the work plan and timelines of the control programme for the next five years.

The terminology defined in the WOAH *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the WOAH official languages. Weblinks to supporting documents in one of the official languages of WOAH may also be provided, where they exist.

All annexes should be provided in one of the WOAH official languages.

The Delegate of the Member Country applying for endorsement of the *official control programme* should submit documentary evidence that the provisions of Article 8.8.39. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for FMD.

1. Introduction

a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and *zones*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of *infection*. Provide maps identifying the features above. Specify whether the application includes any noncontiguous territories.

b) If the endorsed plan is implemented in stages to specific parts of the country, the boundaries of the *zones* should be clearly defined, including the *protection zone* if applied. Provide a digitalised, geo-referenced map with a description of the geographical boundaries of the *zones*.

c) Livestock demographics. Describe the composition of the livestock industry in the country and any *zones*. In particular, describe:

i) the susceptible animal *population* by species and types of production systems;

ii) the number of *herds* or *flocks*, etc. of each susceptible species;

iii) their geographical distribution;

iv) *herd* or *flock* density;

v) the degree of integration and role of producer organisations in the different production systems;

vi) any recent significant changes observed in the production (attach relevant documents if available). Provide tables and maps.

d) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country and any *zones*? Provide estimates of *population* sizes, ~~and~~ geographic distribution and a summary description of their habitat. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?

e) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.2. and 3.3. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.

c) Provide information on any PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.

d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.

e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are animal movements controlled in the country for all susceptible species? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. Official control programme for FMD submitted for WOAH endorsement

Submit a concise plan of the measures for the control and eventual *eradication* of FMD in the country, including:

a) Epidemiology

i) Describe the FMD history in the country, with emphasis on recent years. Provide tables and maps showing the date of first detection, the number and location of *outbreaks* per year, the sources and routes of introduction of *infection*, the types and strains present, the susceptible species involved and the date of implementation of the control programme in the country.

ii) Describe the epidemiological situation of FMD in the country and the surrounding countries or *zones* highlighting the current knowledge and gaps. Provide maps of:

– the geography of the country with the relevant information concerning FMD situation;

– livestock density and movements and estimated FMD prevalence.

b) FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*, and Chapter 3.1.8. of the *Terrestrial Manual*. The following information should be included:

i) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

ii) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc. Provide details of follow-up actions taken on clinical suspicions.

iii) Serological or virological *surveillance*. Explain whether or not serological or virological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for at least the past 24 months, the number of suspected *cases*, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide procedural details of follow-up actions taken on suspicious and positive results and on how these findings are interpreted and acted upon.

Provide criteria for selection of *populations* for targeted surveillance and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

iv) Provide information on circulating strains and the level of *risk* in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.) and that the acquired knowledge assists in more effective implementation of control measures.

v) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

vi) Provide evidence that surveys are carried out to assess *vaccination* coverage and population immunity of the target *populations*, show laboratory evidence that the vaccine used is appropriate for circulating strains of virus, show analysis of *surveillance* data to assess the change in FMD prevalence over time in the target *populations*, assess the control measures (cost effectiveness, degree of implementation, impact). Provide information on outcomes of *outbreak* investigations including *outbreaks* that have occurred despite control measures, documented inspections showing compliance with biosecurity and hygiene requirements.

c) FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 3.1.8. of the *Terrestrial*

Manual are applied. The following points should be addressed:

i) Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country, including the following:

- How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;
- Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the past 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
- Procedures for quality assurance and, if available, the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
- Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
- Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
- Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

ii) If FMD *laboratory* diagnosis is not carried out in 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.

d) Strategies

i) Provide a description of the legislation, organisation and implementation of the current FMD control programme. Outline the legislation applicable to the control programme and how its implementation is organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

ii) Describe FMD control strategies in the country or any *zones*, including in terms of animal movement control, fate of infected and in-contact animals and *vaccination*. Strategies should be based on the assessment of the FMD situation in the *zones*, country and region.

iii) Provide information on what types of vaccines are used and which species are vaccinated. Provide information on the licensing process for the vaccines used. Describe the *vaccination* programme in the country and any *zones*, including records kept, and provide evidence to show its effectiveness, such as *vaccination* coverage, population immunity, etc. Provide details of the studies carried out to determine the *vaccination* coverage and the population immunity, including the study designs and the results.

iv) Describe how the *stamping-out policy* is implemented in the country or any *zones* and under which circumstances.

v) In the event of *outbreaks*, provide evidence of the impact of the control measures already implemented on the reduction in number of *outbreaks* and their distribution. If possible, provide information on primary and secondary *outbreaks*.

e) FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, including details of:

i) Coordination with other countries. Describe any relevant factors in neighbouring countries and *zones* that should be taken into account (e.g. size, distance from the border to affected *herds* or *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries

and *zones* in the same region or ecosystem.

Are *protection zones* in place? If so, provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

ii) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

iii) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

iv) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country or any *zones*. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products and subsequent internal movement. Describe the import measures (e.g. quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.

- Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What *biosecurity* is in place at waste disposal sites?

- Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:

  - animals;

  - genetic material (semen, oocytes and embryos);

  - animal products;

  - *veterinary medicinal products*;

  - other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.

v) Describe the actions available under legislation when an illegal import is detected. Provide information on illegal imports detected and the action taken.

f) Work plan and timelines of the control programme for the next five years, including cessation of *vaccination*. Describe the progressive objectives including expected status to be achieved in the next five years: for *zones* (if applicable) and for the whole country.

g) Performance indicators and timeline. The performance indicators should relate to the most important areas and steps where improvements in the programme are needed. These may include, but are not restricted to, strengthening *Veterinary Services*, legislation, reporting, availability and quality of vaccines, *animal identification* systems, *vaccination* coverage, population immunity, movement control, disease awareness, livestock owners' participatory perception on the effectiveness of the programme, etc. The progressive reduction of *outbreak* incidence towards elimination of FMD virus transmission in all susceptible livestock in at least one *zone* of the country should also be measured and monitored.

h) Assessment of the evolution of the *official control programme* since the first date of implementation. This should include documented evidence demonstrating that the control programme has been implemented and that the first results are favourable. Measurable evidence of success such as the performance indicators should include, but not be limited to, *vaccination* data, decreased prevalence, successfully implemented import measures, control of animal movements and finally decrease or elimination of FMD *outbreaks* in the whole country or selected *zones* as described in the programme. Where relevant, the transition to the use of vaccines, which are fully compliant with the *Terrestrial Manual* in order to enable demonstration of no evidence of FMD virus transmission, should be included in the timeline. This should include documented evidence of the effective implementation of Sections 3 d) and 3 e) above.

i) Describe the funding for the control programme and annual budgets for its duration.

4. Control measures and emergency response

a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the WOAH official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the last five years.

b) In the event of a suspected or confirmed FMD *outbreak*:

i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed regarding suspected *cases* (e.g. livestock standstills)?

ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;

iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;

iv) Describe in detail the control or *eradication* procedures (e.g. forward and backward tracing, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including *vaccination* delivery and cold chain, *stamping-out policy*, movement control, control of *wildlife*, pastured livestock and livestock as pets, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

vi) Provide details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;

vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control

points.

CHAPTER 8.16.

INFECTION WITH RIFT VALLEY FEVER VIRUS

EU	**The EU supports changes to this chapter.**

[…]

Article 8.16.8.

Recommendations for importation of semen and *in vivo* derived embryos of susceptible animals from countries or zones infected with RVFV

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

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

AND

2) either:

   a) were vaccinated against RVF at least 14 days prior to collection; or

   b) were subjected to a serological test on the day of collection, with positive result; or

   c) were subjected to a serological test on two occasions with negative results on the day of collection and at least 14 days after collection~~.~~; or

   d) were subjected to a test for the detection of the agent with negative result on the day of collection.

[…]

Annex 15

CHAPTER 8.18.

INFECTION WITH *TRICHINELLA* SPP.

EU	**The EU thanks the Code Commission for taking onboard previous suggestions to this chapter. Further editorial comments are inserted in the text below.**

Article 8.18.1.

General provisions

Trichinellosis is a widely distributed zoonosis caused by eating raw or undercooked *meat* from *Trichinella* infected food-producing animals or *wildlife*. Given that clinical signs of trichinellosis are not generally recognised in animals, the importance of trichinellosis lies exclusively in the *risk* posed to humans and costs of control in *slaughter* populations.

~~The~~ While the adult parasite and the larval forms live in the small intestine, ~~and~~ the L1 larval stage also lives in the muscles ~~(respectively)~~ of many mammalian, avian and reptile host species. ~~Within the genus *Trichinella*, twelve genotypes have been identified, nine of which have been designated as species. There is geographical variation amongst the genotypes.~~

Prevention of *infection* in susceptible species of domestic animals intended for human consumption relies on the prevention of exposure of those animals to the *meat* and *meat products* of *Trichinella* infected animals. This includes consumption of food waste of domestic animal origin, rodents and *wildlife*.

EU	**The above paragraph should be rephrased as "meat and meat product" are typically eaten by humans, not by animals. The following revision is proposed:** **"Prevention of infection in susceptible species of domestic animals intended for human consumption relies on the prevention of exposure of those animals to ~~the meat and meat products of~~ Trichinella infected animals and their cadavers~~. This includes consumption of~~ or to food waste of susceptible domestic animal origin, rodents and wildlife"**

Meat and *meat products* derived from *wildlife* should be considered a potential source of *infection* for humans. Therefore, untested *meat* and *meat products* of *wildlife* may pose a public health *risk*.

For the purposes of the *Terrestrial Code*, *infection* with *Trichinella* spp. is defined as an *infection* of suids or equids by parasites of the genus *Trichinella*.

This chapter provides recommendations for on-farm prevention of *Trichinella infection* in domestic pigs *(Sus scrofa domesticus)*, and safe trade of *meat* and *meat products* derived from suids and equids. This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005) and Guidelines for the control of *Trichinella* spp. in meat of Suidae (CAC/GL 86-2015).

EU	**Referring only to meat and meat products derived from wildlife as source of human infection while the rest of the document is on meat of susceptible domestic animals as possible source could be unclear. The EU understands that the purpose is to highlight the also susceptible wildlife might be a source, although not further addressed in this chapter. The following paragraph rearrangements and reformulation are proposed for clarity reasons:** **"This chapter provides recommendations for on-farm prevention of Trichinella infection in domestic pigs (Sus scrofa domesticus), and safe trade of meat and meat products derived from suids and equids. This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005) and Guidelines for the control of Trichinella spp. in meat of Suidae (CAC/GL 86-2015).** **For the purposes of the Terrestrial Code, infection with Trichinella spp. Is therefore defined as an infection of domestic suids or equids by parasites of the genus *Trichinella*.** **Nevertheless, meat and meat products derived from susceptible wildlife should also be considered a potential source of infection for humans. Therefore, untested meat and meat products of such wildlife may pose a public health risk."**

~~Methods for the detection of *Trichinella infection* in pigs and other animal species include direct demonstration of *Trichinella* larvae in muscle samples. Demonstration of the presence of *Trichinella* specific circulating antibodies using a validated serological test may be useful for epidemiological purposes.~~

When authorizing the import or transit of the *commodities* covered in this chapter, with the exception of those listed in Article 8.18.2., *Veterinary Authorities* should apply the recommendations in this chapter.

Standards for ~~diagnostic tests~~ diagnosis and information on the epidemiology are described in the *Terrestrial Manual*.

[…]

CHAPTER 8.X.

INFECTION WITH *COXIELLA BURNETII* (Q FEVER)

EU	**The EU thanks the Code Commission for the clarifications provided and supports the adoption of this new chapter.**

Article 8.X.1.

General provisions

Various animal species and humans can be affected by Q fever, but many of them, including *wild* and *feral* animals are considered not to, do not play an epidemiologically a significant role in the epidemiology of the disease. For the purposes of the *Terrestrial Code*, Q fever is defined as an *infection* of domestic and *captive wild* ruminants, dogs, and cats (hereafter 'susceptible animal') with *Coxiella burnetii*.

The following defines the occurrence of *infection* with *C. burnetii*:

1) *C. burnetii* has been isolated and identified as such in a sample from a susceptible animal; or

2) nucleic acid specific to *C. burnetii* has been detected in a sample from a susceptible animal showing clinical signs or pathological lesions consistent with *infection* with *C. burnetii*, or that is epidemiologically linked to a confirmed or suspected *case*; or

3) antibodies specific to *C. burnetii*, that are not the consequence of *vaccination*, have been detected in a sample from a susceptible animal showing clinical signs or pathological lesions consistent with *infection* with *C. burnetii*, or that is epidemiologically linked to a confirmed or suspected *case*.

Standards for diagnosis diagnostic tests and vaccines, as well as information on the epidemiology, are described in the *Terrestrial Manual*.

_____

CHAPTER 8.Z.

INFECTION WITH *TRYPANOSOMA EVANSI* (SURRA)

EU	**The EU supports the adoption of this new chapter.**

Article 8.Z.1.

General provisions

Surra is a disease caused by *Trypanosoma evansi* of the subgenus *Trypanozoon* and may manifest in acute, chronic or clinically inapparent forms.

T. evansi is a blood and tissue parasite that occasionally invades the nervous system. It can infect a large range of domestic and *wild* mammals. The disease has a significant socio-economic impact on animal production, especially in ~~horses, camels, donkeys, buffaloes and cattle~~ equids, camelids and bovines; it can also affect goats, sheep, deer, pigs, rodents and elephants. It has a serious clinical impact in dogs, cats and non-human primates, and may occasionally infect humans.

T. evansi is mainly transmitted mechanically by several biting flies ~~(e.g.~~ such as tabanids and~~,~~ *Stomoxys* spp.~~)~~, but can also be transmitted vertically, iatrogenically and possibly venereally. Additionally, it is transmitted perorally (especially to carnivores) and it can be transmitted biologically by the bite of vampire bats (*Desmodus* spp.), which may act as host, reservoir or *vector*.

Co-infection of *T. evansi* with other *Trypanosoma* species (including *T. vivax*, *T. brucei*, *T. congolense*, *T. simiae*, *T. equiperdum* and *T. cruzi*) may occur although this may not always be detected using routine testing methods.

For the purposes of the *Terrestrial Code*, surra is defined as an *infection* of susceptible animals with *T. evansi*.

For the purposes of this chapter, 'susceptible animals' means domestic and *wild* animals from the ~~following~~ families: Equidae, Camelidae, Bovidae, Suidae, Canidae, and Felidae; the orders Rodentia and Lagomorpha; and non-human primates.

The following defines the occurrence of *Infection* with *T. evansi*:

1) trypanosomes with *Trypanozoon* morphology have been observed in a sample from a susceptible animal and identified as *T. evansi* by the detection of nucleic acid; or

2) trypanosomes with *Trypanozoon* morphology have been observed in a sample from a susceptible animal either epidemiologically linked to a confirmed *case* of *infection* with *T. evansi* or ~~with relevant epidemiological context (including clinical signs, endemicity, origin of the host, absence of other *Trypanosoma* spp., absence of tsetse transmission) to support surra~~ suspected of previous association or contact with *T. evansi*; or

3) nucleic acid specific to *Trypanozoon* has been detected in a sample from a susceptible animal either epidemiologically linked to a confirmed *case* of *infection* with *T. evansi* or ~~with relevant epidemiological context (including clinical signs, endemicity, origin of the host, absence of other *Trypanosoma* spp., absence of tsetse transmission) to support surra~~ suspected of previous association or contact with *T. evansi*; or

4) antibodies specific to *Trypanosoma* spp. have been detected in a sample from a susceptible animal epidemiologically linked to a confirmed *case* of *infection* with *T. evansi* ~~or with relevant epidemiological context (including clinical signs, endemicity, origin of the host, absence of other *Trypanosoma* spp., absence of tsetse transmission) to support surra~~.

For the purposes of the *Terrestrial Code*, the *incubation period* of *infection* with *T. evansi* shall be 90 days in all species of susceptible animals.

For the purposes of this chapter, a temporary importation of horses refers to the introduction of horses into a country or *zone*, for a defined period of time, not exceeding 90 days, during which the *risk* of transmission of the *infection* is mitigated through specific measures under the supervision of the *Veterinary Authority.* Temporarily imported horses are re-exported at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or *zone,* should be defined in advance.

Standards for ~~diagnostic tests~~ diagnosis and information on the epidemiology are described in the *Terrestrial Manual*.

Article 8.Z.2.

Safe commodities

When authorising import or transit of the following *commodities, Veterinary Authorities* should not require any surra-related conditions regardless of the *animal health status* of the *exporting country* or *zone*:

1) pasteurised *milk* and pasteurised *milk products*;

2) hair, wool and fibre;

3) gelatine and collagen;

4) horns, hooves and claws;

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

~~6~~5~~6~~) *meat products*;

~~7~~6~~7~~) hides and skins (except raw);

~~8~~7~~8~~) embryos or oocytes collected, processed and stored in accordance with Chapters 4.8. to 4.10.

Article 8.Z.3.

Country or zone free from surra

A country or *zone* may be considered free from surra when:

1) the *infection* is notifiable in the entire country for at least the past two years;

2) measures to prevent the introduction of *infection* have been in place; in particular, the importations or movements of susceptible animals and other *commodities* into the country or *zone* have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*;

3) and either:

   a) the country or *zone* is historically free as described in point 2 b) of Article 1.4.6.; or

b) for at least the past two years, *surveillance* in accordance with Articles 8.Z.12~~6~~. to 8.Z.15~~9~~. has been in place in the entire country or *zone* and there has been no *case* in the country or *zone*.

In order to maintain its status, a country or *zone* free from ~~*infection with T. evansi*~~ surra should:

1) comply with points 1 and 2 above;

2) if adjacent to an infected country or *zone*, ~~should~~ include an area along the border, in which *surveillance* is conducted in accordance with Articles 8.Z.12. to 8.Z.15.

Article 8.Z.4.

Compartment free from surra

The establishment of a *compartment* free from surra should follow the provisions laid down in this chapter and in Chapters 4.4. and 4.5.

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

Susceptible animals in the free *compartment* should be protected against both iatrogenic and venereal transmission.

Article 8.Z.5.

Recovery of free status

Should a *case* of *infection* with *T. evansi* occur in a previously free country or *zone*, its status may be recovered after the following:

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

2) animals in contact with *cases* have been put immediately under protection from *vector* contact and tested;

3) appropriate *biosecurity* is in place, including *vector* control or protection from *vector* contacts in the affected area in accordance with Articles 1.5.2. and 1.5.3.;

4) *surveillance* in accordance with Articles 8.Z.12. to 8.Z.15. has been carried out with negative results;

5) for six consecutive months, either:

   a) after the last *case* was killed or slaughtered, the animals in contact have undergone monthly repeated ~~serological~~ antibody detection and agent identification (microscope and molecular) tests with negative results in all tests; or

   b) if appropriate trypanocide treatment is applied to the *cases*, after the last *case* was killed, slaughtered or treated, whichever occurred last, both treated and in contact animals have undergone monthly repeated agent identification tests (microscope and molecular) with negative results, and ~~serological~~antibody detection tests with decreasing titres.

If points 1 to 5 are not applied, Article 8.Z.3. applies.

Article 8.Z.6.

Recommendations for importation of equids, camelids, bovids and suids ~~susceptible animals (except dogs and cats)~~ from countries, zones or compartments free from surra

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

1) showed no clinical sign of ~~*infection* with *T. evansi*~~ surra on the day of shipment;

2) were kept since birth or at least ~~six months~~ 90 days prior to shipment in a free country, *zone* or *compartment*;

3) did not transit through an *infected zone* during transportation to the *place of shipment* or were protected from *vectors* or any source of *T. evansi* by the application of effective *biosecurity* during transportation to the place of shipment.

Article 8.Z.7.

Recommendations for importation of equids, bovids and suids ~~susceptible animals (except dogs and cats)~~ from countries or zones infected with *T. evansi*

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

1) showed no clinical sign of ~~*infection* with *T. evansi*~~ surra during isolation and on the day of shipment;

2) were isolated in a *quarantine station* for at least ~~90~~ 45 days prior to shipment, and all animals from the same group ~~*flock or herd*~~ were subjected to antibody detection tests ~~serological and agent identification (microscope and molecular)~~ on samples taken on two occasions, with an interval of 30 days, ~~immediately prior to entering quarantine and within 15 days before being released from quarantine,~~ with negative results.

Article 8.Z.8.

Recommendations for importation of susceptible animals from countries or zones infected with *T. evansi* for ~~immediate~~ direct slaughter

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

1) showed no clinical sign of ~~*infection* with *T. evansi*~~surra on the day of the shipment;

2) a) were kept for the six months prior to shipment in an *establishment* in which *surveillance* in accordance with Articles 8.Z.12., 8.Z.13. and 8.Z.14. demonstrates that no *case* had occurred during that period; or

b) were negative in ~~an agent identification (microscope and molecular) and~~ an antibody detection ~~serological~~ test within 15 days prior to shipment;

~~3) were kept for the six months prior to shipment in an *establishment* in which *surveillance* in accordance with Articles 8.Z.12., 8.Z.13. and 8.Z.14. demonstrates that no *case* had occurred during that period;~~

~~4~~3) were permanently identified and transported under the supervision of the *Veterinary Services* in a *vector*-protected *vehicle*, which underwent *disinfection* and disinsection before *loading*, directly from the *establishment* of origin to the *place of shipment* without coming into contact with other susceptible animals.

Article 8.Z.9.

Recommendations for the temporary importation of horses

When importing on a temporary basis horses that do ~~If the importation of horses on a temporary basis does~~ not comply with the recommendations in Article 8.Z.6. or Article 8.Z.7., *Veterinary Authorities* of *importing countries* should:

1) require:

a) the ~~equids~~ horses be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status *subpopulation* as defined in Chapter 4.17.;

b) the presentation of an *international veterinary certificate* attesting that the ~~equids~~horses:

i) showed no clinical sign of surra on the day of shipment;

~~i~~ii) belong to a high health status *subpopulation* or were negative in an antibody detection test within 15 days prior to departure from the country of origin;

~~ii) showed no clinical sign of *infection* with *T. evansi* on the days of shipments;~~

c) the duration of the temporary importation period and the destination after this period, and the conditions required to leave the country or *zone* be defined;

2) ensure that during their stay in the country or *zone*:

a) measures are taken to protect the horses from *vectors* or any source of *T. evansi* by the application of effective *biosecurity*;

b) the ~~equids~~ horses ~~we~~are not subjected to any practice that may represent a risk of iatrogenic transmission of ~~*infection* with *T. evansi*~~ surra;

c) the ~~equids~~ horses are kept and transported individually in stalls and *vehicles/vessels* which are subsequently cleaned and disinsected before re-use.

Article 8.Z.10.

Recommendations for importation of semen of susceptible animals from countries, zones or compartments free from surra

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

1) the donor males:

a) showed no clinical sign of ~~*infection* with *T. evansi*~~ surra on the day of semen collection;

b) have been kept for at least ~~six months~~ 90 days prior to semen collection in a free country, *zone* or *compartment*; and

2) the semen was collected, processed and stored in a *semen collection centre* in accordance with Chapters 4.6. and 4.7.

Article 8.Z.11.

Recommendations for importation of semen of susceptible animals from countries or zones infected with *T. evansi*

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

1) the donor males:

a) have been kept for at least ~~six months~~ 90 days prior to semen collection in an *establishment* in which *surveillance* in accordance with Articles 8.Z.12., 8.Z.13. and 8.Z.14. demonstrates that no *case* had occurred during that period;

b) showed no clinical sign of ~~*infection* with *T. evansi*~~ surra ~~on the day of semen collection~~ during that period;

c) were ~~negative in an agent identification (microscopic) and~~ subjected to an ~~serological~~ antibody detection test on a blood sample taken on two occasions, with an interval of 30 days, with negative results ~~collected on the day of collection of the semen~~;

~~2) molecular examination of semen for *T. evansi* was negative;~~

~~3~~2) the semen was collected, processed and stored in a *semen collection centre* in accordance with Chapters 4.6. and 4.7.

~~Article 8.Z.11bis.~~

~~Recommendations for importation of fresh meat from susceptible animals from countries or zones infected with *T.evansi*~~

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

~~1) the entire consignment of *meat* comes from:~~

~~a) susceptible animals that showed no clinical signs of surra within 24 hours before *slaughter*;~~

~~b) susceptible animals that were slaughtered in an approved *slaughterhouse/abattoir* and were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3. with favourable results;~~

~~c) carcasses that were submitted to maturation for a minimum period of 48 hours following *slaughter*.~~

~~2) the necessary precautions were taken to avoid contact of the *meat* with any potential source of *T. evansi*.~~

Article 8.Z.12.

Introduction to surveillance

Articles 8.Z.12. to 8.Z.14. define the principles and provide guidance on *surveillance* for ~~*infection* with *T. evansi*~~ surra, complementary to Chapter 1.4. and Chapter 1.5.

The purpose of *surveillance* could be the demonstration of the absence of *infection*, the early detection of *cases*, or the measurement and monitoring of the *prevalence* and distribution of the *infection* in a country, *zone* or *compartment*.

An important component of the epidemiology of surra is the capability of its *vectors*, which provides a measure of disease risk that incorporates *vector* competence, abundance, biting rates, survival rates, host affinity and in the case of biological *vectors*, the extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context. Therefore, *surveillance* for ~~*infection* with *T. evansi*~~ surra should focus on transmission of *T. evansi* in susceptible animals.

The impact and epidemiology of surra widely differs between different regions of the world and therefore, it is not appropriate to provide specific recommendations for all situations. Member Countries should provide scientific data explaining the epidemiology of the disease in the country or *zone* concerned, such as host susceptibility and co-infections with other *Trypanosoma* spp., and adapt the *surveillance* strategies for defining their status to the local conditions. There is considerable latitude available to Member Countries to justify their status at an acceptable level of confidence.

~~Consideration should be given to risk factors such as susceptibility, co-infections with other *Trypanosoma* spp. and climate change.~~

Although *surveillance* in susceptible *wild animals* presents challenges that may differ significantly from those in domestic *animals*, *wildlife* should be considered in the *surveillance* system as they are included in the ~~case~~ definition of the occurrence and can serve as reservoirs of *infection* and as indicators of *risk* to domestic *animals.*

Article 8.Z.13.

General conditions and methods of surveillance

The *surveillance* system for ~~*infection* with *T. evansi*~~ surra should be in accordance with Chapter 1.4. and be under the responsibility of the *Veterinary Authority*.

1) It should include:

   a) formal and ongoing system for detecting and investigating *outbreaks* ~~of disease~~;

   ~~b) each country should establish a *surveillance* system or integrate activities into already established animal health *surveillance* programmes for purposes of sustainablity;~~

   ~~c~~b) the collection and transport of samples from suspected *cases* to a *laboratory* for diagnosis or a procedure for the rapid diagnosis in the field;

   ~~d~~c) appropriate tools, for collection, recording, managing and analysis of data; reporting and dissemination for decision making.

2) In addition, it should, at least:

   a) in a free country or *zone,* have an *early warning system* capable of detecting *T. evansi* which obliges animal owners and keepers and other stakeholders who have regular contact with susceptible animals, as well as *veterinarians* or *veterinary paraprofessionals*, to report promptly any suspicion of ~~*infection* with *T. evansi*~~ surra to the *Veterinary* ~~*Authority*~~ *Services*;

   b) include representative or risk-based serological or parasitological surveys appropriate to the status of the country, *zone* or *compartment*.

An effective *surveillance* system will periodically identify suspected *cases* that require follow-up and investigation to confirm or exclude whether the cause of the condition is *T. evansi*. The rate at which such suspected *cases* are likely to occur will differ between epidemiological situations and cannot therefore be reliably predicted. All suspected *cases* should be investigated immediately, and samples should be taken and submitted to a *laboratory*.

Article 8.Z.14.

Surveillance strategies

The target *population* should include domestic and *wild* susceptible animals of epidemiological significance within the country, *zone* or *compartment.* Active and passive *surveillance* for surra should be ongoing as epidemiologically appropriate. *Surveillance* should be composed of representative or risk-based approaches using parasitological, serological, clinical and entomological methods appropriate for the status of the country, *zone* or *compartment*.

In a free country, *zone* or *compartment,* it is appropriate to focus *surveillance* in an area adjacent to an infected country, *zone* or *compartment*, considering relevant ecological or geographical features likely to interrupt the transmission of surra.

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with *T. evansi* in accordance with Chapter 1.4. and Chapter 1.5., and with the prevailing epidemiological situation.

If a Member Country wishes to declare freedom from surra in a specific *zone*, the design of the *surveillance* strategy should be targeted to the susceptible population within the *zone*.

For random surveys, the sample size selected for testing should be large enough to detect evidence of *infection* if it were to occur at a predetermined minimum expected *prevalence*. The sample size and expected *prevalence* determine the level of confidence in the results of the survey. The Member Country should justify the choice of the minimum expected *prevalence* and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation

of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *infection* history and the different *Trypanosoma* species and other Kinetoplastid species (*T. vivax, T. congolense, T. brucei*, *T. equiperdum*, *T. cruzi* and *Leishmania* spp.) present in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of cross reactions. There should be an effective procedure for following up cross reactions to determine, with a high level of confidence, whether they are indicative of *infection* with *T. evansi* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles involved in *surveillance* are technically well defined. The design of *surveillance* programmes to prove the absence of *infection* with *T. evansi* should be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated.

The results of random or targeted surveys are important in providing reliable evidence that no *infection* with *T. evansi* is present in a country, *zone* or *compartment*. It is, therefore, essential that the survey is thoroughly documented. It is critical to consider the movement history of the animals being sampled when interpreting the results.

An active programme of *surveillance* of susceptible populations to detect evidence of ~~*infection* with *T. evansi*~~ surra is essential to establish the *animal health status* of a country, *zone* or *compartment.*

1. Clinical surveillance

   Clinical *surveillance* aims to detect clinical signs of ~~*infection* with *T. evansi*~~ surra in susceptible animals, particularly during a newly introduced *infection*. However, neither clinical nor post-mortem signs of ~~*infection* with *T. evansi*~~ surra are pathognomonic. Therefore, suspected *cases* of *infection* with *T. evansi* detected by clinical *surveillance* should always be confirmed by direct or indirect laboratory tests that confirm the presence of *T. evansi*.

2. Parasitological surveillance

   Parasitological examination (or agent identification) can be conducted to:

   a) detect active *infection*;

   b) confirm clinically suspected *cases*;

   c) identify parasites at the subgenus level;

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

3. Molecular techniques

   Molecular techniques can be conducted to:

   a) increase the sensitivity of the detection of active *infections*;

   b) confirm clinically suspected *cases*;

   c) identify parasites at the subgenus level (Trypanozoon), or at the species level (*T. evansi*); (in the host and/or the *vector*);

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

4. Serological surveillance

a) Serological testing of susceptible animals is one of the most effective methods for detecting exposure to *T. evansi*. The host species tested should reflect the epidemiology of the disease. Management variables that may influence likelihood of *infection*, such as animal treatment, should be considered.

b) Owing to cross reactions with other Kinetoplastid species, co-infections with these pathogenic agents should be considered when interpreting the results of the serological *surveillance* system.

c) Serological techniques can be ~~conducted~~ used to:

i) demonstrate individual or population freedom;

ii) detect subclinical or latent *infection* by *T. evansi*;

iii) determine by seroprevalence the magnitude of *infection* by *T. evansi* in the host population.

d) Positive test results can have different possible causes:

i) current *infection*;

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

iii) maternal antibodies;

iv) cross reactions with other Kinetoplastid species.

5. Sentinel animals

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

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

b) the investigation of clinical suspect *cases* targeting highly susceptible animals such as dogs (hunting dogs and dogs living around *slaughterhouses/abattoirs*), camels, donkeys or horses.

6. Vector surveillance

This point should be read in conjunction with Chapter 1.5.

For the purposes of this chapter, *vector surveillance* aims at determining different levels of *risk* by identifying the presence and abundance of various *vector* species (biting flies and vampire bats) in an area.

The most effective way of gathering *vector surveillance* data should consider the biology and behavioural characteristics of the local *vector* species and include traps, net, sticky targets or other collection tools. The choice of the number and type of collecting tools to be used and the frequency of their use should be made by considering the size and ecological characteristics of the area to be surveyed. In the *surveillance* of *wildlife* species, molecular techniques may be applied to *vectors*.

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

Article 8.Z.15.

Additional surveillance procedures for recovery of free status

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

Populations under this *surveillance* programme should include:

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

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

3) *animals* moved from previously affected *establishments*;

4) *animals* used to re-populate previously affected *establishments*.

Annex 18

CHAPTER 13.2.

INFECTION WITH PATHOGENIC RABBIT LAGOVIRUSES (RABBIT HAEMORRHAGIC DISEASE)

EU	**The EU supports the adoption of this revised chapter.** **The EU supports the approach proposed by the Code Commission to keep track of the comments already submitted by the EU which will be taken into account when a full revision of the whole chapter will take place.**

Article 13.2.1.

General provisions

For the purposes of the *Terrestrial Code*, rabbit haemorrhagic disease (RHD) is defined as an *infection* of leporids with *Rabbit haemorrhagic disease virus type 1* (RHDV) ~~and~~ or *Rabbit haemorrhagic disease virus type 2* (RHDV2) (hereafter 'pathogenic rabbit lagoviruses').

The following defines the occurrence of *infection* with pathogenic rabbit lagoviruses:

1) antigen or nucleic acid specific to pathogenic rabbit lagoviruses has been detected in a sample from a leporid showing clinical signs or pathological lesions consistent with *infection* with pathogenic rabbit lagoviruses, or epidemiologically linked to a confirmed or suspected *case*; or

2) antibodies specific to pathogenic rabbit lagoviruses, which are not the consequence of *vaccination*, have been detected in a sample from a leporid showing clinical signs or pathological lesions consistent with *infection* with pathogenic rabbit lagoviruses, or epidemiologically linked to a confirmed or suspected *case*.

For the purposes of the *Terrestrial Code*, the *infective period* for ~~rabbit haemorrhagic disease (~~RHD~~)~~ shall be 60 days.

Standards for ~~diagnostic tests~~ diagnosis and vaccines, as well as information on the epidemiology, are described in the *Terrestrial Manual*.

Article 13.2.2.

Country free from RHD ~~free country~~

A country may be considered free from RHD when it has been demonstrated~~shown~~ that no *case* has occurred ~~the disease has not been present~~ for at least the past 12 months ~~one year~~, that no *vaccination* has been carried out in the past ~~previous~~ 12 months, and that virological or serological *surveillance* ~~surveys~~ in both domestic and *wild* ~~rabbits~~ leporids have confirmed the absence of the *infection* ~~disease~~.

This period may be reduced to six months after the last *case* has been destroyed ~~eliminated~~ and *disinfection* procedures have been completed in countries adopting a *stamping-out policy*, and where ~~the~~ serological *surveillance* ~~surveys~~ confirmed that no *case* ~~the disease had not~~ occurred in the *wild* ~~rabbits~~ leporids.

[…]

Annex 19

CHAPTER 15.1.

INFECTION WITH AFRICAN SWINE FEVER VIRUS

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

[…]

Article 15.1.2.

Safe commodities

When authorising importation or transit of the following *commodities*, *Veterinary Authorities* should not require any ASF-related conditions, regardless of the ~~ASF status~~ *animal health status* of the *exporting country* or *zone*:

1) heat-treated *meat products* in a hermetically sealed container with a F~~0~~$_0$ value of 3 or above;

2) gelatine~~.~~;

3) extruded dry pet food;

4) *protein meal*.

Other *commodities* of suids can be traded safely if in accordance with the relevant articles of this chapter.

[…]

Annex 20

CHAPTER ~~X~~16.Z.

INFECTION WITH CAMELPOX VIRUS

EU	**The EU supports the adoption of this new chapter.**

Article ~~X~~16.Z.1.

General provisions

For the purposes of the *Terrestrial Code*, *infection* with ~~c~~*Camelpox virus* is defined as an *infection* of dromedary and bactrian camels (hereafter 'susceptible animals') with ~~c~~*Camelpox virus* ~~of genus *Orthopoxvirus*, family *Poxviridae*~~.

The following defines the occurrence of *infection* with ~~c~~*Camelpox virus*:

1) ~~c~~*Camelpox virus* has been isolated and identified as such in a sample from a susceptible animal; or

2) characteristic ~~o~~*Orthopox* virions have been observed in a sample from a susceptible animal showing clinical signs ~~suggestive of~~ consistent with *infection* with ~~c~~*Camelpox virus* or epidemiologically linked to a confirmed or suspected *case*; or

3) antigen or nucleic acid specific to ~~c~~*Camelpox virus* has been detected in a sample from a susceptible animal showing clinical signs ~~suggestive of~~ consistent with *infection* with ~~c~~*Camelpox virus*, or epidemiologically linked to a confirmed or suspected *case*; or

4) antibodies specific to ~~c~~*Camelpox virus*, that are not the consequence of *vaccination*, have been detected in a sample from a susceptible animal showing clinical signs ~~suggestive of~~ consistent with *infection* with ~~c~~*Camelpox virus*, or epidemiologically linked to a confirmed or suspected *case*.

Standards for ~~diagnostic tests~~ diagnosis and vaccines, as well as information on the epidemiology, are described in the *Terrestrial Manual*.

Annex 21

TERMINOLOGY: USE OF THE TERMS 'COMPETENT AUTHORITY', 'VETERINARY AUTHORITY' AND 'VETERINARY SERVICES'

EU	**The EU supports the adoption of these revised texts.**

GLOSSARY

[...]

ANIMAL FOR SLAUGHTER

means an *animal* intended for *slaughter* within a short time, under the control of the relevant ~~*Veterinary*~~ *Competent Authority*.

[...]

SLAUGHTERHOUSE/ABATTOIR

means premises, including facilities for moving or lairaging *animals*, used for the *slaughter* of *animals* to produce animal products and approved by the ~~*Veterinary Services* or other~~ relevant *Competent Authority*.

Article 1.7.1.

[...]

6. AHS prevention

c) Import control procedures

i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central *Veterinary Services*~~ *Veterinary Authority*. Describe the communication systems between the ~~central authorities~~ *Veterinary Authority* and the *border posts*, and between *border posts*.

[...]

Article 1.7.2.

[...]

6. AHS prevention

c) Import control procedures

i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central *Veterinary Services*~~ *Veterinary Authority*. Describe the communication systems between the ~~central authorities~~ *Veterinary Authority* and the *border posts*, and between *border posts*.

[...]

Article 1.9.1.

[...]

6. CSF prevention

d) Import control procedures

i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central *Veterinary Services*~~ *Veterinary Authority*. Describe the communication systems between the ~~central authorities~~ *Veterinary Authority* and the *border posts*, and between *border posts*.

[...]

Article 1.10.1.

[...]

6. CBPP prevention

c) Import control procedures

i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central *Veterinary Services*~~ *Veterinary Authority*. Describe the communication systems between the ~~central authorities~~ *Veterinary Authority* and the *border posts*, and between *border posts*.

[...]

Article 1.10.2.

[...]

6. CBPP prevention

c) Import control procedures

i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central *Veterinary Services*~~ *Veterinary Authority*. Describe the communication systems between the ~~central authorities~~ *Veterinary Authority* and the *border posts*, and between *border posts*.

[...]

Article 1.10.3.

[...]

3. Official control programme for CBPP submitted for WOAH endorsement

e) CBPP prevention

iii) Import control procedures

- Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central *Veterinary Services*~~ *Veterinary Authority*. Describe the communication systems between the ~~central authorities~~ *Veterinary Authority* and the *border posts*, and between *border posts*.

[...]

Article 1.11.1.

[...]

6. FMD prevention

d) Import control procedures

i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central *Veterinary Services*~~ *Veterinary Authority*. Describe the communication systems between the ~~central authorities~~ *Veterinary Authority* and the *border posts*, and between *border posts*.

[...]

Article 1.11.2.

[...]

6. FMD prevention

d) Import control procedures

i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central *Veterinary Services*~~ *Veterinary Authority*. Describe the communication systems between the ~~central authorities~~ *Veterinary Authority* and the *border posts*, and between *border posts*.

[...]

Article 1.11.3.

[...]

6. FMD prevention

d) Import control procedures

i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central *Veterinary Services*~~ *Veterinary Authority*. Describe the communication systems between the ~~central authorities~~ *Veterinary Authority* and the *border posts*, and between *border posts*.

[...]

Article 1.11.4.

[...]

6. FMD prevention

d) Import control procedures

i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central *Veterinary Services*~~ *Veterinary Authority*. Describe the communication systems between the ~~central authorities~~ *Veterinary Authority* and the *border posts*, and between *border posts*.

[...]

Article 1.11.5.

[...]

3. Official control programme for FMD submitted for WOAH endorsement

e) FMD prevention

iv) Import control procedures

- Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central *Veterinary Services*~~ *Veterinary Authority*. Describe the communication systems between the ~~central authorities~~ *Veterinary Authority* and the *border posts*, and between *border posts*.

[...]

Article 1.12.1.

[...]

6. PPR prevention

c) Import control procedures

i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central *Veterinary Services*~~ *Veterinary Authority*. Describe the communication systems between the ~~central authorities~~ *Veterinary Authority* and the *border posts*, and between *border posts*.

[...]

Article 1.12.2.

[...]

6. PPR prevention

c) Import control procedures

i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central *Veterinary Services*~~ *Veterinary Authority*. Describe the communication systems between the ~~central authorities~~ *Veterinary Authority* and the *border posts*, and between *border posts*.

[...]

Article 1.12.3.

[...]

3. Official control programme for PPR submitted for WOAH endorsement

e) PPR prevention

iii) Import control procedures

- Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central *Veterinary Services*~~ *Veterinary Authority*. Describe the communication systems between the ~~central authorities~~ *Veterinary Authority* and the *border posts*, and between *border posts*.

[...]

Article 3.2.3.

[...]

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

[...]

Article 4.1.1.

[...]

Prerequisites for developing such programmes include:

– quality *Veterinary Services* including legislative framework, *laboratory* capacity and adequate and committed funding;

– appropriate education and training to secure *veterinarians* and *veterinary paraprofessionals*;

– close links with research institutions;

– effective awareness of, and active cooperation with, private stakeholders;

– public-private partnerships;

– cooperation between ~~*Veterinary Authorities*~~ the *Veterinary Authority* and other *Competent Authorities*;

– regional cooperation among *Veterinary Authorities* on transboundary animal diseases.

Article 4.13.2.

[...]

4) any need to transfer the ownership of *animals* to the ~~competent authority~~ *Competent Authority*;

[...]

Should the chosen option for the disposal of dead *animals* be applied near the border of a neighbouring country, the ~~competent authorities~~ relevant *Competent Authority* of that country should be consulted.

Article 4.19.1.

[...]

The *Veterinary Authority* should determine the diseases against which *official control programmes* are to be prepared, developed and implemented, according to an evaluation of the actual or likely impact of the disease. *Official control programmes* should be prepared by the *Veterinary Authority* and ~~*Veterinary Services*~~ other *Competent Authorities* in close collaboration with the relevant stakeholders and other authorities, as appropriate.

[...]

Article 5.1.4.

[...]

3) In case of suspicion, on reasonable grounds, that an official certificate may be fraudulent, the *Veterinary Authority~~y~~ies* of the *importing country* and *exporting country* should conduct an investigation. Consideration should also be given to notifying any third country that may have been implicated. All associated consignments should be kept under official control, pending the outcome of the investigation. The *Veterinary Authorities* of all countries involved should fully cooperate with the investigation. If the certificate is found to be fraudulent, every effort should be made to identify those responsible so that appropriate action can be taken in accordance with the relevant legislation.

Article 5.6.4.

[...]

3) a list of airports in its territory which are provided with an area of direct transit, approved by the ~~relevant~~ *Veterinary Authority* and placed under its immediate control, where *animals* stay for a short time pending further transport to their final destination.

Article 6.3.3.

[...]

The CHPM does not provide inspection measures for specific *hazards*, which remain the responsibility of ~~national competent authorities~~ *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.

[...]

Article 6.3.6.

[...]

The ~~national competent authority(ies)~~ *Competent Authority*(*ies*) should provide an appropriate institutional environment to allow *Veterinary Services* to develop the necessary policies and standards.

[...]

Article 7.4.4.

[...]

1. Health and customs requirements

[...]

Contact the *Veterinary Authorit~~ies~~y* in the country of origin regarding veterinary certification.

[...]

Article 7.7.6.

[...]

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

[...]

Article 8.3.15.

[...]

2) The bluetongue *surveillance* programme should:

a) in a free country or *zone* or seasonally free *zone*, have an *early warning system* which obliges farmers and workers, who have regular contact with domestic ruminants, as well as diagnosticians, to report promptly any suspicion of bluetongue to the *Veterinary ~~Authority~~ Services*.

[...]

Article 8.18.8.

[...]

2) The *surveillance* programme for the pathogenic agent should, at least:

a) in a free country or *zone*, have an *early warning system* which obliges animal owners and keepers and other stakeholders who have regular contact with susceptible animals, as well as *veterinarians* or *veterinary paraprofessionals*, to report promptly any suspicion of *infection* with *T. brucei*, *T. congolense*, *T. simiae* and *T. vivax* to the *Veterinary ~~Authority~~ Services*.

[...]

Article 10.4.27.

[...]

2) The high pathogenicity avian influenza *surveillance* programme should include the following.

a) An *early warning system* for reporting suspected *cases*, in accordance with Article 1.4.5. throughout the production, marketing and processing chain. Farmers and workers who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of avian influenza to the *Veterinary ~~Authority~~ Services*. All suspected *cases* of high pathogenicity avian influenza should be investigated immediately and samples should be ~~taken~~ collected and submitted to a *laboratory* for appropriate tests.

[...]

Article 10.4.29.

[...]

Passive *surveillance*, i.e. sampling of birds found dead, is an appropriate method of *surveillance* in *wild* birds because *infection* with high pathogenicity avian influenza can be associated with mortality in some species. Mortality events, or clusters of birds found dead should

be reported to the ~~local *Veterinary Authorities*~~ *Veterinary Services* and investigated, including through the collection and submission of samples to a *laboratory* for appropriate tests.

[...]

Article 12.2.8.

[...]

The *Veterinary Services* should implement programmes to raise awareness among owners, breeders and workers who have day-to-day contact with horses, as well as *veterinarians*, *veterinary paraprofessionals* and diagnosticians, who should report promptly to them any suspicion of *infection* with *T. equigenitalis* ~~to the *Veterinary Authority Services*~~.

Article 12.7.8.

[...]

The *Veterinary Services* should implement programmes to raise awareness among *veterinarians*, horse breeders, owners, keepers, and riders who have day-to-day contact with equids, as well as *veterinary paraprofessionals* and diagnosticians, who should report promptly to them any suspicion of *infection* with *T. equi* and any suspicion of *infection* with *B. caballi* ~~to the *Veterinary Authority Services*~~.

Article 15.1.29.

[...]

2) The ASF *surveillance* programme should:

   a) include an *early warning system* throughout the production, marketing and processing chain for reporting suspected *cases*. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of ASF to the *Veterinary ~~Authority~~ Services*. The reporting system under the *Veterinary Authority* should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary paraprofessionals*) by government or private sector awareness programmes targeted to all relevant stakeholders. Personnel responsible for *surveillance* should be able to seek expertise in ASF diagnosis, epidemiological evaluation and control;

[...]

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Article 15.2.29.

[...]

2) The CSF *surveillance* programme should:

a) include an *early warning system* throughout the production, marketing and processing chain for reporting suspected *cases*. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of CSF to the *Veterinary ~~Authority~~ Services*. The reporting system under the *Veterinary Authority* should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary paraprofessionals*) by information programmes. Given that many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, *cases* in which CSF cannot be ruled out should be immediately investigated. Other important diseases such as African swine fever should also be considered in any differential diagnosis.

[...]

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Article 15.3.14.

[...]

2) Any PRRS *surveillance* programme should:

a) include the reporting and investigation of suspected *cases*. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of PRRS to the *Veterinary ~~Authority~~ Services*;

[...]

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Annex 3

WORK PROGRAMME FOR
THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

EU	**The EU commends the Code Commission for its continuous efforts to prioritise its heavy work programme, in coordination with other specialist commissions as relevant. We thank the Code Commission for having taken into consideration comments submitted previously. We fully support the revised work programme and its prioritisation. As regards the comprehensive review of the Code chapter on sheep and goat pox, we note that an update of the corresponding chapter in the Manual has been proposed for adoption in May 2024. Given this revised Manual chapter, the EU encourages the Code Commission to embark without delay on work to revise that Code chapter accordingly.** **With respect to the EU comments on the trichinella chapter (Article 1 of chapter 8.18), the EU invites the Code Commission to review any EU submitted comment which were not addressed during the General Session.**

Chapter	Issues	Summary of the work	Status - February 2024		Priority order *
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment) or last TAHSC report reference	
General	Wildlife Health	Overarching consideration on how wildlife animal health is addressed in the *Terrestrial Code*	Preliminary discussions	Noted in Feb 2024 TAHSC report	2
	New chapter on emergency management	Develop a new chapter and potentially modify the existing chapters	Expert consultation	Noted in Feb 2024 TAHSC report	3

	Commodities	Consideration to determine whether several types of highly processed products (such as blood meal, dried plasma, rendered fats, and hydrolysed protein) have a globally standardised production process and meet criteria to be considered safe commodities as regards specific diseases.	Preparatory work	Noted in Feb 2024 TAHSC report	2
	Pet-food commodities	Consider the inclusion of 'extruded dry pet food' and 'heat-treated meat products in a hermetically sealed container with an F0 value of 3 or above' in the list of safe commodities of chapters (when revised).	Preparatory work	Refer to Sep 2022 TASHC report	2
		In Chapter 15.1. Infection with African swine fever virus	Proposed for adoption in May 2024	Noted in Feb 2024 TASHC report (Sep 2023/1)	1
Use of terms	Use of terms: animal health status	- Consider the need to revise definition to incorporate 'herd', and avoid restrictive wording - Possible revision of the Glossary definition - Review use of the terms across the *Code* for consistency -	Preparatory work	Refer to Feb 2020 TAHSC report	1
	Use of terms: animal-based measures / measurables	Review use of the terms across the *Code* for consistency Develop a policy for their use	Circulated for comments (proposed for adoption in May 2024)	Noted in Feb 2024 TAHSC report	2
	Use of terms: notify / notifiable disease / report / reportable disease	Review use of the terms across the *Code* for consistency. Develop a policy for their use	Preparatory work	Refer to Feb 2019 TAHSC report	2

	Use of terms: Competent Authority / Veterinary Authority / Veterinary Services	Review use of the terms across the *Code* for consistency	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Feb 2023/2)	1
User's guide	Revision of the Users' guide (standing item)	Partial revision - to provide more explanation on disease-specific chapters - to develop a new point on terms referring to animals used in the *Terrestrial Code* - work on introduction	Circulated for comments and work in parallel	Noted in Feb 2024 TAHSC report (Sep 2023/2)	1
Glossary	'Death', 'euthanasia', 'slaughter' and 'stunning'	In-depth revision in relation to work on Chs 7.5.-7.6.	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Sep 2019/4)	1
	'Artificial insemination centre'	Change the term to 'semen collection centre'	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Sep 2023/1)	1
	New definitions for 'animal products', 'product of animal origin' and 'animal by-product'	Review use of the terms across the *Code* for consistency. Develop a policy for their use and draft definitions.	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Feb 2023/2)	1
	New definition for 'biological products'	Develop a new definition	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Sep 2023/1)	1
	New definition for 'swill'	Review use of the term across the *Code*. Develop a policy for its use and consider developing a definition. (connected to biosecurity work)	Expert consultation	Noted in Feb 2024 TAHSC report (Sep 2023/1)	1
	Definitions for 'biosecurity' and 'biosecurity plan'	Review as a part of the work on new Chapter on Biosecurity	Expert consultation	Noted in Feb 2024 TAHSC report (Sep 2023/1)	1
	New definition for 'point of exit' and definitions for 'border post' and 'quarantine station'	Review as a part of the work to revise Chs 5.4. to 5.7.	Expert consultation	Noted in Feb 2024 TAHSC report (Sep 2023/1)	1
	New definition for 'veterinary medical use'	Move the definition from Ch 6.9.	Pending adoption of Ch 6.10.	Noted in Sep 2023 TAHSC report	3

	Definition of ‘poultry’	(Not defined yet, related to revision of chapters in Section 10)	Not started	Noted in Feb 2024 TAHSC report	2
	Definition for ‘greaves’	Deletion of the definition	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Sep 2023/1)	1
	Definition for ‘disinfection’	Revision of definition	Expert consultation	Noted in Feb 2024 TAHSC report	2
	New definition for ‘pathogenic agent’	Develop a new definition	Expert consultation	Noted in Feb 2024 TAHSC report	2
	Definition for ‘laboratory’	Revision of definition	Expert consultation	Noted in Feb 2024 TAHSC report	2
	New definition for ‘isolation’	Develop a new definition	Expert consultation	Noted in Feb 2024 TAHSC report	2
	New definition for ‘suspected case’	Develop a new definition	Expert consultation	Noted in Feb 2024 TAHSC report	
Section 1					
1.3.	Diseases, infections and infestations listed by WOAH	Revision to reorder the articles (animal categories), to clarify animal categories in each article, to reorder the diseases in each article, and to align some disease names with the corresponding disease-specific chapters	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Sep 2023/1)	1
1.6.	Procedures for official recognition of animal health status, endorsement of an official control programme, and publication of a self-declaration of animal health status, by WOAH	Partial revision to improve clarity on the ability for Members to hold pathogenic agents within laboratories without affecting their animal health status	Expert consultation	Noted in Feb 2024 TAHSC report (Feb 2023/1)	2
1.11.	Application for official recognition by WOAH of free status for foot and mouth disease	Partial revision to align with the revised Ch 8.8.	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Sep 2023/1)	1

Section 4					
4.4.	Zoning and compartmentalisation	To address necessary points, as relevant, with the development of new Ch 4.4.	Preparatory work	Noted in February 2024 TAHSC report	1
4.Y	New Chapter on implementation of zoning.	Develop a full new chapter. Taskforce by SCAD and TAHSC to work on this issue	Preparatory work	Noted in February 2024 TAHSC report	
4.6.	Collection and processing of semen of animals	Comprehensive revision of chapter	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Sep 2022/3)	1
4.7.	Collection and processing of bovine, small ruminant and porcine semen	Comprehensive revision of chapter	Preparatory work	Refer to Feb 2024 TAHSC report Pending progress of the work on Ch 4.6.	1
4.8.	Collection and processing of *in vivo* derived embryos from livestock and equids	Consider potential amendments as a consequence of the changes in the IETS Manual	Preparatory work	Pending progress of data collection	2
4.9.	Collection and processing of oocytes and *in vitro* produced embryos from livestock and horses	Consider potential amendments as a consequence of the changes in the IETS Manual	Preparatory work	Pending progress of data collection	2
4.13.	Disposal of dead animals	Consider including all potentially contaminated wastes/products/fomites	Preparatory work	Refer to Feb 2022 TAHSC report	2
4.14.	General recommendations on disinfection and disinsection	Comprehensive revision of chapter Consider question from AHG on biosecurity	Preparatory work	Refer to Feb 2022 TAHSC report	2
4.X.	New chapter on biosecurity	Develop a new chapter	Expert consultation	Noted in Feb 2024 TAHSC report (Sep 2023/1)	1
Section 5					
General	Revision of Section 5 Trade measures, import/export procedures and veterinary certification (especially Chs 5.4. to 5.7.)	Comprehensive revision of Chs 5.4., 5.5., 5.6. and 5.7.	Expert consultation (	Noted in Feb 2024 TAHSC report (Sep 2023/1 - for Chs 5.4. and 5.6.)	1

5.2., 5.10.	Certification procedures	Partial revision to review provisions on electronic certification and check model of certificate	Expert consultation	Refer to Sep 2022 TAHSC report	2
5.8.	International transfer and laboratory containment of animal pathogenic agents	- Consider impact of holding PA in labs (and research facilities) - Align with corresponding *Manual* chapter (categories of PA) - Link with work with Nagoya protocol?	Expert consultation (depending Ch 1.6., etc.)	Noted in Sep 2023 TAHSC report	4
5.12.	Model passport for international movement of competition horses	Update the relevant chapters on equine diseases to take into account proposals made by the AHG on HHP Horses Veterinary Certificates	Preparatory work	Noted in Sep 2023 TAHSC report	2
Section 6					
6.2.	The role of the Veterinary Services in food safety systems	Review the chapter based on the revised Glossary definitions for 'CA', 'VA' and 'VS'	Preparatory work	Refer to Sep 2022 TAHSC report	4
6.3.	Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection	Revision to avoid duplication with Ch 6.2., to simplify and to refer to relevant Codex GLs more	Not started	-	4
6.10.	Responsible and prudent use of antimicrobial agents in veterinary medicine	Comprehensive revision of chapter	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Sep 2022/2)	1
6.12.	Zoonoses transmissible from non-human primates	Consider possible inclusion of SARS-CoV-2 in this chapter, possible inclusion of Macacine Herpesvirus 1 and the revision of test schedule and animal species to be tested for tuberculosis (Origin Member requests)	Not started	Refer to Feb 2022 TAHSC report	4

Section 7					
7.1.	Introduction to the recommendations for animal welfare	Partial revision - to include 'five domains' concept - to clarify the meaning of the terms 'animal-based', 'resource-based' and 'management-based' measures etc.	Circulated for comments	Noted in Feb 2024 TAHSC report (Sep 2023/2)	1
7.2., 7.3., 7.4.	Transport of animals by land, sea and air	Comprehensive revision of chapters	Expert consultation	Noted in Feb 2024 TAHSC report	1
7.5.	Slaughter of animals	Comprehensive revision of chapter	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Feb 2021/3)	1
7.6.	Killing of animals for disease control purposes	- Partial revision - Comprehensive revision of chapter	- Partial revision: circulated for comments - Comprehensive revision: Expert consultation	Refer to Sep 2022 TAHSC report	2
Section 8					
8.7.	Infection with epizootic hemorrhagic disease virus	Comprehensive revision of chapter	Not started	Noted in Feb 2024 TAHSC report	3
8.8.	Infection with foot and mouth disease virus	Comprehensive revision of chapter (including harmonisation of chapters with official status recognition)	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Sep 2015/6)	1
8.10.	Japanese encephalitis	Comprehensive revision of chapter (related to works on Chs 8.21., 12.4. and 12.11.)	Expert consultation	Noted in Feb 2024 TAHSC report	2

8.11.	Infection with *Mycobacterium tuberculosis* complex	Partial revision - to add recommendations for camelids and goats - to clarify point 1(b) of Article 8.11.4.	Not started	Refer to Feb 2022 TAHSC report	3
8.13.	New world screwworm and old world screwworm	Partial revision (case definition)	Expert consultation	Noted in Feb 2024 TAHSC report	3
8.14.	Paratuberculosis	Consider amendments to ensure alignment with recently revised *Manual* chapter	Expert consultation	Refer to Sep 2020 TAHSC report	3
8.15.	Infection with rabies virus	Partial revision - to add recommendations on wildlife-mediated rabies	Preparatory work	Refer to Sep 2022 TAHSC report	3
8.16.	Infection with Rift Valley fever virus	Partial revision of recommendations for importation of semen and embryos (follow-up of update of corresponding *Manual* chapter adopted in 2023)	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Sep 2023/1)	1
8.17.	Infection with *Trichinella* spp.	Partial revision of general provisions (follow-up of update of corresponding *Manual* chapter adopted in 2023)	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Sep 2023/1)	1
8.21.	West Nile fever	Comprehensive revision of chapter (related to works on Chs 8.10., 12.4. and 12.11.)	Expert consultation	Noted in Feb 2024 TAHSC report	2
8.X.	New Chapter on Infection with *Coxiella burnetii* (Q fever)	Develop a new chapter	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Sep 2022/3)	1
8.Y.	New Chapter on Infection with Nipah virus	Develop a new chapter	Circulated for comments	Noted in Feb 2024 TAHSC report (Sep 2023/2)	2

8.Z.	New Chapter on Surra	Develop a new chapter	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Feb 2023/2)	1
Section 10					
General	Overall consideration of Section 10 Aves	Consider approach to risk management recommendations for different production sectors, species, commodities, structure of chapter (following latest adopted HAPI) across different diseases.	Preparatory work	Noted in Sep 2023 TAHSC report	3
10.2.	Avian infectious bronchitis	Review trade articles for clarity.	Preparatory work	Noted in Sep 2023 TAHSC report	3
10.3.	Avian infectious laryngotracheitis	Consider amendments to ensure alignment with recently revised *Manual* chapter	Not started	Noted in Sep 2023 TAHSC report	3
10.5.	Infection with *Mycoplasma gallisepticum* (Avian mycoplasmosis)	Full update of the chapter (content and structure) based on the recent update of the *Manual* Chapter. Consider inclusion of *M. synoviae* into a single chapter (and listed disease).	Preparatory work	Noted in Sep 2023 TAHSC report	3
10.9.	Infection with Newcastle disease virus	Revision to align with recent revision of Ch 10.4.	Not started	Noted in Sep 2023 TAHSC report	3
10.X.	Infection with avian metapneumovirus	Develop a new chapter	Expert consultation (SCAD)	Noted in Sep 2023 TAHSC report	3
Section 11					
11.5.	Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)	Harmonisation of chapters with official status recognition	Expert consultation	Noted in Feb 2024 TAHSC report (Sep 2022/3)	1

11.11.	Trichomonosis	Comprehensive revision of chapter	Not started	Refer to Feb 2022 TAHSC report (Sep 2020/2)	3
11.X.	New Chapter on Infection with bovine pestivirus (bovine viral diarrhoea)	Develop a new chapter	Circulated for comments	Noted in Feb 2024 TAHSC report (Sep 2022/4)	1
Section 12					
12.1.	African horse sickness	Harmonisation of chapters with official status recognition Proposals from AHG on AHS and SCAD	Expert consultation	Noted in Feb 2024 TAHSC report (Sep 2022/3)	1
12.3.	Dourine	Comprehensive revision of chapter	Circulated for comments	Refer to Feb 2024 TAHSC report (Feb 2024/1)	2
12.4.	Equine encephalomyelitis (Eastern and Western)	Comprehensive revision of chapter (related to works on Chs 8.10., 8.21. and 12.11.)	Expert consultation	Noted in Feb 2024 TAHSC report	3
12.11.	Venezuelan equine encephalomyelitis	Comprehensive revision of chapter (related to works on Chs 8.10., 8.21. and 12.4.)	Expert consultation	Noted in Feb 2024 TAHSC report	3
Section 13					
13.2.	Rabbit haemorrhagic disease	Partial revision - to add a case definition (with editorial changes)	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Feb 2023/2)	1
		Comprehensive revision of chapter	Preparatory work	Noted in Sep 2023 TAHSC report	3
Section 14					
14.7.	Infection with peste des petits ruminants virus	Reconsider susceptible animals targeted in the chapter and some articles inconsistence	Preparatory work	Noted in Sep 2023 TAHSC report	3
14.8.	Scrapie	Comprehensive revision of chapter	Expert consultation	Noted in Feb 2024 TAHSC report	2

14.9.	Sheep pox and goat pox	Comprehensive revision of chapter	Expert consultation	Noted in Sep 2023 TAHSC report	3
Section 15					
15.3.	Infection with porcine reproductive and respiratory syndrome virus (Article 15.3.9.)	Partial revision to address a concern that the testing regime in relation to semen collection centres is not sufficient to prevent the introduction of the virus through semen from countries that are not free from PRRS (to be reconsidered after revision of Ch 4.7.)	Not started	Refer to Feb 2018 TAHSC report	4
Section 16					
16.Z.	New Chapter on Camelpox	Develop a new chapter	Proposed for adoption in May 2024	Noted in Feb 2024 TAHSC report (Sep 2022/3)	1
Others					
X.X.	New Chapter on Crimean Congo haemorrhagic fever	Develop a new chapter	Pending adoption of corresponding chapter of *Terrestrial Manual*	Noted in Feb 2024 TAHSC report	2

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

4	- ***not active*** - ***not to be immediately started***

List of abbreviations	
AHG	***Ad hoc* Group**
BSC	**Biological Standards Commission**
Ch	**Chapter**
HQ	**WOAH Headquarters**
IETS	**International Embryo Technology Society**
SCAD	**Scientific Commission for Animal Diseases**
TAHSC	**Terrestrial Animal Health Standard Commission**

Annex 22

USER'S GUIDE

EU	**The EU thanks the Code Commission and in general supports this revised User's Guide.** **The clarification on the meaning of terms often used in the Code is very welcome (e.g. 'ruminants', 'bovids', 'Bovidae', 'bovines').**

A. Introduction

1) The WOAH *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) establishes standards for the improvement of terrestrial animal health and welfare and veterinary public health worldwide. The purpose of this guide is to advise the Veterinary Authorities of WOAH Member Countries on how to use the *Terrestrial Code*.

2) Veterinary Authorities should use the standards in the *Terrestrial Code* to set up measures providing for early detection, internal reporting, notification, control or eradication of pathogenic agents, including zoonotic ones, in terrestrial animals (mammals, birds, reptiles and bees) and preventing their spread via international trade in animals and animal products, while avoiding unjustified sanitary barriers to trade.

3) WOAH standards are based on the most recent scientific and technical information. Correctly applied, they protect animal health and welfare and veterinary public health during production and trade in animals and animal products, and in the use of animals.

4) The absence of chapters, articles or recommendations on particular pathogenic agents or commodities does not preclude the application of appropriate sanitary measures by the Veterinary Authorities, provided they are based on risk analyses conducted in accordance with the *Terrestrial Code*.

5) The year that a chapter was first adopted and the year of its last revision are noted at the end of each chapter.

6) The complete text of the *Terrestrial Code* is available on WOAH Web site and individual chapters may be downloaded from: https://www.woah.org/.

B. Terrestrial Code content

1) Key terms and expressions used in more than one chapter in the *Terrestrial Code* are defined in the Glossary, in the case where common dictionary definitions are not deemed to be adequate. The reader should be aware of the definitions given in the Glossary when reading and using the *Terrestrial Code*. Defined terms appear in italics. In the on-line version of the *Terrestrial Code*, a hyperlink leads to the relevant definition.

2) The term "(under study)" is found in some rare instances, with reference to an article or part of an article. This means that this part of the text has not been adopted by the World Assembly of Delegates and the particular provisions are thus not part of the *Terrestrial Code*.

3) The standards in the chapters of Section 1 are designed for the implementation of measures for the diagnosis, surveillance and notification of diseases, infections and infestations. The standards include procedures for notification to WOAH and procedures for the recognition of the animal health status of a country, zone or compartment.

4) The standards in Section 2 are designed to guide the importing country in conducting import risk analysis in the absence of WOAH recommendations on particular pathogenic agents or commodities. The importing country should also use these standards to justify import measures which are more stringent than existing WOAH standards.

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

6) The standards in the chapters of Section 4 are designed for the implementation of measures for the prevention and control of pathogenic agents. Measures in this section include animal identification, traceability, zoning, compartmentalisation, disposal of dead animals, disinfection, disinsection and general hygiene precautions. Some chapters address the specific sanitary measures to be applied for the collection and processing of semen and embryos of animals.

7) The standards in the chapters of Section 5 are designed for the implementation of general sanitary measures for trade. They address veterinary certification and the measures applicable by the exporting, transit and importing countries. A range of model veterinary certificates is provided to facilitate consistent documentation in international trade.

8) The standards in the chapters of Section 6 are designed for the implementation of preventive measures in animal production systems. These measures are intended to assist Member Countries in meeting their veterinary public health objectives. They include ante- and post-mortem inspection, control of hazards in feed, biosecurity at the animal production level, and the control of antimicrobial resistance in animals.

9) The standards in the chapters of Section 7 are designed for the implementation of animal welfare measures. The standards cover production, transport, and slaughter or killing, as well as the animal welfare aspects of free-roaming dog population control and the use of animals in research and education.

10) The standards in each of the chapters of Sections 8 to 16, i.e. disease-specific chapters, are designed mainly to prevent the pathogenic agents of WOAH listed diseases~~, infections or infestations~~ from being introduced into an importing country or from spreading within a country. Some chapters include specific measures to prevent and control the infections of global concern. Sections 8 to 16 each relate to the host species of the pathogenic agent: multiple species or species of Apinae, Aves, Bovinae, Equidae, Leporidae, Caprinae, Suidae and Camelidae. Although WOAH aims to include a chapter for each WOAH listed disease, not all WOAH listed diseases have been covered yet by a specific chapter. This is work in progress, depending on available scientific knowledge and the priorities set by the World Assembly of Delegates.

~~The standards take into account the nature of the traded commodity, the animal health status of the exporting country, zone or compartment, and the risk measures applicable to each commodity.~~

A disease-specific chapter covers some or all of the following components:

- Chapter title and number;
- Article on general provisions, including definition~~s~~ of the disease and the animal hosts that play a significant role in the epidemiology of the disease, and definition of its occurrence ('case definition')~~, and the animal hosts that play a significant role in the epidemiology of the disease~~;
- Article on safe commodities;
- Articles on provisions for animal health status applied to countries, zones, compartments or herds/flocks;
- Articles on recommendations for safe trade of commodities;
- Articles on inactivation of the pathogenic agents present in specific animal products, materials or fomites; and
- Articles on surveillance of the disease.

Not all disease-specific chapters include all these components and some chapters may include only one ~~the first~~ article on the definition of occurrence for the purpose of notification to WOAH. Each chapter includes only those provisions considered, at the time of adoption, relevant to address WOAH Members' needs with regards to the specific disease; and that are supported by sound scientific and technical knowledge.

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

of the moved or traded commodity, the animal health status of the exporting country, zone or compartment of origin, and the risk mitigation measures applicable to each commodity.

C. Specific issues

1) Notification

Chapter 1.1. describes Member Countries' obligations under Organic Statutes of the Office International des Epizooties. Listed and emerging diseases, as prescribed in Chapter 1.1., are compulsorily notifiable. Member Countries are encouraged to also provide information to WOAH on other animal health events of epidemiological significance.

Chapter 1.2. describes the criteria for the inclusion of an infection or infestation in the WOAH List and Chapter 1.3. gives the current list. Diseases are divided into nine categories based on the host species of the aetiological agents.

2) Diagnostic tests and vaccines

It is recommended that specified diagnostic tests and vaccines in *Terrestrial Code* chapters be used with a reference to the relevant section in the WOAH *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereafter referred to as the *Terrestrial Manual*). Experts responsible for facilities used for disease diagnosis and vaccine production should be fully conversant with the standards in the *Terrestrial Manual*.

3) Freedom from a disease, infection or infestation

Article 1.4.6. provides general principles for declaring a country or zone free from a disease, infection or infestation~~. This article applies when there are no~~ and may be complemented by specific requirements in the listed disease-specific chapters.

4) Prevention and control

Chapters 4.4. and 4.5. describe the measures that should be implemented to establish zones and compartments. Zoning and compartmentalisation should be considered as some of the tools used to control diseases and to facilitate safe trade.

Chapters 4.6. to 4.12. describe the measures which should be implemented during collection and processing of semen and embryos of animals, including micromanipulation and cloning, in order to prevent animal health risks, especially when trading these commodities. Although the measures relate principally to WOAH listed diseases or infections, general standards apply to all infectious disease risks. Moreover, in Chapter 4.8. diseases that are not listed are marked as such but are included for the information of Member Countries.

Chapter 4.15. addresses the specific issue of the control of bee diseases and some of its trade implications. This chapter should be read in conjunction with the specific bee disease chapters in Section 9.

Chapter 6.5. is designed for the implementation of general biosecurity measures in intensive poultry production. Chapters 6.6., 6.13. and 6.14. provide recommendations for some specific on-farm prevention and control plans for the unlisted foodborne pathogenic agent *Salmonella* as part of the Veterinary Services mission to prevent, eliminate or control food safety hazards in animal production.

Chapter 6.12. deals specifically with the zoonotic risk associated with the movements of non-human primates and gives standards for certification, transportation and import conditions for these animals.

5) Trade requirements

Animal health measures related to international trade should be based on WOAH standards. A Member Country may authorise the importation of animals or animal products into its territory under conditions different from those recommended by the *Terrestrial Code*. To scientifically justify more stringent measures, the importing country should conduct a risk analysis in accordance with WOAH standards, as described in Chapter 2.1. Members of the WTO should refer to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

Chapters 5.1. to 5.3. describe the general obligations and ethical responsibilities of importing and exporting countries in international trade. Veterinary Authorities and all veterinarians directly involved in international trade should be familiar

with these chapters. Chapter 5.3. also describes the WOAH informal procedure for dispute mediation.

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

6) International veterinary certificates

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

International veterinary certificates underpin international trade and provide assurances to the importing country regarding the health status of the animals and products imported. The measures prescribed should take into account the health status of both exporting and importing countries, and zones or compartments within them, and be based upon the standards in the *Terrestrial Code*.

The following steps should be taken when drafting international veterinary certificates:

a) identify the diseases, infections or infestations from which the importing country is justified in seeking protection because of its own health status. Importing countries should not impose measures in regards to diseases that occur in their own territory but are not subject to official control programmes;

b) for commodities capable of transmitting these diseases, infections or infestations through international trade, the importing country should apply the relevant articles in the listed disease-specific chapters. The application of the articles should be adapted to the disease status of the country, zone or compartment of origin. Such status should be established according to Article 1.4.6. except when articles of the relevant listed disease chapter specify otherwise;

c) when preparing international veterinary certificates, the importing country should endeavour to use terms and expressions in accordance with the definitions given in the Glossary. International veterinary certificates should be kept as simple as possible and should be clearly worded, to avoid misunderstanding of the importing country's requirements;

d) Chapters 5.10. to 5.13. provide, as further guidance to Member Countries, model certificates that should be used as a baseline.

7) Guidance notes for importers and exporters

It is recommended that Veterinary Authorities prepare “guidance notes” to assist importers and exporters understand trade requirements. These notes should identify and explain the trade conditions, including the measures to be applied before and after export and during transport and unloading, and the relevant legal obligations and operational procedures. The guidance notes should advise on all details to be included in the health certification accompanying the consignment to its destination. Exporters should also be reminded of the International Air Transport Association rules governing air transport of animals and animal products.

[…]

D. Name of animal species

In the *Terrestrial Code*, common terms (in bold in the table below) referring to animals are based on scientific names as shown below.

Higher level terms	Terms based on Order or Sub-order	Terms based on Family	Terms based on Sub-Family	Terms based on Tribe	Terms based on Genus
Class 'Insecta'	-	Family 'Apidae'	Sub-Family 'Apinae' '**bees**' means animals of Sub-Family 'Apinae'	Including animals of Tribe: • 'Apini'	Including animals of Genus: • 'Apis' '**honey bees**' means animals of Genus Apis.
				Including animals of Tribe: • 'Bombini'	Including animals of Genus: • 'Bombus' '**bumble bees**' means animals of Genus Bombus.
				Including animals of Tribe: • 'Meliponini' '**stingless bees**' means animals for Tribe 'Meliponini'	-
Class 'Aves' '**avian**' means animals of class Aves	Order 'Galliformes'	-	-	-	Including animals of Genus: • 'Gallus' • 'Meleagris' etc. '**chicken**' means *Gallus gallus domesticus*. '**turkey**' means *Meleagris gallopavo*.
	Order 'Anseriformes'	-	-	-	Including animals of Genus: • 'Anser' • 'Branta' • 'Anas' etc. '**geese**' means animals of Genera Anser and Branta. '**ducks**' means *Anas platyrhynchos*. ('**domestic ducks**' means *Anas platyrhynchos domesticus*.)
'**mammals**' means animals of Class 'Mammalia' '**ungulates**' means animals	'**ruminants**' means animals of Sub-order 'Ruminantia'	'**bovids**' means animals of Family 'Bovidae'	'**bovines**' means animals of Sub-Family 'Bovinae'	-	Including animals of Genus: • 'Bos' • 'Bubalus' • 'Bison' • 'Syncerus' etc.
			'**caprines**' means animals of Sub-Family 'Caprinae'	-	Including animals of Genus: • 'Ovis' • 'Capra', etc.

of Order 'Artiodactyla' (even-toed ungulates) and Order 'Perissodactyla' (odd-toed ungulates) '**artiodactyls**' means animals of Order 'Artiodactyla' (even-toed ungulates)					'**sheep**' means *Ovis aries*. '**goats**' means *Capra hircus* (domestic goats) and *Capra aegagrus* (wild goats).
			Sub-Family 'Antilopinae'	-	Including animals of Genus: • 'Gazella' • 'Antilope' • 'Dibatag', etc.
		'**cervids**' means animals of Family 'Cervidae'	Sub-Family 'Cervinae'	-	Including animals of Genus: • 'Cervus' • 'Dama', etc.
			Sub-Family 'Capreolinae'	-	Including animals of Genus: • 'Capreolus' • 'Odocoileus' • 'Rangifer', etc.
	Sub-Order 'Suina'	'**suids**' means animals of Family 'Suidae'	-	-	Including animals of Genus: • 'Sus' • 'Phacochoerus' • 'Hylochoerus', etc. '**pigs**' means *Sus scrofa* (domestic and wild) .
	Sub-Order 'Tylopoda'	'**camelids**' means animals of Family 'Camelidae'	Sub-Family 'Camelinae'	-	Including animals of Genus: • 'Camelus' • 'Lama' • 'Vicugna' '**dromedary camels**' means *Camelus dromedarius*. '**bactrian camels**' means *Camelus bactrianus*. ~~'**alpacas**' means *Lama guanicoe pacos.*~~ ~~'**llamas**' means *Lama guanicoe glama*~~. '**New World camelids**' means animals of Genus ~~alpacas and~~ Lama~~s~~ and Vicugna.
	Sub-Order 'Hippomorpha'	'**equids**' means animals of Family 'Equidae'	'**equines**' means animals of Sub-Family 'Equinae'	-	Including animals of only Genus 'Equus' '**horses**' means *Equus ferus caballus*. '**donkeys**' means *Equus africanus asinus*. '**mules**' means *Equus africanus asinus* (male) × *Equus ferus caballus* (female). '**zebras**' means animals of subgenus Hippotigris.

	'**lagomorphs**' means animals of Order 'Lagomorpha'	'**leporids**' means animals of Family 'Leporidae'	-	-	Including animals of Genus: • 'Oryctolagus' • 'Lepus' • 'Sylvilagus' '**rabbits**' means animals of Genus Oryctolagus'. '**hares**' means animals of Genus Lepus. '**European hares**' means *Lepus europaeus*.
	'**carnivores**' means animals of Order 'Carnivora'	'**canids**' means animals of Family 'Canidae'	Sub-Family 'Caninae'	-	Including animals of Genus: • 'Canis' '**dogs**' means *Canis lupus familiaris*.
		'**felids**' means animals of Family 'Felidae'	-	-	Including animals of Genus: • 'Felis' '**cats**' means *Felis catus*.
		Family 'Mustelidae'			Including animals of Genus: • 'Mustela' '**ferrets**' means *Mustela furo*.
	'**rodents**' means animals of Family 'Rodentia'	-	-	-	-
	'**bats**' means of animals of Order 'Chiroptera'	-	-	-	-
	'**non-human primates**' means animals of Order 'Primates' except for humans (Genus 'Homo')	-	-	-	-

In each chapter of the *Terrestrial Code*, scientific names of the animals are provided when the vernacular names used in the chapter do not include all the species as described in this table, e.g. 'bovines (*Bos indicus, B. taurus, B. grunniens, Bubalus bubalis* and *Syncerus caffer*)', which in that example does not include animals of genus bison, or when the list of animals is very long, e.g. 'animals of the families *Suidae* and *Cervidae*, the subfamilies *bovinae*, *caprinae* and *antilopinae* of the family *Bovidae*, and *Camelus bactrianus*'.

Annex 23

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

EU comment

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

The EU has two more comments.

Article 7.1.1.

General considerations

Animal welfare means the physical and mental state of an *animal* in relation to the conditions in which it lives and dies.

An *animal* experiences good welfare if the *animal* is healthy, comfortable, well nourished, safe, is not suffering ~~severely or for a long time~~ from avoidable unpleasant states such as pain, fear and *distress*, and is able to express behaviours that are important for its physical and mental state.

EU comment

The EU proposes deleting the word "avoidable":

"An *animal* experiences good welfare if the *animal* is healthy, comfortable, well nourished, safe, is not suffering from ~~avoidable~~ unpleasant states such as pain, fear and *distress*, and is able to express behaviours that are important for its physical and mental state."

Justification:

According to the Code Commission, "avoidable" was added "to reinforce the idea of minimising any negative experience". This gives room to the interpretation, that good welfare is present as long as a business operator makes a "best effort" to minimise negative experience. However, this is not necessarily true, e.g. negative experience is unavoidable in pigs/poultry stunned with CO_2/waterbath or in animals with diseases/injuries incurred despite an operator's best effort.

The addition of "avoidable" and the reasoning also contradict Mellor 2016 (https://doi.org/10.3390/ani6030021, p. 15): "Animal welfare is a state that is subjectively experienced by an animal; it is a state within the animal."

Last and not the least the deletion of "avoidable" will make the whole sentence more straight forward and easy to understand without opening a room for wider or even misinterpretation of the whole concept.

Good *animal welfare* requires disease prevention and appropriate veterinary care, shelter, management and nutrition, a stimulating and safe environment, humane handling and humane *slaughter* or *killing*. Good animal welfare is not only about avoiding negative experiences to *animals*, but also providing them with positive experiences. While *animal welfare* refers to the state of the *animal*,

the treatment that an *animal* receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

Article 7.1.2.

Guiding principles for animal welfare

1) ~~That t~~There is a critical relationship between animal health and *animal welfare*.

2) ~~That~~ While the ~~internationally recognised~~ "five freedoms" (freedom from hunger, thirst and malnutrition; freedom from fear and *distress*; freedom from physical and thermal discomfort; freedom from pain, injury and disease; and freedom to express normal patterns of behaviour) provide valuable guidance in *animal welfare*~~.~~, the 'five domains' (nutrition, environment, health, ~~behavioural interactions~~ behaviour, and mental state) support the systematic scientific assessment of *animal welfare*.

3) ~~That t~~The ~~internationally recognised~~ "three Rs" (reduction in numbers of *animals*, refinement of experimental methods and replacement of *animals* with non-animal techniques) provide valuable guidance for the use of *animals* in science.

4) ~~That t~~The scientific assessment of *animal welfare* involves diverse elements which need to be considered together, and that selecting and weighing these elements often involves value-based assumptions which should be made as explicit as possible.

5) ~~That t~~The use of *animals* in agriculture, education and research, and for companionship, recreation and entertainment, makes a major contribution to the wellbeing of people.

6) ~~That t~~The use of *animals* carries with it an ethical responsibility to ensure the welfare of such *animals* to the greatest extent practicable.

7) ~~That i~~improvements in farm *animal welfare* can ~~often~~ improve productivity and food safety, and hence lead to economic benefits.

8) ~~That t~~The equivalent welfare outcomes based on performance criteria, rather than identical systems based on design criteria, ~~be~~ are the basis for comparison of *animal welfare* standards and recommendations.

Article 7.1.3.

Scientific basis for recommendations

1) Welfare is a broad term which includes the many elements that contribute to an *animal*'s quality of life, including its physical and mental states ~~those referred to in the "five freedoms" listedabove~~.

2) The scientific assessment of *animal welfare* has ~~progressed rapidly in recent years and~~ formed~~s~~ the basis of the recommendations of the *Terrestrial Code* for animal welfare. Welfare assessment can be either at a point in time or over a period of time such as a lifetime. There is value in using the 'five freedoms' and 'five domains' models. The 'five domains' model allows consideration to be given to both the degree and cumulation of positive and negative experiences over the duration of the animal's life.

3) Some measures of *animal welfare* involve assessing the degree of impaired functioning associated with injury, disease and malnutrition. Other measures provide information on *animals*' needs and positive or negative affective states ~~such as hunger, pain and fear~~, often by measuring the strength of *animals*' preferences, motivations and aversions. Others assess the physiological, behavioural and immunological changes or effects that *animals* show in response to various challenges.

4) Such measures can lead to criteria and indicators that help to evaluate how different methods of managing *animals* influence their welfare.

Article 7.1.4.

Guiding principles for the use of measures to assess animal welfare

~~1) the OIE~~ WOAH *animal welfare* standards ~~to be applicable globally, they should~~ emphasise the ~~favourable~~ consequences that any treatments on *animals* may have on their welfare and ~~they should be applicable globally. outcomes for the *animals*, although, in some circumstances, it~~ may include recommendations on ~~be necessary to recommend~~ specific conditions of the

animals' environment and management~~. Outcomes are generally measured by assessing the extent to which *animals* experience the "five freedoms" described in Article 7.1.2.~~

2) For each principle listed in Article 7.1.5., the most relevant criteria (or measur~~able~~s), ideally comprising animal-based measures, defined as an evaluation of a response of an *animal* or as an effect on an *animal* used to assess its welfare, should be included in the standard. Any given animal-based measure ~~may~~ should be linked to one or more of these ~~than one~~ principles.

3) Recommendations should, whenever possible, define explicit targets or thresholds that should be met for animal-based measures. Such target values should be based on relevant science and experience of experts.

4) In addition to animal-based measures, ~~one may use~~ resource-based measures, defined as an evaluation of a feature of the environment in which the *animal* is kept or to which is exposed and management-based measures, defined as an evaluation of what the *animal handler* does, and with which management processes or tools, may be used. ~~may be used and~~ The use of any of these three types of measures should be defined on the basis of science and expert experience showing that a welfare outcome is clearly linked to an *animal* as well as to a resource or ~~to~~ a management procedure.

5) ~~Users of the standard~~ ~~Members should select~~Tthe most ~~appropriate animal-based~~ relevant measures from among those listed in the standards should be selected for ~~their~~ a given farming system or environment~~, from among those listed in the standard~~. Welfare ~~O~~outcomes can be measured by an assessment of individuals or *animal* groups, or a representative sample of those, using data from *establishments*, transport or *slaughterhouses/abattoirs*. *Competent Authorities* should collect all data relevant ~~for the users~~ to set target and threshold values.

6) Whatever the basis of the measure, if welfare outcomes are unsatisfactory, ~~users~~ ~~Members~~ relevant ~~should consider what~~ changes to resources or management ~~are necessary~~ should be applied to improve the welfare outcomes.

Article 7.1.5.

General principles for the welfare of animals in livestock production systems

1) Genetic selection should always take into account the health and welfare of *animals*.

2) *Animals* chosen for introduction into new environments should be suited to the local ~~climate~~ conditions, including their adaptability ~~and able to adapt~~ to local climate, diseases~~, parasites~~ and nutrition.

3) The physical environment, including the substrate (walking surface, resting surface, etc.), should be suited to the species so as to minimise risk of injury and transmission of diseases ~~or parasites~~ to *animals*.

EU comment

The EU proposes rephrasing paragraph 3 as follows:

"The physical environment, including the substrate (walking surface, resting surface, etc.), should be suited to the ~~spec~~species *animals* so as to minimise risk of injury and transmission of diseases ~~or parasites to *animals*~~."

Justification:

"Species" is too narrow because animals of the same species may have varying or different needs and necessities depending, among others, on the purpose of keeping, age and physiologic or health status (e.g. new-born/hatched animals different from growing or adult animals).

4) The physical environment should allow comfortable ~~resting,~~ and safe resting and ~~comfortable~~ movement including normal postural changes, and the opportunity to perform ~~types of~~ natural behaviours that *animals* are motivated to perform.

5) Social grouping of *animals* should be managed to ~~allow~~ promote positive social behaviour and minimise injury, *distress* and chronic fear.

6) For housed *animals*, air quality, air flow, temperature and humidity should not be ~~aversive~~ detrimental and should support good animal health and welfare ~~and not be aversive~~. Where and when extreme weather conditions occur, *animals* should not be prevented from using their natural methods of thermo-regulation.

7) *Animals* should have access to sufficient *feed* and water, suited to the *animals*' age and needs, to maintain normal health and performance ~~productivity~~ and to prevent severe or prolonged hunger and~~,~~ thirst, malnutrition and ~~or~~ dehydration.

8) Diseases ~~and parasites~~ should be prevented and controlled as much as possible through good management practices and *biosecurity*. *Animals* with serious health problems should be isolated and treated promptly or killed humanely if treatment is not feasible or recovery is unlikely.

9) Alternatives to painful procedures should be used. Where painful procedures cannot be avoided, the ~~resulting~~ pain should be managed to the extent that available methods allow.

10) The handling of *animals* should foster a positive relationship between humans and *animals* and should not cause injury, panic, lasting fear or avoidable stress.

11) Owners and handlers should have sufficient training, skills and knowledge to ensure that *animals* are treated in accordance with these principles.

CHAPTER 7.6.

ANIMAL WELFARE AT THE TIME OF KILLING

EU comment

The EU thanks the Code Commission for its work revising this chapter.

As a general comment, the EU points out that the title, the introduction, and the scope of this chapter imply dealing exclusively with animal welfare.

However, this is not the case, as Art. 7.6.4, for example, describes the general organisation of killings, whereby animal welfare is only one of many aspects (the focus is usually on effective animal disease control). Article 7.6.3. also addresses several other non-animal welfare aspects such as costs, biosecurity, occupational health and safety and the environment.

Specific comments are inserted in the text below.

Article 7.6.1.

Introduction

Animals are killed for a variety of reasons, including for contagious disease control, in case of natural or man-made disasters, when they are otherwise suffering from disease or injuries or for economic reasons. It is important to consider their welfare during this process.

EU comment

The EU suggests considering more concrete formulation than only "economic reasons" or if not possible to add some examples on what is meant by economic reasons.

Justification:

The scope of the chapter should be better defined.

Article 7.6.2.

Scope

This chapter identifies hazards to animal welfare during *killing* and provides recommendations for the appropriate procedures for killing. It provides animal-based and other measures to assess the level of welfare during the process and recommends appropriate remedial actions to be applied.

This chapter applies to the killing of domestic and *captive wild* ruminants, equids, birds, pigs, rabbits, camelids and mustelids for all purposes, except for slaughter which is covered by Chapter 7.5. Animal welfare during slaughter.

This chapter should be read in conjunction with the guiding principles for *animal welfare* provided in Chapter 7.1.

Article 7.6.3.

General principles for the operations regarding the killing of animals

The decision as to whether to kill animals should not be delayed if there is any risk to the welfare of those animals. The recommendations in this Chapter are based on the premise that a decision to kill the animals has been made and they address the need to ensure the welfare of the animals until they are dead.

All personnel involved in the killing of animals should have the relevant skills and competencies.

As necessary, operational procedures should be adapted to the specific circumstances on the premises and should address, apart from animal welfare, the cost of the method, operators' safety and mental health, biosecurity and environmental aspects.

EU comment

The EU suggests placing the cost aspect at the end of the list:

"As necessary, operational procedures should be adapted to the specific circumstances on the premises and should address, apart from animal welfare, ~~the cost of the method,~~ operators' safety and mental health, biosecurity ~~and,~~ environmental aspects and the cost of the method."

Justification:

It seems inappropriate to mention the cost aspect immediately after animal welfare and before the other factors mentioned.

It seems more appropriate to change the order of words, to emphasize the importance to consider operator's safety and health, biosecurity and environmental impact over cost.

During decision making and prior to killing the animals, normal husbandry, especially supply of feed and water, should be maintained until the animals are killed.

EU comment

The EU suggests replacing "normal" by "appropriate" in the sentence above:

"During decision making and prior to killing the animals, ~~normal~~ appropriate husbandry, especially supply of feed and water, should be maintained until the animals are killed".

Justification:

It seems more relevant to use the word "appropriate" rather than "normal". Practices that are part of the "normal" routine for the animals may need to be adjusted depending on the situation.

The handling and movement of animals should be minimised and carried out in accordance with the recommendations described below.

Animal restraint should be sufficient to facilitate effective killing, and in accordance with animal welfare and operator safety requirements. When restraint is required, killing should follow with minimal delay.

EU comment

The EU suggests the following changes to the sentence above:

"Animal restraint should be sufficient to facilitate effective killing, and in accordance with animal welfare and operator safety requirements. When ~~restraint~~ an animal is restrained ~~is required, killing should follow with minimal delay~~ it should be promptly killed without delay."

Justification:

To emphasise that restraining causes stress and that the animal therefore should be killed as quickly as possible.

Killing methods used should result in immediate death or loss of consciousness lasting until death. When loss of consciousness is not immediate, induction of unconsciousness should involve as little aversion as possible and should not cause avoidable distress, fear and pain.

Young animals should be killed before older animals on which they are dependent to reduce potential distress.

For disease control purposes and for biosecurity considerations, infected animals should be killed first, followed by in-contact animals, and then remaining animals.

EU comment

The EU suggests deleting above sentence:

"~~For disease control purposes and for biosecurity considerations, infected animals should be killed first, followed by in-contact animals, and then remaining animals.~~"

Justification:

The procedure described can lead to additional handling and thus be detrimental to animal welfare. This hazard is disproportionate to the added value for disease control/biosafety.

In case if not possible to delete it to consider as compromise the following:

"For disease control purposes and for biosecurity considerations, infected animals ~~should~~ may be killed first, followed by in-contact animals, and then remaining animals. In case infected animals are killed first, negative consequences to the welfare of other animals should be avoided as far as possible."

There should be continuous monitoring of the operational procedures to ensure they are consistently effective regarding animal welfare, operator safety and *biosecurity*.

When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on animal welfare, operator safety, *biosecurity and responsible personnel*.

EU comment

The EU suggests adding "and environment impacts" at the end of the two sentences:

"There should be continuous monitoring of the operational procedures to ensure they are consistently effective regarding animal welfare, operator safety, ~~and~~ biosecurity and environmental impacts."

"When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on animal welfare, operator safety, biosecurity and responsible personnel and environmental aspects."

Justification:

For consistency within art. 7.6.3.

If operational procedures cover environmental aspects, then the environmental impacts should also be monitored.

Article 7.6.4.

Organisational structure for the operations regarding the mass killing of animals

EU comment

The term "mass killing" does not cover all situations of killing of animals.

It may be suitable in the context of killing for disease control purposes, but Art. 7.6.1. covers also some other reasons such as natural or man-made disasters or when they are otherwise suffering from disease or injuries or for economic reasons. At present, we are not sure if the structure of this Chapter intends to cover the other situations separately. This should be the case, as the operational procedures/contingency plans may be different in relation to whether they concern killing for disease control purposes, natural or man-made disasters or other reasons.

Operational activities should be led by the *Competent authority* who has the authority to ensure the required *animal welfare* and *biosecurity* standards.

The Competent authority should nominate a responsible agent for all activities across one or more affected locations or premises who should be supported by coordinators for planning operations and logistics to facilitate efficient operations.

The responsible agent of the *Competent authority* should provide overall guidance to personnel and logistic support for operations at all affected locations or premises to ensure consistency in adherence to the *Terrestrial Code's animal welfare* and animal health recommendations.

A specialist team, led by a team leader answerable to the responsible agent nominated by the *Competent Authority*, should be deployed to work on each affected location or premises. In some situations, personnel may be required to fulfil more than one function. Each team should contain a *veterinarian* or have access to veterinary advice at all times.

EU comment

The EU suggests replacing "in some situations" by "when needed":

"~~In some situations~~, When needed, personnel may be required to fulfil more than one function. Each team should contain a *veterinarian* or have access to veterinary advice at all times."

Justification:

If the formulation "in some situations" is kept, then it should be specified which are these situations.

Emergency plans should be in place and contain details of responsibilities, management structure, disease control strategies, operational procedures and necessary equipment and resources. *Animal welfare* considerations should always be addressed in these emergency plans. The plans should include a strategy to ensure that an adequate number of personnel competent in the *killing* of animals is available.

Depopulation under disease control emergency plans should be performed under the supervision of *Competent Authority* and address any *animal welfare* issues that may result from standstill or any other animal movement restriction.

In considering the *animal welfare* issues associated with *killing* animals, the key personnel, their responsibilities, and competencies required are described in Article 7.6.5.

In other situations that do not necessarily involve the *Competent Authority*, the personnel responsible should follow the recommendations of this chapter.

EU comment

The EU suggests removing "other" before situations and to move the last sentence up as follows:

"In ~~other~~ situations that do not necessarily involve the *Competent Authority*, the personnel responsible should follow the recommendations of this chapter.

In considering the animal welfare issues associated with killing animals, the key personnel, their responsibilities, and competencies required are described in Article 7.6.5."

Justification:

If "other" is kept, then it should be specified which are these other situations. For the sake of consistency, it is proposed to change the order of sentences.

Article 7.6.5.

Responsibilities and competencies of the specialist team for the operations regarding the mass killing of animals

EU comment

Same comment as above regarding the term "mass killing".

1. Team leader

a) Responsibilities

(i) plan overall operations on affected location or premises;

(ii) determine and address requirements for *animal welfare*, operator safety and *biosecurity*;

EU comment

The EU suggests adding "and environment aspects" at the end of the sentences:

"(ii) determine and address requirements for animal welfare, operator safety ~~and~~ biosecurity <u>and environmental aspects</u>."

Justification:

In order to be consistent with art. 7.6.3 also "environmental aspects" should be mentioned.

(iii) organise and manage team of people to facilitate *killing* of the relevant animals on the location or premises in accordance with national regulations and these recommendations;

(iv) determine logistics required;

(v) monitor operations to ensure *animal welfare*, operator safety and *biosecurity* requirements are met;

EU comment

The EU suggests adding "and environment requirements" at the end of the sentences:

"(v) monitor operations to ensure animal welfare, operator safety ~~and~~ biosecurity '<u>and environmental</u>'requirements are met;

Justification:

In order to be consistent with art. 7.6.3 also "environmental requirements" should be mentioned.

(vi) report upwards on progress and problems;

(vii) provide a written report at the conclusion of the *killing* operation, describing the practices adopted and their effect on *animal welfare*, operator safety, efficacy of *biosecurity* and environmental impact.

b) Competencies

i) knowledge of relevant animal husbandry practices;

ii) knowledge of *animal welfare* and the underpinning behavioural, anatomical and physiological processes involved in the *killing* operation;

EU comment

The EU suggests replacing "underpinning" by "underlying":

"ii) knowledge of animal welfare and the ~~underpinning~~ '<u>underlying</u>' behavioural, anatomical and physiological processes involved in the killing operation;"

Justification:

"Underlying" is considered a better and more appropriate wording in this context.

iii) skills to manage all activities on the location or premises and deliver outcomes on time;

iv) awareness of psychological effects on farmer, team members and general public;

v) communication skills;

vi) capacity to evaluate the environmental impacts caused by their operation.

2. Veterinarian

a) Responsibilities

i) determine and supervise the implementation of the most appropriate *killing* method to ensure that animals are killed without avoidable pain and distress;

ii) determine and implement the additional requirements for *animal welfare*, including the order of *killing*;

iii) ensure that confirmation of the *death* of the animals is carried out by competent persons at appropriate times after the *killing* procedure;

iv) minimise the risk of disease spread within and from the location or premises through the supervision of *biosecurity*;

v) continuously monitor *animal welfare* and *biosecurity* during killing process;

EU comment

The EU carefully assessed point v) on "continuously monitoring ….". We consider it is important to keep "continuously" as we see its deletion as a substantial lowering of the level of animal welfare.

vi) collaborate with the team leader on the written report at the conclusion of the *killing*.

b) Competencies

i) ability to assess *animal welfare*, especially the effectiveness of *killing* and to correct any deficiencies;

ii) ability to assess *biosecurity* risks.

3. Animal handlers

a) Responsibilities

i) review on-site facilities in terms of their appropriateness;

ii) design temporary animal handling facilities, when required;

iii) move and restrain animals;

iv) report *animal welfare* and *biosecurity* issues to the *veterinarian*.

b) Competencies

i) animal handling in emergency situations and in close confinement is required;

ii) understanding of *biosecurity*.

EU comment

The EU suggests adding:

"<u>iii) understanding of species-specific behaviour.</u>"

Justification:

For being able to report animal welfare issues, handlers should be able to recognise changes in behaviour that could mean there is a welfare issue.

4. Personnel in charge of killing animals

a) Responsibilities

i) k*illing* of the animals using an appropriate method;.

ii) confirm the death of the animals.

b) Competencies

i) safe use and maintenance of relevant equipment;

ii) familiarity with the techniques of restraining and killing the species involved;

iii) knowledge to assess effective *killing*.

5. Personnel in charge of disposal of dead animals

a) Responsibilities

i) An efficient dead animal disposal (to ensure *killing* operations are not hindered) should be ensured.

EU comment

The EU suggests adding "and spreading of disease is avoided/minimised" after hindered:

"i) An efficient dead animal disposal (to ensure killing operations are not hindered '<u>and spreading of disease is avoided/minimised</u>') should be ensured."

Justification: 'dead animal disposal' is also part of biosecurity procedures

b) Competencies

i) The personnel should be competent to use and maintain available equipment and apply techniques for the species involved.

EU comment

The EU suggests adding "and should understand the principles of biosecurity and worker safety" after involved:

"i) The personnel should be competent to use and maintain available equipment and apply techniques for the species involved "and should understand the principles of biosecurity and worker safety"."

Justification:

For consistency on attention for these aspects further up in the chapter.

6. Breeder, owner, keeper or manager

a) Responsibilities

i) assist when requested.

b) Competencies

i) specific knowledge of his/her animals and their environment.

Article 7.6.6.

Considerations in the planning of the operations regarding the mass killing of animals

EU comment

Same comment as above regarding the term "mass killing".

Many activities will need to be conducted on affected location or premises, including the *killing* of animals. The team leader should develop a plan for *killing* animals on the location or premises which should include consideration of:

a) minimising handling and movement of animals;

b) *killing* the animals on the affected location or premises; however, there may be circumstances where the animals may need to be moved to another location for *killing*; when the *killing* is conducted at a *slaughterhouse/abattoir*, the recommendations in Chapter 7.5. should be followed;

c) the species, number, age and size of animals to be killed, and the order of *killing* them;

d) methods of *killing* the animals, and their cost;

e) housing, husbandry, location of the animals as well as accessibility of the farm or the place they are situated;

f) the availability and effectiveness of equipment needed for *killing* of the animals, as well as the time necessary to kill the required number of animals using such methods;

g) the availability on the location or premises of facilities that will assist with the *killing*, and the necessity of any additional facilities;

EU comment

The EU suggests the following change:

"g) the availability on the location or premises of facilities that will be used to assist with the killing, and the necessity of any additional facilities;"

Justification:

Linguistic and editorial.

h) potential *biosecurity* and environmental impact of the operations;

i) the health and safety of personnel conducting the *killing*;

j) any legal issues that may be involved, for example where restricted veterinary drugs may be used, or where the process may impact on the environment;

k) the presence of other nearby premises holding animals;

l) possibilities for removal and disposal of dead animals.

The plan should minimise the negative animal welfare impacts of the *killing* by taking into account the different phases of the procedures to be applied for *killing*.

Competences and skills of the personnel handling and *killing* animals should be included in the operational plan.

Article 7.6.7.

Hazards to animal welfare

For the purpose of this chapter, *hazards to animal welfare* means a factor with the potential to adversely affect *animal welfare*.

EU comment

The EU suggests the following editorial change:

"For the purpose of this chapter, hazards to animal welfare means a factor with the potential to adversely affect animal welfare."

Justification:

Linguistic and editorial.

When killing animals, they may be exposed to different *animal welfare* hazards including improper restraining, rough handling, forced movement, absence of or improper design, inadequate construction and maintenance of premises, adverse weather conditions, unexpected loud noise and ineffective *killing* methods. Exposure to multiple hazards to a*nimal welfare* can have a negative cumulative effect on the animals [Moberg and Mench, 2000]. Hazards to animal welfare can be minimised mainly by appropriate design of premises and choice of equipment, and through good management, training and competency of personnel.

EU comment

The EU suggests the following changes:

"When killing animals, they may be exposed to different *animal welfare* hazards including improper restraining, rough handling, forced movement, absence of or improper design of

premises, inadequate construction and maintenance of premises, adverse weather conditions, unexpected loud noise and ineffective stunning and/or *killing* methods.

Justification:

There is a need to specify the absence of or improper design of what is meant.

The ineffective stunning methods and in particular the prolonged stun-to-kill interval is a serious animal welfare hazard (EFSA)

Article 7.6.8.

EU comment

The EU points out that there is a large overlap with Chapter 7.5 with regard to indicators. The EU suggests examining the extent to which it would be preferable to replace the text in Art. 7.6.8 with references to Chapter 7.5. The current version of Chapter 7.6 does not deal with indicators. Indicators are a complex issue and, in the opinion of the EU, should preferably be described depending on the stun/kill method, in order to promote comprehensibility and avoid misunderstandings. If a list of indicators is retained, it should be added that multiple indicators need to be considered simultaneously and that insufficient stunning should be assumed in the event of conflicting results.

Please see below for some of the EU's specific difficulties with the text.

Measures to assess animal welfare at the time of killing

Hazards to animal welfare at the time of killing should be assessed using animal-based measures. However, consideration should be given to the resources provided as well as the design and management of the method.

These animal-based measures should be routinely used in the monitoring of the state of consciousness and death.

1. The following animal-based measures can be useful indicators of animal welfare. These measures can be considered as tools to monitor the efficiency of design and management, given that they can affect animal welfare.

EU comment

The EU suggests the following changes:

"Hazards to animal welfare at the time of killing should be assessed using animal-based measures. However, consideration should be given to the resources provided as well as the design of the equipment and management of the method for stunning and killing.

These animal-based measures should be routinely used in the monitoring of the state of consciousness and death.

1. The following animal-based measures can be useful indicators of animal welfare. These measures can be considered as tools to monitor the efficiency of design of the equipment and management of the method for stunning and killing, given that they can affect animal welfare.

Justification:

There is a need to specify design of what is meant. We suppose that it is of the equipment.

Therefore, there is a need to specify which method is meant.

The ineffective stunning methods and in particular the prolonged stun-to-kill interval is a serious animal welfare hazard (EFSA)

a) Immediate collapse

Effective stunning can be recognised from the immediate loss of posture leading to collapse of the animal. Ineffectively stunned animals, on the other hand, will fail to collapse or will attempt to regain posture after collapse. Some ineffectively stunned animals, may occur, for example, if captive bolt shooting position is wrong or electrically immobilised animals lose posture, but remain conscious. The absence of immediate collapse is always indicative of consciousness.

EU comment

The text does not take into account that appropriate immobilisation may prevent collapse.

Justification:

To illustrate the opening remark to the article

b) Tonic–clonic seizures

Effective stunning often results in the presence of tonic–clonic seizures. Tonic seizures can be recognised by an arched back and rigidly flexed legs under the body and will last for several seconds. It is followed by clonic seizures lasting for seconds and manifested as leg kicking or paddling. The absence of tonic–clonic seizures may be indicative of consciousness [Van der Wal, 1971].

c) Righting reflex [Atkinson et al, 2013; Terlow et al, 2016]

Ineffectively stunned animals and those recovering consciousness will attempt to raise their heads or shake their heads after stunning, which is referred to as righting reflex.

EU comment

"Ineffectively stunned animals and those recovering consciousness ~~will~~may attempt to raise their heads or shake their heads after stunning, which is referred to as righting reflex."

Justification:

To illustrate the opening remark to the article

d) Rhythmic breathing [Atkinson et al, 2013; Kamenik et al, 2019, Vecerek et al, 2020]

Effective stunning will result in immediate onset of apnoea (absence of breathing). Ineffectively stunned animals and those recovering consciousness will start to breathe in a pattern commonly referred to as rhythmic breathing, which may begin as gagging and lead to respiratory cycles of inspiration and expiration. Breathing can be recognised from the regular flank and/or mouth and nostril movements. Recovery of breathing, if not visible through these movements, can be checked by holding a small mirror in front of the nostrils or mouth to look for the appearance of condensation due to expiration of moist air.

EU comment

Brief gasping/gagging may also occur following proper electrical stunning.

Justification:

To illustrate the opening remark to the article

e) Corneal reflex:

The corneal reflex is elicited by touching or tapping the cornea. Ineffectively stunned animals and those recovering consciousness will blink in response to the stimulus. Effectively stunned and stuck (bled) animals show the absence of the corneal reflex during any key stage. On the other hand, ineffectively or poorly stunned animals and those recovering consciousness prior to sticking or during bleeding are expected to show the presence of the corneal reflex at any key stage. It is worth noting that placement of electrical stunning tongs (electrodes) over the eyes of animals may render this indicator invalid.

EU comment

During epileptiform activity induced by electric stunning, the indicator is always invalid. A captive bolt shot may disable the corneal reflex without the animal being unconscious. Both aspects also apply to (f), (g) and (2)(b).

Justification:

To illustrate the opening remark to the article

f) Palpebral reflex

The palpebral reflex is elicited by touching or tapping a finger on the inner/outer eye can thus or eyelashes. Correctly stunned animals will not show a palpebral reflex. Ineffectively stunned animals and those recovering consciousness will blink in response to the stimulus at any key stage. It is worth noting that placement of electrical stunning tongs (electrodes) over the eyes of animals may render this indicator invalid.

g) Eye movement

Eye movements and the position of the eyeball can be recognised from close examination of eyes after stunning. Correctly stunned animals will show fixed eyes, and this can be recognised from wide open and glassy eyes with clearly visible iris/cornea in the middle. Eyeballs may be obscured in some animals owing to rotation into the eye socket following effective stunning. Ineffectively stunned animals and those recovering consciousness will show eye movements [EFSA AHAW Panel, 2013, Kamenik et al, 2019]

2. The following animal-based measures can be use as indicators of consciousness but are not sensible to indicate unconsciousness. Therefore, they can be use in addition to the previously mentioned animal-based measures:

a) Response to painful stimuli

Poor stunning can be recognised from the response to painful stimulus. The absence of response to a painful stimulus indicates unconsciousness following stunning. [Terlow et al, 2016. Kemenik et al, 2018]

b) Spontaneous blinking

Conscious animals may show spontaneous blinking and therefore this sign can be used to recognise ineffective stunning or recovery of consciousness after stunning. However, not all the conscious animals may show spontaneous blinking. Spontaneous blinking can be used as an indicator at all key stages of monitoring. It is worth noting that placement of electrical stunning tongs (electrodes) over the eyes of animals may render this indicator invalid. [Gregory et al, 2007; Terlouw et al, 2016, Kamenik et al, 2018]

c) Vocalisation

Vocalisation is expected only in conscious animals and can be used as an indicator in all key stages of monitoring. However, not all conscious animals will vocalise, and hence the absence of vocalisation does not always mean that the animal is unconscious. [Atkinson et al, 2013; Kamenik et al., 2018]

3. The following animal-based measures can be used as the confirmation of death before carcass disposal:

a) Muscle tone

Immediately after killing, dead animals will lose muscle tone, which can be recognized from the completely relaxed legs, floppy ears, and relaxed jaws.

b) Heartbeat

Onset of death leads to permanent loss of heartbeat, which can be ascertained physically by using a stethoscope or by palpation, where possible. [Vogel et al., 2011]

c) Dilated pupils

Dilated pupils (mydriasis) are an indication of death.

Article 7.6.[…].

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Annex 25

CHAPTER 8.Y.

INFECTION WITH NIPAH VIRUS

EU	**The EU thanks the Code Commission and in general supports this new chapter. Comments are inserted in the text below.**

Article 8.Y.1.

General provisions

Nipah virus can infect a wide range of species, including humans, but only pigs and horses are considered to play a significant role in the epidemiology of the disease. For the *Terrestrial Code*, *infection* with Nipah virus is defined as an *infection* of pigs and horses ~~and pigs~~ (hereafter 'susceptible animal') with Nipah virus.

The following defines the occurrence of *infection* with Nipah virus:

1) Nipah virus has been isolated and identified as such in a sample from a susceptible animal; or

2) antigen or nucleic acid specific to Nipah virus has been detected in a sample from a susceptible animal showing clinical signs or pathological lesions consistent with *infection* with Nipah virus, epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with Nipah virus; or

3) seroconversion specific to Nipah virus, which is not the consequence of *vaccination*, has been detected in a susceptible animal; or

4) antibodies specific to Nipah virus, which are not the consequence of *vaccination*, have been detected in a sample from a susceptible animal epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with Nipah virus.

EU comment	**The EU thanks the Code Commission for considering previous comments on this point. It also seeks assessments of the points expressed below.** **Point 3 appears not to be in line with other case definitions where the presence of antibodies should be epidemiologically linked to other disease occurrences or suspicious.** **It is important that the general approach to case definitions (occurrence of infection) follow a similar approach throughout the Code. It is also important that the competent authority balances the information it has received with the ongoing epidemiological information before an outbreak is confirmed. Keeping point 3) above would imply that the competent authority cannot factor in the epidemiological situation.** **Therefore the proposed approach is not clear and it is proposed to delete point 3):** **" ~~3) seroconversion specific to Nipah virus, which is not the consequence of vaccination, has been detected in a susceptible animal; or~~"**

Standards for diagnosis and vaccines, as well as information on the epidemiology, are described in the *Terrestrial Manual*.

_____

CHAPTER 12.3.

INFECTION WITH *TRYPANOSOMA EQUIPERDUM* (DOURINE)

EU	**The EU thanks the Code Commission and in general supports this new chapter. Comments are inserted in the text below.**

Article 12.3.1.

General provisions

Dourine is a disease of equids caused by *Trypanosoma equiperdum* of the subgenus *Trypanozoon* mainly transmitted directly from animal to animal during coitus. It may also be transmitted vertically and iatrogenically. Dourine may manifest in acute, chronic or clinically inapparent forms.

After a transient blood multiplication, *T. equiperdum* invades tissues, especially genital organs and may also invade the nervous system.

For the purposes of the *Terrestrial Code*, dourine is defined as an *infection* of domestic and *captive wild* equids with *T. equiperdum*.

The following defines the occurrence of infection with *Trypanosoma equiperdum*:

1) Trypanosomes with *Trypanozoon* morphology have been observed in a sample from an domestic and *captive wild* equids showing clinical signs consistent with dourine and linked to a suspected *case* of *infection* with *T. equiperdum* or found in an area where surra is not known to occur; or

2) trypanosomes with *Trypanozoon* morphology have been observed in a sample from an domestic and *captive wild* equids epidemiologically linked to a confirmed *case* of *infection* with *T. equiperdum*; or

3) nucleic acid specific to *Trypanozoon* has been detected in a sample from an equid epidemiologically linked to a confirmed *case* of *infection* with *T. equiperdum* ; or

4) antibodies have been detected in a sample from an domestic and *captive wild* equids epidemiologically linked to a confirmed *case* of *infection* with *T. equiperdum*.

For the purposes of the *Terrestrial Code,* the *incubation period* of *infection* with *T. equiperdum* shall be six months. *Infective period* shall be lifelong.

EU	**We noticed that the chapters on surra and dourine provide different incubation period for both diseases, even if both are caused by trypanosomes. In addition, incubation period for infection with *T. brucei*, *T. congolense*, *T. simiae* and *T. vivax* is set out for 90 days in Chapter 8.19., the same as for surra.**

	Therefore, we suggest to review and consider an alignment, either to 90 days as for surra and infection with *T. brucei*, *T. congolense*, *T. simiae* and *T. vivax*, or six months as for dourine, for all trypanosomosis. **The rationale is the lack of a specific test for differentiation of trypanosomes.**

For the purposes of this chapter, a temporary importation of horses refers to the introduction of horses into a country or *zone*, for a defined period of time, not exceeding 90 days, during which the *risk* of transmission of the *infection* is mitigated through specific measures under the supervision of the *Veterinary Authority.* Temporarily imported horses are re-exported at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or *zone,* should be defined in advance.

Standards for diagnosis and information on the epidemiology are described in the *Terrestrial Manual*.

Article 12.3.2.

Safe commodities

When authorising the import or transit of the following *commodities*, *Veterinary Authorities* should not require dourine-related conditions regardless of the *animal health status* of the *exporting country* or *zone*:

1) pasteurised *milk* and pasteurised *milk products*;

2) hair, wool and fibre;

3) gelatine and collagen;

4) hooves;

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

6) *meat products*;

7) hides and skins (except raw);

8) embryos or oocytes collected, processed, and stored in accordance with Chapters 4.8. to 4.10.;

9) *protein meal.*

Article 12.3.3.

Country or zone free from dourine

A country or *zone* may be considered free from *infection* with *T. equiperdum* when:

1) the *infection* is notifiable in the entire country for at least the past two years;

2) measures to prevent the introduction of the *infection* have been in place; in particular, the importations or movements of equids and other *commodities* into the country or *zone* have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*;

3) and either:

a) the relevant provisions in point 2 b of Article 1.4.6. have been complied with; or

b) for at least the past two years, there has been no *case* in the country or *zone* and *surveillance* in accordance with Articles 12.3.11. to 12.3.14. has been in place in the entire country.

Article 12.3.4.

Compartment free from dourine

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

Article 12.3.5.

Recovery of free status

Should a *case* of *infection* with *T. equiperdum* occur in a previously free country or *zone*, its status may be recovered after the following:

1) all infected equids have been either isolated and slaughtered, or killed and appropriately disposed of;

2) equids which have been in contact with infected equids were tested and all positive equids were isolated and slaughtered, or killed and appropriately disposed of; and,

3) For six months after the last *case* was slaughtered or killed:

a) the equids in contact have undergone monthly repeated serological and agent detection tests with negative results in both tests;

b) *surveillance* in accordance with Articles 12.3.11. to 12.3.14. has been carried out with negative results;

c) appropriate *biosecurity* has been in place

Otherwise, Article 12.3.3. applies.

Article 12.3.6.

Recommendations for importation of equids from countries, zones or compartments free from dourine

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

1) showed no clinical signs of *infection* with *T. equiperdum* on the day of shipment;

2) were kept since birth or at least six months prior to shipment in the free country, *zone* or *compartment* of origin or were imported from a free country, *zone* or *compartment*.

EU	**We suggest to revise the residency period of equids prior to shipment in a country, zone or compartment of origin in line with a decision taken for the length of the incubation period for dourine, as indicated in the comment to Article 12.3.1.**

Article 12.3.7.

Recommendations for importation of equids from countries, zones or compartments not free from dourine

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

1) showed no clinical signs of dourine on the day of shipment;

2) for at least 45 days prior to shipment were not used for breeding (including artificial insemination, semen collection, use as teasers) and did not have any direct or indirect sexual contact with other horses; and

3) during this period, all equids from the same group were subjected to an antibody detection test on samples taken on two occasions, with an interval of 30 days, with negative results.

Article 12.3.8.

Recommendations for the temporary importation of horses

When importing on a temporary basis for purposes other than breeding and rearing horses that do not comply with the recommendations in Article 12.3.6. or Article 12.3.7., *Veterinary Authorities* should:

1) require:

   a) that the horses be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status *subpopulation* as defined in Chapter 4.17.;

   b) the presentation of an *international veterinary certificate* attesting that the horses:

      i) showed no clinical sign of infection with *T. equiperdum* on the days of shipments;

      ii) if not belonging to a high health status *subpopulation,* were negative in an antibody detection test within 15 days prior to departure from the country of origin ;

   c) the duration of the temporary importation period, the destination after this period, and the conditions required to leave the country or *zone* be defined;

2) ensure that during their stay in the country or *zone*, the horses:

   a) are not used for breeding (including artificial insemination, semen collection, use as teasers) and do not have any direct or indirect sexual contact with other horses;

b) are not subjected to any practice that may represent a risk of transmission of *infection* with *T. equiperdum.*

Article 12.3.9.

Recommendations for importation of semen from countries, zones or compartments free from dourine

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

1) the donor males:

   a) showed no clinical signs of *infection* with *T. equiperdum* on the day of collection of the semen;

   b) were kept for the six months prior to semen collection in a country, zone or compartment free from dourine;

2) the semen was collected, processed and stored in a *semen collection centre* accordance with Chapters 4.6. and 4.7.

Article 12.3.10.

Recommendations for importation of semen from countries or zones not free from dourine

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

1) the donor males:

   a) have been kept for at least six months prior to semen collection in an *establishment* in which *surveillance* in accordance with Articles 12.3.11. to 12.3. 14. demonstrates that no *case* had occurred during that period;

   b) showed no clinical sign of *infection* with *T. equiperdum* during that period;

   c) were subjected to an antibody detection test on a blood sample taken on two occasions, with an interval of 30 days, with negative results;

2) the semen was collected, processed and stored in a *semen collection centre* accordance with Chapters 4.6. and 4.7.

Article 12.3.11.

Introduction to surveillance

Articles 12.3.11. to 12.3.14. define the principles and provide guidance on *surveillance* for *infection* with *T. equiperdum*, complementary to Chapter 1.4.

The purpose of *surveillance* could be the demonstration of the absence of *infection*, the early detection of *cases*, or the measurement and monitoring of the *prevalence* and distribution of the *infection* in a country, *zone* or *compartment*.

The most important component of the epidemiology of dourine is sexual transmission, therefore sexually mature equids are considered the target population. Notwithstanding, iatrogenic transmission should also be considered.

The impact and epidemiology of dourine widely differs between different regions of the world, and between different type of animal production systems. For instance considering the presence or absence of other trypanosomes and therefore, it is not appropriate to provide specific recommendations for all situations. Member Countries should provide scientific data explaining the epidemiology of the disease in the country or *zone* concerned, such as host susceptibility (e.g. horse, donkey, mule) and co-infections with other *Trypanosom*a

spp., and adapt the *surveillance* strategies for defining their status to the local conditions. There is considerable latitude available to Member Countries to justify their status at an acceptable level of confidence.

Article 12.3.12.

Principles of surveillance for dourine

The following principles are complementary to Chapter 1.4. and should be applied by Member Countries seeking to achieve and demonstrate freedom from infection as well as being part for *official control programme* in countries where the disease is endemic.

In countries where other trypanosomes infection occur in equids, the diagnosis of dourine is challenging because the clinical signs are not pathognomonic, and diagnostic methods are not species specific. As a consequence it is difficult to perform differential diagnosis between *Trypanosoma equiperdum* and other Trypanozoon infections.

Surveillance for *infection* with *Trypanosoma equiperdum* should encompass not only clinical signs and relevant sampling and testing, but also information on animal husbandry practices and epidemiological context, including sexual contacts, breeding history of the equid, international and other animal movements, contact patterns, presence of other trypanosomes, and *vectors* (biting flies including tsetse flies). The *Veterinary Services* should implement programmes to raise awareness among farmers, owners, breeders and workers, who have day to day contact with equids, as well as *veterinarians*, *veterinary paraprofessionals* and diagnosticians. Those persons should observe and report promptly any suspicion of dourine to the *Veterinary Services*.

Under the responsibility of the *Veterinary Authority*, Member Countries should have in place a *surveillance* system in accordance with the Chapter 1.4. and, in particular:

- the formal and ongoing system for detecting and investigating *cases* should include all suspicions of *infection* with Trypanosomes;
- the procedure for the rapid collection and transport of samples from suspected *cases* to a *laboratory* for diagnosis should include the relevant types and methods of sampling for dourine as described in the *Terrestrial Manual*;
- the *laboratory* is approved for diagnosis of dourine.

Special attention is to be made to low susceptible animals such as donkeys and mules that can act as healthy carriers and reservoir of *Trypanosoma equiperdum.*

Article 12.3.13.

Surveillance for early warning of dourine

1) An ongoing *surveillance* programme for dourine should be in place and be designed to detect the presence of dourine in the country or *zone* in a timely manner.

2) The dourine *surveillance* programme should include the following.

   a) An *early warning system* for reporting suspected animals described in Article 12.3.12., in accordance with Article 1.4.5.

   b) Implementation, as relevant, of regular and frequent clinical inspection of individual equids at risk of dourine that could, for instance, include equids that were imported from countries not free from dourine.

Article 12.3.14.

Surveillance for demonstrating freedom from dourine

1. Requirements for declaring freedom of the entire country, a *zone* or a *compartment* from dourine

Transparency in the application of different methodologies is essential to ensure consistency in decision-making, ease of understanding, fairness and rationality. The assumptions made, the uncertainties, and the effect of these on the interpretation of the results, should be documented.

The design of the *surveillance* programme will depend on the epidemiological circumstances and it should be planned and implemented in accordance with this chapter and Article 1.4.6. This requires the availability of demographic data on the equids population and the support of a *laboratory* able to undertake identification of dourine through parasite detection and antibody tests.

Data from different *surveillance* activities can be included to increase the sensitivity of the *surveillance* system. If this is to be done, data from structured (e.g. surveys and active *surveillance*) and non-structured (e.g. passive *surveillance*) sources should be combined.

The *surveillance* programme should include *surveillance* of different equids subpopulations (e.g. thoroughbred, saddle horses (riding horses), working horses, ponies, donkeys, mules).

Documentation of freedom from dourine should provide details of the equids population, the occurrence of suspected *cases* and how they were investigated and dealt with. This should include the results of *laboratory* testing and the *biosecurity* and control measures to which the animals concerned were subjected during the investigation.

In order to maintain freedom of an establishment within an infected country or zone and to demonstrate no case has occurred, passive surveillance relying on clinical observation alone is insufficient. Depending on the prevailing epidemiological situation and assessed risk for the introduction of *T.equiperdum*, samples should also be collected on a routine basis for parasite detection and antibody tests. There should also be systematic screening of horses that are introduced into the establishment for the absence of dourine.

2. Additional requirements for recovery of free status

In addition to the general conditions described in this chapter, a Member Country seeking recovery of country or *zone* free status, including a *containment zone* established in accordance with Article 4.4.7., should show evidence of an active *surveillance* programme (clinical inspection and serological surveillance) to demonstrate absence of dourine.

Populations under this *surveillance* programme should include:

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

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

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