

Report of the Meeting of WOAH Terrestrial Animal Health Standards Commission

Annex 1

Original: English (EN)

5 to 14 September 2023
Paris

EU comment

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

A number of general comments on this report of the September 2023 meeting of the Code Commission are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report.

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

Introduction and Members contribution

This report presents the work of the WOAHA Terrestrial Animal Health Standards Commission (hereinafter 'the Code Commission'), which met from 5 to 14 September 2023, at the WOAHA Headquarters in Paris, France.

The Code Commission thanked the following Members for providing comments: Argentina, Australia, Brazil, Canada, China (People's Republic of), Chinese Taipei, Japan, Mexico, New Caledonia, New Zealand, Norway, South Africa, Switzerland, Thailand, the United Kingdom (UK), the United States of America (USA), Members of the WOAHA Americas Region, the Member States of the European Union (EU), the African Union Inter-African Bureau for Animal Resources (AU-IBAR) on behalf of African Members of WOAHA. The Commission also thanked the following organisations for providing comments: the International Coalition for Farm Animal Welfare (ICFAW), International Wool Textile Organisation (IWTO), as well as various experts of the WOAHA scientific network.

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

Status of annexes

Texts in **Part A (Annexes 4 to 23)** are presented for comments and will be proposed for adoption at the 91st General Session in May 2024. Texts in **Part B (Annexes 3 and 24 to 31)** are presented for comments.



**World Organisation
for Animal Health**
Founded as OIE

Standards Department

[TCC.Secretariat@woah.org]

12, rue de Prony
75017 Paris, France

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

How to submit comments

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

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

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

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

Deadline for comments

Comments on texts circulated for comment (Part A and Part B) must be emailed to the Secretariat by **29 December 2023** to be considered at the February 2024 meeting of the Code Commission.

Where to send comments

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

Date of the next meeting

The Code Commission noted the dates for its next meeting: **6 to 16 February 2024**.

Table of Contents

1. Welcome	8
1.1. Deputy Director General-International Standards and Science	8
1.2. Director General	9
1.3. Transparency of the WOAAH process for the elaboration of Standards	9
2. Adoption of the agenda	10
3. Cooperation with Other Specialist Commissions	10
3.1. Scientific Commission for Animal Diseases	10
3.2. Biological Standards Commission	10
3.3. Aquatic Animals Health Standards Commission	12
4. Work Programme and priorities	12
4.1. Comments received on the Code Commission Work Programme	13
4.2. Ongoing priority topics (other than texts circulated for comments)	13
4.2.1. Wildlife health	14
4.2.2. Animal hosts to be targeted by WOAAH Standards for a listed disease of terrestrial animals	14
4.2.3. Revision of Chapter 4.4. Zoning and compartmentalisation	15
4.2.4. Revision of chapters on the welfare of animals during transport by land, sea and air (Chapters 7.2., 7.3. and 7.4.)	16
4.2.5. Revision of Chapter 7.6. Killing for disease control purposes	17
4.2.6. Revision of Chapter 10.5. Infection with <i>Mycoplasma gallisepticum</i> (Avian mycoplasmosis)	17
4.2.7. Revision of chapters on equine encephalitis (Chapter 8.10. Japanese encephalitis, 12.4. Equine encephalitis (Eastern and Western) and 12.11. Venezuelan equine encephalomyelitis)	18
4.3. Items under consideration for inclusion in the work programme	18
4.4. New proposals and requests for inclusion in the work programme	19
4.4.1. Revision of User's guide	19
4.4.2. Revision of Chapter 1.3. Diseases, infections and infestations listed by WOAAH	19
4.4.3. Revision of Glossary definition for 'poultry'	19
4.4.4. Revision of Chapter 10.2. Avian infectious bronchitis	19
4.5. Prioritisation of items in the work programme	20
5. Texts circulated for comments and proposed for adoption in May 2024	22
5.1. Glossary	22
5.2. Diseases, infections and infestations listed by WOAAH (Chapter 1.3.)	23
5.3. General hygiene in semen collection and processing centres (Chapter 4.6.)	24
5.4. Revision of Chapter 4.7. Collection and processing of bovine, small ruminant and porcine semen	26

5.5.	Revision of Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine.....	27
5.6.	Slaughter of animals (Chapter 7.5.) and associated Glossary definitions.....	34
5.7.	Infection with foot and mouth disease virus (Chapter 8.8.) and Application for official recognition by WOAAH of free status for foot and mouth disease (Chapter 1.11.).....	42
5.8.	Infection with Rift Valley fever virus (Chapter 8.16.)	48
5.9.	Infection with <i>Trichinella</i> spp. (Chapter 8.18.)	49
5.10.	Infection with <i>Coxiella burnetii</i> (Q fever) (New Chapter 8.X.).....	49
5.11.	Infection with <i>Trypanosoma evansi</i> (New Chapter 8.Z.)	50
5.12.	Infection with <i>Mycoplasma mycoides</i> subsp. <i>mycoides</i> SC (Contagious bovine pleuropneumonia) (Chapter 11.5.).....	54
5.13.	Infection with bovine pestiviruses (bovine viral diarrhoea) (New Chapter 11.X.)	55
5.14.	Infection with African horse sickness virus (Chapter 12.1.).....	56
5.15.	Revision of Articles 13.2.1. and 13.2.2. of Rabbit haemorrhagic disease (Chapter 13.2.)	59
5.16.	Revision of Chapter 15.1. Infection with African swine fever virus.....	60
5.17.	New chapter Infection with Camelpox virus (Chapter 16.Z.)	60
5.18.	Terminology: Use of terms ‘Competent Authority’, ‘Veterinary Authority’ and ‘Veterinary Services’	61
6.	Texts circulated for comments.....	62
6.1.	User’s Guide	62
6.2.	New chapter on biosecurity (Chapter 4.X.) and associated Glossary definitions.....	63
6.3.	Revision of Chapters 5.4. to 5.7. and associated Glossary definitions	64
6.4.	Revision of Chapter 7.1. Introduction to the recommendations for animal welfare	65
6.5.	New chapter on infection with Nipah virus (Chapter 8.Y.).....	66
6.6.	New Chapter 14.8. Scrapie and use of terms ‘greaves’	67
7.	Updates on WOAAH initiatives relevant to the Code Commission	68
7.1.	Animal health forum and General Session technical item - HPAI	68
7.2.	WOAH Observatory	69
7.3.	Global Burden of Animal Diseases (GBADs)	70
7.4.	WOAH Global Animal Welfare Strategy	70
7.5.	<i>Terrestrial Code</i> data standardisation	70
7.5.1.	Framework for disease-specific chapters of the <i>Terrestrial Code</i>	70
7.5.2.	Commodities	71
7.6.	WOAH Standards online navigation tool	72
7.7.	Emergency management.....	72
7.8.	Community Animal Health Workers (CAHW)	73
7.9.	Editorial Board of the Scientific and Technical Review	73
8.	Updates on the other standard-setting bodies and international organisations	74
8.1.	Update on Codex’s works.....	74

8.2.	Update on collaboration with International Air Transport Association (IATA)	75
8.3.	Update on collaboration with the International Embryo Technology Society (IETS).....	75
8.4.	Update on collaboration with International Horse Sports Confederation (IHSC)	76
8.5.	Update on collaboration with Secretariat of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)	76
8.6.	Collaboration with private sector/industry organisations	77

List of Annexes

- Annex 1. Adopted agenda.
- Annex 2. List of participants

Texts for comments and proposed for adoption (PART A)

- Annex 4. Glossary: 'animal product', 'biological product', 'commodity', 'death', 'euthanasia', 'germinal products', 'greaves', 'semen collection centre', 'slaughter' and 'stunning'
- Annex 5. Chapter 1.3. Diseases, infections and infestations listed by WOAAH (in track change)
- Annex 6. Chapter 1.3. Diseases, infections and infestations listed by WOAAH (clean text)
- Annex 7. Chapter 4.6. General hygiene in semen collection and processing centres
- Annex 8. Chapter 4.7. Collection and processing of bovine, small ruminant and porcine semen
- Annex 9. Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine
- Annex 10. Chapter 7.5. Slaughter of animals
- Annex 11. Chapter 8.8. Infection with foot and mouth disease virus
- Annex 12. Chapter 1.11. Application for official recognition by WOAAH of free status for foot and mouth disease
- Annex 13. Chapter 8.16. Infection with Rift Valley fever virus
- Annex 14. Chapter 8.18. Infection with *Trichinella* spp.
- Annex 15. Chapter 8.X. Infection with *Coxiella burnetii* (Q Fever)
- Annex 16. Chapter 8.Z. Infection with *Trypanosoma evansi*
- Annex 17. Chapter 11.5. Infection with *Mycoplasma mycoides* subsp. *Mycoides* SC (Contagious bovine pleuropneumonia)
- Annex 18. Chapter 11.X. Infection with bovine pestiviruses (Bovine viral diarrhoea)
- Annex 19. Chapter 12.1. Infection with African horse sickness virus
- Annex 20. Chapter 13.2. Rabbit haemorrhagic disease
- Annex 21. Chapter 15.1. Infection with African swine fever virus
- Annex 22. Chapter 16.Z. Infection with Camel pox virus
- Annex 23. Terminology: Use of terms 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'

Texts for comments (PART B)

- Annex 3. Work programme
- Annex 24. User's Guide
- Annex 25. Glossary: 'biosecurity', 'biosecurity plan', 'border post', 'container', 'point of exit', 'quarantine station', 'swill' and 'vehicle/vessel'
- Annex 26. Chapter 4.X. Biosecurity

-
- Annex 27. Chapter 5.4. Measures and procedures applicable in the exportation of commodities
 - Annex 28. Chapter 5.6. Measures and procedures applicable in the importation of commodities
 - Annex 29. Chapter 7.1. Introduction to the recommendations for animal welfare
 - Annex 30. Chapter 8.Y. Infection with Nipah virus
 - Annex 31. Chapter 14.8. Scrapie

1. Welcome

1.1. Deputy Director General-International Standards and Science

Dr Montserrat Arroyo, WOAHA Deputy Director General, International Standards and Science (WOAH DDG ISS), met with the Code Commission on 6 September 2023 and welcomed members and thanked them for their ongoing contributions to the work of WOAHA. Dr Arroyo commended the Commission for its ambitious agenda and extended her appreciation to the members' employing institutions and national governments.

Dr Arroyo informed the Commission that, with the objective of improving the transparency, documentation, and traceability of the standard-setting process, the Director General has agreed to a stepwise approach for the publication of comments considered by the relevant Specialist Commission (see item 1.3 of this report).

Dr Arroyo informed the Commission that the Organisation is currently dedicating efforts to various IT projects with the aim of creating tools that will facilitate access to WOAHA information and input mechanisms, including: i) the evolution of the system for collecting annual reports from Reference Centres; ii) a digitalised system for navigating WOAHA International Standards, including a mechanism for the visualisation of sanitary measures recommended for the international trade of commodities for terrestrial animals; iii) an improved system for self-declaration of disease status and; iv) a repository of PVS reports. The goal of all these IT projects is to improve and simplify the access to the relevant information, including facilitating accessibility and consultations of WOAHA standards by WOAHA Members, to enhance the traceability of WOAHA's work and to interconnect all the tools.

Dr Arroyo informed the Commission that the Call for experts for seeking nomination for election or re-election to the next term of the WOAHA Specialist Commissions (2024-2027) has closed and the next step is the assessment of eligible applicants by the Nomination Evaluation Committee. She noted that more information will be provided to the Delegates in due course. Dr Arroyo acknowledged the strengthening of collaboration with the other Specialist Commissions, emphasising the importance of harmonising and adopting a consistent approach to common work themes. Dr Arroyo highlighted the outcomes of 2022 and 2023 meetings of the Presidents of the Specialist Commissions and the agreed approach for the procedure for the elaboration of WOAHA Standards.

The Commission thanked Dr Arroyo for these updates.

The Commission fully supported the decision to promote the transparency of Member's comments. The Commission noted that this would be in line with several changes recently implemented by the Commission in its reports to improve the transparency, documentation, and traceability of the standard-setting process, as well as to improve the communication with Members. Notably, these changes concern the management and prioritisation of the work programme for the development and revision of the *Terrestrial Code*, more specifically, to provide clearer information on inputs and decision making. The Commission also highlighted that this should be accompanied by tools to support Members in the preparation of their inputs and with clear procedures on the management of these inputs. The Commission highlighted that this would also serve to promote Members awareness of the standard-setting process and the standards themselves.

The Commission and Dr Arroyo discussed some of the outcomes of the 90th General Session, notably the texts proposed for adoption that were withdrawn from adoption due to a lack of consensus. The Code Commission noted that the revised chapter 8.8. had been withdrawn to be further worked and a modification to one article of chapter 8.15. was not adopted. The Commission and Dr Arroyo agreed on the need to make every effort to reach consensus on new text or revisions, not only because it is described as such in the Organisation's Basic Texts, but also because agreement among Members on the content of the standards is essential to get ownership of the recommendations by the Members, and for these to be meaningful and implemented. The Commission and Dr Arroyo concurred that building consensus was

a process which comprises many steps, from the identification of a need to the development of the work, the consultation with Members, and discussions at the General Session. It was highlighted that commenting on the work of the Commission throughout the standard-setting process is critical as it allows the Commission to address Members concerns and needs at early stages of the work. The Commission also highlighted the importance of Members engaging in discussions about the work programme.

The members of the Commission thanked Dr Arroyo for the excellent support provided by the Secretariat.

1.2. Director General

Dr Monique Eloit, the WOAHA Director General, met the Code Commission on 11 September 2023 and thanked its members for their support and commitment to achieving WOAHA objectives.

Dr Eloit remarked on the positive outcomes of the 90th General Session and highlighted the positive response to the change in its format, which included an Animal Health Forum on Avian Influenza and facilitated interactive discussions.

Dr Eloit informed the Commission that WOAHA is currently undergoing a consultancy to evaluate the Organisation's Basic Texts from both a technical and legal viewpoint. The importance of this consultancy is to introduce a more robust and transparent approach to the Organisation's procedures, supported by a solid legal basis. The revision of the Basic Texts is essential to maintaining WOAHA's credibility among Members and stakeholders. She noted that more information will be provided to the Delegates in due course.

The Commission thanked Dr Eloit for these updates and agreed on the importance of evaluating the Organisation's Basic Texts. The Commission highlighted the importance of building awareness at national level on the WOAHA standard-setting process to support the Delegates in achieving a sustainable and effective engagement in this process.

1.3. Transparency of the WOAHA process for the elaboration of Standards

The Secretariat informed the Commission that the WOAHA Director General had agreed to implement a stepwise approach to improve the transparency of the WOAHA process for the elaboration of Standards, which will include the publication of comments of Members considered by the Specialist Commissions and their responses, and an evolution of the reports of the Aquatic Animals Commission, the Code Commission and the Biological Standards Commission. This is also to align with the 7th Strategic Plan. The Secretariat also noted that this proposal had been discussed with the Presidents of the three Commissions at a meeting after the 90th General Session in May 2023 and that they supported this approach.

The Secretariat explained that this process also aims to ensure that Members can gain a better understanding of the complexity and range of opinions, as well as of Commission decisions, and that this will result in a better understanding of Members concerns and should also improve the quality of the comments received.

The Secretariat explained that this would be a progressive process, that will start in March/April 2024 with the publication only on the Delegates website of comments considered on new and revised standards during the February 2024 meetings of the respective Commissions, which will happen at the same time of the respective February 2024 reports. This process will include an evolution of the Commission reports towards full transparency of comments considered and Commissions responses, which will result in better documentation and traceability of the WOAHA process for the elaboration of Standards. The Secretariat noted that Delegates will be kept well informed throughout this process, including a detailed communication that will be sent after the publication of this report.

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 responses, as relevant, as noted below.

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

Procedures for listing decisions for pathogenic agents of terrestrial animals

The Code Commission was informed that, taking the experience gained in recent implementation of the [Standard Operation Procedure for listing decisions for pathogenic agents of terrestrial animals](#), the Secretariat had reviewed some of the internal processes for its implementation, especially to ensure adequate implementation and documentation of the Step regarding the consideration by the DDG and the Specialist Commission of the relevance of undertaking a listing assessment.

Susceptibility of racing pigeons to high pathogenicity avian influenza

The Secretariat informed the Code Commission that, at its February 2023 meeting, the Scientific Commission discussed the susceptibility of racing pigeons to high pathogenicity avian influenza viruses, following a query received by WOAAH headquarters from the International Veterinary Pigeon Association, Racing Pigeon Partners and the Fédération Colombophile Internationale.

Noting the Scientific Commission's opinion that pigeons are not effective in transmitting the high pathogenicity avian influenza viruses mechanically or naturally, the Code Commission highlighted that racing pigeons are by definition not considered poultry for the purposes of Chapter 10.4. Infection with high pathogenicity avian influenza viruses, provided that they have no direct or indirect contact with poultry or poultry facilities. Therefore, infection of racing pigeons with HPAIV should not affect the animal health status of the country or zone.

However, the Commission wished to remind Members that the implementation of prevention and control measures at national level is the responsibility of each countries' Veterinary Services, and it is each Member's prerogative to develop the mechanisms that are relevant in the national context.

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 2023/2024 review cycle.

Given that the revision of some of these chapters could impact the corresponding chapters in the *Terrestrial Code*, the Code Commission agreed to continue to work closely with the Biological Standards Commission to ensure that relevant amendments in the corresponding chapters of the *Terrestrial Code* and the *Terrestrial Manual* are well coordinated. The Code Commission was informed that experts who undertook the review of a *Terrestrial Manual* chapter would also be requested to provide advice regarding

the possible need to consequentially amend an existing Code chapter. The Biological Standards Commission would ensure that this information is provided to the Code Commission, when appropriate.

A meeting of the Bureaus (i.e., the President and the two Vice-Presidents) of the Code Commission and the Biological Standards Commission was held on 7th September 2023 and chaired by WOAHH DDG ISS. The purpose of this meeting was for the two Bureaus to update each other on the relevant work of each Commission on topics of common interest, and to discuss and agree on the planning and coordination on these topics.

The Bureaus discussed the following topics:

- the *Terrestrial Manual* chapters to be reviewed in the 2023/2024 review cycle, and the progress of development and revision of *Terrestrial Code* chapters,
- the Biological Standards Commission's work to develop a new section that would describe the rationale for the selection of tests for different purposes given in a table in all disease chapters of the *Terrestrial Manual*,
- ongoing considerations on Chapter 3.9.1. African swine fever (infection with African swine fever virus) of the *Terrestrial Manual*,
- new proposed Glossary definition for 'biological products' (see item 5.1 of this report),
- the need to revise Chapter 5.8. International transfer and laboratory containment of animal pathogenic agents of the *Terrestrial Code*,
- the potential need to update Chapter 2.1.1. Laboratory methodologies for bacterial antimicrobial susceptibility testing of the *Terrestrial Manual*, to address some comments received on the revised *Terrestrial Code* Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine (see item 5.5 of this report),
- selected comments received on the revised Chapter 8.8. Infection with foot and mouth disease virus (see item 5.7 of this report),
- the use of the term 'seroconversion' in the *Terrestrial Code*,
- the use of the terms 'subclinical' and 'asymptomatic' in the *Terrestrial Code* and the *Terrestrial Manual*.
- *Terrestrial Manual* chapters on non-listed diseases.

The Bureau of the Code Commission informed that the Commission agreed to change a sentence in Article X.X.1. of a disease-specific chapter that referred to the *Terrestrial Manual* to 'Standards for diagnosis and vaccines, as well as information on the epidemiology, are described in the *Terrestrial Manual*'. This change aims to avoid duplication of information or potential inconsistencies between the respective chapters of the *Terrestrial Code* and the *Terrestrial Manual*. The Bureau of the Code Commission explained that the disease-specific chapters in the *Terrestrial Manual* provide standards for diagnosis that include not only diagnostic tests but also clinical diagnosis. The Bureaus agreed on this approach, and it was noted that this change would be considered, as appropriate, when disease-specific chapters are revised or newly developed.

Concerning the reference to 'seroconversion' in the *Terrestrial Code*, the Bureaus considered an analysis prepared by the Secretariat summarising its usage across the *Terrestrial Code*. Noting that there are some variations as to how to describe the point referring to serological test among case definitions of disease-specific chapters, the Bureaus agreed that clearer justifications should be provided when case definitions refer to seroconversion and that a distinction between seroconversion and a single detection of specific antibodies, and their application in case definitions, should be clarified. Furthermore, the Bureau of the Code Commission proposed that the Biological Standards Commission discuss minor

amendments to the definition of the term 'seroconversion' in the Glossary of terms in the *Terrestrial Manual*, for it to be used *mutatis mutandis* in the *Terrestrial Code*.

The Bureaus discussed the use of the term 'asymptomatic' in the *Terrestrial Code*. The Biological Standards Commission noted that this term is not used in the *Terrestrial Manual* as it is no longer considered an appropriate term for animals. Based on this information, the Code Commission agreed to use only the term 'subclinical' in the *Terrestrial Code* to refer also to diseases that show no clinical signs.

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 comments are noted under the relevant agenda item of this report. The Code Commission also encouraged Members to read the [Biological Standards Commission's report](#) for the details of its inputs.

3.3. Aquatic Animals Health Standards Commission

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

- the approach taken by both Commissions in the development of their work plan/work programme and prioritisation of items,
- the approach for the review of the use of Glossary definitions for 'Competent Authority', 'Veterinary Authority', 'Veterinary Services' and 'Aquatic Animal Health Services' in the *Terrestrial Code* and the *Aquatic Code* (see item 5.18 of this report),
- framework for disease-specific chapter of the *Terrestrial Code* (see item 7.5.1 of this report),
- the Code Commission's plan to revise User's guide (see item 6.1 of this report),
- the Code Commission's plan to develop a new chapter on biosecurity (see item 6.2 of this report),
- the Code Commission's plan to revise Chapters 5.4. to 5.7. in the *Terrestrial Code* (to inform the Aquatic Animals Commission of the status) (see item 6.3 of this report),
- the Code Commission's plan to revise Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine in the *Terrestrial Code* (to inform the Aquatic Animals Commission of the status) (see item 5.5 of this report),
- the Aquatic Animals Commission's plan to revise Chapter 4.3. Application of Compartmentalisation, and Chapter 4.2. Zoning and compartmentalisation, in the *Aquatic Code* (to exchange the Code Commission's experience in the last revision of Chapter 4.4. Zoning and compartmentalisation, and development of Chapter 4.5. Application of compartmentalisation, in the *Terrestrial Code* with the Aquatic Animals Commission),
- the Aquatic Animals Commission's plan to develop Chapter 4.X. Emergency disease preparedness, and Chapter 4.Y. Outbreak management, and the Code Commission's plan to develop standards on emergency management (see item 7.7 of this report).

4. Work Programme and priorities

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

4.1. Comments received on the Code Commission Work Programme

Comments were received from Canada, New Caledonia, New Zealand, Switzerland, the USA, Members of the WOAHAmericas Region, the EU and IWTO (International Wool Textile Organisation).

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 item.

The Code Commission noted a comment to improve presentation of the Code Commission report by using table format capturing the summary of the comments and the Commission's responses to them. The Commission explained that this would be considered in the work to improve the transparency of the WOAHAmericas process for the elaboration of Standards. (See item 1.3 of this report).

The Code Commission noted a Member comment expressing concerns on the precautionary approach that the Member thinks has been taken in chapters recently drafted. The Commission acknowledged that the perception of risks may vary among experts involved in drafting new or revised standards, in the same way that variation is also observed between comments of different Members. Nonetheless, the Commission highlighted that the Commission's role is that the *Terrestrial Code* is based on the most recent scientific and technical information, as clarified in the User's guide, and are developed through discussion with Members and experts to achieve a balanced approach ensuring safety while avoiding unnecessary barriers to trade.

The Code Commission discussed a comment pointing out that some Members notify WOAHAmericas of detection of certain influenza A high pathogenicity viruses of avian origin in (wild) mammals in accordance with point 1(f) of Article 1.1.3., while others notify similar detections in accordance with point 1 of Article 1.1.5., and requesting the advice of the Commission regarding the interpretation of the *Terrestrial Code* on that issue. The Commission considered that there is a substantial difference between Article 1.1.3. which implies mandatory notification, and thus applies to listed diseases as defined in the relevant disease-specific chapter, and Article 1.1.5., that encourages voluntary report and applies to other animal health information. In the issue raised by the Members comment, all three listed diseases caused by avian influenza viruses refer to birds, not mammals. Nonetheless, the Commission was of the view that the meaning of the term 'an unusual host species' referred to in point 1(f) of Article 1.1.3. might not be clear enough and result in some ambiguity regarding the previous statement, as well as regarding the definition of emerging disease. The Commission highlighted that Members should provide WOAHAmericas with any important information on influenza A viruses and requested the Secretariat to prepare a discussion paper on that issue, so that it can be further discussed with the Scientific Commission, the Biological Standards Commission and the WOAHAmericas Headquarters.

The Code Commission acknowledged a comment requesting to revise Article 14.9.9. (Recommendations for importation of skins, fur, wool and hair from sheep and goats from countries considered infected with sheep pox and goat pox) of Chapter 14.9. Sheep pox and goat pox. The Commission noted that the work to revise the chapter was recently added to its work programme in February 2023 and explained that the comment would be considered in that work.

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

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

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

4.2.1. Wildlife health

Background

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

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

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

Discussion

The Secretariat informed the Commission that, following previous discussions, it had presented the Commission's work programme to the WOAH Working Group on Wildlife at its June 2023 meeting, and that the Working Group reviewed the work programme and identified areas where the epidemiology of the disease warranted review and further consideration of wildlife.

The Secretariat reported that the Working Group would comment on relevant chapters as part of the review process, for them to be considered by the Code Commission along with other comments received.

The Commission thanked the Working Group for their contribution and acknowledged the comments received for the current meeting from the Working Group on Chapter 12.1. Infection with African horse sickness virus, Chapter 8.8. Infection with foot and mouth disease virus and Chapter 13.2. Rabbit haemorrhagic disease.

The Commission requested the Secretariat to continue this effective collaboration and to promote the contribution of the Working Group at early stages of the relevant work items.

4.2.2. Animal hosts to be targeted by WOAH Standards for a listed disease of terrestrial animals

Following recent discussions on disease-specific chapters and taking into consideration the opinion of experts, Member comments, and notably when considering new proposals on the 'case definitions' endorsed by the Scientific Commission, the Code Commission had highlighted the importance of clarifying the rationale to substantiate why certain animals were included in the definitions and others no. The Code Commission and the Scientific Commission had also agreed at its February 2023 meetings that this point would be discussed and reported as part of the process to assess pathogenic agents for inclusion in the WOAH list.

Following the work to develop a Framework for disease-specific chapters of the *Terrestrial Code* (see item 7.5.1 of this report), the 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 an analysis prepared by the Secretariat summarising how selected disease-specific chapters, most of which were recently adopted, addressed 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)'; and 'animals for which trade recommendations are provided' and noted that there were differences among chapters.

The Commission agreed to develop a clear and consistent approach to define how host animals for a listed disease are included in the *Terrestrial Code* and the *Terrestrial Manual*, clarifying its purpose and implications.

The Commission appointed a member from the Commission to work with the Secretariat to progress this work and requested that this issue be discussed with the Scientific Commission and the Biological Standards Commission in February 2024.

4.2.3. Revision of Chapter 4.4. Zoning and compartmentalisation

Background

At its September 2021 meeting, the Code Commission discussed specific issues raised in the context of the 88th General Session on several texts that were adopted at that General Session. Among these topics, the Commission agreed with a comment to consider amending Article 4.4.7. of Chapter 4.4. Zoning and compartmentalisation to clarify that a time limit should be defined for a containment zone. The Code Commission recalled a similar proposal that had been made by the Scientific Commission and that had been discussed at the Code Commission's February 2021 meeting. The Code Commission discussed possible ways to address this request and shared 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 WOAHA grants an official animal health status. The Code Commission requested that the Secretariat prepare the revised draft text, taking into consideration the Scientific Commission's recommendations, to be presented for its consideration at its September 2023 meeting.

Discussion

The Code Commission considered a proposed revised Article 4.4.7.

The Commission noted that some comments received on other disease-specific chapters recently circulated for comment (see items 5.7, 5.12 and 5.14 of this report) showed differences of understanding around critical aspects of the implementation of zoning.

The Commission reminded Members that the need to provide clearer guidance on the implementation of zoning, previously included in its work programme, was removed in September 2021. The Commission also noted that a thematic study was currently being undertaken by the WOAHA Observatory on this topic that could provide valuable information on the current state of implementation of related WOAHA Standards and challenges faced by Members.

The Commission thus agreed not to proceed with its review of the revised Article 4.4.7. at this time but rather to expand the scope of this work item to also consider the need to clarify critical concepts in Chapter 4.4. Zoning and compartmentalisation with regards to the implementation of zoning and eventually to develop further guidance to Members. The Commission requested the Secretariat to prepare a plan to address this work, to be considered in collaboration with the Scientific Commission at the respective February 2024 meetings.

4.2.4. 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 WOAHA 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.

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

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.

Discussion

The Secretariat informed the Commission that 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 has been established and will meet for its first meeting from the 28–30 November 2023. The Commission acknowledged the importance of this work and requested that the Secretariat report on the progress of the *ad hoc* Group's work at its February 2024 meeting.

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

The Secretariat presented a working document to the Code Commission that outlined 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 Chapter 7.4. of the *Terrestrial Code* and Chapter 10 of the IATA LAR share very similar content, and both organisations cross-reference the other Organisation's text in its respective text. However, the process and time frames for revision of the respective texts differs and so alignment is not always assured.

The Commission was reminded that a WOAHA representative has been a member of the IATA Live Animal and Perishable Board (LAPB), which determines the LAR, since 2006 and that WOAHA has had a Collaboration Agreement with IATA since 2008.

The Secretariat reminded the Commission that, at the 49th General Session in 1981, WOAHA "...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.

Considering this history and the issue of ensuring alignment of the two texts, the Code Commission discussed the option of deleting text in Chapter 7.4. that is included in Chapter 10 of the IATA LAR given that the LAR was officially approved as the 'guideline for the carriage of live animals by air' since 1981. The Code Commission requested that the Secretariat discuss with the *ad hoc* Group on the revision of Chapters 7.2. and 7.3. 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 stocking density recommendations, 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 stakeholders and that there are mechanisms for Members to propose changes to the text of 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.

4.2.5. Revision of Chapter 7.6. Killing for disease control purposes

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 some Glossary definitions.

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

Discussion

The Commission considered the *ad hoc* Group report and the revised draft Chapter 7.6.

The Commission acknowledged the work of the *ad hoc* Group and agreed to continue to work on the draft chapter with the aim of circulating a first draft to Members in its February 2024 report.

4.2.6. Revision of Chapter 10.5. Infection with *Mycoplasma gallisepticum* (Avian mycoplasmosis)

Background

At its September 2022 meeting, the Code Commission considered a comment made at the 89th General Session that Chapter 10.5. Infection with *Mycoplasma gallisepticum* only addressed *M. gallisepticum* and not *M. synoviae*, while both pathogens were listed in Chapter 1.3., and that Chapter 3.3.5. Avian mycoplasmosis (*Mycoplasma gallisepticum*, *M. synoviae*) of the *Terrestrial Manual* addressed both pathogenic agents.

The Commission agreed on the need to clarify the way these pathogenic agents are addressed in the *Terrestrial Code* and that there should be a coherent approach between the *Terrestrial Code* and the *Terrestrial Manual*. The Commission agreed to include this item in its work programme and requested the Secretariat to seek expert advice on the inclusion of *M. gallisepticum* and *M. synoviae* in one disease-specific chapter, including the development of case definitions, and to undertake this work in coordination with the Scientific Commission.

Discussion

The Code Commission considered the opinion of the Scientific Commission and experts and agreed to include *M. synoviae* in Chapter 10.5. and to revise the chapter to expand the recommendations to align with the level of detail provided in other disease-specific chapters.

In addition, the Commission agreed that this work should be addressed as part of its work to review Section 10 Aves (see item 4.5 of this report).

4.2.7. Revision of chapters on equine encephalitis (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 Chapters 8.10. Japanese encephalitis in its work programme following requests from Members. The Commission also noted that the revisions of Chapter 12.4. Equine encephalitis (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 approach the revisions of these three disease-specific chapters together, to ensure a consistent logic is applied to all three chapters. The Commission also agreed that Chapter 8.21. 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 for the chapters, the Code Commission requested a scientific assessment of the susceptible animals, 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 WOAHA list of notifiable terrestrial animal diseases in accordance with Chapter 1.2. of the *Terrestrial Code*.

Discussion

The Commission was informed by the Secretariat that the requested assessments for Japanese encephalitis, Equine encephalitis (Eastern and Western), and Venezuelan equine encephalomyelitis had been undertaken by experts on the subject and were being considered by the Scientific Commission at its September 2023 meeting, and that the conclusions will be presented to the Code Commission for consideration at its next meeting, together with a proposed plan to address the revision of the chapters.

The Commission acknowledged on 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 in order to ensure a consistent approach for these diseases.

4.3. Items under consideration for inclusion in the work programme

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

- Development of a new Glossary definition for 'biological products'
- Revision of Chapter 8.16. Infection with Rift Valley fever virus

-
- Revision of Chapter 8.18. Infection with *Trichinella* spp.
 - Development of a new chapter on infection with Nipah virus.

The Commission agreed to add these topics to its work programme. For specific discussions on each topic, see item 5.1, 5.8, 5.9 and 6.5 of this report.

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

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

4.4.1. Revision of User's guide

The Code Commission discussed the need to revise the User's Guide, as proposed by the President of the Code Commission, at the 90th General Session in May 2023. (See item 6.1 of this report.)

4.4.2. Revision of Chapter 1.3. Diseases, infections and infestations listed by WOA

To address some issues identified during recent work on the development of new or revised disease-specific chapters, the Code Commission agreed to add a revision of the Chapter 1.3. Diseases, infections and infestations listed by WOA, to its work programme. (See item 5.2 of this report.)

4.4.3. Revision of Glossary definition for 'poultry'

Background

In May 2023, at the 90th General Session, the WOA Americas region requested that the definition of 'poultry' be included in the Commission's work programme to be reviewed to ensure it provided Members with greater flexibility and to clarify issues for non-poultry or birds that had no epidemiological significance. The QUADs Alliance (Australia, Canada, New Zealand, the UK and the USA) supported this request. In response, the President of the Code Commission noted that this request would be included on the agenda of the Code Commission's September 2023 meeting.

Discussion

The Code Commission considered the request made at the 90th General Session and comments received to review the Glossary definition for 'poultry'.

The Code Commission agreed to add the revision of the definition for 'poultry' to its work programme as priority 4 and agreed that this work should be addressed as part of its work to review Section 10 Aves (see item 4.5 of this report).

4.4.4. Revision of Chapter 10.2. Avian infectious bronchitis

Background

In March 2023, WOA received a query from a Member about the difficulty it faced in interpreting Article 10.2.3. Recommendations for the importation of day-old birds of Chapter 10.2. Avian infectious bronchitis for the international veterinary certificate for the export of day-old birds.

Discussion

The Code Commission reviewed Article 10.2.3. and agreed that the article was not clear and therefore agreed to add the revision of Chapter 10.2. to its work programme and requested that the work be addressed as part of its work to review Section 10 Aves (see item 4.5 of this report).

The Code Commission explained that the correct interpretation of point 4 is to apply 'point 4(a) **and** either 4(b) or 4(c)', i.e. an exporting country should comply with 'points 4(a) and 4(b)' or 'points 4(a) and 4(c)'.

The Code Commission also acknowledged that it was not possible to demonstrate freedom from avian infectious bronchitis by serology test and thus noted that 'based on the results of serological tests' should be deleted from point 4(a). The Commission agreed not to propose this amendment now but rather when the Chapter 10.2. is considered for revision.

4.5. Prioritisation of items in the work programme

Based on a number of considerations and the progress of the different topics since its last meeting, as well as specific discussions 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:

- Standards on emergency management.
- Glossary definitions for 'artificial insemination centre', 'biological products', 'biosecurity', 'biosecurity plan', 'swill', 'point of exit', 'border post', 'quarantine station', 'veterinary medical use', 'poultry', 'greaves'.
- Chapter 1.3. Diseases, infections and infestations listed by WOA. H.
- Chapter 1.11. Application for official recognition by WOA. H. of free status for foot and mouth disease.
- Chapter 5.8. International transfer and laboratory containment of animal pathogenic agents
- Chapter 8.16. Infection with Rift Valley fever virus.
- Chapter 8.17. Infection with *Trichinella* spp.
- Chapter 8.21. West Nile fever.
- Chapter 8.Y. Infection with Nipah virus.
- General consideration of Section 10 Aves.
- Chapter 10.2. Avian infectious bronchitis.
- Chapter 10.X. Infection with avian metapneumovirus.
- Chapter 13.2. Rabbit haemorrhagic disease (comprehensive revision of the chapter).
- Chapter 14.7. Infection with peste des petits ruminants virus.

Items removed:

-
- All texts adopted at the 90th General Session, in May 2023.
 - Chapter 5.11. Model veterinary certificate for international movement of dogs, cats and ferrets originating from countries considered infected with rabies.
 - Chapter 8.15. Infection with rabies virus (a work to revise provisions for the importation of vaccinated dogs from infected countries or zones).

The Code Commission agreed to add a work “General consideration of Section 10 Aves” to its work programme given the new requests and ongoing work on chapters of Section 10 Aves (see items 4.2.6 and 4.4.4 and Annex 3 of this report), the request to revise the Glossary definition for ‘poultry’ (see item 4.4.3 of this report) and the need to clarify some poultry related terms such as ‘egg commodities’ (see item 7.5.2 of this report). The Commission explained that the objective would be to consider the risk management approach and recommendations for different production sectors, species, commodities, and the structure of chapters across different diseases (following the recently updated HPAI chapter), to ensure consistency, and requested that the Secretariat develop a plan to proceed with the work, including developing Terms of Reference of an *ad hoc* Group to address this work. The Commission emphasised that it would be important to consider the coordination with the Biological Standards Commission in terms of the revision of relevant chapters in the *Terrestrial Manual* and with the Scientific Commission, in terms of the potential need to consider assessing some diseases against the listing criteria and prioritising and coordinating works to develop case definitions.

With regards to removal of the item to revise provisions for the importation of vaccinated dogs from infected countries or zones in Chapter 8.15. Infection with rabies virus, the Commission explained that it removed this item from its work programme, following the high number of Members that indicated their opposition to the revisions proposed at the 90th General Session in May 2023.

The Code Commission updated its work programme accordingly.

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

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

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

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

Additionally, the Commission thanked Members who commented on work items at an early stage of progress, 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 order 3 and 4) and submit to the Secretariat points of interest for a specific work, as well as available information, evidence, or expertise that could be taken into consideration for the development of the work.

The updated work programme is presented in [Annex 3](#), for comments.

EU comment

The EU commends the Code Commission for its continuous efforts to prioritise its heavy work programme, in coordination with other specialist commissions as relevant. We thank the Code Commission for having taken into consideration comments submitted previously. We fully support the revised work programme and its prioritisation. In annex 3, specific suggestion is provided on the simplification of the data to be provided by Member Countries for the annual reconfirmation of their official statuses.

5. Texts circulated for comments and proposed for adoption in May 2024

The Code Commission discussed the following new or revised texts which are circulated for comments and 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 New Caledonia, Switzerland and the EU.

Background

At its September 2019 meeting, the Code Commission considered the use of the terms 'commodities', 'animal products', 'products of animal origin' and 'animal by-products' 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 terms. 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 be developed for 'animal products' and 'germinal products', worked on draft text and sent proposed revised and new definitions for Member comments.

Discussion

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' are presented as part of [Annex 4](#) for comments and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

The EU in general supports the proposed changes to the Glossary and provides in Annex 4 two comments.

b) New Glossary definition for ‘biological products’

Background

At its February 2023 meeting, the Code Commission discussed the terms ‘commodities’, ‘animal products’, ‘products of animal origin’ and ‘(animal) by-products’ 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 ‘biological products’ used in the definition for ‘commodity’, the Code Commission agreed that there was a need to develop a new Glossary definition for this term, and requested that this be discussed with the Biological Standards Commission at the next meeting of the Bureaus in September 2023.

Discussion

The Code Commission considered an analysis prepared by the Secretariat presenting the use of ‘biological products’ in the *Terrestrial Code* and related terms in the *Terrestrial Manual*, as well as the Glossary definition for ‘biological products’ in the *Aquatic Code*. The Code Commission developed a new definition for ‘biological products’, which was agreed by the Biological Standards Commission.

The new Glossary definition for ‘biological products’ is presented as part of [Annex 4](#) for comments 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.

The replacement of the Glossary definition for ‘artificial insemination centre’ with ‘semen collection centre’ is presented as part of [Annex 4](#) for comments and will be proposed for adoption at the 91st General Session in May 2024.

d) ‘greaves’

In the work to revise Chapter 14.8. Scrapie, the Code Commission agreed to remove ‘greaves’ from the Glossary. (See item 6.6 of this report.)

The deletion of definition for ‘greaves’ is presented as part of [Annex 4](#) for comments and will be proposed for adoption at the 91st General Session in May 2024.

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

During recent work on the development of new or revised disease-specific chapters, the Code Commission noted the following issues in Chapter 1.3. Diseases, infections and infestations listed by WOA:

- the order of animal categories, i.e., the order of articles, is not in line with Sections in Volume II of the *Terrestrial Code*,
- the scope of animal species in some articles of the chapter is still not clear nor in line with Section titles (e.g., Article 1.3.4. mentions 'equine' diseases in the chapeau paragraph, whereas the title of Section 12 is EQUIDAE),
- the diseases in each article are not necessarily in alphabetical order,
- some disease names need to align with the title of the corresponding disease-specific chapter.

To address these issues, the Code Commission agreed to make the following amendments to Chapter 1.3.:

- reorder the articles to align with the order used in Sections of Volume II,
- align the animal categories noted in the chapeau 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 infections of 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, the Commission considered that these amendments could be presented for adoption at the 91st General Session in May 2024.

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

EU comment

The EU supports the proposed changes to this chapter. A comment is provided in Annex 5.

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

Comments were received from Australia, Brazil, Mexico, New Zealand, Switzerland, Thailand, the UK, the USA, the AU-IBAR 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*. This work had been requested to resolve inconsistencies among the chapters and to ensure that the texts reflected the latest scientific evidence and best practices regarding risk mitigation measures in the collection and processing of semen of animals. The *ad hoc* Group was also requested to consider the inclusion of provisions to address 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 meeting and revised in June 2022 by an expert with the support of a Commission member.

At its September 2022 meeting, the Code Commission considered the draft chapter and circulated a revised Chapter 4.6. General hygiene in semen collection and processing centres and noted the need to replace the term 'artificial insemination centre' in the Glossary with 'semen collection centre', for

consistency with the revised chapter. However, the Commission agreed to propose the change to the Glossary after receiving feedback from Members on the proposed revised chapter.

At its February 2023 meeting, the Code Commission considered comments received, amended the draft chapter, as relevant, and circulated it for comment.

Discussion

General comments

The Code Commission noted comments supporting the proposed amendments.

The Commission noted that the term 'animal health status' was used in many instances throughout this chapter, referring to the 'status of animals' (e.g. point 2 of Article 4.6.2.), and agreed that this use did not align with the Glossary definition, which refers to the status of a country, zone or compartment, and agreed to amend the text, as appropriate.

Article 4.6.1.

In point 3 (d) the Code Commission agreed with comments noting that containers for short-term storage and transport may not be subject to freezing temperatures maintained under liquid nitrogen, and added the term 'frozen' before semen, and refused to add somatic cells, to clarify that this provision only refers to frozen semen. The Commission also amended the text of Article 4.6.6. for consistency.

Article 4.6.2.

The Code Commission agreed with comments to move first two paragraphs to the end of the article to better reflect that the Veterinary Authority should consider all conditions described in this article when approving a semen collection centre.

The Commission agreed with comments to include a requirement for the supervising veterinarian to communicate with the Veterinary Services in the event of a disease incursion or serious adverse hygiene event, at the end of the third paragraph.

In the fifth paragraph, the Commission agreed to delete 'stored and/or' before dispatched, as it considered it redundant in the context of the sentence.

The Commission did not agree with a comment to replace 'identification' with 'information', as the term 'identification' has a more specific meaning relating to the data needed.

In point 5(c) the Commission agreed with a comment to add 'based on the manufacturer's recommendations' at the end of the sentence for clarity.

Article 4.6.3.

The Commission did not agree with a comment to include specific references to animal welfare. There is already a general statement to animal welfare in Article 4.6.1. that covers this matter for the whole chapter.

In the fourth paragraph, the Code Commission did not agree with a comment to reinstate the deleted sentence. The Commission reiterated that, while the deleted sentence may be a valid recommendation, it does not pertain to the objective of this chapter, which is to provide recommendations to mitigate the risk of the introduction and spread of listed diseases of fresh, chilled, or frozen semen.

Article 4.6.5.

In the ninth paragraph, the Code Commission did not agree with a comment to expand the scope and reminded Members that this recommendation did not apply to semen which is processed immediately after collection.

In the tenth paragraph, the Commission did not agree with a comment to delete the last sentence, as it considered that this reflected current best practices.

In points 1 and 4, the Commission agreed with comments to delete prescriptive details on specific methods and amended the text accordingly.

Article 4.6.6.

In the first, second, and third paragraph, the Code Commission amended the text to align with proposed changes in terminology from 'germplasm storage tank' to 'cryogenic tank'.

In the third paragraph, the Code Commission agreed with comments to amend the text to refer to the desired outcomes and remove prescriptive details.

Glossary

Noting the progress of the draft text and following previous discussions, the Commission agreed to amend the Glossary by replacing the term 'artificial insemination centre' with 'semen collection centre'. The Commission also introduced editorial amendments noting that 'approved' was a defined term.

The revised Chapter 4.6. General hygiene in semen collection and processing centres, and the amended definition for 'semen collection centre', replacing 'artificial insemination centre', are presented as [Annex 7](#) and as part of [Annex 4](#), respectively, for comments and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

The EU thanks the Code Commission for taking into account the comments previously submitted and in general supports the proposed changes to this chapter. Comments are provided in the text below.

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

Background

As noted in the item 5.3 above, at its September 2019 meeting, the Code Commission agreed 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.

Noting the progress on the revised Chapter 4.6. (see item 5.3 of this report), the Commission considered the next steps to proceed with the revision of Chapter 4.7. Collection and processing of bovine, small ruminant and porcine semen.

Discussion

The Code Commission reminded that it had previously agreed to revise these two chapters as an ensemble, aiming at the following scopes:

- Chapter 4.6. would provide overarching general guidance for the hygienic production of semen without any cross-references to disease-specific chapters; and

-
- Chapter 4.7. would provide the health requirements, without any cross-references to disease-specific chapters, that animals should comply with before entering and during the stay at a 'semen collection centre', for the semen to be considered safe for international trade if collected and processed in compliance with Chapter 4.6.

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

Nonetheless, the Code Commission noted that the revised Chapter 4.6. proposed a comprehensive approach covering all aspects of semen collection, processing, and storage, for all species of interest in a single chapter, and that the content of current Articles 4.7.5., 4.7.6. and 4.7.7. is redundant and not aligned with the content of the new chapter.

Noting that the revised Chapter 4.6. is being circulated again and will be proposed for adoption in May 2024, the Commission agreed to propose at the same time the replacement of 'artificial insemination centre' with 'semen collection centre' and 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 or Chapter 4.6.

In addition, 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.

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

EU comment

The EU supports the proposed changes to this chapter.

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

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

Background

At its February 2019 meeting, in response to comments received and after the revision of some definitions in Chapter 6.9. Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals had been adopted in 2018, the Code Commission agreed to include in its work programme a review of Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine.

Based on advice from the WOAHA Working Group on Antimicrobial Resistance (AMR Working Group) on the revision of Chapter 6.10., 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 was informed that the revised Codex Code of Practice had been adopted at the Codex Alimentarius Commission in November 2021, and that the AMR

Working Group, at its October 2021 meeting, had agreed to work on the development of a revised Chapter 6.10.

At its September 2022 meeting, the Code Commission discussed the revised chapter drafted by the 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 and identified those that needed the advice of the AMR Working Group and requested that the AMR Working Group undertake this work and report back to the Commission at its September 2023 meeting. The Code Commission also requested the Biological Standards Commission to provide its opinion on comments referring to the establishment of clinical breakpoints.

Discussion

The Code Commission was informed that a Subgroup of the AMR Working Group met several times physically and electronically between March 2023 and June 2023 to address the comments provided by the Commission. The AMR Working Group at its July 2023 meeting validated the report of the AMR Subgroup and proposed additional amendments in Articles 6.10.1., 6.10.3. and 6.10.6. The Commission encouraged Members to read item 2.2 of the AMR Working Group report regarding this chapter.

The Code Commission discussed comments together with the recommendations from the AMR Subgroup and the Working Group. The Code Commission commended the AMR Subgroup and the Working Group for its comprehensive work.

The Code Commission wished to note that, where it agreed with a recommendation of the AMR Subgroup, the explanation is provided in the Subgroup report, and is not repeated in this report. Therefore, Members should read the Subgroup report, in conjunction with this report, which is available at [this web page](#).

General comments

In response to a comment that some of the proposed changes could be difficult to implement by all Members and therefore wording such as 'whenever applicable' or 'whenever possible' should be added to some of the texts to allow flexibility, the Code Commission clarified that, as is the case for all recommendations of the *Terrestrial Code* except for provisions on disease notification, the recommendations provided are implicitly assumed to be implemented in so far as the Member countries' capacities allow.

The Commission reiterated that the draft revised chapter was aligned with the latest version of the Codex Code of Practice, where deemed relevant and feasible.

In response to a comment suggesting that detailed guidance on monitoring and reporting of any AMR microorganisms detected, the Code Commission reminded Members that Chapter 6.8. Harmonisation of national antimicrobial resistance surveillance and monitoring programmes provided the recommendations on AMR surveillance and monitoring programmes.

The Code Commission noted a comment that the scope of 'animal breeders, owners and keepers' is larger than 'animal producers' and that it should be noted that it is difficult to include pet owners under the supervision of the Veterinary Authority. The Commission emphasised that this chapter should be designed to provide recommendations to whoever is responsible for the animal. The Commission explained that pet owners have a shared responsibility to minimise the spread of AMR microorganisms.

The Code Commission agreed with a comment to further clarify the content and scope of National Action Plans (NAP) and revised Article 6.10.3. accordingly, to include references to relevant documents, in

particular the Global Action Plan that is currently under revision and existing guidance for developing NAPs for AMR.

The Code Commission noted a comment that the same measures cannot necessarily be applied to food-producing and non-food-producing animals because of different purposes of rearing and treatment policy, and therefore, parts for food producing and non-food-producing animals should be described separately in the chapter. The Commission explained that, in principle, this chapter provided general recommendations which are applied to both food-producing and non-food-producing animals and considered the differences in food-producing and non-food-producing animals, types of production systems and country regulatory contexts. The Commission also noted a comment stating that there may be instances in which the appropriate measures could not be implemented because rapid treatment is prioritised in veterinary clinical practices for non-food producing animals, and therefore, feasibility should be considered in the description regarding veterinary medicine for non-food producing animals. The Commission explained that the objective of 'veterinary medicine practices' is similar for both food-producing animals and non-food-producing animals.

Article 6.10.1.

In the second paragraph, in response to a comment, the Code Commission agreed to replace 'Competent Authority' with 'Competent Authorities' given that in some countries, there may be more than one Competent Authority involved.

In the same paragraph, the Code Commission did not agree with a comment to add 'including premixes, powders and solutions intended for oral administration' after 'veterinary medicinal products containing antimicrobial agents' as it considered that they were covered in the Glossary definition for 'veterinary medicinal product'.

In the third paragraph, the Code Commission agreed with a comment to add 'good' before 'animal husbandry practices' for clarity.

In the same paragraph, the Code Commission did not agree with a comment to add 'such' before 'measures to prevent infectious animal diseases' as the previous sentence does not focus on measures for prevention.

Article 6.10.2.

In the first paragraph, the Code Commission agreed with the amendments proposed by the AMR Subgroup and moved its content to the end of the article and adjusted the text accordingly. In this same paragraph, the Code Commission did not agree with a comment to reinstate the term 'practical' as it considered it unnecessary given that all measures should be practical and applicable.

In the same paragraph, the Code Commission did not agree with a comment to delete 'and animal welfare' as it considered that improved animal health contributes to good animal welfare and that good animal welfare contributes to reducing stress which leads to the prevention of disease and thereby reducing antimicrobial use.

In point 4, in response to a comment, the Code Commission agreed to replace 'the maintenance of' with 'maintaining' for clarity, and to replace 'animal' with 'veterinary' for consistency.

Article 6.10.3.

In point 1, in the first paragraph, in response to comments, the Code Commission agreed to add 'environment' as it considered that the Competent Authorities should coordinate with the environmental sector in a One Health approach to promote the responsible and prudent use of antimicrobial agents.

In the same paragraph, the Code Commission did not agree with a comment to add 'aim to' before 'incorporate' as it considered that the text was clear as written.

In the same paragraph, in response to a comment that it is important to involve farmers in the development of the National Action Plan, the Code Commission added ', and other relevant stakeholders' after 'public health professionals'.

In point 1, in the second paragraph, in response to a comment to add 'education on' after 'incorporate', the Code Commission agreed to add ', and educate on' instead, as it considered that the National Action Plan should describe actions to take to combat AMR.

In point 1, in the third paragraph, the Code Commission did not agree with a comment to replace 'evidence-based' with 'science-based', as it considered that providing evidence is part of science-based approach and 'evidence-based' is preferable in this context.

In the same paragraph, the Code Commission did not agree with a comment to delete 'professional' as it considered that professional organisations could include academia and relevant authorities.

In point 2, in the deleted first paragraph, the Code Commission agreed with a comment to reinstate the text, to highlight that Competent Authorities should actively work to address the issue of unlicensed, adulterated and counterfeit products. However, the Commission considered that the recommendation should be specific to veterinary medicinal products containing antimicrobial agents, rather than general recommendation for veterinary medicinal products, and thus made necessary amendments and agreed to move the amended text to the end of this article, as new point 16, where it was better placed.

In point 2, in the second paragraph, the Code Commission agreed with a comment to delete 'proposed' before 'post-marketing surveillance programmes' for clarity.

In point 2, in the sixth paragraph, the Code Commission agreed with the amendments proposed by the AMR Subgroup and emphasised that, while not all WOAHA Members are members of Veterinary International Conference on Harmonization (VICH) the VICH guidelines may be useful for Competent Authorities to better regulate the approval of veterinary products containing antimicrobial agents.

The Code Commission and the AMR Subgroup did not agree with a comment to add a new paragraph stating that antimicrobial agents should not be granted regulatory approval for the purposes of growth promotion or yield increase, as it considered that this was not within the scope of this chapter. The Commission reminded Members that, at its September 2022 meeting, the Commission had agreed that growth promoters are not within the remit of this chapter as it was not included in 'veterinary medical use of antimicrobial agents' which is defined in Chapter 6.9. Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals. The Commission reiterated that the definition for the term 'veterinary medical use of antimicrobial agents' would be moved into the Glossary, and deleted from Chapter 6.9., once the revised Chapter 6.10. has been adopted. Nevertheless, to further emphasise the scope of the chapter, the Commission, in agreement with the AMR Subgroup, proposed to add 'for treatment, control and prevention of diseases and' after 'Regulatory approval is granted' in the fifth paragraph of this point.

In point 4, the Code Commission agreed with a comment to delete 'therapeutic' as it considered that the term might be confusing and might be considered the same as treatment.

In point 4(a)(iii), the Code Commission agreed with a comment to amend the bullet points, to put them in logical order and to improve readability.

In point 4(a)(iii), in response to a comment, the Code Commission partially agreed with the advice of the AMR Subgroup and added an additional new paragraph 'Further dose determination studies may be

conducted to examine the microbiological and clinical response to several dose levels or dosing intervals.’. It considered that Competent Authorities may also consider other relevant evidence provided by studies other than pharmacokinetics and pharmacodynamics studies used for the determination of dose and dosing regimens. The Commission considered that this recommendation should not be limited to antibacterial and thus ‘microbiological’ is more appropriate than ‘bacteriological’.

In point 6, the Commission agreed with a comment to move this point referring to the establishment of clinical breakpoints to after the point on control of advertising (i.e., as new point 12) for reasons of clarity and coherence. In the same point, in response to comments, the Code Commission was of the view that the Competent Authority should support the development of clinical breakpoints for each bacteria-antimicrobial-animal species combination and that clinical breakpoints should be established in accordance with Chapter 2.1.1. Laboratory methodologies for bacterial antimicrobial susceptibility testing of the *Terrestrial Manual*. The Commission noted that the AMR Subgroup agreed with comments to refer to internationally-recognised antimicrobial susceptibility committee(s)/organisations such as Clinical and Laboratory Standards Institute (CLSI) but agreed not to refer to this in the text as it considered that Chapter 2.1.1. of the *Terrestrial Manual* notes such committee(s)/organisations. The Commission made amendments accordingly.

In point 7, the Code Commission did not agree with a comment to delete point 7, as it considered that this point was relevant for this article.

In point 8, that was deleted and moved to after the point on assessment of the potential of antimicrobial agents to select for resistance, i.e. as new point 6, the Code Commission noted a comment stating that there are neither international guidelines available, nor supporting documents with scientific evidence, nor established methods for an assessment of the impact on the relevant animal environment, and therefore, it was premature to propose the inclusion of a risk assessment in the point. The Commission also noted a comment that very limited quantitative data on antimicrobial resistance in the environment exists. In conclusion, given that an assessment of the environment should be conducted as described in Chapter 6.11. Risk analysis for antimicrobial resistance arising from the use of antimicrobial agents in animals, the Commission agreed to delete the first paragraph, and to add a reference to the Chapter 6.11. in the second sentence.

In new point 8(q), the Code Commission did not agree with a comment to replace ‘lay’ with ‘laying’ as it considered it grammatically correct, as written.

In new point 8, in response to a comment to add a new point, the Code Commission partially agreed with recommendations from the AMR Subgroup and added a new point ‘known signs of overdose and information about its treatment’ as it considered that this is usually included in the Summary of Product Characteristics and useful and practical information.

In new point 11, in response to a comment to add ‘or to persons permitted to supply veterinary medicinal products’ the Code Commission agreed with the AMR Subgroup’s recommendation to add this new text. In addition, the Commission explained that this would cover, for example, pharmacists who are permitted to supply veterinary medicinal products and should be able to access the information related to veterinary medicinal products containing antimicrobial agents.

In point 13, in the title, the Code Commission did not agree with a comment to add ‘as appropriate’ as the addition did not add any value and was not needed for any recommendations of the *Terrestrial Code*.

In point 13, in the first paragraph, the Code Commission agreed to replace ‘food animal owners’ with ‘owners of food-producing animals’ for consistency with rest of the chapter.

In the same paragraph, the Code Commission did not agree with a comment to add ‘, as appropriate for the audience targeted’ at the end of the paragraph, as it was clear as written.

In point 13(e), the Code Commission agreed with a comment to change the order of risk management and risk communication, for consistency with Chapter 2.1. Import risk analysis of the *Terrestrial Code*.

In point 14, in the first paragraph, the Code Commission agreed with a comment to add ‘In accordance with Chapter 6.9.’ at the beginning of the paragraph for clarity.

In point 14, the Code Commission and the AMR Subgroup agreed to add a new point. The Commission emphasised that fostering of antimicrobial stewardship is relevant as an expected outcome of collection of data of antimicrobial use. However, the Commission noted that the term ‘stewardship’ may be difficult to translate into French and Spanish and requested that the AMR Working Group develop an alternative text.

In point 15(a), the Code Commission did not agree with a comment to replace ‘veterinary medical use’ with ‘veterinary medicinal products’ and explained that the intent was to refer to ‘veterinary medical use’ as defined in Chapter 6.9. Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals.

In point 15(d), the Code Commission agreed with a comment to replace ‘authorization’ with ‘regulatory approval’ for consistency throughout the *Terrestrial Code*.

In point 15(f), the Code Commission did not agree with a comment to delete ‘new antimicrobial agents’, as it considered that promoting the development of new antimicrobial agents was one of the issues that the Competent Authority should address. The Commission reminded Members that the intent of this point was not to encourage the use of new antimicrobial agents.

Article 6.10.4.

In point 1(d), in response to a comment, the Code Commission replaced ‘The data will’ with ‘These data may’ for clarity. The Code Commission agreed to merge points 1(c) and 1(d) for clarity and given that reporting of susceptibility testing is not mandatory but would be relevant under 1(c). The Commission explained that this amendment was aligned with the corresponding text under Article 6.10.3.

In point 2(c), in response to a comment to clarify this point, the Code Commission replaced ‘guarantee’ with ‘ensure’ but did not agree with other proposed changes as it considered the text clear as written.

In point 3(b), the Code Commission did not agree with a comment to edit the text to align it with text in Section 5.1 of the Codex Code of Practice, as it considered that the text was already aligned with the Codex Code of Practice (i.e., Section 5.2 Responsibilities of manufacturers and marketing authorization holders).

Article 6.10.5.

In point 1, in response to a comment, the Code Commission made amendments for consistency with text used throughout the chapter.

In point 2(b), in response to a comment, the Code Commission agreed to add ‘and contact information’ before ‘of prescriber’ as it considered it necessary information.

Article 6.10.6.

In point 1(b), the Code Commission agreed with a comment to delete 'routinely' as it considered that it may imply the use of antimicrobial agents as growth promoters, which was not the intent of this point.

In the same point, the Code Commission did not agree with a comment to add 'good' before 'animal husbandry practices' as it considered the text was clear as written, and the adjective 'inadequate' already qualified the practices.

In the same point, the Code Commission did not agree with a comment to paraphrase the point in a more positive way as it considered that inadequate animal husbandry could lead to the routine use of antimicrobial agents.

In the same point, the Code Commission did not agree with a comment to replace 'avoid using' with 'not use' as the text was clear as written.

In point 1(d), the Code Commission did not agree with a comment to replace 'available diagnostic laboratory information' with 'when available, current diagnostic laboratory information' as it considered the text clear as written. The Commission explained that veterinarians do not always need to wait for diagnostic laboratory information to become available before prescribing/using antimicrobial agents.

In point 1(f), in response to a comment, the Code Commission made amendments for clarity. Nevertheless, the Commission did not agree to add ', as appropriate' after 'supportive therapy' as the text was clear as written.

In point 2, in the first paragraph, in response to comments, the Code Commission replaced 'effectiveness of the treatment' with 'choice of an effective treatment' for clarity.

In point 2, in the second paragraph, the Code Commission agreed with a comment to add ', conducting additional diagnostic testing, as needed,' after 'including reviewing the diagnosis' for completeness.

In point 2, in the third paragraph, the Code Commission agreed with a comment to delete 'and for reasons of animal welfare' as it considered that the phrase did not provide any additional clarity.

In point 2, in the fourth paragraph, the Code Commission did not agree with a comment to add 'and when needed' as the addition did not provide any additional clarity.

At the end of point 2, the Commission amended the text to address the following comments.

In point 3, in the second paragraph, in response to comments, the Code Commission, in agreement with the AMR Working Group, agreed to add 'or national lists' at the end of the first sentence, for consistency with the Codex Code of Practice. Further the Commission moved the paragraph at the end of point 2, given that the second sentence of the paragraph concerned the choice of antimicrobial agent.

Article 6.10.7.

In point 4, the Code Commission agreed with a comment to replace 'withdrawal-time' with 'withdrawal period' for consistency in the rest of the chapter and with Codex Code of Practice.

Article 6.10.8.

In point 1, the Code Commission agreed with a comment to replace 'food animal breeders, owners and keepers' with 'breeders, owners and keepers of food-producing animals' for consistency in the rest of the chapter.

In point 2(a), given that the examples of the preventive measures described in this point are not necessarily measures to prevent diseases, the Code Commission agreed to delete the examples. In addition, it added 'and control' after 'preventive' to include measures to control diseases.

In points 2(a) and 2(b), the Code Commission did not agree with a comment to merge points 2(a) and 2(b) as it considered that the points were different.

In point 2(b), the Code Commission agreed with a comment to replace 'address' with 'implement' to reinforce the notion that this paragraph is intended to promote actions. The Commission deleted 'as appropriate' as it considered it not necessary.

In point 2(c), the Code Commission did not agree with a comment to replace 'pathogenic agents' with 'pathogens' to ensure consistency in the convention used throughout the *Terrestrial Code*.

In point 2(j), the Code Commission did not agree with a comment to add ', or have their veterinarian maintain,' as this is addressed in the second sentence of this point. The Commission also noted that recording of antimicrobial susceptibility data was also described under point 4 of Article 6.10.6. on responsibilities of veterinarians.

Article 6.10.9.

In new point 6, the Code Commission did not agree with a comment to add 'and report to *Competent Authorities* per national or regional guidelines or instructions' as it considered that it was not a responsibility of breeders, owners or keepers of non-food producing animals.

In response to a comment, the Code Commission agreed to add a new point 7 as it considered that veterinarians and breeders, owners or keepers of non-food producing animals have a shared responsibility to ensure that only antimicrobial agents from authorised sources are administered.

The revised Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine, is presented as [Annex 9](#), for comments and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

The EU would like to thank the Code Commission for taking previous EU comments into consideration and, in general, supports the proposed changes to this chapter. Comments are provided in Annex 9.

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

Comments on Chapter 7.5. were received from Australia, Canada, China (People's Rep of), Chinese Taipei, Japan, Mexico, New Caledonia, New Zealand, Norway, Switzerland, Thailand, the UK, the USA, the EU and ICAFW.

Comments on Glossary definitions were received from Australia, Mexico, New Caledonia, Norway, Switzerland, the UK, 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 for 'euthanasia', 'slaughter', 'stunning', 'death', 'distress', 'pain' and 'suffering'.

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 four times and the Code Commission received the support of the *ad hoc* Group to address the comments received. The revised draft Chapter 7.5. and associated Glossary definitions were last circulated for comments in the Code Commission's February 2023 report.

Discussion

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

a) Animal welfare during slaughter (Chapter 7.5.)

General comments

The Code Commission reviewed the use of the terms 'birds' and 'poultry' to ensure consistency throughout the chapter and amended the text accordingly.

Article 7.5.2.

In the last sentence of the first paragraph, the Code Commission agreed to add 'and corrective' after 'remedial' to emphasise that remedial actions are appropriate to remove specific issues and corrective actions are undertaken to prevent the issue from reoccurring.

The Code Commission agreed to delete the last paragraph as it was not relevant given the scope of the chapter.

Article 7.5.4.

In the second paragraph, the Code Commission agreed to add 'and smell' to the list of examples, to be consistency with Article 7.5.8. which includes 'protection from olfactory overstimulation'.

Article 7.5.5.

In the first paragraph, last sentence, the Code Commission agreed to amend the text to emphasise the importance of considering animal-based measures, when selecting key stunning parameters.

Article 7.5.6.

In the first paragraph, the Code Commission agreed to delete 'dedicated' as it considered the word was redundant.

Article 7.5.7.

In the second paragraph, first sentence, the Code Commission did not agree to add 'demonstrate' as it would be too complex to 'demonstrate' understanding and noted that the key point is that the animal handler understands. The Code Commission agreed to delete 'suffering' to improve consistency across the chapter. The Commission also reviewed the use of the terms 'pain, fear, distress and suffering' throughout the chapter to ensure they were used appropriately and amended the text accordingly.

In the third paragraph, the Code Commission did not agree to add a sentence to indicate that retraining of personnel is necessary in case of failure to demonstrate competency as it was considered too much detail, and it was implicit that training is a continuous process. The Commission did not agree to add a

sentence to specify the frequency at which the training should be conducted or details of the training as it considered this to be too prescriptive for the purposes of this chapter of the Code.

Article 7.5.8.

In the fourth indent, the Code Commission did not agree to replace 'visual, auditory and olfactory overstimulation' with 'extremes of brightness or darkness, excessive noise and adverse smells' as it did not improve the clarity of the text.

In the eighth indent, the Code Commission did not agree to add 'and fatigue' to the list, as this was addressed in the ninth indent 'other vulnerabilities'.

In the ninth indent, the Code Commission did not agree to add 'cull' to the list of examples, as animals to be culled are not necessarily in a bad condition.

In the second paragraph, the Code Commission did not agree to add 'visual and aural' as types of distractions because the recommendation is valid for any types of distractions and examples are not needed in this context.

In the third paragraph, the Code Commission did not agree to add 'and well-drained' as it is implicitly covered under 'non-slip'. The Commission did not agree to add 'appropriate for the species concerned' at the end of the first sentence regarding flooring as it considered this to be implicit.

Article 7.5.11.

In the first paragraph, the Code Commission did not agree to add a sentence describing what emergencies are, as it considered this to be too much detailed for the purposes of this chapter.

In the second paragraph, the Code Commission did not agree to add 'plans should be easily visible and accessible by staff' as this is addressed in the first sentence which specifies that the plan should be communicated.

In the second paragraph, the Code Commission did not agree to add 'emergency plans should be practices facilitating smooth implementation...' as it considered this was too much detailed for the purposes of this chapter.

In the second paragraph, the Code Commission agreed to add 'and these plans should be tested regularly' as it is a new relevant concept to ensure well-functioning of plans.

Article 7.5.12.

In the first paragraph, the Code Commission did not agree with a comment to delete the entire paragraph because this was a duplication of the paragraph found under Article 7.5.24. and noted that in this context, the repetition is needed. The Code Commission did not agree with a comment to merge Article 7.5.12. and Article 7.5.24, as it is important that these articles can be read as standalone articles.

In the first paragraph, last sentence, the Code Commission did not agree to delete 'health and' as it is an important concept to consider when transporting animals and should not be dissociated from 'welfare'.

In the second paragraph, point 1, the Code Commission did not agree to add 'the suffering could be exacerbated, and the animal could deteriorate to death' as it is already noted that suffering may be increased.

In the first sentence of the second paragraph, point 1, the Code Commission did not agree to replace 'suffered from an injury' with 'sustained injuries during transport' as it considered it was clear that this is during transport. It did not agree to add 'and exposure to build-up excrement' or to add 'heat stress from proximity to the vehicle engine or high stocking density' as adding examples was not necessary.

In the second sentence of the second paragraph, point 1, the Commission did not agree to add 'leading to thermal stress and the risk of the build-up of noxious gases' as it was considered to be excessively detailed for the purposes of this chapter.

In point 2, the Code Commission did not agree to add the examples 'breathing difficulties, lying down' or 'down, moribund' as the Commission considered that examples were not necessary.

In the first sentence of the first paragraph, point 3, the Code Commission did not agree to add 'within 15 to 60 minutes' to specify the period within which animals should be unloaded after arrival as this it was considered to be too prescriptive. The Code Commission did not agree to add 'and with care' as it considered this was clear as written.

In the third paragraph, point 3, the Code Commission added 'throughout the slaughter process, except under specific conditions, such as for aggressive or sick animals' in response to comments to clarify the circumstances in which animals should not be isolated.

In the fourth paragraph, point 3, the Code Commission did not agree to add 'clean and adequate' as it is implicit that 'drinking water' is clean.

In the fifth paragraph, point 3, the Code Commission did not agree to delete 'lactating or pregnant animals and young neonate animals' from the list of conditions that should be prioritised for slaughter upon arrival at the slaughterhouse/abattoir, as there are situations where these categories of animals do arrive at slaughterhouse/abattoir. In addition, the Code Commission agreed to delete part of the second sentence as it considered this to be too much detail for the purposes of this chapter.

In the fifth paragraph point 3, the Code Commission did not agree to reinstate the last sentence as it considered this to be out of the scope of this article.

In the first sentence, point 4, the Code Commission did not agree to replace 'extreme temperature' with 'adverse conditions' as it considered that the current text was clear as written.

In the second sentence, point 4, the Code Commission did not agree to add examples. It amended the sentence '...means of temperature and humidity control' to be more inclusive and for consistency with other chapters.

In point 4, the Code Commission did not agree to add a sentence to specify that cull dairy cows are also vulnerable because it is not a species-specific recommendation.

Article 7.5.13.

In point 2(d), The Code Commission did not agree to add more examples and deleted all examples and added 'referring to distress' to be more inclusive. This change was applied throughout the chapter.

In point 2, the Code Commission did not agree to add a measure 'use of devices making excessive noise' as this is not an animal-based measure and 'excessive' is not measurable.

In the first paragraph point 3, the Code Commission did not agree to add a sentence to specify that ramps should bear the weight to which they are subjected, as it considered this was implicit.

In the fourth paragraph, point 3, the Code Commission did not agree to add 'and to encourage smooth movement of animals', and noted that the important point was that the animal should be able to see where it is going.

In the seventh paragraph, point 3, the Code Commission did not agree to replace 'violent' with 'harmful', as under no circumstances should animal handlers resort to violent acts, whereas there might be circumstances where acts known to be harmful may occur.

In the ninth paragraph, point 3, the Code Commission did not agree to add 'preferable familiar' to define groups of animals, as it considered this was clear as written.

In the second sentence of the twelfth paragraph, point 3, the Code Commission did not agree to add the example 'in emergency situations, when the safety of animals or humans is at risk', as it considered this was addressed in the text.

In the twelfth paragraph, point 3, the Code Commission did not agree to add a sentence 'Electric goads must not be used repeatedly on the same animal' as it considered that such an act would be considered a violent act when the objective is to move animals, which is covered in the seventh paragraph of this article.

In the second sentence of the thirteenth paragraph, point 3, the Code Commission agreed to add 'pregnant animals' as these animals are more metabolically stressed due to their physical state.

Article 7.5.14.

In point 1(g), the Code Commission did not agree to add 'discomfort or distress' as it was clear as written.

In the second paragraph, point 3, the Code Commission did not agree to change '12 hours' to '24 hours' as the objective is to slaughter the animals as soon as they arrive at the slaughterhouse.

In the second paragraph, point 3, the Code Commission did not agree to add text on the need for food points to be designed according to the species and age of the animals and for water supply points to be in sufficient number as it considered this too descriptive.

In the first sentence of the last paragraph, point 3, the Code Commission did not agree to add 'and slaughtered as soon as possible after separation or both' as it was clear as written.

In the second sentence of the last paragraph, point 3, the Code Commission agreed to replace 'catastrophic' with 'severe' to improve clarity, but it did not agree to add examples nor to add 'without delay' after 'euthanised' as it was clear as written. The Code Commission did not agree to add a sentence to specify that 'appropriate protection from adverse weather should be provided' as this is addressed in the third paragraph.

In point 4, the Code Commission did not agree to reinstate 'when moving to the stunner and when stunned' as it was clear as written.

Article 7.5.15.

In point 2(f), the Code Commission did not agree to delete 'frequency of' as the frequency of use is the animal-based measure.

In the sixth paragraph, point 3, the Code Commission did not agree to add 'upright restraint is less stressful for animals' as the current text correspond to a recommendation for when a restrainer to rotate an animal is used.

In the first paragraph, point 4, the Code Commission did not agree to add that pigs should have enough space to lie down or that gondolas should be designed to minimise the risk of injury as it considered it was clear as written.

Article 7.5.16.

In the second paragraph, point 3, the Code Commission did not agree to add 'and be killed immediately' at the end of the first sentence as it considered it was clear as written. It did not agree to add text to specify that ineffective stunning should be addressed as it considered this to be redundant.

In point 3, the Code Commission did not agree to add a paragraph to address stun-to-stick, as this is addressed in the chapeaux of this article and also in the Articles 7.5.6., 7.5.7., 7.5.8. and 7.5.9. regarding management, training, design and throughputs.

Article 7.5.17.

The Code Commission did not agree to add the new concept of 'diathermic syncope' as it is still under study.

In the fourth sentence, point 1, the Code Commission agreed to delete part of the sentence as it already noted in the second sentence.

In seventh sentence, point 1, the Code Commission did not agree to add 'or unusual anatomy' as it considered it was clear as written.

In point 2, the Code Commission agreed to add 'or palpebral reflex and' and to apply this throughout the chapter, as relevant, for consistency.

In the first sentence, point 4, the Code Commission did not agree to add that the risk of ineffective stunning increases in animals with a thick skull because it is already noted in the first paragraph of point 1.

Article 7.5.18.

In point 2, the Code Commission did not agree to re-order the measures in the order that they would occur because sometimes they occur all at the same time or with no specific order.

In the first paragraph, point 2, the Code Commission did not agree to add 'once the epileptiform convulsion have subsided' because the measure is the palpebral reflex regardless of when or where it occurred.

In point 4, the Code Commission agreed to delete the attribution of the responsibility to the Competent Authority as the parameters should be determined based on scientific evidence and highlight the responsibility of the operators.

Article 7.5.19.

In point 3, the Code Commission agreed to add a new indent 'stocking density of the gondola or restraint for pigs' as it is a hazard to animal welfare.

In point 3, the Code Commission moved the text in the fifth and sixth indents to the end of the section and reorganised the text as a paragraph as these two indents were not recommendations for stunning but rather recommendations on how to monitor the animal-based measures.

In point 4, the Code Commission did not agree to delete the second sentence as according to expert opinion the use of group stunning can pose some animal welfare benefits. In addition, it did not agree to add wording to specify the concentration of CO₂ for stunning as it considered it was too prescriptive.

Article 7.5.20.

In point 3, the Code Commission did not agree to add examples as it considered it clear as written.

In point 3, on slaughter with stunning section, the Code Commission agreed to add a new point (c) on the need to bleed the animals without delay when animals are stunned with a reversible method. In point 3, slaughter without stunning section, the Code Commission did not agree to add new points as it considered these were too prescriptive.

In point 4, the Code Commission did not agree to add a bleeding method 'severing of the brachiocephalic trunk via chest sticking' for pigs, as the text was clear as written.

Article 7.5.22.

The Code Commission did not agree with the proposal to move Articles 7.5.22. and 7.5.23. after Article 7.5.12. and move Articles 7.5.34. and 7.5.35. after Article 7.5.24. as the current flow of the chapter is appropriate.

In the last sentence of the first paragraph, the Code Commission did not agree to add 'both the standard operating procedures and' as it did not consider it necessary to specify all the places where the principles should be described.

In point 2, the Code Commission did not agree that there is a contradiction between the reference to animals unable to walk in the section 'free-moving animals' because it is referring to the category of animals 'free-moving' and 'in containers' and not to the state of the animal.

Article 7.5.23.

In point 1(e), the Code Commission did not agree to add 'neck, one leg, fur, or wings' to the list of examples as they are already addressed by the terms listed.

In point 1(f), in response to a question to clarify the meaning of the term 'dragging', the Code Commission explained that dragging means forcefully moving an animal against its will and that the use of ropes to lead or guide animals is not covered in this point.

The Code Commission did not agree to add a new point 4 'blunt force trauma as a method of euthanasia is an unacceptable practice' as this is not the scope of this chapter and is addressed in Chapter 7.6.

Article 7.5.24.

In point 2, the Code Commission did not agree to add examples 'down, moribund', as it considered that the text was clear as written.

In point 3, the Code Commission did not agree to add 'and the holding time for poultry should not be more than six hours' as this may be a recommendation on a practical point of view, but not on welfare basis.

In point 3, the Code Commission did not agree to add the concept that immediate action should be taken if animal welfare is compromised as it was clear as written.

In point 4, the Code Commission did not agree to add that poultry is especially sensitive to extreme temperature as this is not species-specific.

In point 4, the Code Commission did not agree to add a sentence recommending that measures should be taken at the farm of origin or during transport in the case of repeated occurrence of trapping as this is outside the scope of the chapter.

Article 7.5.25.

In point 2(a), the Code Commission agreed to add 'or dislocated joints' as this can increase the pain associated with shackling while the animal is conscious.

Article 7.5.26.

In point 2(a), the Code Commission agreed to add 'reddening of the ears' as an animal-based measure for rabbits to be consistent with Article 7.5.24.

Article 7.5.27.

In the title, the Code Commission agreed to add 'before stunning' to distinguish from situations where animals are removed from the containers after they have been stunned.

In point 1, the Code Commission did not agree to add a new point f) 'birds that are not removed from containers before washing the containers' as it refers to an activity that does not take place during unloading.

In the third paragraph, point 3, the Code Commission did not agree to add 'harmful acts' as they are addressed in Article 7.5.35. The Commission agreed to delete the examples to be consistent with the approach take in other articles.

In point 4, the Code Commission agreed to delete the entire point because the text is not a species-specific measure and refers to 'any animals'.

Article 7.5.28.

In point 2(d), the Code Commission agreed to delete 'and pain caused by excessive force of restraint or shackling' as this is not specifically mentioned as a measure in Article 7.5.5.

Article 7.5.29.

In the first sentence, point 2, the Code Commission agreed to delete the equivalent sentence in Articles 7.5.30. and 7.5.31. for consistency and to align with text in the new Article 7.5.16.

In the fifth paragraph, point 3, the Code Commission agreed to reword the text for clarity.

Article 7.5.30.

In the last paragraph, point 3, the Code Commission did not agree to add 'such as controlled atmosphere stunning' as it is up to the Members to decide which method to use.

In point 4, third indent (for frequency from 400-600Hz), the Code Commission did not agree to replace '600' with '1500' or to delete the last paragraph, noting that the text considered relevant reference and is based on scientific evidence which reports that a frequency above 600 Hz does not induce unconsciousness.

In point 4, The Code Commission agreed to insert the recommendation from the current version of Chapter 7.5., Section 5, that 'birds should receive the current for at least 4 seconds' to reduce uncertainty about the time required for an effective stun in birds.

Article 7.5.31.

In point 2, the Code Commission agreed to delete the sections on 'cervical dislocation' and 'decapitation' as it considered that these methods should not be considered appropriate for stunning.

Article 7.5.32.

In the first paragraph, the Code Commission agreed to delete the last sentence as it considered it was not a recommendation.

In point 3, the Code Commission agreed that there was an inconsistency between the recommended CO₂ concentration in point 3 and in the second paragraph of point 4. Therefore, the Commission agreed to keep the recommended 40% for carbon dioxide concentrations as stated in point 3 and deleted the second paragraph under point 4.

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

Discussion

The Code Commission considered the comments received on the proposed amendments to the definitions related to Chapter 7.5. Animal welfare during slaughter. i.e., 'death', 'euthanasia', 'slaughter', 'stunning', and 'suffering'.

'death'

The Code Commission did not agree with comments to keep the definition for 'death' and reminded Members that this had been discussed at its February 2023 meeting and the rationale was clearly noted in the February 2023 Code Commission report, being that the common dictionary definition is adequate for its use in the Terrestrial Code.

'euthanasia'

The Code Commission agreed with comments to include text that emphasised euthanasia as an action carried out for the purpose of promoting animal welfare.

'slaughter'

The Code Commission did not agree to modify the definition to add the rapid and irreversible loss of consciousness, as this was relevant for the definition of killing but not for the definition of slaughter.

'stunning'

The Code Commission did not agree to several proposed amendments, as it considered the definition clear as written and the propositions did not add clarity.

'suffering'

The Code Commission agreed to keep the definition of 'suffering' unchanged in Chapter 7.8. Use of animals in research, and not to include a new definition in the Glossary given the opposing Member comments on the text.

The revised Chapter 7.5. Slaughter of animals, and the revised Glossary definitions of 'death', euthanasia', slaughter' and 'stunning' are presented as [Annex 10](#) and as part of [Annex 4](#), respectively, for comments and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

The EU thanks WOAHA for having taken into consideration most of our previous comments.

While the EU welcomes and supports this revised chapter and it still has a few comments presented in Annex 10.

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

Comments were received from Argentina, Australia, Canada, China, New Zealand and the UK, for the Code Commission's September 2023 meeting.

Comments were received from Australia, Japan, the UK, Members of the WOAHA Asia-Pacific Region, Members of the WOAHA Americas Region, the AU-IBAR and the EU, prior to and at 90th General Session in May 2023.

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 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.

In February 2023, the Code Commission, in agreement with the Scientific Commission, considered that no changes were required in Chapter 1.11. Application for official recognition by WOAHA of free status for foot and mouth disease, to reflect changes in Chapter 8.8., at this stage. Nonetheless, the Scientific Commission had agreed to review the questionnaire of Chapter 1.11. after the adoption of Chapter 8.8., noting that changes should not significantly impact the application for official recognition by WOAHA.

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 noting the importance of the chapter in terms of its impact on national policies and international trade, he decided to withdraw the proposed chapter in order to continue working towards building consensus and informed that the Commission would continue working on the draft chapter with continuous solid scientific background and expertise to develop a new proposal and a revised Chapter 1.11. with the aim of proposing them for adoption in 2024. The President also invited Members to submit any additional comments on this work for consideration by the Commission at its next meeting in September 2023.

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.

In response to a comment that expressed disappointment with the decision to withdraw the revised chapter from adoption at the 90th General Session, the Code Commission reminded Members that the effort to reach consensus is a cornerstone of WOA's standards-setting process, mandated by the Organisation's Basic Texts. Additionally, the Commission highlighted that the discussion of a proposed text with the World Assembly during a General Session is part of the process and there is always a possibility that further work may be needed before consensus is reached for the text to be adopted. The Commission reminded Members that Standards not only should be based on the latest scientific and technical evidence, but also once they are agreed and adopted, should be implemented.

The Commission acknowledged several comments which were addressed in discussing the corresponding parts of the chapter. The Commission also noted some comments proposing adding new elements to this revision but did not agree to expand the scope of the work at this stage as the current main objective was to address the remaining points on the draft text. The Commission requested the Secretariat to record these new requests to be taken into consideration in future work.

The Commission noted a comment from the WOA Working Group on Wildlife that expressed support for the proposed amendments and also noted that there may be value in emphasising the limited epidemiological role that all wildlife other than African buffalo play in the transmission of the foot and mouth disease virus (FMDV) and how this could be improved in the trade and management recommendations. The Commission reiterated that this would not be addressed at this stage but agreed that this point should be further discussed with the Biological Standards Commission and the Scientific Commission to assess the potential need to review that point of the chapter. The Commission requested the Secretariat to record this proposal so it could be taken into consideration in future work.

The Commission acknowledged several comments, including some considerations from the Scientific Commission, referring to the implementation of zoning, notably containment zones, and that they should be addressed with a broader perspective in Chapter 4.4. than only in this chapter. The Commission requested the Secretariat to record these comments so they can be taken into consideration as part of future work to revise Chapter 4.4. Zoning and compartmentalisation (see item 4.2.3 of this report).

Following a discussion at its February 2023 meeting, the Commission reviewed the information provided by the industry to support the drafting of a new article on recommendations for the safe trade of 'fetal bovine serum'. The Commission thanked the industry for the information provided but considered that the current draft was too close to adoption to incorporate this change. The Commission requested the Secretariat to prepare, in consultation with experts, a new draft article for safe trade of 'fetal bovine serum' based on the evidence provided and to present it for the Commission's consideration, after the proposed revised chapter has been adopted.

Article 8.8.1.

In point 2, in response to comments (in this and other articles), the Code Commission amended the text to clarify how the different epidemiologically significant hosts included in the definition of the disease were referred to across the chapter. Additionally, noting the amendments proposed to the User's Guide (see item 6.1 of this report), the Commission agreed to delete the definition of 'bovine' for the purposes of the chapter as it was considered no longer necessary. The Commission amended the text across the chapter to reflect these changes.

In point 6, the Code Commission did not agree with a comment to provide further details on the duration of carrier status. The Commission considered the inputs of the Biological Standards Commission and the Scientific Commission at their September 2023 meetings and noted that the main objective of this reference was to support some specific provisions in the chapter, such as the need to remove the head from carcasses before trading in certain cases, or the potential impact of African buffalo on the animal health status. The Commission agreed to amend the text for clarity, and recommended that more detailed information on the duration of the carrier state, as well as the differences between species or strains be considered for inclusion in the *Terrestrial Manual*.

In last sentence, the Code Commission proposed an amendment to better reflect the relevant information provided in the *Terrestrial Manual*. This same amendment will also be considered when revising other disease specific chapters.

Article 8.8.1bis.

The Code Commission did not agree with a comment to remove 'UHT milk and derivatives thereof' and 'protein meal'. The Commission reiterated its previously stated position that these two commodities followed globally defined manufacturing processes and fulfilled the criteria applied by WOAHA for assessing the safety of commodities in Chapter 2.2. In this same line, the Code Commission did not agree with a comment to reinstate the previous articles providing specific measures for trade for some of these products.

The Commission acknowledged a comment proposing the inclusion of 'milk powder and butter' in the list as safe commodities. The Commission noted that the request was supported by a national risk assessment to assess the likelihood of transmission of FMDV in milk powder and butter for human consumption, manufactured from infected milk collected from infected premises and commercially processed according to commonly employed national dairy industry standards. The Code Commission considered that the supporting document had some valuable information, but its scope remained within the national context, that it did not refer to globally defined manufacturing processes that would invariably be applied to the specific commodities, and agreed not to add these commodities to the list for the moment and invited the Member to submit further information for consideration, including the detailed treatment that the products were systematically subjected to when processed.

Article 8.8.2.

In point 3, the Code Commission did not agree with a comment to replace 'and' by 'or' before habitat, as it considered that both the distribution and the characteristics of the habitat in which the animals are located are critical to understanding the potential impact of wild and feral susceptible animals on the animal health status of a country or zone.

In point 4, the Commission acknowledged comments opposing the proposed amendments that would give the possibility for countries or zones free from FMD where vaccination is not practised to introduce vaccinated animals in accordance with the provisions in the *Terrestrial Code*, without having their animal health status being affected. The Commission reminded Members that the risk mitigation measures provided in the relevant articles for importation are sufficient for such animals to be considered safe and consequently this introduction implies no additional risk. Regarding a comment that these changes would impose an additional burden on importing countries that are free without vaccination such as increased surveillance and traceability and identification of imported animals, the Commission reminded Members that the implementation of the standards at the national level is the prerogative of each Member. The Commission also acknowledged the agreement of the Scientific Commission on this point, which refers as well to Article 8.8.40.

In point 5, the Commission agreed to amend the text for clarity and to move some of the context to the last paragraph of Article 8.8.8. as it considered it unnecessarily detailed and redundant. The Commission highlighted that this point, as all the other similar points in other disease-specific chapters, aimed to manage the risk of entry, which is mitigated if the importations or movements of commodities into the country or zone have been carried out following the provisions in this chapter and other relevant chapters of the *Terrestrial Code*.

Article 8.8.3.

In point 1(b), the Code Commission agreed to remove the text ‘in the unvaccinated subpopulations’ after ‘FMDV’, as it considered it redundant taking into consideration the definitions in Article 1.

In point 1(e), the Commission, in agreement with the Scientific Commission, amended the text for clarity.

Article 8.8.3bis.

In the second and third paragraphs, the Code Commission amended the text for clarity.

Article 8.8.5bis.

In point 3, the Code Commission, in agreement with the Scientific Commission, amended the text considering that enhanced surveillance in the rest of the country or zone would be overly demanding if an effective early warning system is in place, which should be the case in a free country or zone. Therefore, the Code Commission proposed instead that enhanced awareness be in place in the rest of the country or zone.

In the last paragraph, the Commission, in agreement with the Scientific Commission, amended the text for clarity.

Article 8.8.6.

In the last paragraph, the Code Commission, in agreement with the Scientific Commission, amended the text for clarity.

Article 8.8.7.

In point 1, the Code Commission did not agree with a proposal to add a new point (d) to consider options for recovery of freedom where a stamping-out policy is not applied, but where emergency vaccination and surveillance are applied. The Commission noted that a ‘stamping out policy’, which is defined in the Glossary and described in Chapter 4.19., implies the killing of at least the infected animals, and that is a *sine qua non* condition for the application of the quicker recovery provisions of this article; in other scenarios, where infected animals are not killed, freedom could always be regained following the relevant articles (Article 8.8.2. or Article 8.8.3.).

Article 8.8.8.

In the last paragraph, the Code Commission amended the text to include content removed from Article 8.8.2., and added ‘For ruminants, the head, including the pharynx, tongue and associated lymph nodes, was either destroyed or treated in accordance with Article 8.8.31.’

Article 8.8.11.

The Code Commission agreed with a comment to clarify the scope of the articles in terms of animal species. The Commission considered the input from the Biological Standards Commission and the

Scientific Commission at their September 2023 meetings, notably the confirmation by the Biological Standards Commission that the NSP test is not species specific and agreed to replace 'domestic ruminants and pigs' with 'susceptible animals' in the title.

In points 3 and 4, in response to a comment on a discrepancy between previous opinions expressed by the Code Commission and the Biological Standards Commission about the diagnostic tests recommended, the Commission considered the input from the Biological Standards Commission and the Scientific Commission at their September 2023 meetings, and noted their general support to the proposed provisions and agreed with the recommendation of the Biological Standards Commission to remove 'virological and' in point 3, as serology is enough for non-vaccinated animals.

Article 8.8.12.

In the title, the Code Commission replaced 'domestic ruminants and pigs' with 'susceptible animals', following the rationale explained in Article 8.8.11.

Article 8.8.14.

The Code Commission agreed with a comment to delete point 1(c), as it was considered redundant (to point 2).

Article 8.8.21.

In the title, the Code Commission, replaced 'domestic ruminants and pigs' with 'susceptible animals', following the rationale explained for Articles 8.8.11. and 8.8.12. and amended points 1 and 2 in consequence.

Article 8.8.22.

In the title, the Code Commission deleted 'and water buffaloes (*Bubalus bubalis*)' following the rationale and amendments introduced in Article 8.8.1. and amended the relevant points of the article in consequence. Also, the Commission agreed to remove '(excluding feet, head and viscera)', and moved it to point 2(b)(i) to follow the conventions for the *Terrestrial Code*.

The Commission did not agree with a comment to add a new article on 'Direct transfer within a country of FMD susceptible animals from a free zone, for slaughter in a slaughterhouse/abattoir located in an infected zone, including containment zone (whether vaccination is practised or not)', as it was not linked with specific risk mitigation. Nonetheless, the Commission acknowledged that there was a need to address how the meat from such animals could be traded safely without unjustified barriers and added a new point 1.

Article 8.8.22bis.

In the title, the Code Commission removed 'domestic' following the convention for the *Terrestrial Code*, to clarify that the measures would apply to all suids and amended the relevant points of the article in consequence.

In point 1, the Commission added references to Articles 8.8.10., 8.8.11., and 8.8.11bis., in line with the changes proposed to Article 8.8.22., because all pigs imported in accordance with the recommendations should be considered safe.

Article 8.8.22ter.

In the title, the Code Commission removed 'domestic' based on the same rationale as in Article 8.8.22bis. Also, the Commission agreed to remove '(excluding feet, head and viscera)', and moved it to point 5(c)(i) to follow the conventions for the *Terrestrial Code*.

In point 4, the Commission added references to Articles 8.8.10., 8.8.11., 8.8.11bis., in line with the changes proposed to Article 8.8.22., because all sheep and goats imported in accordance with the recommendations should be considered safe.

Article 8.8.23.

In point 2, the Code Commission added references to Articles 8.8.22., 8.8.22bis. or 8.8.22ter., since meat imported in accordance with the recommendations of these articles is considered safe, so are meat products thereof.

Article 8.8.25.

In point 1(b) the Code Commission agreed with a comment to add a new point (ii) as an alternative treatment.

Article 8.8.31.

In the title, the Code Commission added 'susceptible animals', following the convention for the *Terrestrial Code* and the rationale explained for previous points, and amended the relevant points of the article in consequence.

In point 3, the Code Commission amended the text by merging the two paragraphs, for clarity.

The Commission added a new point 4 'Any equivalent treatment which has been demonstrated to inactivate FMDV in meat and meat products' to follow the convention of the *Terrestrial Code*.

Article 8.8.35.

The Code Commission, considering the advice from WOAHP Reference Laboratories experts, agreed with comments to review the proposed article. The Commission noted the expert opinions that one HTST treatment is not sufficient to completely inactivate FMDV, and that the condition of 'pH lower than 7' is not sufficiently defined in that it does not necessarily encompass significant acidification of the product, thus amended the text based on the scientific references provided by Members and the WOAHP experts.

Article 8.8.40.

The Code Commission reiterated, in agreement with the Scientific Commission, that previously and newly introduced vaccinated animals should be considered in the same manner in the strategy and design of the surveillance programme.

The 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.

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

The Code Commission considered a draft revised Chapter 1.11. Application for official recognition by WOAHP of free status for FMD proposed by the Scientific Commission at its September 2023 to address all modifications required to align with the revised Chapter 8.8. The Commission agreed to circulate the revised Chapter 1.11. for comment.

The revised Chapter 8.8. Infection with foot and mouth disease virus, and Chapter 1.11. Application for official recognition by WOAHA of free status for foot and mouth disease, are presented as [Annex 11](#) and [Annex 12](#), respectively, for comments and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

The EU would like to thank the Code Commission for considering the EU comments submitted prior and during the 2023 WOAHA General session. The EU is concerned by the revision of this chapter.

Important comments on these chapters are provided in Annexes 11 and 12.

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

Background

At its February 2023 meeting, the Code Commission noted that the corresponding Chapter 3.1.19. Rift Valley fever (infection with Rift Valley fever virus) of the *Terrestrial Manual* had been amended to include diagnostic tests suitable for trade in live animals, i.e., the ratings of the RT-PCR and antigen detection in Table 1 for the purpose individual animal freedom from infection prior to movement was upgraded from ‘-’ to ‘++’ and would be proposed for adoption at the 90th General Session in May 2023. The Commission agreed that, once the revised *Terrestrial Manual* chapter has been adopted, it would review relevant trade provisions in Chapter 8.16. Infection with Rift Valley fever virus of the *Terrestrial Code*.

Discussion

The 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 and proceeded with its planned review of relevant articles.

The Code Commission considered the need to revise the relevant articles on recommendations for importation of susceptible animals, semen and embryos, i.e., Articles 8.16.6. to 8.16.8. of Chapter 8.16.

In Articles 8.16.6. and 8.16.7., the Code Commission agreed not to change the recommendations as it considered that the current provisions were sufficient.

In Article 8.16.8., the Code Commission agreed to add a new point 2(d) ‘were subjected to a test for the detection of the agent with negative result on the day of collection’, as it considered that this option was a valid, practical measure for ensuring the safe trade of semen and embryos.

The Commission noted that, as these amendments were a consequence of changes to the corresponding Chapter 3.1.19. of the *Terrestrial Manual*, they would be proposed for adoption at the 2024 General Session. The Commission also highlighted that the other articles of this chapter were not for comment.

The revised Article 8.16.8. of Chapter 8.16. Infection with Rift Valley fever virus is presented as [Annex 13](#) for comments and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

The EU supports the proposed changes to this chapter.

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

Background

At its February 2023 meeting, the Code Commission noted that the corresponding Chapter 3.1.22. Trichinellosis (infection with *Trichinella* spp.) of the *Terrestrial Manual* had been amended and included a change to the number of taxon of the pathogenic agent, and would be proposed for adoption at the 90th General Session in May 2023. The Commission agreed to include a partial revision of Chapter 8.18. Infection with *Trichinella* spp. on its work programme, to align the number of taxon of the pathogenic agent with the corresponding chapter of the *Terrestrial Manual*, pending its adoption.

Discussion

The 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 and proceeded with its planned review of relevant text in Article 8.18.1.

In Article 8.18.1., the Code Commission considered that there was no need to repeat information contained in the *Terrestrial Manual* that had no specific value for the purposes of the *Terrestrial Code* Chapter, and agreed to delete text that referred to taxon of the pathogenic agent and to methods for the detection of the pathogenic agent.

The Code Commission considered that, in principle, the changes in the *Terrestrial Code* and in the *Terrestrial Manual* did not have an impact in the related Codex Alimentarius Standards but noted that the numbering of the *Terrestrial Manual* had been modified. The Commission requested that the Secretariat work with the Codex Secretariat to ensure that all references to WOHAI Standards in 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) are updated.

The revised Article 8.18.1. of Chapter 8.18. Infection with *Trichinella* spp., is presented as **Annex 14** for comments and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

The EU in general supports the proposed changes to the chapter and invites the Code Commission to take this opportunity to review the case definition and align it with the approach taken in other disease chapters. A further comment is inserted in Annex 14.

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

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

Background

In September 2022, the Code Commission agreed to add the development of a new chapter for Infection with *Coxiella burnetii* (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 burnetii* (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 twice, the last time in the February 2023 Code Commission meeting report.

Discussion

The Commission noted comments supporting the proposed new chapter.

Article 8.X.1.

The Code Commission did not agree with a comment to add 'in its spread' after 'role' as considered it was implicit.

In point 2 and point 3, the Commission did not agree with comments to replace 'confirmed or suspected case' with 'susceptible animal infected with *C. burnetii*' because this was the convention for the *Terrestrial Code*.

Article 1.3.1. of Chapter 1.3.

In view of the progress of the proposed amendments, the Code Commission agreed to amend the disease name in Article 1.3.1. to 'in Article 1.3.1. to 'Infection with *Coxiella burnetii* (Q fever)' and to circulate the proposed amendment.

The new Chapter 8.X. Infection with *Coxiella burnetii* (Q fever), and the revised Article 1.3.1. are presented as [Annex 15](#) and as part of [Annex 5](#), respectively, and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

The EU in general supports the proposed changes to this chapter. A comment is provided in Annex 15.

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

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

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 comment and extensively discussed but due to the need to clarify the scope of these chapters in terms of host species and pathogenic agents, in February 2018, both Commissions agreed to put Chapters 8.Z. and 12.3. on hold and to progress work on Chapter 8.18. Infection with *Trypanosoma brucei*, *T. congolense*, *T. simiae* and *T. vivax*, which was adopted in May 2021. Both Commissions had also agreed that, notwithstanding 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 8.18.

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

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. 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 and circulated the draft chapter for comments.

The *ad hoc* Group was reconvened in July 2023 to address selected comments on Chapter 8.Z. and to draft a revised Chapter 12.3.

Discussion

The Code Commission considered the *ad hoc* Group report and commended the *ad hoc* Group for its work and highlighted that Members should read the *ad hoc* Group meeting report in conjunction with this report. The Code Commission wished to note that, where it agreed with a recommendation of the *ad hoc* Group, the explanation is provided in the report, and is not repeated in this report.

The Code Commission discussed comments together with the inputs from the *ad hoc* Group convened in July 2023.

General comments

In response to a comment pointing out that the terms 'surra' and 'infection with *Trypanosoma evansi*' are used interchangeably in the chapter, the Code Commission explained that, as in other chapters where both the common name of the disease and the name of the listed disease are kept, the common name 'surra' is used to refer to the disease in general throughout the chapter (including for epidemiology, status, clinical signs, etc.), while the name of the listed disease 'infection with *Trypanosoma evansi*' is used to refer to cases or outbreaks throughout the chapter. The Commission made amendments to the text to clarify this point, as relevant.

Article 8.Z.1.

In the second paragraph, the Code Commission did not agree with a comment to add 'in late stage' after 'the nervous system' and to add 'who lack trypanosome lysis factors such as Apol-1' after 'infect humans', as it considered that these additions would not provide any added value for the purposes of the chapter of the *Terrestrial Code*.

In the third paragraph, in response to a comment that there is no evidence of venereal transmission for *T. evansi* in any species and therefore surra was not a risk in semen, the Code Commission noted that the *ad hoc* Group convened in July 2023 was of the opinion that although the specific mechanism for venereal transmission for *T. evansi* is unknown, it does occur and therefore it cannot be ruled out. The Commission therefore agreed to keep the articles on recommendations for importation of semen, i.e., Articles 8.Z.10. and 8.Z.11.

In the sixth paragraph, in response to a comment to highlight that camels, domestic buffaloes, donkeys and horses are the most important, the Code Commission considered that this was already clear in the second paragraph, and that no amendments were necessary. The Commission also explained that this was one of the reasons why it is not necessary to provide recommendations for the importation of, among others, dogs and cats in this chapter (See Article 8.Z.6. below).

In point 1, in response to a comment querying whether this point means that, if nucleic acid is detected but trypanosomes are not detected, there is no occurrence of the infection, the Commission clarified that this case will be covered by point 3, if relevant. The Commission explained that normally the first point of the definition of the occurrence of an infection in a disease-specific chapter refers to the confirmation of

the presence of the pathogenic agent in an animal, in a form capable of producing and transmitting disease, irrespective of other conditions.

In points 2 to 4, comments were received to clarify these points. Given that the *ad hoc* Group's opinion was that it is important to consider the epidemiological context when diagnosing a case of surra due to the close relationship and similarities among *T. brucei*, *T. evansi* and *T. equiperdum*, and that the Group proposed to describe the information in the articles on surveillance, the Code Commission agreed with the *ad hoc* Group's proposal and simplified these text to align with the approach used in other disease-specific chapters. In response to a comment on point 4 referring to antibody detection test, the Commission reiterated that seropositivity is sufficient to define the occurrence if it is detected in a sample from a susceptible animal epidemiologically linked to a confirmed case.

In the eighth paragraph, the Code Commission noted a comment stating that the incubation period defined for all species of susceptible animals, i.e., 90 days, might be too long for some species, and thus it could lead to increased complications and unnecessary export preparation times for those animals. The Commission agreed to keep the incubation period at 90 days, i.e., the longest period, as is done in other disease-specific chapters. Nevertheless, the Commission considered that this point was important in drafting new or revised disease-specific chapters for diseases with multiple host species. Therefore, the Commission agreed to further discuss this point with the Scientific Commission and the Biological Standards Commission. The Code Commission noted that the 90 days was recommended by the *ad hoc* Group convened in June 2021.

Article 8.Z.2.

In response to a comment to delete 'meat' and 'meat products' from the list of safe commodities, the Code Commission, in agreement with the *ad hoc* Group that there may be a residual risk, agreed to delete 'meat' and to reinstate the article on recommendations for the importation of meat, i.e. Article 8.Z.11bis. However, the Commission, in agreement with the *ad hoc* Group, did not agree to delete 'meat products' as it considered that is complied with Chapter 2.2., as, given the Glossary definition for meat products, the parasite would no longer be viable and would therefore be non-infective.

The Code Commission, in agreement with the *ad hoc* Group, did not agree with a comment to delete 'embryos or oocytes' from the list of safe commodities. The parasite could contaminate the exterior of harvested embryos, but the risk would be mitigated through the standard handling process in accordance with Chapters 4.8. to 4.10. of the *Terrestrial Code*.

Article 8.Z.3.

In response to a comment to improve clarity, the Code Commission made amendments to the text.

Article 8.Z.4.

In response to comments to clarify what is an 'effective biosecurity management system' and that there is no mention of surveillance in the article, the Code Commission explained that Chapter 4.5. Application of compartmentalisation (referred to in the first paragraph of the article), addressed these points.

Article 8.Z.6.

The Commission noted comments querying the reason why dogs and cats are excluded from this article. The Commission also noted that, based on the proposal of one Member, the *ad hoc* Group proposed to reinstate an article on recommendations for the importation of dogs and cats from infected countries or zones that had been originally provided by the *ad hoc* Group convened in June 2021 and not retained by the Code Commission after advice from the Scientific Commission. The Commission extensively discussed this point and agreed again not to include recommendations for dogs and cats. The Commission reiterated that the role of dogs and cats in the epidemiology of this disease, although not negligible (the reason why they are included in the susceptible species), is much less important than other susceptible animals, especially in terms of spread through international trade.

In point 2, the Code Commission agreed with a comment to replace '6 months' with '90 days' given the incubation period defined in Article 8.Z.1. This amendment was applied throughout the chapter as appropriate.

Article 8.Z.7.

In point 2, the Code Commission agreed with the amendments proposed by the *ad hoc* Group, which addressed some comments received on this point.

In the same point, in response to a comment to include requirements on appropriate vector-protected quarantine, the Code Commission explained that the Glossary definition for 'quarantine station' that is referred to in this point is adequate and encouraged Members to review the revised definition proposed for 'quarantine station' in this report. (See item 6.3 of this report.)

The Code Commission noted that the *ad hoc* Group pointed out that camels could carry the parasite in the absence of an antibody response, and thus were of the opinion that special recommendations for camels would be necessary for point 2 of Article 8.Z.7. However, the *ad hoc* Group did not have sufficient time to discuss suitable recommendations on this point. The Commission was informed that the Scientific Commission had requested expert opinion on this point and requested the Secretariat to report back at its next February 2024 meeting.

Article 8.Z.8.

In response to a comment, the Code Commission clarified, in agreement with the opinion of the *ad hoc* Group, that the recommendations provided in the article were much more stringent than for Article 8.Z.9., and that an antibody detection test would be sufficient and that there was no need to require both an agent identification and antibody detection test.

In point 3, the Code Commission agreed with a comment that if there was a surveillance programme in the establishment, testing of individual animals was not necessary, and amended the text accordingly.

In point 4, the Code Commission did not agree with a comment that the measures described in this point are overly trade restrictive, as it considered them relevant to address risks of vector attacks during transportation from the establishment of origin to the place of shipment.

Article 8.Z.9.

In point 1, in response to a comment, the Code Commission made amendments to the text. The Commission explained that it was too strict to require testing of equids from a high health status subpopulation.

Article 8.Z.10.

The Code Commission noted a comment to consider routine serological testing of all susceptible donor animals with negative results, rather than requiring a long residency period described in the article. The Commission noted that this point would be discussed as part of the work to revise Chapter 4.7.

Article 8.Z.13.

In point 1(b), the Code Commission agreed with a comment to delete this point, as it considered that the reference to Chapter 1.4. in the first paragraph addressed this point.

Article 8.Z.14. and Article 8.Z.15.

In response to comments to compare these articles with articles on surveillance in Chapter 8.19. Infection with *Trypanosoma brucei*, *T. congolense*, *T. simiae* and *T. vivax*, the Code Commission explained that it was not necessary to reopen the discussion given that there are only slight differences between the relevant articles.

In point 3, the Code Commission did not agree with a comment to delete the point as it considered that it was not redundant, the angles between points 2 and 3 being distinct: it is important to distinguish the animals that are moved from previously affected establishments from establishments epidemiologically linked to the outbreak.

The new Chapter 8.Z. Infection with *Trypanosoma evansi* is presented as **Annex 16** for comments and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

The EU would like to thank the Code Commission for taking into account previous comments. The EU, in general, supports this proposed new chapter. A comment is inserted in Annex 16.

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

Comments were received from Australia, Canada, China (People's Republic of), Chinese Taipei, Mexico, New Zealand, Switzerland, the UK, the USA, the AU-IBAR and the EU.

Background

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

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

At its September 2022 meeting, the Code Commission reviewed all proposals, introduced additional amendments for clarity and consistency with other chapters, and circulated the revised chapter for comments. The revised Chapter 11.5. was circulated twice for comments, the last time in the Code Commission's February 2023 meeting report.

Discussion

General comments

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

The Commission did not agree with a comment to add a definition for 'epidemiological link' in the Glossary. The Commission noted that this term was used in different contexts depending on the chapters, and it was not possible to give a single definition.

The Commission did not agree with a comment to replace '*infection with Mmm*' with 'CBPP' across the chapter because 'CBPP' was defined at the beginning of the chapter. The Commission noted that this was not an inconsistency and explained again that although the convention for the *Terrestrial Code* is to define listed diseases as '*infection with [pathogenic agent]*', the common name of the disease is often used in the chapters, to refer to freedom status (as is the case for CBPP) and to the disease surveillance in general.

Article 11.5.1.

In point 3, the Code Commission agreed with comments to add 'or' at the end of points (a) and (b), and to replace 'and' by 'or' after 'Mmm' in points (b) and (c).

Article 11.5.4.

In point 2, the Code Commission agreed with a comment to delete point (a) as it was covered by point (b).

Article 11.5.5bis.

After point 7, the Code Commission did not agree with a comment to add a new point describing elements of the epidemiological situation, and request further guidance to define what would be considered as 'effective controls' in the subsequent paragraph, as it considered it too detailed and prescriptive. Nonetheless, the Commission noted that some of these points could be addressed as part of potential future work regarding the implementation of zoning (see item 4.2.3 of this report).

Article 11.5.8.

In point 3, the Code Commission did not agree with a comment to add provisions to be implemented within the territory of importing countries. The Commission explained that the recommendations for importation in the *Terrestrial Code* are those considered sufficient to ensure adequate risk mitigation and assume that no further measures are considered necessary for importing countries.

In point 3, the Commission did not agree with a comment to replace 'place of shipment' with 'slaughterhouse/abattoir', as the provisions of this article are deemed to be certified by exporting countries and so they cannot refer to measures to be applied outside of their territory.

Article 11.5.10.

In point 1(c), in response to a comment, the Code Commission agreed to add 'that did not meet the same health requirements' after 'bovines' to clarify that for the isolation, animals should be considered as a collection herd and not individuals.

In point 1(d), the Commission agreed to move the point as the initial point for certification to follow the logical order used in the certification process.

Article 11.5.12.

In points (c) and (d), the Code Commission amended the text to reflect the changes introduced in Article 11.5.10.

Article 11.5.13.

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

In point 3, the Commission did not agree with a comment to delete the second and third paragraph, and explained that although the content was similar to point 2, the repetition was considered needed as both points provide requirements for 'Demonstration of freedom' and endorsement of 'official control programmes'.

The revised Chapter 11.5. Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia), is presented as [Annex 17](#) for comments and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

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

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

Comments were received from New Zealand, Norway, Switzerland, the UK 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.

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

The proposed new Chapter 11.X. Infection with bovine pestivirus (Bovine viral diarrhoea), was circulated twice, the last time in the February 2023 Code Commission meeting report.

Discussion

General comments

The Code Commission did not agree with comments to amend the chapter to consider only persistently infected animals to avoid transiently infected animals falling under the case definition. The Commission reiterated its previous position that any infection should be notified, and the potential difference in relevance of persistently infected animals in the context of prevention and control of this disease, should be taken into consideration in management measures.

Article 11.X.1.

The Code Commission did not agree with comments questioning the bovine species in the definition of the disease, the Code Commission reiterated its position to keep the text as proposed and referred Members to the opinion of experts and the Scientific Commission that only *Bos taurus*, *Bos indicus* and *Bubalus bubalis* play a significant epidemiological role in the disease. The Commission noted that the Biological Standards Commission is planning to review the corresponding *Terrestrial Manual* chapter in the 2023/2024 review cycle and agreed that this point could be further considered, if necessary, after the adoption of a revised *Terrestrial Manual* chapter.

The Code Commission did not agree with comments to add 'detection of seroconversion to bovine pestivirus' as a third option to confirm a case and encouraged Members to refer to the September 2021 report of the Scientific Commission and the corresponding Chapter 3.4.7. Bovine viral diarrhoea, of the *Terrestrial Manual*, which states that serology is not appropriate for confirming suspect cases.

Article 1.3.2. of Chapter 1.3.

In view of the progress of the proposed amendments, the Code Commission 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 new Chapter 11.X. Infection with bovine pestiviruses (Bovine viral diarrhoea), and the revised Article 1.3.2. are presented as **Annex 18** and as part of **Annex 5**, respectively, and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

The EU cannot support the currently proposed case definition and seeks its re-evaluation. Important comments are provided in Annex 18.

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

Comments were received from Australia, Chinese Taipei, Mexico, New Zealand, South Africa, Switzerland, the USA, the AU-IBAR and the EU.

Background

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

At its September 2022 meeting, the Code Commission reviewed the amendments proposed by the *ad hoc* Group which met in December 2016 and endorsed by the Scientific Commission in February 2021, and amended the draft chapter, as relevant, and circulated the revised Chapter 12.1. Infection with African horse sickness virus, for comments.

At its February 2023 meeting, the Code Commission discussed the comments received, made additional amendments, and circulated the revised chapter for comments.

Discussion

Article 12.1.1.

In point 3, in response to comments, the Code Commission proposed to amend the text for clarity and to avoid duplication.

New Article 12.1.1bis.

The Code Commission reminded Members that, at its February 2023 meeting, in response to a comment, the Commission had requested the Secretariat to seek expert advice to provide a draft list of 'safe commodities'. The Secretariat, from May to July 2023, consulted four experts and the Commission considered their inputs.

The Code Commission agreed to include the following safe commodities in a new Article 12.1.1bis. Also provided below is a rationale:

- 'milk and milk products', given that active vectors are the exclusive transmission pathway for infection with AHSV, and thus it meets criterion of point 1 of Article 2.2.2.;
- 'meat and meat products', given that active vectors are the exclusive transmission pathway for infection with AHSV and thus it meets criterion of point 1 of Article 2.2.2.; moreover, the pH of meat as a commodity is likely to inactivate the virus and thus meets criterion of point 2(b) of Article 2.2.2. It is to be noted that while AHS has been known to infect and cause mortality among domestic dogs that ingest AHSV contaminated meat, carnivores have not been demonstrated to play any role in the transmission of the infection;

-
- 'hides and skins', given that active vectors are the exclusive transmission pathway for AHSV and thus it meets criterion of point 1 of Article 2.2.2.;
 - 'hooves', given that, according to experts, the virus is not present in hooves of infected animals and thus meets criterion of point 1 of Article 2.2.2., and that active vectors are the exclusive transmission pathway for AHSV and thus it meets criterion of point 1 of Article 2.2.2.;
 - 'gelatine and collagen', given that active vectors are the exclusive transmission pathway for AHSV and thus it meets criterion of point 1 of Article 2.2.2., and that the manufacturing process of gelatine and collagen results in the inactivation of any residual viral particles potentially present in the raw material used and thus it meets criterion of point 2 of Article 2.2.2.;
 - 'sterile filtered horse serum', given that active vectors are the exclusive transmission pathway for AHSV and thus it meets criterion of point 1 of Article 2.2.2.; and that, while the virus is present in high concentration in blood and certain organs, only trace amounts can be found in serum, tissue fluids and excretions and that the manufacturing process of 'sterile' filtered horse semen results in the absence of any residual viral particles potentially present in the raw material used, and thus it meets criterion of point 2 of Article 2.2.2.

The Code Commission agreed not to include 'manure' that had been proposed by one expert, given that the commodity was difficult to define.

Article 12.1.2.

In point 1(b), in response to a comment that passive surveillance relies on clinical signs and wild or feral zebra and certain donkeys are unlikely to display clinical signs, the Code Commission reminded Members that this point was also included in many disease-specific chapters because it is always possible to collect some information by passive surveillance, e.g. monitoring of dead wild animals, while there is no benefit of active surveillance.

In point 1(d)(iii), in response to a comment that, while agreeing with the point that no disease surveillance is necessary where the absence of *Culicoides* is demonstrated in accordance with Chapter 1.5. Surveillance for arthropod vectors of animal diseases, it needs to be made clear that an early warning system and passive surveillance are still required, the Commission explained that a reference to the relevant point in Article 1.4.6. (which indeed requires early warning system and passive surveillance) is included in the first paragraph. However, the Commission agreed to replace 'point 2' with 'point 2(a)' for clarity. In addition, in point 1(d)(i), the Commission also agreed to add 'point 2(b) of' before 'Article 1.4.6.' for clarity.

The Code Commission agreed to delete point 1(d)(iii) after considering the opinion of the Scientific Commission that there are few, if any, countries that could be considered free of all species of *Culicoides*, and that Chapter 1.5. is a general chapter and not aimed at demonstrating absence of vectors and that Articles 12.1.11. to 12.1.13. already include the relevant reference to Chapter 1.5.

Article 12.1.8. and Article 12.1.9.

In response to a Member comment that a recent risk assessment undertaken by that Member found no evidence that the disease is transmitted in equine semen, oocytes or embryos, the Code Commission encouraged the Member to submit the scientific evidence to the Commission, in order to consider if the risk assessment included other commodities as safe commodities. If so, those commodities should be assessed against the criteria of Chapter 2.2.

Article 12.1.10.

In point 2(a)(i), the Code Commission noted a comment to consider guidelines for a method for official recording on which horses have been treated and what chemical repellents have been used. The Commission considered that the issue of insecticide residues was important, but this was out of the remit of the chapter. The Commission wished to remind Members that WOAAH had undertaken work on the use of antiparasitic drugs and encouraged Members to refer to item 4.3.3 of the Commission's September 2022 report.

Article 12.1.13.

In the first paragraph, in response to comments, the Code Commission proposed amendments for clarify.

In point 2, in the first paragraph, in response to a comment, the Code Commission did not agree to add 'and mules' after 'donkeys', noting that while donkeys show limited clinical signs of AHS, mules are much more susceptible.

In the same paragraph, the Code Commission did not agree with a comment to delete the sentence "Surveillance plans should include consideration of species that display clinical signs less commonly, such as donkeys or zebras" that was added at the Commission's February 2023 meeting. The Commission reiterated that it was important to ensure that serological surveillance is in place for such animals which have a longer viraemic period and milder clinical signs potentially hindering detection of the disease.

The revised Chapter 12.1. Infection with African horse sickness virus is presented as [Annex 19](#) for comments and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

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

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

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

Background

At its September 2021 meeting, the Scientific Commission recommended that Chapter 13.2. Rabbit haemorrhagic disease, be revised as the current chapter did not contain a case definition nor provisions for recovery of free status.

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

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

At its February 2023 meeting, the Code Commission discussed the case definition that had been endorsed by the Scientific Commission and agreed to add this case definition, with some amendments, to Article 13.2.1. The Commission also amended Article 13.2.2. to reflect the expanded host range of the case definition, i.e., replacement of rabbit with 'leporids' and to harmonise terminology used in other

disease-specific chapters. The revised Articles 13.2.1. and 13.2.2. of Chapter 13.2. were circulated for comments.

Discussion

The Code Commission noted comments supporting the proposed amendments.

The Code Commission did not agree with a comment to limit the definition of the disease to domestic and captive wild leporids. While the Commission acknowledged the difficulties in conducting surveillance in wild animals, it highlighted that wild leporids play a significant role in the epidemiology of this disease and should be included. The Commission reminded that the relevance of the different hosts for the specific provisions (animal health status, surveillance, international trade) are presented in the specific articles.

Article 13.2.1.

In point 2, the Code Commission did not agree to amend the text to also cover subclinical infections. While the Commission agreed that subclinical infections should be taken into consideration for the surveillance of the disease, the Commission considered that they can be confirmed only based on the detection of antibodies. The Commission noted that such cases would be confirmed based on the provisions in point 1, and reminded that these points are considered independent, and each of them should be self-sufficient to confirm the occurrence of the infection.

Article 13.2.2.

The Code Commission acknowledged comments on the need to further revise the content of the article to better address the impact of domestic and captive wild leporids in the animal health status, as well as the surveillance in vaccinated populations. However, the Commission noted that the scope of this revision was originally aiming to incorporate new provisions to define the occurrence of the infection, which was urgent to facilitate notification to WOAHA, and reminded that the changes in Article 13.2.2. were mainly editorial and to align with the newly developed Article 13.2.1. The Commission reminded that a full revision of the chapter, including the development of surveillance provisions, was already included in the Commission work programme, and requested the Secretariat to capture these points in view of that work, while inviting Members to submit proposals with scientific evidence on other aspects of the chapter.

Article 1.3.7. of Chapter 1.3.

In view of the progress of the proposed amendments, the Code Commission agreed to amend the disease name in Article 1.3.7. from 'Rabbit haemorrhagic disease' to 'Infection with pathogenic rabbit lagoviruses (Rabbit haemorrhagic disease)' and decided to circulate the proposed amendment for comments.

The revised Articles 13.2.1. and 13.2.2. of Chapter 13.2. Rabbit haemorrhagic disease, and the revised Article 1.3.7. are presented as [Annex 20](#) and as part of [Annex 5](#), respectively, and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

The EU in general supports the proposed urgently needed changes to this chapter to create a case definition and clarify notification procedures.

The EU supports the approach proposed by the Code Commission to keep track of the comments already submitted by the EU and that these comments are taken into account when a full revision of the whole chapter will take place.

For ease of reference in the future revision of this chapter, the EU provides in Annex 20 the comments already submitted on the changes in Article 13.2.2.

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

Background

At its February 2023 meeting, in response to a comment 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, as priority 2, and requested that Secretariat review this commodity against the criteria in Chapter 2.2. Criteria applied by WOAHP for assessing the safety of commodities, using available scientific evidence, and report back at its September 2023 meeting.

Discussion

The Code Commission reviewed the information provided by the Secretariat including 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 and should therefore be added to the list of safe commodities in Article 15.1.2.

The Code Commission proposed to amend point 1 of Article 15.1.2., to ensure consistency with changes 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.

The Code Commission reminded Members that these proposed amendments were only to address this specific request on safe commodities and that the chapter was not open for further comments.

The revised Article 15.1.2. is presented as **Annex 21** for comments and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

The EU, in general, supports the proposed changes and submits one comment in Annex 21.

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

Comments were received from Australia, Switzerland and the EU.

Background

At its September 2020 meeting, the Code Commission agreed with a request 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' recommendations, 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.

The proposed new Chapter 16.Z. Infection with Camelpox virus, was circulated for comments twice.

Discussion

Article 16.Z.1.

In the first paragraph, the Code Commission noted a comment that the addition of New World camelids as susceptible species in Article 16.Z.1. had not been accepted by the Commission while the corresponding *Terrestrial Manual* chapter states that New World camelids are susceptible to Camel pox. The Code Commission reminded Members that only host animals that are considered to play a significant role in the epidemiology of the disease are included as ‘susceptible animals’ in Article X.X.1. of disease-specific chapters of the *Terrestrial Code*.

However, the Commission agreed that the current usage of the term “susceptible animals” in disease-specific chapters may be confusing and agreed to address this issue in related work (see item 4.2.2 of this report).

In the same paragraph, the Code Commission did not agree with a comment to reinstate ‘of genus *Orthopoxvirus*, family *Poxviridae*’ as it considered the text was clear as written, as the naming of the species was sufficient to determine the susceptible animals.

In point 4, the Code Commission did not agree with a comment to delete the point and reminded Members that these points of this article are considered independent and each one could confirm the occurrence of the infection. The Commission noted that these points were based on experts’ advice. The Commission reiterated its position that this point is only one option and even if this option may have a limited utility especially in endemic countries where vaccination is widely practiced, it would be useful in other situations.

In the last paragraph, the Code Commission proposed some amendments. The Commission explained that the disease-specific chapters in the *Terrestrial Manual* provide standards for diagnosis that include not only diagnostic tests but also clinical diagnosis. Furthermore, the Commission decided to add ‘as well as information on the epidemiology’ and not to include unnecessary information on the disease in Article X.X.1. in order to avoid any potential inconsistencies between corresponding chapters in the *Terrestrial Code* and the *Terrestrial Manual*.

Article 1.3.9. of Chapter 1.3.

In view of the progress of the proposed amendments, the Code Commission agreed to amend the disease name in Article 1.3.9. from ‘Camel pox’ to ‘Infection with camel pox virus’ and to circulate the proposed amendment.

The new Chapter 16.Z. Infection with camel pox virus and the revised Article 1.3.9. are presented as [Annex 22](#) and as part of [Annex 5](#), respectively, and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

The EU supports this new chapter.

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

Comments were received from Switzerland, the USA, 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. However, before proposing these amendments for comments, the Commission wished to discuss its conclusions with the Aquatic Animals Commission to ensure alignment with the use of corresponding terms in the *Aquatic Code*. The two Commissions agreed to circulate proposed amendments in their respective February 2023 report to allow Members to consider them at the same time. The Commission also agreed to propose amendments for the use of these terms in the User’s Guide.

Discussion

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

The Code Commission agreed to make two additional amendments to replace Veterinary Services with Veterinary Authority in Article 12.2.8. of Chapter 12.2. Infection with *Taylorella equigenitalis* (CEM), and Article 12.7.8. of Chapter 12.7. Infection with *Theileria equi* and *Babesia caballi* (Equine piroplasmosis), which were adopted in May 2023, for harmonisation with the amendments being proposed in this annex for other *Terrestrial Code* texts.

The revised texts are presented as [Annex 23](#) for comments and will be proposed for adoption at the 91st General Session in May 2024.

EU comment

The EU supports these proposed changes to the Code.

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

The Code Commission discussed the need to revise the User’s Guide, as proposed by the President of the Code Commission, at the 90th General Session in May 2023.

Given its recent work on the development of new or revised disease-specific chapters and a framework for disease-specific chapters (see item 7.5.1), the Code Commission agreed to revise the User’s Guide to provide a more detailed explanation about the disease-specific chapters. The Commission also agreed 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 intention to continue working on the User’s Guide.

The Code Commission encouraged WOAHA Members to read the User’s Guide as it provides useful information when implementing WOAHA standards.

The revised User’s Guide is presented as [Annex 24](#) for comments.

EU comment

The EU thanks the Code Commission for revising the guide. The EU supports the proposed changes and a comment is provided in Annex 24.

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

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, after consideration of a discussion-paper on objectives, scopes and concepts to be covered in a new draft chapter, 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 at their February 2023 meetings.

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 proposed content was appropriate and requested that the *ad hoc* Group be reconvened to continue its work to develop a draft chapter and to revise current Glossary definitions for 'biosecurity' and 'biosecurity plan' and propose a new definition for 'swill', taking into consideration the feedback from both the Code Commission and the Scientific Commission.

The *ad hoc* Group met in May 2023.

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 considered the *ad hoc* Group's report and commended the *ad hoc* Group for its work.

The Code Commission reviewed the draft Chapter 4.X. and the proposed revision of current Glossary definitions for 'biosecurity' and 'biosecurity plan' a new definition for 'swill' taking into consideration the feedback from the Scientific Commission.

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

Biosecurity

The Code Commission considered the proposed amendments. It agreed to add 'behavioural' to include the human behaviour component into the definition due to its relevance while implementing biosecurity. It agreed to replace 'animal diseases, infections or infestations' with 'pathogenic agents' as it was more accurate terminology in this context. It also agreed to reorder the preposition 'to, within and from' in the order of the nouns to which they correspond to improve syntax. It agreed to delete the term 'animal' in front of 'population' as the Glossary definition of 'population' implicitly refers to 'animal' already.

Biosecurity plan

The Code Commission considered the proposed amendments and made additional changes. It agreed to replace 'plan' with 'document or series of documents' to describe more clearly what a plan is. It agreed

to add the term 'establishment' to align with the Glossary definition of 'biosecurity'. To improve clarity, it added 'and factors' after 'potential pathways' as whilst 'pathways' play an important role in the introduction and spread of pathogenic agents, it is the 'factors' rather than the 'pathways' themselves that enable the establishment of a pathogenic agent. Therefore, it is important to consider both 'pathways and factors' when developing a biosecurity plan. The Commission agreed to add the concept of mechanisms to evaluate the performance of the biosecurity plan and its update as part of the definition.

Swill

The Code Commission discussed at length the proposed new definition for 'swill' taking into account the opinion from the Scientific Commission. To align with the proposed new Glossary definition for 'animal products', the Code Commission grouped the terms 'meat', 'meat products', 'animal by-products' and 'other animal products' under one term 'animal products' to define 'swill' and, considering a comment from the Scientific Commission, agreed to add 'which may be used as feed' to emphasise that 'swill' may be fed to animals as opposed to 'food scraps' that are typically discarded.

The Code Commission considered options to translate the term 'swill' into Spanish such as 'desechos' and 'desperdicios', and into French such as 'eaux grasses' and encouraged Members to propose the most appropriate term to be used in Spanish and French versions of the *Terrestrial Code*.

b) Draft new Chapter 4.X. Biosecurity

The Code Commission considered the text of the new draft Chapter 4.X. considering the feedback from the Scientific Commission. It made changes to address the Scientific Commission's suggestions, where relevant, and to ensure consistency in style and language with other chapters of the *Terrestrial Code*. The Code Commission substituted the positions of draft Article 4.X.10. and draft Article 4.X.11. as it considered this provided a more logical flow to first address training and awareness before evaluation.

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

The draft new Chapter 4.X. Biosecurity and the revised Glossary definitions of 'biosecurity' and 'biosecurity plan' and new definition of 'swill', are presented as [Annex 26](#) and as part of [Annex 25](#), respectively, and are circulated for comments.

EU comment

The EU in general supports the changes to the glossary and this new chapter. However, it invites the Code Commission to revise it completely. In particular, the way how the Veterinary Authority is involved in biosecurity activities should be reviewed. Specific comments are provided in Annexes 25 and 26.

6.3. 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 given that some of the chapters in this section required updating to better support Members in managing the risks of introduction of diseases through the importation of commodities.

At its September 2021 meeting, the Code Commission reviewed the current chapters of Section 5 and agreed that the revision of Chapters 5.4. to 5.7. should be given priority. The Commission also discussed the scope of the revisions and requested that the Secretariat further develop the scope of this work.

At its February 2022 meeting, the Code Commission requested that an *ad hoc* Group be convened to progress this work and discussed 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. The Commission requested that all relevant comments be provided to the *ad hoc* Group for its consideration. The first meeting of the *ad hoc* Group was convened in November 2022 to propose an approach for the revised chapters, including the main structure, title and scope for each chapter.

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 exit of the exporting country)', 'transit' and 'importation (from arrival 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). The Commission also provided feedback on the proposed structure for each new chapter and the proposed revision of some Glossary definitions. The second meeting of the *ad hoc* Group was convened in June 2023 to draft the revised chapters.

Discussion

The Code Commission considered the *ad hoc* Group report and the new draft Chapter 5.4. Measures and procedures applicable in the exportation of commodities, the new draft Chapter 5.6. Measures and procedures applicable in the importation of commodities, the new Glossary definition for 'point of exit' and revised Glossary definitions for 'border post' and 'quarantine station'.

The Code Commission was informed that the *ad hoc* Group also started preparations to draft a new Chapter 5.5. Measures and procedures applicable in the transit of commodities and a new Chapter 5.7. Facilities, but, due to time limitations, could not finalise these two chapters. The *ad hoc* Group is scheduled to meet in November 2023 to progress this work and will submit its report for the consideration of the Code Commission's February 2024 meeting.

The Code Commission commended the *ad hoc* Group for its comprehensive work and encouraged Members to read [the report](#) in conjunction with the new draft chapters and revised glossary definitions.

The Code Commission noted that, when drafting the chapters, the *ad hoc* Group considered the new Glossary definitions for 'animal products' and 'germinal products' and a revised Glossary definition for 'commodity' that were circulated for comments in the Commission's February 2023 report. The Commission also noted that, given that the current Glossary definitions for 'container' and 'vehicles/vessels' are defined only in the context of transportation of animals, the *ad hoc* Group proposed that the Commission consider revising these definitions to include other commodities, and noted that it had drafted the chapters based on this proposal.

The Code Commission made some additional amendments to the draft Chapters 5.4. and 5.6. to improve clarity and ensure the chapter is within the remit of the Veterinary Authority or Competent Authorities and aligned with other chapters of the *Terrestrial Code*, where relevant.

The Code Commission agreed with the revised Glossary definitions for 'border post' and 'quarantine station' and the new Glossary definition for 'point of exit' that were drafted by the *ad hoc* Group. The Commission explained that, once the revised definitions, have been adopted, the terms (i.e. 'border post' and 'quarantine station') will be replaced with the revised ones (i.e. 'border inspection post' and 'quarantine centre') throughout the *Terrestrial Code*.

The new Chapters 5.4. Measures and procedures applicable in the exportation of commodities, and 5.6. Measures and procedures applicable in the importation of commodities, are presented as [Annex 27](#) and [Annex 28](#), respectively, for comments.

EU comment

The EU in general supports the proposed new chapters.

Specific comments are provided in Annexes 28 and 29.

The revised Glossary definitions of 'border post', 'container', 'quarantine station' and 'vehicle/vessels' and the new Glossary definition for 'point of exit' are presented as part of [Annex 25](#) for comments.

EU comment

The EU in general supports the proposed changes to the glossary. Comments are provided in Annex 25.

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

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 WOAHA 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 so 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.

Discussion

The Commission considered the revised draft text proposed to address the 'five domains' concept and agreed to include new text in point 2 of Article 7.1.2.

The Commission also made a number of amendments throughout the chapter to improve readability and clarity including Article 7.1.1., to emphasise the importance of providing positive experiences to animals to achieve a good welfare state, and to address the terms 'animal-based', 'resource-based' and 'management-based measures' in Article 7.1.4.

The revised Chapter 7.1. Introduction to the recommendations on animal welfare, is presented as [Annex 29](#), for comments.

EU comment

The EU thanks WOAHA and welcomes the revision of this Chapter along the "five domains" approach. The EU would like to point to comments included in Annex 29.

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

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 (NVE). The Code Commission noted that the case definition endorsed by the Scientific Commission describes NVE as an infection of horses, pigs, dogs, and cats (animal hosts), while NVE is listed in Chapter 1.3. as a swine disease. 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 the single-article chapter. The Code Commission highlighted that if a change was considered for either in pathogenic agents or in its hosts, that this should be done through an assessment against the listing criteria in accordance with Chapter 1.2.

In February 2023, the Biological Standards Commission and the Scientific Commission were informed of the Code Commission's opinion and the potential conflict concerning the susceptible animal species in the case definition with the *Terrestrial Manual* Chapter 3.1.15. Nipah and Hendra virus disease, that was adopted in May 2022. In the Scientific Commission's endorsed case definition, it was proposed that NVE be defined as infection of horses, pigs, dogs, and cats with Nipah virus. However, the recently adopted *Terrestrial Manual* Chapter 3.1.15. indicated that companion animals (i.e., dogs and cats) do not seem to play a role in the epidemiology of the disease. The Biological Standards Commission noted the significant role of horses in the epidemiology of NVE and the uncertainty about the role of dogs and cats, and proposed an amendment to Chapter 3.1.15. to clarify the uncertainty with regards to the significance of dogs and cats in the epidemiology of NVE. Correspondingly, the Scientific Commission amended the draft case definition to delete dogs and cats and limit the scope of susceptible animal species to pigs and horses.

Discussion

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 agreed to include an option on 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. (See item 3.2 of this report.)

The Commission agreed to amend the name of the listed disease in Chapter 1.3. 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). The Commission agreed to propose these amendments to Chapter 1.3. closer to the adoption of the new draft Chapter 8.Y.

The new Chapter 8.Y. Infection with Nipah virus, is presented as [Annex 30](#) for comments.

EU comment

The EU in general supports the proposed new chapter provided the comments in Annex 30 are considered.

6.6. New Chapter 14.8. Scrapie and use of terms 'greaves'

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 therefore it needed to progress this work. The Commission requested the Secretariat to collate all pending issues and to report back to the Commission so it could consider a way forward.

At its September 2021 meeting, the Code Commission reviewed the 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. The Code Commission agreed that this assessment should be done before starting any work on Chapter 14.8. The Commission requested that an assessment be presented to the WOAHH DDG ISS in line with the Standard Operating Procedure for listing decisions for pathogenic agents of terrestrial animals.

In February 2022, the Secretariat informed the Code Commission that the WOAHH 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 change the priority level to 'priority 2'. Noting that the Members requested that, as part of the update, live animal testing and testing for genetic resistance to scrapie be included as valid methods for ensuring the safe trade of sheep and goats, the Commission requested the Secretariat to prepare a document summarising whether the corresponding Chapter 3.8.11. Scrapie of the *Terrestrial Manual* provides sufficient information for such testing.

Discussion

a) Revision of Chapter 14.8. Scrapie

The Code Commission considered a discussion paper prepared by the Secretariat and noted that Chapter 3.8.11. Scrapie of the *Terrestrial Manual* provided information on genetic resistance to scrapie and on genetic screening for resistance.

Reviewing the description on genetic resistance, the Commission noted that the *Terrestrial Manual* chapter describes the validity of genetic screening for resistance to classical scrapie mainly in sheep, i.e., selection of breeding stock based on the most scrapie-resistant animals with appropriate *PrP* genotypes produces progeny with reduced risk of developing disease. However, recalling that some Members had requested to consider testing for genetic resistance as valid methods for ensuring the safe trade of sheep and goats, and their germinal products, the Commission requested that the Biological Standards Commission be asked to consider adding more information on the genetic resistance and its testing in the *Terrestrial Manual*. This information would help revising articles on provisions for animal health status or articles on recommendations for safe trade of certain commodities in the Code Chapter 14.8. The Code Commission noted that there was no precedent of providing such recommendations that take into account genetic resistance of animal hosts to a disease in the *Terrestrial Code*, and that it would need in-depth specific discussions, including with the Scientific Commission, the Biological Standards Commission and relevant experts, when drafting the revised chapter.

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 Secretariat develop a plan to undertake the revision of the chapter, including Terms of Reference for an *ad hoc* Group.

b) Use of term 'greaves'

The Code Commission noted that the term 'greaves' was only used in Chapter 14.8., reviewed the use of the term in the chapter and noted it was principally next to the term 'protein meal'. 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.

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 it now for comments, only with the amendment to remove 'greaves'.

The current Chapter 14.8. is presented as **Annex 31** for comments.

EU comment

The EU in general supports the proposed changes to this chapter as regards “greaves” and, at the same time, proposes several comments on the chapter in Annex 31.

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

EU comment

The EU supports the proposed change.

7. Updates on WOAAH initiatives relevant to the Code Commission

7.1. Animal health forum and General Session technical item - HPAI

The Commission was updated on the first Animal Health Forum (AHF) fully dedicated to avian influenza, which was organised during WOAAH's recent 90th General Session. In light of the ongoing global avian influenza crisis, the Technical Item titled 'Strategic Challenges in the Global Control of High Pathogenicity Avian Influenza' set the stage for the forum, and WOAAH Members adopted a Resolution which will serve as basis for shaping future avian influenza control activities. The Resolution underscores the importance of Members respecting and implementing WOAAH international standards to effectively combat avian influenza.

The Commission was updated on the progress of updating the GF-TADS avian influenza global strategy. The strategy is expected to be a short high-level document presenting the background, objectives, theory of change and the governance that rely on strong involvement at regional level. The strategy's purpose is to guide and create a global coordination framework to support regional and country action plans dedicated to the prevention and control of HPAI.

The Commission was updated on the WOAAH avian influenza framework that is being developed to implement Resolution No. 28 adopted at the 90th General Session. The framework defines the activities, outputs and expected outcomes for the next two years to address the strategic challenges in the global control of HPI that were discussed during the 90th WOAAH General Session. This framework has been developed in consultation with the WOAAH scientific network, the technical departments at WOAAH Headquarters and WOAAH Regional and Sub-regional representations.

Finally, the Commission was informed that the WOAAH Working Group on Wildlife at its June 2023 meeting, prepared a brief statement on considerations associated with emergency vaccination of high conservation value species against avian influenza, in response to the global concern regarding avian influenza and its potential impact on wildlife. The Commission was also informed that the Working Group noted that the current *Terrestrial Code* chapter of avian influenza provides recommendations on surveillance and reporting of HPAI in wild birds but not on wild mammals. The Working Group discussed the available guidance on response to HPAI outbreaks in marine mammals and proposed next steps to draft a practical guide for field response to HPAI outbreaks in marine mammals, with a focus on biosecurity and sample collection and carcass disposal with the assistance of the WOAAH Collaborating Centre Health of marine mammals.

The Commission commended the various activities presented to address the current global avian influenza crisis and supported the outcomes of the AHF and the adopted Resolution.

The Commission acknowledged the Working Group's discussion on *Terrestrial Code* chapter on avian influenza and noted that the Chapter 10.4. focuses on High pathogenicity avian influenza in poultry with the objective to mitigate animal and public health risks, and that the provisions in the chapter serve that purpose. The Commission was aware of the reported HPAI outbreaks in terrestrial and marine mammals and noted that further clarification would be needed on the epidemiological role of such animals for this disease before considering needs to amend the *Terrestrial Code*. The Commission noted that the Biological Standards Commission planned to review the *Terrestrial Manual* chapter on avian influenza and reminded that if at a given point, a change in the *Terrestrial Code* is to be discussed because of an update in the *Terrestrial Manual*, a request should be submitted to be considered for inclusion in the Code Commission's work programme.

7.2. WOAHS Observatory

The WOAHS Observatory provided an update on the state of play of the programme and made a summary of the main developments since the February 2023 Code Commission meeting. The Commission was informed that the deliverables of the WOAHS Observatory will now comprise:

- **Dashboards:** The Observatory indicators will be monitored on an annual basis, and the dashboards will be updated annually as well. The publication of the complete annual report will be discontinued.
- **Comprehensive monitoring report:** A full report will now be issued every five years. This timeline will allow this report to also provide insights into specific aspects of WOAHS's strategic plans.
- **Observatory report for the Specialist Commissions:** A short report will be made available every three years. These reports will aid the newly elected Specialist Commissions in producing their work plans.
- **Thematic studies:** One to two thematic studies will be conducted each year, depending on the workload and the needs. The outcomes of these studies will be published in reports and/or dashboards and/or other types of deliverables depending on the topic.

The Observatory informed the Commission on the progress of the thematic studies on the implementation of WOAHS Standards on animal welfare during transport and on zoning and compartmentalisation. The Commission thanked the Observatory for the update and noted that the information, these studies will provide on the level of implementation of standards, as well as on the challenges faced by Members to implement them, will be of great value to assist its work to review the relevant standards, some of which are already included in its work programme.

The Observatory also sought guidance from the Commission on the content of the Observatory reports for the Specialist Commissions which would be presented for every new Commission term, to inform the development of their work programme. The Code Commission highlighted that it would expect such reports should provide consolidated information on the implementation of Standards and the challenges or barriers for Members to put them into practice. The Commission stressed that this will be an important new element to support its exchanges with Members on the development and prioritisation of the work programme.

7.3. Global Burden of Animal Diseases (GBADs)

The Code Commission was provided with an update on the progress of the programme since the February 2023 Code Commission meeting. The Secretariat provided a report on key milestones reached on the scientific validation of the GBADs approach, demonstration of GBADs utility in Ethiopia, and refinement of the GBADs knowledge engine prototype. Focus has been on: (i) enhancing GBADs dataflows and analytics, (ii) strengthening the logical flows between different methods, (iii) completing early estimations of disease burden in Ethiopia, (iv) submitting papers to peer-reviewed journals, (v) generating and

improving dashboards, and (vi) meeting key information dissemination milestones. In the coming months, the work plan will centre on the second external independent assessment of the GBADs approach, ensuring global acceptance of the work, documenting GBADs methods, and securing funding for the next phase of the GBADs programme to ensure the sustainability of the programme. The report also included additional WOAAH activities relating to the economics of animal health, such as the economics of anti-microbial use and resistance.

The Commission thanked the Secretariat for the information presented and expressed appreciation for the programme outcomes.

7.4. WOAAH Global Animal Welfare Strategy

Background

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

Discussion

The Secretariat provided an update of relevant activities of the GAWS work plan, including the next Global Animal Welfare Forum 'Developing national animal welfare legislation; different paths for the same destination' which will take place at WOAAH Headquarters on 2–3 November 2023 and aims to provide a forum to discuss technical and regulatory aspects of the development of national animal welfare legislation based on relevant WOAAH Standards to support Members in ensuring good governance to achieve good animal welfare. The Secretariat reported that approximately 50 participants will be invited including selected Delegates and Focal Points from each region, Regional Commission Presidents, representatives from AW Collaborating Centres and International Organisations with collaboration agreements. The Commission noted this update.

7.5. Terrestrial Code data standardisation

7.5.1. Framework for disease-specific chapters of the *Terrestrial Code*

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.

In September 2021, the Commission and the Secretariat initiated the work on the Framework for disease-specific chapters of the *Terrestrial Code* that would define key articles, describe the information to be considered for inclusion in each article, and the format.

The objective of the framework is to have a document that outlines the format and content of a disease-specific chapter that can serve as a reference for those undertaking work on the development of new or revised disease-specific chapters to ensure harmonisation amongst chapters. This work will contribute to the development of consistent and sustainable disease-specific chapters in the *Terrestrial Code*.

The Secretariat developed a draft framework for a disease-specific chapter, which has been reviewed by the Code Commission and the Scientific Commission.

Discussion

The Code Commission was updated that, after its February 2023 meeting, the Secretariat together with the appointed members of the Code Commission, continued to work on the draft to improve the document. The objectives of the new format are to provide 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 WOAHS Standards, and conventions regarding the use of terms, wording and structure.

The Code Commission acknowledged this excellent initiative and agreed 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 may help Members gain a better understanding of disease-specific chapters in the *Terrestrial Code*, and proposed that the framework be provided to Members, for information only, once it is finalised.

The Code Commission agreed to work to finalise the framework by its February 2024 meeting and requested that it be shared with the Scientific Commission and the Biological Standards Commission in February 2024, for information. Moreover, the Code Commission requested the Secretariat to use the Framework in upcoming disease-specific chapter revisions and provide feedback.

7.5.2. Commodities

Background

At its February 2023 meeting, the Code Commission noted an update from the Secretariat on the development of internal processes to manage commodities' names and their listing as safe commodities in *Terrestrial Code* chapters, following the SOP agreed at its September 2021 meeting.

The Commission nominated members from the Commission to work with the Secretariat to progress work to develop a consolidated approach to managing commodities' names. There were five virtual meetings since the February 2023 meeting, and the nominated Commission members reviewed all the existing terminology and identified standardised rules for naming the commodities.

Discussion

The Code Commission considered the proposal from the Secretariat and appointed Commission members for a set of rules and a categorised tree, considering the Harmonized Commodity Description and Coding System (generally referred to as 'Harmonized System' or simply 'HS') developed by the World Customs Organization (WCO), to achieve consistency in the naming of commodities in the context of the WOAHS internal SOP.

The Commission agreed with the proposal and highlighted the importance of implementing the SOP when developing or reviewing *Terrestrial Code* chapters to ensure consistency across the *Terrestrial Code*. The Commission 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.

In light of this work and other discussions at this and recent meetings, the Code Commission noted that there was a need to consider some commodity groups 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.

7.6. WOAH Standards online navigation tool

The WOAH Standards Department informed the Commission of the project to develop a new WOAH Standards Online Navigation Tool. This project is aimed at improving how WOAH Standards are displayed and made available to Members and other users. The project will enhance the display of the *Aquatic Code*, *Terrestrial Code*, *Aquatic Manual* and *Terrestrial Manual* on the WOAH website. The project will also include a specific tool aimed at providing specific search functions for the visualisation of sanitary measures recommended for the international trade of commodities for terrestrial animals. The tool is also expected to simplify the annual updating process of the content of the Standards.

The project is aligned with the goals of the 7th Strategic Plan and will provide significant benefits for WOAH Members, including enhanced accessibility to WOAH Standards and efficiency in information retrieval, supporting the implementation of WOAH Standards. The project will also bring benefits to the Organisation itself, by improving the efficiency of internal processes and the interoperability across various datasets related to WOAH Standards.

The Commission expressed interest and support for the project and recognised the importance of facilitating Members' access to achieve better understanding and use of WOAH Standards.

7.7. Emergency management

The WOAH Preparedness and Resilience Department informed the Commission on the WOAH emergency management programme, under which several activities have been conducted, including the development of guidance for Members such as on simulation exercises and animal welfare during disasters.

The Commission was informed that recommendations for WOAH to develop standards in emergency management were proposed in the 2022 General Session Technical Item 'Organisation for Animal Health, Veterinary Services and Aquatic Animal Health Services engagement in global, regional, and national emergency management systems' and adopted in the associated Resolution (No. 28). Furthermore, in April 2023, WOAH hosted a Global Conference on Emergency Management which rallied support of WOAH's Membership and stakeholders to further strengthen emergency management capacities of Veterinary Services.

In this context, the Commission discussed the proposal to develop standards on emergency management in the *Terrestrial Code*. Considering the increasingly complex risk landscape these would support the evolving needs of Veterinary Services and address gaps in the existing standards.

The Code Commission acknowledged that there were some references to emergency management in the *Terrestrial Code*, such as in Chapter 3.2. on the Quality of Veterinary Services and Chapter 4.19. on Official control programmes for listed and emerging diseases. The Code Commission also noted that the two emergency management critical competencies of WOAH's Performance of Veterinary Services (PVS) Evaluation were not well supported by current *Terrestrial Code* chapters when compared to other critical competencies.

The Code Commission noted the importance of the topic, and given the broad scope, agreed to include in its work programme a new horizontal work item to improve how 'emergency management' is addressed in the *Terrestrial Code*, which could include both the revision of existing content and the development of new one. The Commission requested the Secretariat to further scope the work and to prepare a

discussion paper on the objectives, scope and proposed approach for the work, including draft Terms of Reference for a potential *ad hoc* Group to be presented at the next Commission meeting.

7.8. Community Animal Health Workers (CAHW)

The WOAHA Capacity Building Department provided the Code Commission with an update on WOAHA activities in the context of the current, ongoing project, 'Strengthening the enabling environment for community animal health workers (CAHWs) through development of competency and curricula guidelines. The Secretariat reminded that CAHWs were identified as a category of Veterinary Paraprofessionals in 2003 by the *ad hoc* Group on the Role of Private Veterinarians and Veterinary Paraprofessionals (VPPs) in the Provision of Animal Health Services and also that WAHIS has been collecting data from Members on numbers of CAHWs along with numbers of veterinarians and VPPs for their annual reports for a number of years.

The Commission was also informed that the development of competency and curriculum guidelines for CAHWs, as a continuation of earlier activities that resulted in the publication of competency (2012) and curriculum (2013) guidelines for veterinarians and competency (2018) and curriculum (2019) guidelines for VPPs. The objective of these activities is to develop guidance for educators and trainers to ensure that veterinary personnel are trained to possess specific competencies that enable them to participate effectively in the national Veterinary Services to implement WOAHA standards. The Secretariat pointed out that in certain regions, notably Africa, South Asia and Southeast Asia, CAHWs are present in considerable numbers and may provide basic clinical services and support national animal disease reporting and surveillance activities though the regulatory and educational frameworks under which they operate are highly inconsistent. Therefore, the development of CAHW competency and curricular guidelines under the current project is intended to support two important objectives. First, to establish criteria for creating quality and consistency in the training of CAHWs and second, to provide veterinary statutory bodies with a framework for recognizing the training and qualifications of CAHWs for potential registration.

The Secretariat shared the current working definition of CAHWs which was developed for use with the current CAHW *ad hoc* Group, and a discussion ensued on the definition and various aspects of its content. The Commission provided feedback on the information presented and welcomed the progress of the project and the continuity with previous activities in which the Commission had been involved. The Commission acknowledged the role CAHWs play in practice and recognised the importance of promoting the quality and consistency of their training as a critical step in formalising their involvement within the national regulatory frameworks.

7.9. Editorial Board of the Scientific and Technical Review

The Head of the WOAHA Publications Unit explained why a new Editorial Board was being established for WOAHA's peer reviewed journal, the Scientific and Technical Review. Although the content is of high quality and robust editorial and reviewing processes are in place, the publication lacks governance to ensure its scientific credibility.

The Editorial Board will monitor and foster the quality and impact of the Scientific and Technical Review and will also advise on WOAHA's overall publications strategy on request. The role of the Board will be mainly advisory, but it will also participate in reviewing content occasionally and will attend two meetings per year.

The Code Commission was asked to nominate a candidate for the Editorial Board who could commit to the role. Given that the mandate of the current Commission will end in May 2024, the term of the first nominated candidate will run until September 2024.

The Code Commission agreed that the creation of a new Editorial Board would be a positive step forward for WOAHA's publications and agreed to share a member nomination from the Commission with the

Secretariat. They also suggested that it might be useful to consider asking an expert external to WOAHS to join the Editorial Board.

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. Update on Codex's works

The Secretariat updated the Code Commission on relevant Codex Alimentarius work during the past year (from September 2022 to August 2023).

The Code Commission acknowledged that the Codex Committee of Food Labelling (CCFL) had considered a discussion paper on sustainability labelling claims and had agreed to establish an electronic working group to discuss the matter more thoroughly. The Commission requested that the Secretariat provide an update on the progress of this work, in particular on the possible inclusion of animal welfare labelling in the Codex guidelines, at its future meeting.

The Code Commission noted that the Codex Committee on Food Hygiene would consider a discussion paper on the possible revision of the existing Guidelines for the Control of *Campylobacter* and *Salmonella* in Chicken Meat (CXG 78-2011) at its next March 2024 meeting. The Commission noted that these guidelines include many references to Chapters 6.5. and 6.6. of the *Terrestrial Code*, and requested the Secretariat to promote good coordination with this work and provide an update on the progress at its future meeting.

The Code Commission noted that the Codex Committee on Food Import and Export Inspection and Certification Systems had agreed to forward the proposed draft guidelines on recognition and maintenance of equivalence of national food control systems to the Codex Alimentarius Commission for adoption in November 2023. The Commission also noted that CCFICS had agreed to forward a project document on the revision of 'Principles for traceability/product tracing as a tool within a food inspection and certification (CXG 60-2006)' to the Codex Alimentarius Commission for approval as new work in November 2023. The Commission emphasised that it is critical to ensure this work takes into consideration many existing WOAHS Standards, as relevant. The Commission noted in particular *Terrestrial Code* Chapters 4.1., 4.2., 4.3., 5.1., 5.2. and 5.3., and requested the Secretariat assess the coordination needs between the two organisations and provide an update on the progress of this work at its future meeting.

Finally, the Code Commission requested that the Secretariat work with the Codex Secretariat to ensure that all references to WOAHS Standards in 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) are updated, following the adoption of an updated Chapter 3.1.22. Trichinellosis (Infection with *Trichinella* spp.) of the *Terrestrial Manual* at the 90th General Session in May 2023 (see point 5.9 of this report).

8.2. Update on collaboration with International Air Transport Association (IATA)

Background

WOAHS has been a member of the International Air Transport Association (IATA) Live Animal and Perishable Board (LAPB) since 2006 and has had a Collaboration Agreement with IATA since 2008. WOAHS has been actively engaged with IATA for the past 17 years.

The *Terrestrial Code* Chapter 7.4. 'Transport of animals by air' and the IATA Live Animal Regulations (LAR) Chapter 10 share similar content, and both organisations cross-reference their text to one another. However, the process and frequency of revision of the two texts differ and the alignment is not always ensured.

Discussion

The Secretariat informed the Commission that during the 56th meeting of the LAPB board, WOH provided an update on the status of the revision of the three WOH transport chapters. The Secretariat met several times with the Special Cargo Operations, Safety and Security team of IATA to exchange views on the options to collaborate during the revision of the WOH Chapter 7.4. Transport of animals by air, to which IATA committed to contribute.

The Commission noted that the ongoing revision of Chapters 5.4. to 5.7. of the *Terrestrial Code* (see item 4.1.5. of this report) may be of interest for IATA and requested the Secretariat to inform them of this work.

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

Background

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

At its February 2023 meeting, the Code Commission was updated on the work of IETS, particularly on the developments in the technologies and use of *in-vitro*-produced embryos, as well as its relevance in the context of international trade. The Commission discussed the potential to update the *Terrestrial Code* to address the development of recommendations on disease risk mitigation measures for *in-vitro*-produced embryos but recognised that there was still not sufficient standardisation of the practices nor consolidated data on *in-vitro* produced embryos and agreed to follow the progress of these technologies and to consider developing new standards or revising existing standards when sufficiently standardised references were available.

The Commission also noted that the updated 5th edition of the IETS Manual had recently been made commercially available including several changes and requested the Secretariat to liaise with IETS to consider potential needs to amend to current *Terrestrial Code* chapters as a consequence and report back at its next meeting.

Discussion

The Secretariat informed the Commission on an exchange with IETS representatives and presented a detail of the changes in the 5th edition of the IETS Manual compared to the 4th edition.

The Commission thanked IETS for the productive collaboration and noted that the latest version of IETS disease categorisation is presented in Appendix B of the 4th Edition of the IETS Manual, not in the 5th edition and that amendments to the categorisation are still being discussed.

The Commission noted that there are some differences between the disease categorisation in the 4th Edition of the IETS Manual and that used in Article 4.8.14. of the *Terrestrial Code*, nevertheless, noting that the IETS categorisation is under discussion and that the integral revision of Chapter 4.8 of the *Terrestrial Code* is already included in the Commission's work programme, the Commission agreed not to amend the *Terrestrial Code* at this stage and to address this topic as part of the future revision, taking into account the need to avoid plain cross references to texts that are not considered International Standards.

8.4. Update on collaboration with International Horse Sports Confederation (IHSC)

The WOAHS Status Department updated the Code Commission on the collaboration between WOAHS and the International Horse Sports Confederation (IHSC), an organisation that gathers the Fédération Equestre Internationale (FEI), and the International Federation of Horseracing Authorities (IFHA). The Commission was informed on the activities undertaken since the first cooperation agreement, in 2013, which has included the development and revision of WOAHS Standards to facilitate the safe movement of competition horses, as well as supporting the implementation of WOAHS Standards through mechanisms such as the High Health High Performance framework (HHP) and the equine disease-free zones (EDFZ).

The Code Commission noted the wide portfolio of past and current activities and thanked the IHSC for productive collaboration in the development and revision of WOAHS Standards, particularly in the recent updates of *Terrestrial Code* chapters on horse disease adopted at the last General Session, which have included for the first time special provision for the temporary movement of horses, aiming to facilitate the international movement of competition horses. The Commission highlighted the ongoing work of the WOAHS-IHSC Technical Committee concerning the compilation and analysis of information on veterinary certificates and requirements to move horses internationally and noted that this work could provide valuable information to progress some other items in the Code Commission's work programme, such as the revision of Chapter 5.12. Model passport for international movement of competition horses.

The Commission requested the Secretariat to provide an update on the progress of these projects in future meetings and to collaborate with the WOAHS-IHSC Technical Committee in scoping the future work of the revision of Chapter 5.12. based on the information gathered.

8.5. Update on collaboration with Secretariat of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

The Secretariat updated the Code Commission on the collaboration with the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), an international treaty of 184 Parties, with the objective that international trade in specimens of wild animals and plants does not threaten the survival of the species. The Secretariat informed the Commission that CITES and WOAHS formalised their collaboration in 2015, and the agreement is being revised to address the new needs of CITES Parties and WOAHS Member States. The Secretariat noted that the proposed updated MOU provides for collaboration on animal health and welfare standards, guidelines for safe legal international trade and transport of wild animals, and safe and fast transport of biological samples from wild animals for diagnosis or identification.

The Commission highlighted the complementary mandates and common goals of both organisations and emphasised the importance of strengthening this collaboration to achieve an efficient management of risks and impacts of international trade of wildlife. The Commission agreed on the importance of promoting the collaboration of Veterinary Services and CITES Management Authorities at the national level to ensure effective coordination in the implementation of sanitary measures in line with WOAHS Standards and the issuance of CITES permits, as well as on the close collaboration and information exchange during import controls.

The Code Commission noted the ongoing work undertaken in collaboration with the WOAHS Working Group on Wildlife to consider how to better address wildlife in the *Terrestrial Code* (see item 4.2.1 of this report) and expressed interest in further considering proposals for their work programme to contribute to improving the practical coordination of WOAHS and CITES mechanisms.

8.6. Collaboration with private sector/industry organisations

The Secretariat informed the Code Commission of an analysis undertaken on the participation of international organisations representing the private sector or industry sectors in the Code Commission's activities. The Commission was updated on which of the agreements held by WOAAH with other International Organisations included collaboration in standards setting, as well as on which of these organisations had provided comments to the Code Commission reports during the past ten years (2013–2023).

The Commission reminded that International Organisations with a cooperation agreement with WOAAH play a role in the standards-setting process, as they can comment on Specialist Commission reports and can make an intervention (not vote) at a General Session.

Based on a proposal developed by the Secretariat, the Commission discussed the added value these organisations bring to the work of the Commission. The Commission acknowledged the importance for these organisations to follow the WOAAH standards-setting activities and noted that they can submit proposals for the development or revision of WOAAH Standards, they can provide comments on ongoing work, with a special focus on the suitability of the proposed standards regarding production practices and industry processes, which is critical for their practical implementation; and that they should also promote awareness and engagement of national organizations in discussions with WOAAH Delegates at national level to promote their participation in the standards-setting process, as well as to promote the implementation of WOAAH Standards.

Additionally, the Commission agreed that international organisations representing the private sector or industry provide important support to the work of the Code Commission through the Secretariat by providing information on relevant practices and industrial processes from a global perspective, beyond differences in national regulatory frameworks; they contribute with additional expertise from their own technical bodies or experts' network; and, they provide references to other relevant standards, particularly about industry practices. The Commission highlighted that these contributions have been particularly valuable in discussions around the definition of processed commodities and the specific mechanisms involved in their production (key for the assessment of 'safe commodities').

The Commissions encouraged the Secretariat and partner organisations to actively engage in fostering an active communication, to promote proactive and sustainable participation in WOAAH standards-setting activities.

../Annexes

Annex 1. Adopted Agenda

MEETING OF THE WOAHP TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 5 to 14 September 2023

1. **Welcome**
 - 1.1. Deputy Director General
 - 1.2. Director General
2. **Adoption of agenda**
3. **Cooperation with other Specialist Commissions**
 - 3.1. Scientific Commission for Animal Diseases
 - 3.1.1. Listing assessment SOP
 - 3.1.1.1. Step 2-2
 - 3.1.2. Emerging diseases SOP
 - 3.1.3. Susceptibility of racing pigeons to high pathogenicity avian influenza
 - 3.1.4. Epidemiological significance of susceptible animals
 - 3.2. Biological Standards Commission
 - 3.2.1. Biological Standards Commission's recommendations to the *Terrestrial Code*
 - 3.3. Aquatic Animals Commission
4. **Code Commission's work programme not including texts proposed for comments or adoption**
 - 4.1. **Ongoing work items (not in order of priority)**
 - 4.1.1. Wildlife health (Coordination with Wildlife Working Group)
 - 4.1.2. Revision of Chapter 4.4. Zoning and compartmentalisation
 - 4.1.3. Revision of Chapter 4.7. Collection and processing of bovine, small ruminant and porcine semen
 - 4.1.4. New chapter on biosecurity (Chapter 4.X.)
 - 4.1.5. Revision of Chapters 5.4. to 5.7.
 - 4.1.6. Revision of Chapter 7.1. Introduction to the recommendations on animal welfare ('Five domains' concept, use of terms 'animal-based measures' and 'measurables')
 - 4.1.7. Revision of Chapter 7.4. Transport of animals by air
 - 4.1.8. Revision of Chapter 7.6. Killing of animals for disease control purposes
 - 4.1.9. Revision of Chapter 10.5. Infection with *Mycoplasma gallisepticum* (Avian mycoplasmosis)
 - 4.1.10. Revision of Chapter 12.3. Dourine
 - 4.1.11. Revision of chapters on equine encephalitis (Chapters 8.10. Japanese encephalitis, 12.4. Equine encephalitis (Eastern and Western) and 12.11. Venezuelan equine encephalomyelitis)
 - 4.1.12. Revision of Chapter 14.8. Scrapie and use of terms 'greaves'
 - 4.1.13. Revision of Chapter 15.1. Infection with African swine fever virus (addition of extruded dry pet food to safe commodities)
 - 4.2. **Items under consideration for inclusion in work programme**
 - 4.2.1. New Glossary definition for 'biological products'
 - 4.2.2. New Glossary definition for 'semen collection centre'
 - 4.2.3. Infection with Rift Valley fever virus (Chapter 8.16.) (recommendation from the Biological Standards Commission)

- 4.2.4. Infection with *Trichinella* spp. (Chapter 8.18.) (recommendation from the Biological Standards Commission)
 - 4.2.5. New chapter on Nipah virus encephalitis (Chapter 8.Y.)
 - 4.3. New proposals and requests for inclusion in work programme**
 - 4.3.1. Revision of User's guide
 - 4.3.2. Revision of Chapter 1.3.
 - 4.3.3. Revision of Glossary definition for 'poultry'
 - 4.3.4. Revision of Chapter 10.2. Avian infectious bronchitis
 - 4.4. Prioritisation of items in work programme**
 - 5. Follow-up of chapters recently adopted**
 - 5.1. Definition for 'suffering'
 - 6. Texts circulated for comments**
 - 6.1. In May 2023 General Session**
 - 6.1.1. Infection with foot and mouth disease virus (Chapter 8.8.) and Application for official recognition by WOAAH of free status for foot and mouth disease (Chapter 1.11.)
 - 6.2. In February 2023 meeting report**
 - 6.2.1. New Glossary definitions for 'animal products' and 'germinal products' and revision of Glossary definition for 'commodity'
 - 6.2.2. General hygiene in semen collection and processing centres (Chapter 4.6.)
 - 6.2.3. Slaughter of animals (Chapter 7.5.) and Glossary definitions for 'death', 'euthanasia', 'slaughter' and 'stunning'
 - 6.2.4. Infection with *Coxiella burnetii* (Q fever) (New Chapter 8.X.)
 - 6.2.5. Infection with *Trypanosoma evansi* (New Chapter 8.Z.)
 - 6.2.6. Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia) (Chapter 11.5.)
 - 6.2.7. Infection with bovine pestiviruses (bovine viral diarrhoea) (New Chapter 11.X.)
 - 6.2.8. Infection with African horse sickness virus (Chapter 12.1.) (with inputs from SCAD & advice from experts on safe commodities)
 - 6.2.9. Rabbit haemorrhagic disease (Chapter 13.2.)
 - 6.2.10. Infection with Camelpox virus (New Chapter 16.Z.)
 - 6.2.11. Terminology: Use of terms 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'
 - 6.3. Previously circulated**
 - 6.3.1. Responsible and prudent use of antimicrobial agents in veterinary medicine (Chapter 6.10.)
 - 7. Updates on WOAAH initiatives relevant to the Code Commission**
 - 7.1. Animal health forum and General Session technical item – HPAI
 - 7.2. WOAAH Global Animal welfare strategy
 - 7.3. *Terrestrial Code* data standardisation
 - 7.3.1. Framework for *Terrestrial Code* standards
 - 7.3.2. Commodities
 - 7.4. WOAAH standards navigation tool
 - 7.5. Emergency management
 - 7.6. Community Animal Health Workers (CAHW)
 - 7.7. WOAAH Observatory
 - 7.8. Global Burden of Animal Diseases (GBADs)
 - 7.9. Editorial Board of the Scientific and Technical Review
 - 7.10. Publication of Member comments
-

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

8.1. Update on Codex's works

8.2. Update on collaboration with International Air Transport Association (IATA)

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

8.4. Update on collaboration with Secretariat of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

8.5. Collaboration with private sector/industry organisations

8.6. Update on collaboration with International Horse Sports Confederation (IHSC)

9. Meeting review

10. Date of next meeting

Annex 2. List of Participants

MEETING OF THE WOAHP TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 5 to 14 September 2023

MEMBERS OF THE COMMISSION

Dr Etienne Bonbon

(President)
Seconded National Expert
European Commission,
Brussels,
BELGIUM

Dr Salah Hammami

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

Dr Gaston Maria Funes

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

Dr Bernardo Todeschini

(member)
Agricultural Attaché,
Ministry of Agriculture, Livestock
and Food Supply of Brazil
Brussels,
BELGIUM

Dr Kiyokazu Murai

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

**Dr Lucio Ignacio Carbajo
Goñi**

(member)
Veterinarian
Béjar (Salamanca)
SPAIN

WOAH HEADQUARTERS

Dr Gillian Mylrea

Head
Standards Department

Dr Francisco D'Alessio

Deputy Head
Standards Department

Dr Yukitake Okamura

Chargé de mission
Standards Department

Dr Leopoldo Stuardo

Chargé de Mission
Standards Department

Ms Elizabeth Marier

Chargée de mission
Standards Department

Dr Su Youn Park

Chargée de mission
Standards Department

© **World Organisation for Animal Health (WOAH), 2023**

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

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

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

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

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

EU comment

The EU commends the Code Commission for its continuous efforts to prioritise its heavy work programme, in coordination with other specialist commissions as relevant. We thank the Code Commission for having taken into consideration comments submitted previously. We fully support the revised work programme and its prioritisation.

In relation to the EU comments on the FMD Chapter, but in a more general manner for all diseases with an official status as recognised by WOAAH, the EU invites the Code Commission and the SCAD to prioritise their work in view of a simplification of the data to be provided by Member Countries for the annual reconfirmation of their official statuses. This should lead to a simplification of the questionnaires in the Terrestrial Code and, in turn, make the data requested by WOAAH Secretariat simpler to retrieve and submit for the national administrations.

Chapter	Issues	Summary of the work	Status - September 2023		Priority order *
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	
General	Wildlife Health	Overarching consideration on how wildlife animal health is addressed in the <i>Terrestrial</i>	Preliminary discussions	Noted in Feb 2023 TAHSC report	3
	New chapter on emergency management	Develop a new chapter	Preparatory work	Noted in Sep 2023 TAHSC report	3
	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	Preparatory work	Refer to Sep 2022 TASHC report	2

		commodities of chapters (when revised).			
		In Chapter 15.1. Infection with African swine fever virus	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 TASHC report (Sep 2023/1)	1
Use of terms	Use of terms: animal health status	<ul style="list-style-type: none"> - Consider the need to revise wording to incorporate 'herd', and avoid restrictive wording - Possible revision of the Glossary definition - Review use of the terms across the <i>Code</i> for consistency 	Preparatory work	Refer to Feb 2020 TAHSC report	3
	Use of terms: animal-based measures / measurables	Review use of the terms across the <i>Code</i> for consistency Develop a policy for their use	Preparatory work	Noted in Feb 2023 TAHSC report	2
	Use of terms: notify / notifiable disease / report / reportable disease	Review use of the terms across the <i>Code</i> 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 <i>Code</i> for consistency	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 TAHSC report (Feb 2023/2)	1
User's guide	Revision of the Users' guide (standing item)	Partial revision <ul style="list-style-type: none"> - to provide more explanation on disease-specific chapters - to develop a new point on terms referring to animals used in the <i>Terrestrial Code</i> 	Circulated for comments	Noted in Sep 2023 TAHSC report (Sep 2023/1)	1
Glossary	'Death', 'euthanasia', 'slaughter' and 'stunning'	In-depth revision in relation to work on Chs 7.5.-7.6.	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 TAHSC report (Sep 2019/4)	1

	'Artificial insemination centre'	Change the term to 'semen collection centre'	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 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 <i>Code</i> for consistency. Develop a policy for their use and draft definitions.	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 TAHSC report (Feb 2023/2)	1
	New definition for 'biological products'	Develop a new definition	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 TAHSC report (Sep 2023/1)	1
	New definition for 'swill'	Review use of the term across the <i>Code</i> . Develop a policy for its use and consider developing a definition. (connected to biosecurity work)	Circulated for comments	Noted in Sep 2023 TAHSC report (Sep 2023/1)	1
	Definitions for 'biosecurity' and 'biosecurity plan'	Review as a part of the work on new Chapter on Biosecurity	Circulated for comments	Noted in Sep 2023 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.	Circulated for comments	Noted in Sep 2023 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 determined yet)	Not started	Noted in Sep 2023 TAHSC report	4
	Definition for 'greaves'	Deletion of the definition	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 TAHSC report (Sep 2023/1)	1
Section 1					

1.3.	Diseases, infections and infestations listed by WOA	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	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 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 WOA	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 2023 TAHSC report (Feb 2023/1)	2
1.11.	Application for official recognition by WOA of free status for foot and mouth disease	Partial revision to align with the revised Ch 8.8.	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 TAHSC report (Sep 2023/1)	1
Section 4					
4.4.	Zoning and compartmentalisation	(Not yet determined)	Preparatory work	Noted in Sep 2023 TAHSC report	1
4.6.	Collection and processing of semen of animals	Comprehensive revision of chapter	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 TAHSC report (Sep 2022/3)	1
4.7.	Collection and processing of bovine, small ruminant and porcine semen	Comprehensive revision of chapter	Preparatory work	Pending progress of the work on Ch 4.6.	1
4.8.	Collection and processing of <i>in vivo</i> 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 <i>in vitro</i> 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	Circulated for comments	Noted in Sep 2023 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.	Circulated for comments (for Chs 5.4. and 5.6.) Expert consultation (for Chs 5.5. and 5.7.)	Noted in Sep 2023 TAHSC report (Sep 2023/1)	1
5.2.	Certification procedures	Partial revision to review provisions on electronic certification	Expert consultation	Refer to Sep 2022 TAHSC report	3
5.8.	International transfer and laboratory containment of animal pathogenic agents	- Consider impact of holding PA in labs (and research facilities) - Align with corresponding <i>Manual</i> 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	Preparatory work	Noted in Sep 2023 TAHSC report	2

		AHG on HHP Horses Veterinary Certificates			
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	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 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 Sep 2023 TAHSC report	2
7.2., 7.3., 7.4.	Transport of animals by land, sea and air	Comprehensive revision of chapters	Expert consultation	Noted in Sep 2023 TAHSC report	2

7.5.	Slaughter of animals	Comprehensive revision of chapter	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 TAHSC report (Feb 2021/3)	1
7.6.	Killing of animals for disease control purposes	Comprehensive revision of chapter	Expert consultation	Refer to Sep 2022 TAHSC report	2
Section 8					
8.8.	Infection with foot and mouth disease virus	Comprehensive revision of chapter (including harmonisation of chapters with official status recognition)	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 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 Sep 2023 TAHSC report	2
8.11.	Infection with <i>Mycobacterium tuberculosis</i> complex	Partial revision - to add recommendations for camelids and goats - to clarify point 1(b) of Article 8.11.4.	Not started	Refer to Feb 2022 TAHSC report	3
8.13.	Paratuberculosis	Consider amendments to ensure alignment with recently revised <i>Manual</i> chapter	Not started	Refer to Sep 2020 TAHSC report	4
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 <i>Manual</i> chapter adopted in 2023)	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 TAHSC report (Sep 2023/1)	1
8.17.	Infection with <i>Trichinella</i> spp.	Partial revision of general provisions (follow-up of update of corresponding <i>Manual</i> chapter adopted in 2023)	Circulated for comments	Noted in Sep 2023 TAHSC report (Sep 2023/1)	1

			(proposed for adoption in May 2024)		
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 Sep 2023 TAHSC report	2
8.X.	New Chapter on Infection with <i>Coxiella burnetii</i> (Q fever)	Develop a new chapter	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 TAHSC report (Sep 2022/3)	1
8.Y.	New Chapter on Infection with Nipah virus	Develop a new chapter	Circulated for comments	Noted in Sep 2023 TAHSC report (Sep 2023/1)	1
8.Z.	New Chapter on Surra	Develop a new chapter	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 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 <i>Manual</i> chapter	Not started	Noted in Sep 2023 TAHSC report	3
10.5.	Infection with <i>Mycoplasma gallisepticum</i> (Avian mycoplasmosis)	Full update of the chapter (content and structure) based on the recent update of the <i>Manual</i> Chapter.	Preparatory work	Noted in Sep 2023 TAHSC report	3

		Consider inclusion of <i>M. synoviae</i> into a single chapter (and listed disease).			
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 <i>Mycoplasma mycoides</i> subsp. <i>mycoides</i> SC (Contagious bovine pleuropneumonia)	Harmonisation of chapters with official status recognition	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 TAHSC report (Sep 2022/3)	1
11.11.	Trichomonosis	Comprehensive revision of chapter	Expert consultation	Refer to Feb 2022 TAHSC report (Sep 2020/2)	3
11.X.	New Chapter on Infection with bovine pestivirus (bovine viral diarrhoea)	Develop a new chapter	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 TAHSC report (Sep 2022/3)	1
Section 12					
12.1.	African horse sickness	Harmonisation of chapters with official status recognition Proposals from AHG on AHS and SCAD	Circulated for comments (proposed for adoption in May 2024)	Noted in Feb 2023 TAHSC report (Sep 2022/3)	1
12.3.	Dourine	Comprehensive revision of chapter	Expert consultation	Refer to Feb 2023 TAHSC report	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 2023 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 2023 TAHSC report	3
Section 13					
13.2.	Rabbit haemorrhagic disease	Partial revision - to add a case definition (with editorial changes)	Circulated for comments (proposed for adoption in May 2024)	Noted in Sep 2023 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	Preparatory work	Noted in Sep 2023 TAHSC report	3
14.8.	Scrapie	Comprehensive revision of chapter	Preparatory work	Noted in Sep 2023 TAHSC report	2
14.9.	Sheep pox and goat pox	Comprehensive revision of chapter	Preparatory work	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 Camel pox	Develop a new chapter	Circulated for comments (proposed for	Noted in Sep 2023 TAHSC report (Sep 2022/3)	1

			adoption in May 2024)		
Others					
X.X.	New Chapter on Crimean Congo haemorrhagic fever	Develop a new chapter	Expert consultation	Noted in Feb 2023 TAHSC report Pending ongoing work on case definition	2

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

List of abbreviations	
AHG	<i>Ad hoc</i> 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
--

GLOSSARY

EU comment

The EU in general supports the proposed changes to the Glossary and provides two comments which are related.

ANIMAL PRODUCTS

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

EU comment

The EU queries the exclusion of germinal products from the definition of ‘animal products’. Indeed, germinal products are products originating from animals which represent comparable health risks as other animal products. In addition, germinal products are derived from animal production.

It is noted that there is a specific definition for ‘germinal products’ provided below, but this should not prevent the definition of ‘animal products’ to include germinal products as well.

As such, the definition of ‘animal products’ should include germinal products.

At the same time the definition of ‘commodity’ should be reviewed.

BIOLOGICAL PRODUCTS

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

COMMODITY

means live animals, ~~animal products of animal origin, animal genetic material~~ germinal products, biological products and pathological material.

EU comment

As a consequence of the proposed change in the definition of ‘animal products’, germinal products should be deleted from the definition of ‘commodity’.

BEATH

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.~~

GERMINAL PRODUCTS

means animal semen, oocytes, embryos and *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 ~~for~~ storage of semen.

SLAUGHTER

means **the** any ~~killing procedure that causes the death of an animal by bleeding of~~ **an** animals **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; ²⁷ in the absence of slaughter, the procedure would allow the animal to recover consciousness.

CHAPTER 1.3.

**DISEASES, INFECTIONS AND INFESTATIONS LISTED BY
WOAH**

EU comment

The EU supports the proposed changes to this chapter.

For future reference, when updating the chapter on Nipah virus encephalitis, in this chapter that disease should be placed in the category of diseases of multiple species (Article 1.3.1).

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 *Trypanosoma brucei*, *Trypanosoma congolense*, *Trypanosoma simiae* and *Trypanosoma vivax*
- Infection with Aujeszky's disease virus
- Infection with bluetongue virus
- Infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*
- Infection with *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 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 1.3.24.

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

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- ~~Bovine viral diarrhoea~~
- Enzootic bovine leukosis
- Haemorrhagic septicaemia
- Infection with bovine pestiviruses (Bovine viral diarrhoea)
- Infection with lumpy skin disease virus
- Infection with *Mycoplasma mycoides* subsp. *mycoides* (Contagious bovine pleuropneumonia)
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Infection with *Theileria annulata*, *Theileria orientalis* and *Theileria parva*

-
- Trichomonosis.

Article 1.3.37.

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 1.3.45.

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 *Burkholderia mallei* (Glanders)
- Infection with African horse sickness virus
- Infection with equid herpesvirus-1 (Equine rhinopneumonitis)
- Infection with equine arteritis virus
- Infection with equine influenza virus
- Infection with *Taylorella equigenitalis* (Contagious equine metritis)
- Infection with *Theileria equi* and *Babesia caballi* (Equine piroplasmosis)

-
- Venezuelan equine encephalomyelitis.

Article 1.3.58.

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 1.3.63.

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 1.3.76.

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 1.3.82.

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 Camel pox virus
 - Infection of with Middle East respiratory syndrome coronavirus.
-

CHAPTER 4.6.

**~~GENERAL HYGIENE IN SEMEN COLLECTION,
PROCESSING AND STORAGE~~****EU comment**

The EU thanks the Code Commission for taking into account the comments previously submitted and in general supports the proposed changes to this chapter. Comments are provided in the text below.

Article 4.6.1.

General provisions

The objective of this chapter is to provide recommendations that will reduce the likelihood of introduction and spread of *listed diseases* and contamination of fresh, chilled, or frozen semen ~~of from~~ various species of donor animals with ~~potentially~~ pathogenic agents in a *semen collection centre*.

1) This chapter provides recommendations on:

- 1a) procedures for the collection, processing, and storage of semen ~~of from~~ bovine, ovine, caprine, porcine, equine, and cervid donor animals;
- 2b) ~~biosecurity measures for the operation of semen collection centres;~~
- 3c) 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 minimize this risk. The *Veterinary Authority* should provide the regulatory standards and ~~for~~ 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, the recommendations in this chapter may also be appropriately applied 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 comprised of:~~

- 1a) animal accommodation facilities;
- 2b) semen collection facilities;
- 3c) semen processing facilities, including mobile laboratories processing units;
- 4d) semen storage facilities;
- 5e) 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,

- 1a) 'biosecure' refers to the state of a place or facility, in which *biosecurity* is effectively implemented effectively;
- 2b) 'resident facility' means a biosecure animal accommodation facility where donor and teaser animals are kept for the purpose of semen collection;
- 3c) '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;
- 4d) '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 ~~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 for 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 contacts with *wildlife* should be implemented. ~~If 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.~~

EU comment

What kind of species is the paragraph referring to? If the other species is for example dogs to herd the bulls then the paragraph makes sense, however, if the species are referring to multiple species for semen collection i.e. both sheep and goats, then it seems incorrect to delete the last sentence, as the sheep and goats should be kept in separate biosecurity facilities.

- 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.
- 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*.
- 5) In accordance with a biosecurity plan:
- ia) ~~The~~ entry of visitors to any part of the *semen collection centre* where *biosecurity* is required should only be allowed if authorised and controlled;
 - ib) ~~Appropriate~~ protective clothing and footwear only for use within the *semen collection centre* facilities should be provided;
 - ic) ~~Footbaths~~ should be provided, where necessary, and regularly cleaned and the disinfectant renewed based on the manufacturer's recommendations;
 - id) any additional measures such as complete change of clothing or shower may be required depending on the risks; and
 - ie) ~~Records~~ should be kept of the daily movements of all staff and visitors that enter the *semen collection centre*.
- 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) 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*.
- 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.

EU comment

The EU suggests to re-insert, before the last paragraph, the sentence: “The semen collection centre should be approved by the Veterinary Authority”.

Rationale: The proposed sentence seems to be missing and thereby there is no direct obligation to approve the semen collection centres by the Veterinary Authority.

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 provides 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., 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 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 removed 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 with the same *animal health status* should be processed at the same time. Semen from donors with a different *animal health status* or from different species may be processed consecutively if appropriate hygienic measures in accordance with the *biosecurity plan* have been implemented.

Semen should be collected 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,~~ The receptacle containing freshly collected semen should be ~~stopped or covered~~ in a way to prevent contamination as soon as possible after collection, until processing. During processing, containers containing the semen should be ~~stopped 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 ~~stopped~~ 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.

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*.

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 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.

Only new liquid nitrogen should be used to fill or top up ~~cryogenic germplasm storage~~ tanks.

CHAPTER 4.7.

COLLECTION AND PROCESSING OF BOVINE, SMALL RUMINANT AND PORCINE SEMEN

EU comment

The EU supports the proposed changes to this 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 8.11.5.
- 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 *Tritrichomonas foetus*, 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) *Campylobacter fetus* 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) *Campylobacter fetus* 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), divexacin (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.~~

CHAPTER 6.10.

RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE

EU comment

The EU would like to thank the Code Commission for taking previous EU comments into consideration and, in general, supports the proposed changes to this chapter. Comments are inserted in the text below.

As a general comment EU proposes to amend the title of this chapter as follows: “**RESPONSIBLE AND PRUDENT VETERINARY MEDICAL USE OF ANTIMICROBIAL AGENTS ~~IN VETERINARY MEDICINE.~~**” This is to align with the wording used throughout this chapter by using the existing definitions in Chapter 6.9. Article 6.9.2.

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* and stakeholders such as the veterinary pharmaceutical industry, *veterinarians, animal feed manufacturers, distributors, and food-animal producers-breeders, owners and keepers*, who are involved in any or all of the following activities: the authorization regulatory approval, production, control, importation, exportation, sales, advertising, distribution and use of veterinary medicinal products (VMPs) containing antimicrobial agents.

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 marketing authorization and their implementation when *antimicrobial agents* are administered to *animals* and is part of good veterinary and good agricultural good animal husbandry practices. All measures to keep animals healthy, such as preventing infectious animal-diseases 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 both their effectiveness efficacy and safety in animals;
- 2) complying with the ethical obligation and economic need to keep animals in good health;
- 3) preventing or reducing the transfer of resistant microorganisms or resistance determinants within animal populations, between animals, humans, and the relevant animal environment the environment and between animals and humans;
- 4) contributing to the maintenance maintaining of the effectiveness efficacy and usefulness of antimicrobial agents used in animal veterinary and human medicine;
- 5) protecting consumer health by ensuring the safety of food of animal origin with respect to residues of antimicrobial agents.

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 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 which can help to minimise the need for antimicrobial use in animals.

EU comment to Article 6.10.2

In this Article the term efficacy is replaced by the term effectiveness, while in Article 6.10.3. the term efficacy is used. It is unclear what these terms denote throughout the text.

The EU proposes:

- **Point 1:** to avoid overlap between current points 1 and 4, the EU proposes to merge point 1 with point 4 of this Article and rephrase point 1 as follows: **“preserve both their the effectiveness efficacy and safety of antimicrobial agents used in animals and contribute to maintaining the effectiveness of antimicrobial agents used in humans;”** Safety is an attribute of veterinary medicinal products whereas agents have intrinsic properties. The point is about agents.
- **Point 3:** to align with the rest of the document, the EU proposes to delete the hyphen in the word “micro-organisms”.
- **Point 4:** As suggested before, the EU proposed to merge with point 1 and delete point 4: **“~~contributing to maintaining the effectiveness of antimicrobial agents used in veterinary and human medicine;~~”**

Article 6.10.3.

Responsibilities of the Competent Authorities

1. National Action Plan for Antimicrobial Resistance

The *Competent Authorities* 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 WOA, 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* 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* should allocate budgetary resources for the design and implementation of the relevant part of their National Action Plan including communication strategies. The *Competent Authorities* should also conduct regular monitoring and evaluation of the National Action Plan.

EU comment

Article 6.10.3, point 1

First paragraph, third sentence:

The EU proposes to amend as follows: “Furthermore, the Competent Authorities 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 EU considers that development and implementation of training sessions for all professionals concerned is key for the implementation of the National Plans.

National Action Plans should incorporate, and educate on, best management practices, including disease prevention and control measures, biosecurity policies and development of animal health programmes to reduce the burden of animal disease thereby reducing the need for antimicrobial use. As part of National Action Plans for antimicrobial resistance, the *Competent Authorities* 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.

EU comment

Article 6.10.3, point 1

- **Second paragraph, first sentence**

For clarity reasons the EU proposes to amend as follows: “National Action Plans should incorporate, and educate inform on, ...”.

National Plans are not expected to provide education.

- **Third paragraph**

For clarity reasons, the EU proposes to rephrase to: “National Action Plans should include recommendations to relevant professional organisations as appropriate to develop evidence-based, species- or sector-specific antimicrobial use guidelines.”

42. 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:

- evaluate the effectiveness ~~efficacy~~ of administrative controls on the import of these VMP-veterinary medicinal products;
- evaluate the validity of the registration procedures of the exporting and/or ~~and~~ manufacturing country as appropriate;
- develop the necessary technical co-operation with an experienced relevant authorities ~~relevant authorities~~ *Competent Authority* to check the quality of imported VMP-veterinary medicinal products as well as the validity of the recommended conditions of use.

The *Competent Authorities* ~~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 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.

EU comment

Article 6.10.3. Point 2,

Fifth paragraph

In line with the explanations provided by the Code Commission in the report of the meeting and for reasons of clarity and alignment with the definitions of Chapter 6.9, the EU suggests to amend this paragraph, as follows: “Regulatory approval is granted for treatment, control and prevention of diseases and veterinary medical use of antimicrobial agents, on the basis of the data submitted by a pharmaceutical company or other applicant and only if the criteria of quality, safety, and

efficacy are met. Veterinary medical use of antimicrobial agents excludes growth promotion, therefore regulatory approval for veterinary medicinal products should not be granted for such purpose.”

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 regimens, (dose, dosing interval and duration of the treatment), and withdrawal period as relevant ~~and different durations of treatment that are proposed~~.

The *Competent Authority* should ~~expedite~~ implement timely ~~the~~ regulatory approval processes for new *antimicrobial agents* or treatment options, including alternatives to 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.

EU comment

Article 6.10.3.Point 2,

Eighth paragraph

Considering 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 amend this sentence as follows: “The *Competent Authority* should implement timely regulatory approval processes for new antimicrobial agents or treatment other options, including alternatives to the use of antimicrobials, in order[...].”

23. Quality control of antimicrobial agents and VMP veterinary medicinal products containing antimicrobial agents

The *Competent Authority* should make sure that the quality of the *veterinary medicinal products* was determined by the applicant in accordance with national and international guidance to ensure that:

Quality controls should be performed:

- a) the specifications of *antimicrobial agents* in compliance with the provisions of *good manufacturing practices*;
- b) ~~to ensure that analysis specifications of *antimicrobial agents* used as active ingredients comply with the provisions of registration documentations (such as monographs) approved by the relevant *Competent Authority*;~~
- cb) ~~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;

-
- dc) to ensure the stability and compatibility of antimicrobial agents are stable and compatible when mixed with feed or drinking water;
- ed) to ensure that all antimicrobial agents and the VMP veterinary medicinal products containing them are manufactured to the appropriate quality and in compliance with the provisions of good manufacturing practices purity in order to guarantee their safety and efficacy.

34. Assessment of therapeutic efficacy

The Competent Authority should conduct an assessment of the therapeutic efficacy based on data provided in the relevant regulatory approval application submitted by the applicant to enable marketing:

a) Preclinical trials

i) Preclinical trials should:

- establish the spectrum of activity of antimicrobial agents against relevant pathogenic agents and non-pathogenic agents (commensals);
- assess the capacity of the antimicrobial agents to select for resistance *in vitro* and *in vivo*, taking into consideration intrinsically resistant and pre-existing resistant strains and strains with acquired resistance;
- establish an appropriate dosage regimen (dose, dosing interval and duration of the treatment) and route of administration necessary to ensure the therapeutic efficacy of the antimicrobial agents and limit the selection of antimicrobial resistance. Pharmacokinetic and pharmacodynamic data and models can assist in this appraisal. Such data together with clinical data could be used by independent experts to establish clinical breakpoints per animal species, antimicrobial agent and pathogen combination.

ii) The activity of antimicrobial agents towards the targeted microorganism should be established by pharmacodynamics investigations. The following characteristics criteria should be taken into account:

- spectrum of activity and mode of action;
- minimum inhibitory 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 use of combinations of antimicrobial agents should be scientifically supported.

b) Clinical trials

Clinical trials in the target *animal* species should be performed to confirm the validity of the claimed therapeutic indications and dosage regimens established during the preclinical phase. The following criteria should be taken into account:

- diversity of the clinical cases encountered when performing multi-centre trials;
- compliance of protocols with good clinical practice;
- eligibility of studied clinical cases, based on appropriate criteria of clinical and bacteriological diagnoses;
- parameters for qualitatively and quantitatively assessing the efficacy of the treatment.

45. Assessment of the potential of antimicrobial agents to select for resistance

Other studies may be requested in support of the assessment of the potential of *antimicrobial agents* to select for resistance. The applicant for regulatory approval ~~The party applying for market authorisation should~~, where possible, supply data derived in target *animal* species under the intended conditions of use.

For this assessment the following may be considered:

- the concentration of ~~either active antimicrobial agents or and, where appropriate, active~~ metabolites in the gut of the *animal* (where the majority of ~~potential food-borne pathogenic and commensal bacteria agents~~ reside) at the defined dosage level;
- the antimicrobial activity of the antimicrobial agents and metabolites in the intestinal environment;
- ~~the~~ the pathway for the human exposure to antimicrobial resistant microorganisms, antimicrobial resistance determinants and antimicrobial residues in the relevant animal environment;
- the presence of and potential degree for co-selection, co-resistance and cross-resistance;
- 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.

EU comment

Article 6.10.3, point 6

In the second sentence, the EU proposes to add a hyphen after food for clarity. The sentence should be amended as follows: “For both food- and...”

~~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.~~

57. 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.~~

ab) ~~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.

~~68.~~ Assessment Protection of the impact on the relevant animal environment

~~An assessment of the impact of the proposed antimicrobial use on risks to the relevant environment should be conducted in accordance with national or international guidelines.~~

~~The Competent Authority should consider the results of an antimicrobial resistance environmental risk assessment. For both food and non-food producing animals the following risk factors should be taken into consideration as appropriate: reuse of wastewater for irrigation, use of manure, other waste based fertilizers for soil fertilization, transfer of antimicrobial resistant genes or bacteria in veterinary practice. When a significant antimicrobial resistance risk is determined the need for monitoring and proportionate risk management measures should be discussed.~~

798. 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*;
 - b) active ingredient and class;
 - c) pharmaceutical form;
 - d) quantitative composition;
 - e) pharmacological properties;
 - f) any potential adverse effects;
 - g) target *animal* species and, as appropriate, age or production category;
 - h) therapeutic indications;
 - i) target microorganisms;
 - j) dosage regimen and route of administration;
 - k) withdrawal periods;
 - l) incompatibilities and interactions;
 - m) storage conditions and shelf-life;
 - n) operator safety;
 - o) particular precautions before use;
 - p) precautions for the protection of the environment;
 - q) use during pregnancy, lactation or lay;
 - r) particular precautions for the proper disposal of unused ~~un-used~~ or expired products;
 - s) information on conditions of use relevant to responsible and prudent use of antimicrobials and minimising the development of resistance;
 - t) Contraindications;
 - u) known signs of overdosage and information about its treatment.

§109. Post-marketing antimicrobial resistance surveillance

The *Competent Authority* should assess the information collected through existing pharmacovigilance and surveillance programmes, including reporting of lack of response/efficacy, and any other relevant scientific data. These information sources should form part of the comprehensive strategy to detect and minimise antimicrobial resistance.

In addition, to this, the following 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.

91110. 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;
- ~~ed~~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 should develop effective procedures for the safe collection and disposal or destruction of unused or expired VMPs-veterinary medicinal products containing antimicrobial agents. Their labels should have appropriate instructions for disposal and destruction.

101211. Control of advertising

All advertising of antimicrobial agents should be compatible with the principles of responsible and prudent use and should be controlled by codes of advertising standards. ~~The relevant authorities~~The Competent Authority ~~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 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*.

1113. Training related to the use of antimicrobial agents and antimicrobial resistance

The *Competent Authority* should take a key role in promoting training for responsible and prudent use of antimicrobials and on antimicrobial resistance. The target audiences for the training on the 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 owners of food-producing animal owners and manufacturers of medicated animal feed. This training may should focus on preserving the effectiveness of antimicrobial agents and include:

- a) information on disease prevention, management and mitigation strategies;
- b) 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) 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 WOAHA List of Antimicrobial Agents of Veterinary Importance
- d) information on the appropriate storage conditions before and during use and proper disposal of unused or expired veterinary medicinal products;
- e) record keeping;
- f) 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;
- g) 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;
- h) the collection and reporting of antimicrobial resistance and antimicrobial use data to the *Competent Authority* to complement existing national and international surveillance programmes;
- i) information on disease prevention, management and mitigation strategies that can contribute to reducing the need to use antimicrobial agents in animals.

EU comment

Article 6.10.3. point 13

In the first paragraph, for consistency reasons, the EU proposes to add breeders and animal keepers in line with other occurrences throughout the text and rephrase as follows: “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 the training on the use of antimicrobial agents should include all the relevant stakeholders and organisations, such as the veterinary pharmaceutical industry, veterinary 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 and manufacturers of medicated *animal feed*.”

14. Monitoring of antimicrobial use

In accordance with Chapter 6.9., 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.

15. Knowledge gaps and Research

The Competent Authority ~~relevant authorities~~ should encourage coordination of public- and industry-funded research, in the following areas but not limited to: for example on methods to identify and mitigate the public health risks associated with specific antimicrobial agent uses, or on the ecology of antimicrobial resistance.

- a) improve the knowledge about the mechanisms of action, pharmacokinetics and pharmacodynamics of antimicrobial agents to optimize the dosage regimens for veterinary medical use and their effectiveness;
- b) improve the knowledge about the mechanisms of transmission, selection, co-selection, emergence and dissemination of resistance determinants and resistant microorganisms in *animal populations*, and 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 *animals* 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*;

-
- 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 animals 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 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;
- ed) 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.

4. Training

The veterinary pharmaceutical industry should participate in training programmes as defined in point ~~13~~4 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 records of:
 - a) date of supply;
 - 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.

EU comment

Article 6.10.5, point 2

It is not clear whether the records requested should cover all transactions, purchases and sales, or only sales by retailers. If the latter, the EU proposes to rephrase as follows: “2) The recommendations on the responsible and prudent use of *veterinary medicinal products* containing antimicrobial agents should be reinforced by retail distributors who should keep for an appropriate period detailed sale records of:

- a) date of sale supply;**”

- 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 134 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 animals~~.

The veterinarians should only prescribe antimicrobial agents for animals under their care. The veterinarian should consider safe and effective non-antimicrobial options or alternatives to antimicrobials before prescribing antimicrobial agents.

Some of the responsibilities described in this article may be applicable to veterinary paraprofessionals or other suitably trained persons according to the national legislation.

EU comment

Article 6.10.6. introductory part

In the second paragraph, considering 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 amend this phrase as follows: “The *veterinarians* should only prescribe *antimicrobial agents for animals* under their care. The *veterinarian* should consider safe and effective alternatives to the use of antimicrobials before prescribing *antimicrobial agents*.”

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;
- 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;~~
- 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 supportive therapy, 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:

ia) the clinical experience of the *veterinarians*, their diagnostic insight and therapeutic judgement;

ib) diagnostic laboratory information (pathogenic agent isolation, identification and ~~antibiogram~~ antimicrobial susceptibility testing);

ic) pharmacodynamics properties of the selected antimicrobial agent, including the activity towards the pathogenic agents involved;

id) the appropriate dosage regimen and route of administration;

ie) pharmacokinetics and tissue distribution to ensure that the selected therapeutic agent is effective at the site of *infection*;

if) the epidemiological history relevant to of the animal or animals being treated rearing unit, particularly in relation to the antimicrobial resistance profiles of the pathogens pathogenic agents involved.

Should a first-line antimicrobial treatment fail or should the disease recur, an investigation a second line treatment should be undertaken based on the results of diagnostic tests. In the absence of such results, an appropriate antimicrobial agent belonging to a different class or sub-class should be used to reassess the circumstances including reviewing the diagnosis, 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 animals 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 WOH 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 use of the selected ~~VMP~~ veterinary medicinal product containing antimicrobial agents chosen

EU Comment

Article 6.10.6. point 3

Title

To better reflect the content of point 3, which includes the use of compounded products and in line with the definition of ‘veterinary medical use of antimicrobial agents’ in chapter 6.9, the EU proposes to change the title to: “Appropriate veterinary medical use of the selected veterinary medicinal product containing antimicrobial agents”.

The A-prescription of a ~~VMP~~ veterinary medicinal product containing *antimicrobial agents* should indicate precisely the dosage regimen, the withdrawal period where applicable, and when considering group treatments, the total amount of ~~VMP~~ veterinary medicinal products containing *antimicrobial agents* to be provided, which will depend ~~depending~~ on the dosage, duration of treatment, and the number of *animals* to be treated.

EU Comment

Article 6.10.6. point 3

First paragraph

In line with the explanations provided by the Code Commission in the report of the meeting and based on the definitions of Chapter 6.9, the EU proposes to add the following sentence: Veterinary medical use of antimicrobial agents excludes growth promotion, therefore veterinarians should not prescribe veterinary medicinal products containing antimicrobial agents for such use.

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* breeder, owner or keeper.

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 periods ~~to be used~~, as applicable. It is the *veterinarian's* responsibility to define the conditions of responsible and prudent use in such a case including the dosage regimen, the route of administration and the withdrawal period.

EU Comment

Article 6.10.6. point 3

Third paragraph

- As extra-label is an exceptional use, the EU proposes to begin this paragraph by reiterating the general principle that the use must be according to the label. Therefore, EU proposes to add the following to the beginning of the paragraph: “The *veterinary medical use of veterinary medicinal products* should, in principle, be in

line with the Summary of Product Characteristics (SPC) or equivalent summary. The extra-label or off-label use of a [...]

- **To align with the definitions in chapter 6.9, the EU proposes to change as follows: “The extra-label or off-label use of a 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~~ or prevention of diseases, [...]**”

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 ~~the~~ VMP veterinary medicinal products containing *antimicrobial agents* should be kept in conformity with the national legislation. ~~Information~~ Records should include the following, as appropriate:

a) commercial name of the *veterinary medicinal products*;

b) name of the *antimicrobial agents* in the *veterinary medicinal products*;

~~abc)~~ 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;

~~cd)~~ route of administration;

~~de)~~ *animal species*;

~~ef)~~ number of *animals* treated;

~~fg)~~ clinical condition treated;

~~gh)~~ treatment schedules including *animal* identification and length of the withdrawal period;

~~hi)~~ antimicrobial susceptibility data, including laboratory records of pathogenic agent isolation, identification and susceptibility testing obtained from isolates;

~~ij)~~ comments concerning the response of the *animal or* *animals* to treatment;

~~jk)~~ the investigation of adverse reactions associated with 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~~4~~ 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 ~~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.
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;~~
- ef) use *veterinary medicinal products* VMP-containing antimicrobial agents in accordance with product label instructions, including storage conditions, ~~and or the instructions of the attending-prescribing veterinarian;~~ 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;
- fg) comply with ~~and record~~ the recommended withdrawal periods to ensure that residue levels in *animal*-derived food do not present a *risk* for the consumer;
- gh) use ~~VMP-*veterinary medicinal products*~~ containing antimicrobial agents within the expiry date and dispose of unused and expired surplus ~~VMP-*veterinary medicinal products*~~ containing antimicrobial agents under conditions safe for the 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;
- hi) maintain all the laboratory records of bacteriological and susceptibility tests; these data should be made available to the veterinarian responsible for treating the *animals*;

EC Comment

Article 6.10.8. point 2

Paragraph j

In the EU's view this responsibility should be shared between the veterinarians and the animal keepers, owners and breeders. Therefore, the EU proposes to rephrase this paragraph as follows: “j) maintain, or have their veterinarian maintain, all the laboratory records of bacteriological and susceptibility tests; if these data are not maintained by the veterinarian responsible for treating the animals, the data should be made available to them ~~the veterinarian responsible for treating the animals;~~”

- ik) keep adequate records of all ~~VMP-*veterinary medicinal products*~~ containing antimicrobial agents used, including the following:
 - i) name of the product and active substance, and batch number and expiry date;

EU comment

Article 6.10.8, point 2

paragraph k) subparagraph i)

In the EU's view the name of the active substance is important, especially in the cases of use of compounded (extemporaneous) products. Therefore, the EU proposes to reword as follows: “i) name of the product ~~and~~ or the active substance and batch number, as relevant;”

- 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;~~
- jj) 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 131 of Article 6.10.3.

It is recommended that food *animal producer* organisations work in cooperation with the veterinary professional organisations to implement existing guidelines for the responsible and prudent use of ~~VMP~~ veterinary medicinal products containing *antimicrobial agents*.

Article 6.10.9.

Responsibilities of breeders, owners and keepers of non-food producing animals

Animal breeders, owners and keepers, with the assistance and guidance of a *veterinarian*, are responsible for the health and welfare of their *animals* and should:

- 1) implement the wellness plans and preventative health plans recommended by their *veterinarian*;
- 2) strictly follow their *veterinarian's* recommendations and ensure that if any, the administration of *veterinary medicinal products* containing *antimicrobial agents* follows the veterinary prescription;

-
- 3) avoid administering over the counter, ~~leftover and expired~~ human and ~~animal~~ veterinary antimicrobials agents to their animals;
 - 4) not administer remaining or expired human and veterinary antimicrobials agents to their animals;
 - 45) inform their veterinarian or veterinary paraprofessional of the administration of any additional medicinal products than those prescribed by the veterinarian during the consultation;
 - 56) 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.
-

DRAFT CHAPTER 7.5.

ANIMAL WELFARE DURING SLAUGHTER

EU comment

The EU thanks WOAAH for having taken into consideration most of our previous comments. While the EU welcomes and supports this revised chapter and it still has a few comments to share with WOAAH.

Article 7.5.1.

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 economical returns [Blokhuys *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. cattle, buffalo, bison, sheep, goats, horses, donkeys, mules, ruminants, equids and pigs, and animals in containers (e.g. 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 chapterFor 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 animal welfare hazards

Hazards to animal welfare during each of the pre-slaughter stages have an ~~an 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 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 in 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.

EU comment:

Suggestion to keeping the last sentence of the paragraph above:

“However, key stunning parameters should be considered alongside animal-based measures”

Justification:

Key stunning parameters should always be considered and not only taking into account animal-based measures. Key stunning parameters are especially crucial in cases where animals cannot fully be individually checked, such as animal being stunned in containers with modified atmosphere stunning. They are also crucial in cases where physical reactions are absent, in particular to prevent electro-immobilization during electrical stunning.

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 measurable~~ 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 their 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~~ its key working parameters and procedures. Personnel *stunning, post-stun* shackling and bleeding animals should be able to identify and take corrective actions in case of: ineffective 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 impact s on the welfare of animals. ~~They 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
- watering and feeding 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 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 *slaughter*. 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 throughput is (number of animals slaughtered per hour)~~

The throughput of the *slaughterhouse/abattoir* is the number of animals slaughtered per hour. It should never exceed the maximum specification 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. #Throughput may also need to be reduced depending on their 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 cleaned, well maintained, and including calibration, 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 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 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.

2-) Animal-based and other measurable 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. Provisions 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.

EU comment:

The EU suggests keeping this last sentence of the paragraph above.

Justification:

It is important that the Code contains a certain level of practical indication so that it may be use as an instrument for guidance. There is not much scientific debate regarding the need to milk dairy cows at least twice a day.

4-) Species-specific recommendations:

Some species such as Ppigs 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 very more 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 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 measurable 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. The gradient should not be too steep preventing 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 preventing animals from moving forward voluntarily and solid side barriers should be in place.”

Justification:

Linguistic suggestion

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 ~~ethanised~~ without moving them and without delay. Refer to Articles 7.5.19. and 7.5.20~~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 of 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 not be used repeatedly if the animal fails to respond and should not last longer than one second [Ritter *et al.*, 2008].

EU comment:

“Such instruments should not be used on equids, camelids, ratites, sheep and goats of any age, animals known to be pregnant animals or on calves or piglets.”

Justification:

View that it is quite difficult to control the exact stage of the pregnancy we propose to not use electric goads to animals known to be pregnant.

~~Mechanical Other Handling 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;₂
- b) absence of protection against ~~extremes~~ adverse in weather or climate conditions, leading to thermal stress;₂
- c) sudden or excessive noises, including from personnel, machinery, metal yards and gates facilities, and equipment and gates, leading to fear;₂
- d) insufficient space to lie down and move freely leading to fatigue and aggressive behaviour;₂
- e) poor design and maintenance leading to distress and injuries;₂

- 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 measurable 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);

EU comment:

The EU proposes to add “bruising” in the examples of injuries and to delete letter i):

“d) injuries (e.g. lameness, bruising, open wounds, fractures),”

“i) carcass bruising.”

Justification:

The carcass refers to the body of the dead animal. Therefore, we propose to delete “carcass” and to move “bruising” amongst the examples of injuries.

- 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) 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, Animals which that are not expected to be slaughtered after within 12 hours of arrival should be fed as appropriate for the age and species and 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 neonate 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 (see Article 7.5.1922.).

EU comment:

Suggestion to add “without delay” at the end of the sentence:

Animals that are very ill or down or have severe injuries should be euthanized without delay. (see Article 7.5.22.).

Justification:

To limit the welfare risks for such animals and to prevent potential unnecessary suffering.

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;
- e) fear caused by prolonged *restraint*, which may exacerbate insecure or excessive *restraint*.

In addition, 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 measurable 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.

EU comment:

Suggestion to remove "frequency of " and to keep only "use of electric goads" in the text:

“(f) ~~frequency of use of electric goads.~~”

Justification:

To be coherent with the handling of free-moving animals.

3.1 Recommendations:

Where individual restraint is used, ~~The~~ restrainer should be narrow enough that the animals cannot move ~~either~~ backwards or forwards 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 restraining 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 animals should enter the restrainer until equipment and personnel are ready to stun and slaughter that animal.

No animals 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 Bison and cervids, as well as any species which may be processed with or without stunning.

Article 7.5.16.

General principles for 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 avoid prevents pain and suffering to animals and also improves workers' safety.

Mechanical stunning is divided into penetrative 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. Low 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 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. CO₂ 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 painful 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 occurs 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 indicate 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 indicate a 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 indicate a 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 reach 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 are 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.*, 2015/2014];
- 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 (low 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 painful to inhale should preferably not be used to stun or kill pigs

4. Species specific recommendations:

Non penetrative 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 painful 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.

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 occurs 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 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* 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, Penetrative 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. 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. ~~Low 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, fracture of the skull and ineffective *stunning* are more likely to occur with in young animals such as calves, when a higher bolt velocity is used. Absence of or incorrect restraint can lead to an incorrect shooting position.

EU comment

The EU suggests amending the paragraph above as follows (*sentences are numbered for ease of reference*):

“[...] 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).¹ The latter devices are not effective for stunning adult pigs (sows/boars), cattle with thick skull hair and bulls.² The main *hazards preventing effective leading to ineffective mechanical *stunning* (including short-lasting unconsciousness)* are incorrect shooting position and incorrect direction of the impact.³ These may cause ineffective *stunning* and pain or short-lasting unconseiousness.⁴ An incorrect shooting position can be the result of absent or incorrect restraint.⁵ Shots fired at cranial sutures or otherwise induced skull fractures can reduce the impact energy and thus the stunning effectiveness.⁶ 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.⁷ ~~Low 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*.⁸ ~~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].⁹ If not applied correctly, fracture of the skull and ineffective *stunning* are more likely to occur with in young animals such as calves, when a higher bolt velocity is used.¹⁰ Absence of or incorrect restraint can lead to an incorrect shooting position.¹¹”

Justification (broken down by sentence number as indicated above):

- 2) This reflects the current state of research and technology (EFSA 2004, 2020, AVMA 2016, 2020) and should be made clear here. In contrast, sentence 9 is too vague.
- 3) The new wording takes up the only additional aspect from sentence 4, creating a direct link to sentence 5, which is identical in content to sentence 11.
- 6) Sentence 10 is not convincing because the non-penetrating method can cause skull fractures even in adult animals and when used correctly (literature as above). In addition, the sentence could lead to the misunderstanding that slower bolt velocities are favourable. Finally, the paragraph does not yet mention skull sutures.
- 7) Air pressure in the device itself is the decisive factor. The connection between the “line” and the device could also be leaky, for example.

For wild 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.

EU comment

The EU suggests amending the first sentence of the paragraph as follows:

“For wild or feral animals, as well as certain extensively reared animals, on-site shooting with a free bullet in the brain can be an alternative to prevent stressful handling and transport.”

Justification:

The method can also be a welfare-friendly alternative for e.g. domestic pigs and cattle kept outdoors. This does not seem to be reflected in the current wording.

2-) Animal-based and other measurable measures include:

Mechanical stunning:

Animal-based measures of an effective stun are 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.

EU comment:

The above should be listed separately and be replaced in other articles through this chapter: “absence of corneal reflex; or absence of palpebral reflex”

Justification:

When 1 of the 2 reflexes occurs, it is very unlikely that there was an effective stun.

Animal-based measures The presence of any of the following signs may indicate 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-penetrating 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 energized 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.

EU comment:

Same comment as above and namely to list separately and to replace in other articles trough this chapter: “absence of corneal reflex; or absence of palpebral reflex”

Justification:

When 1 of the 2 reflexes occurs, it is very unlikely that there was an effective stun.

Animal-based measures of ineffective stun or recovery of consciousness are: The presence of any of the following signs may indicate a 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 ~~reach~~ be 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 effective electrical parameters, should 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].

EU comment:

The EU suggests differentiating the parameters for bovines by animal category:

~~– 1.15 [AVMA] to 1.28 A for bovines [EFSA 2020b],~~

“>1.28 for cattle and >1.25 for calves”

Justification:

According to EFSA (Welfare of Cattle at slaughter, 2020): The minimum recommended currents for head-only stunning are >1.28 A and 1.25 A for cattle and calves, respectively (HSA, 2016a,b)

- = 1.25 A for slaughter (finished) pigs [AVMA].

- = 1.8 A for sows and boars [AVMA].

EU comment:

The EU suggests not differentiating the parameters for pigs by animal category:

~~“ 1.25 A for slaughter (finished) pigs [AVMA],~~

~~– 1.8 A for sows and boars [AVMA],”~~

“1,3 A for pigs,”

Justification:

According to EFSA (Welfare of pigs at slaughter, 2020), under the ideal tong position, a current of 0.5 A delivered using a 50 Hz sine wave alternating current (AC) would be sufficient,

whereas, when the tongs are placed just behind the ears a current of 1.3 A would be necessary to stun pigs (Hoenderken, 1978; Anil, 1991). Under commercial conditions, it is not always easy to place the electrodes in the ideal position, and therefore, a minimum of 1.3 A is recommended when the electrodes are placed behind the ears.

= 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. CO₂ 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 painful to inhale should preferably not be used to stun or kill pigs.

2-) Animal-based and other measurable 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.

EU comment:

Same comment as above and namely to list separately and to replace in other articles trough this chapter: “absence of corneal reflex; or absence of palpebral reflex”

Justification:

When 1 of the 2 reflexes occurs, it is very unlikely that there was an effective stun.

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:

e) ~~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 (low 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 painful 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, if such methods allow animals-pigs to be stunned in groups and it has a short induction phase, they could present a certain animal welfare benefit 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 animal 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.

EU comment :

**The EU suggests adding the following sentence at the end of the above paragraph:
“The restraining should be maintained until the animal is unconscious.”**

Justification:

Important to also mentioned it here even though it is mentioned in the restraining.

2-) Animal-based and other measurable measures include:

The main animal-based measurable is the blood flow (rate and duration). For animal-based and other measurable measures of return of consciousness after *stunning*, see Article 7.5.16.

In cases of bleeding without *stunning* the animal-based and other measurable measures that indicate loss of consciousness include all the following: absence of muscle tone; absence of corneal reflex 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;

e 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 before~~ not 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, the vertebral arteries will continue to provide blood to the brain. Furthermore and can cause any occlusion of the cut major arteries, will slowing exsanguination. Therefore, bleeding with a cut of the brachiocephalic trunk should always be preferred in cattle bovines.

Article 7.5.2118.

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.

EU comment:

The EU suggests adapting the paragraph above as follows:

“Foetuses in the uterus are considered ~~not~~ unlikely to achieve consciousness [EFSA, 2017; Mellor, D. J. et al., 2005]. However, if removed from the uterus the foetus ~~may~~ is more likely to perceive pain or other negative impacts affect.”

Justification:

The change reflects more accurately the cited EFSA opinion (<https://doi.org/10.2903/j.efsa.2017.4782> cf. page 56 number 5 bullet 3). “Affect” seems to be the more appropriate term: “the conscious emotion that occurs in reaction to a thought or experience” (Merriam-Webster Dictionary <https://www.merriam-webster.com/dictionary/affect#dictionary-entry-3>).

2-) Animal-based and other measurable 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 ethanasia (captive bolt followed by bleeding) should be carried out immediately.

4-) Species-specific recommendations:

~~None identified.~~

Article 7.5. ~~2219~~.

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 measurable 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 the~~ The following practices for handling animals are unacceptable 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 the~~ 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, 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 7.5.2421.

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 measurable 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 measurable 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 measurable 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) animals vocalizing vocalisation 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 Articles 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)~~ absence of protection against adverse weather or climate conditions ~~extremes in climate~~ leading to thermal stress;
- ~~d)~~ sudden or excessive noises, including from personnel, leading to fear;
- ~~e)~~ insufficient space to lie down and move freely leading to fatigue and aggressive behaviour;
- ~~f)~~ not being inspected or accessible for emergency killing when necessary.

2-) Animal-based and other measurable 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 7.5.2724.

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) handling and removal of animals from containers before stunning;
- d) incorrect design of manual or mechanical tipping manually or using mechanical equipment that cause animals to falling 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 resulting in piling or injury.

2-) Animal-based and other measurable measures include:

- a) animals falling;
- b) struggling, including wing flapping;
- c) escape attempts;

- d) vocalisation referring to distress;
- e) injuries, dislocations, fractures;
- f) piling-off 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, swing 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 are not conducive to maintaining good animal welfare. These systems, when used, should be have an incorporated with a mechanism to facilitate birds 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 7.5.2825.

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 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 upside down by inserting both legs into metal shackles. During shackling, the birds are also subjected to compression of their legs and wing flapping by their neighbour(s), leading to distress, pain and fear.

EU comment :

The EU suggests also adding “rabbits” after “birds”:

“b) Shackling birds and rabbits upside down by inserting both legs into metal shackles. During shackling, the birds are also subjected to compression of their legs and wing flapping by their neighbour(s), leading to distress, pain and fear.

Justification:

See EFSA scientific opinion 'Stunning methods and slaughter of rabbits for human consumption; EFSA Journal 2020;18(1):5927, p. 38

- c) Inappropriate shackling (e.g. shackles are too narrow or too wide, birds are hung shackled by one leg, or when one bird 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.

EU comment:

The EU suggests adding “rabbits” after “birds” in the above paragraph: “Inappropriate shackling (e.g. shackles are too narrow or too wide, birds and rabbits are shackled by one leg, or when one bird or a rabbit is shackled on two different adjacent shackles) leads to distress, pain and fear.”

Justification:

See EFSA scientific opinion 'Stunning methods and slaughter of rabbits for human consumption; EFSA Journal 2020;18(1):5927, p. 38

- 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 measurable 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, animals should be handled and restrained to minimise without provoking struggling 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 struggling. 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 struggling, 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, shackling 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 7.5.2926.

Head-only electrical stunning

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 measurable 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 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 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~~ 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~~ Effective 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:

- 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, 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 ~~inappropriate~~insufficient 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.

In the case of ineffective *stunning* or recovery, animals should be re-stunned ~~immediately~~ using a backup system and 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 maximize 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 *stunning* systems which avoid these associated animal welfare hazards.

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.

For water-bath *stunning* depending on the frequency, minimum parameters are recommended for the following species [EFSA, 2019]:

- For ffrequency 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.

Chicken and turkeys should not be stunned at frequencies higher than 600 Hz.

Article 7.5.3128.

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 precision and often physical strength to restrain and stun the animals. A 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 captive bolt

An incorrect shooting position or incorrect captive bolt parameters (not hitting the skull with sufficient force) will mis-stun 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-stun 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 applies to the brain, the loss of consciousness may be delayed, is not immediate and, in some cases, 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, 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 measurable measures include:

Penetrative and non-penetrative captive bolt and percussive blow to the head

With birds, 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 palpebral reflex, apnoea; the absence of rhythmic breathing and the presence of immediate collapse loss of posture; presence of tonic-clonic seizure.

EU comment:

The above should read: “the absence of corneal reflex; the absence of palpebral reflex;”

Justification:

When 1 of the 2 reflexes occurs, it is very unlikely that there was an effective stun; + editorial.

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 palpebral reflex; rhythmic breathing.

EU comment :

Similar comment as above to list separately: “presence of palpebral reflex”.

Justification:

For clarity /editorial.

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 ~~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 ~~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 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 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 first former is less dependent on the operator's strength than the latter.

Cervical dislocation should not be undertaken performed 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 7.5.3229.

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 evaluated as 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 or a combination of these variables.

EU comment:

The text could be improved by adding a sentence concerning the risk factor of a too high stocking density: 'From a practical point of view it is important to realise that also a too high stocking density may cause insufficient exposure to the modified atmosphere'.

Justification:

From a practical point of view, the "stocking density" also plays a role here. (If there are too many animals, they can lie on top of each other and animals can end up in "air pockets", e.g. under feathers). See also EFSA Guidance on the assessment criteria for applications for new or modified stunning methods regarding animal protection at the time of killing; EFSA Journal 2018;16(7):5343, p. 31-34

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 (CO₂) 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 measurable 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 immediately ~~any~~ corrective measures 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 or palpebral reflex, dilated pupils and relaxed carcass.

EU comment:

The above should read: “absence of corneal reflex, ~~or~~ absence of palpebral reflex,”

Justification:

When 1 of the 2 reflexes occurs, it is very unlikely that there was an effective stun /very unlikely that there is unconsciousness.

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 CO₂ 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 CO₂ 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 CO₂ 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, the 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 of~~ causes 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, bruising, 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 measurable measures include:

The main animal-based ~~measurable measure~~ is the blood flow (rate and duration). For animal-based and other ~~measurable measures~~ measures of return of consciousness after *stunning* (see ~~Article 7.5.16~~ Article 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 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 % before reaching the scalding tank or other potentially painful 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 only in to unconscious birds~~ 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 ~~an~~ 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 measurable 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 being 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.~~35~~32.

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)~~ 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 the~~ 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~~.

References

- Anonymous (2017). Animal welfare aspects in respect of the slaughter or killing of pregnant livestock animals (cattle, pigs, sheep, goats, horses). *EFSA Journal* 15:4782.
- Anonymous. (2013). Scientific Opinion on monitoring procedures at slaughterhouses for bovines. *EFSA Journal* 11:3460.
- Anonymous. (2018). Technical Note No 19 Carbon Dioxide Stunning and Killing of Pigs. Humane Slaughter Association, UK. <https://www.hsa.org.uk/downloads/technical-notes/tn19-carbon-dioxide-stunning-and-killing-of-pigs.pdf>.
- AVMA Guidelines for the Humane Slaughter of Animals. (2016). Available from: <https://www.avma.org/KB/Resources/Reference/AnimalWelfare/Documents/Humane-Slaughter-Guidelines.pdf>.
- Barton-Gade P and Christensen L. (1998). Effect of different stocking densities during transport on welfare and meat quality in Danish slaughter pigs. *Meat Science*, 48, 237–247.
- Blokhuis, H., Keeling, L., Gavinelli, A. and Serratos, J. (2008). Animal welfare's impact on the food chain. *Trends in Food Science & Technology*, 19 (2008), 79-88.
- Dalmáu, A., Palliser, J., Pedernera, C., Muñoz, I., Carreras, R., Casal, N., Mainau, E., Rodríguez, P., Velarde, A. (2016). Use of high concentrations of carbon dioxide for stunning rabbits reared for meat production. *World Rabbit Science*, 24: 25-37.
- Daly, C.C., Gregory, G. and Wotton, S.B. (1987). Captive bolt stunning of cattle: effects on brain function and role of bolt velocity. *British Veterinary Journal* 143 574-580.
- EFSA. (2004). Welfare aspects of animal stunning and killing methods. Scientific Report of the Scientific Panel for Animal Health and Welfare on a request from the Commission related to welfare aspects of animal stunning and killing methods. Available from: <http://www.efsa.europa.eu/de/scdocs/doc/45.pdf>.
- EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare). (2013a). Scientific opinion on monitoring procedures at slaughterhouses for bovines. *EFSA Journal* 2013. 11, 3460. Available from: <http://dx.doi.org/10.2903/j.efsa.2013.3460>.
- EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare). (2013b). Scientific opinion on monitoring procedures at slaughterhouses for sheep and goats. *EFSA Journal* 2013. 11, 3522. Available from: <http://dx.doi.org/10.2903/j.efsa.2013.3522>.
- EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare). (2013c). Scientific Opinion on the electrical parameters for the stunning of lambs and kid goats. *EFSA Journal* 2013. 11(6):3249. <https://doi.org/10.2903/j.efsa.2013.3249>.
- EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare). (2015). Scientific Opinion on the scientific assessment of studies on electrical parameters for stunning of small ruminants (ovine and caprine species). *EFSA Journal* 13(2):4023. <https://doi.org/10.2903/j.efsa.2015.4023>.
- EFSA AHAW Panel (EFSA Panel on Animal Health and Animal Welfare). (2017). Scientific Opinion on the animal welfare aspects in respect of the slaughter or killing of pregnant livestock animals (cattle, pigs, sheep, goats, horses). *EFSA Journal* 2017;15(5):4782, 96 pp. Available from : <https://doi.org/10.2903/j.efsa.2017.4782>.
- EFSA AHAW Panel (EFSA Panel on Animal Health and Animal Welfare). (2019). Scientific Opinion on the Slaughter of animals: poultry. *EFSA Journal* 2019;17(11):5849, 91 pp. Available from : <https://doi.org/10.2903/j.efsa.2019.5849>.
- EFSA AHAW Panel (EFSA Panel on Animal Health and Animal Welfare). (2020a). Scientific Opinion on stunning methods and slaughter of rabbits for human consumption. *EFSA Journal* 2020;18(1):5927, 106 pp. <https://doi.org/10.2903/j.efsa.2020.5927>.
- EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare). (2020b). Welfare of cattle at slaughter. *EFSA Journal*; 18(11):e06275. <https://doi.org/10.2903/j.efsa.2020.6275>.
- Finnie, J.W. (1993). Brain damage caused by captive bolt pistol. *J. Comp. Pathol.* 109:253–258.
- Finnie, J.W., J. Manavis, G.E. Summersides and P.C. Blumbergs. (2003). Brain Damage in Pigs Produced by Impact with a Non-penetrating Captive Bolt Pistol. *Aust. Vet. J.* 81:153-5.
- Gibson, T.J, Johnson, C.B, Murrell, J.C, Hulls, C.M., Mitchinson, S.L., Stafford, K.J., Johnstone, A.C. and Mellor, D.J. (2009). Electroencephalographic responses of calves to slaughter by ventral neck incision without prior stunning. *New Zealand Veterinary Journal* 57 77-83.
- Gibson, T.J., Mason, C.W., Spence, J.Y., Barker, H. and Gregory, N.G. (2014). Factors Affecting Penetrating Captive Bolt Gun Performance. *Journal of Applied Animal Welfare Science* 18 222-238.
- Gibson, Troy J., Emma King, Jade Spence, and Georgina Limon. (2019). Pathophysiology of Concussive Non-Penetrative Captive Bolt Stunning of Turkeys. *Animals* 9, no. 12: 1049. <https://doi.org/10.3390/ani9121049>.

Grandin, T. (1980). Mechanical, electrical and anesthetic stunning methods for livestock. *International Journal for the Study of Animal Problems*, 1(4), 242-263.

Gregory, N.G. (2004). *Physiology and Behaviour of Animal Suffering*. Blackwell Science, Oxford, p. 227. ISBN: 0-632-06468-4.

Gurung S, White D, Archer G, Zhao D, Farnell Y, Byrd J, Peebles E, Farnell M. (2018). Evaluation of alternative euthanasia methods of neonatal chickens. *Animal* 8, 37. doi:10.3390/ani8030037.

Humane Slaughter Association (HSA) (2023) Available from: <https://www.hsa.org.uk/concussion-stunning/equipment-4>

Johnson, C.B., Mellor, D.J., Hemsworth, P.H. and Fisher, A.D (2015). A scientific comment on the welfare of domesticated ruminants slaughtered without stunning. *New Zealand Veterinary Journal* 63 58-65.

Jongman, E. and Fisher, A. (2021). Euthanasia of laying hens: an overview. *Animal Production Science*, 61(10), p.1042.

Lara, L. and Rostagno M. (2018). Animal welfare and food safety in modern animal production, in *Advances in Agricultural Animal Welfare, Food Science, Technology and Nutrition*, Pages 91-108.

Mellor D. (2003). Guidelines for the humane slaughter of the fetuses of pregnant ruminants. *Surveillance* 30:26-28.

Mellor, D.J., Diescha, T.J., Gunn, A.J. and Bennet, L. (2005). The importance of 'awareness' for understanding fetal pain. *Brain Research Reviews* 49 (2005) 455–471.

Mellor D. (2010). Galloping colts, fetal feelings, and reassuring regulations: putting animal-welfare science into practice. *JVME* 37(1):94-100.

Micera, Elisabetta, Albrizio, Maria, Surdo, Nicoletta C., Moramarco, Angela M. and Zarrilli, Antonia. (2010). Stress-related hormones in horses before and after stunning by captive bolt gun, *Meat Science*, 84(4), 634-637.

Nielsen, S. S., Alvarez, J., Bicoût, D. J., Calistri, P., Depner, K., Drewe, J. A., Garin-Bastuji, B., Rojas, J. L. G., Schmidt, C. G., Michel, V., Chueca, M. A. M., Roberts, H. C., Sihvonen, L. H., Stahl, K., Calvo, A. V., Viltrop, A., Winckler, C., Candiani, D., Fabris, C., Mosbach-Schulz, O., Stede, Y. van der and Spoolder, H. (2020). Stunning methods and slaughter of rabbits for human consumption. *EFSA Journal*, 18(1), e05927.

North American Meat Institute (NAMI). (2017~~2021~~). *Recommended Animal Handling Guidelines & Audit Guide: A Systematic Approach to Animal Welfare*. Rev. 4.

Pleiter, H. (2010). Review of Stunning and Halal Slaughter. *Meat and Livestock Australia*.

Ritter MJ, Ellis M, Murphy CM, Peterson BA and Rojo A. (2008). Effects of handling intensity, distance moved, and transport floor space on the stress responses of market weight pigs. *Journal of Animal Science*, 8, 43.

Stiewert AM, Archer GS. (2021). Comparing two captive bolt devices on market age Pekin ducks. *Journal of Applied Poultry Research* 30(2), 100162.

Visser, E. Kathalijne, Ellis, Andrea D. and Van Reenen, Cornelis G. (2008). The effect of two different housing conditions on the welfare of young horses stabled for the first time. *Applied Animal Behaviour Science*, 114(3), 521-533.

von Holleben, K., von Wenzlawowicz, M., Gregory, N., Anil, H., Velarde, A., Rodriguez, P., Cenci Goga, B., Catanese, B., Lambooij, B. (2010). Report on good and adverse practices—animal welfare concerns in relation to slaughter practices from the viewpoint of veterinary sciences. Dialrel report. Deliverable. 1, 3. <http://www.dialrel.eu/images/veterinary-concerns.pdf>.

Walsh JL, Percival A, Turner PV. (2017). Efficacy of blunt force trauma, a novel mechanical cervical dislocation device, and a non-penetrating captive bolt device for on-farm euthanasia of pre-weaned kits, growers, and adult commercial meat rabbits. *Animals (Basel)* 7:100.

Woolcott CR, Torrey S, Turner PV, Serpa L, Schwean-Lardner K, Widowski TM. (2018) Evaluation of Two Models of Non-Penetrating Captive Bolt Devices for On-Farm Euthanasia of Turkeys. *Animals (Basel)*. Mar 20;8(3):42. <https://pubmed.ncbi.nlm.nih.gov/29558419/>.

CHAPTER 8.8.

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

The EU would like to thank the Code Commission for considering the EU comments submitted prior and during the 2023 WOAHA General session. The EU is concerned by the revision of this chapter.

The main concern lies in the change in risk to which Member Countries with an official status of “Country or zone free from FMD where vaccination is not practised” are exposed due to different importation rules (c.f. Article 8.8.2. points 4. and 5.).

As clarified several times by SCAD, importation of vaccinated animals into a country or zone free from FMD where vaccination is not practised implies additional surveillance and administrative burden for the Veterinary Authority in several steps.

The EU invites the SCAD and the Code Commission to simplify the requirements to for the maintenance of the official status for the maintenance of the official status “Country or zone free from FMD where vaccination is not practised”.

The EU would like thank the Code Commission for addressing the issue of Chapter 1.11. “Application for official recognition by the WOAHA of free status for foot and mouth disease”. It is assumed that changes to Chapter 1.11. will be adopted at the same time as changes in Chapter 8.8.

Important comments on this chapter and on Chapter 1.11. are provided below.

Article 8.8.1.

General provisions

- 1) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with foot and mouth disease virus (FMDV). Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contacts between them. Amongst *Camelidae*, only Bactrian camels (*Camelus bactrianus*) are sufficiently susceptible to have potential for epidemiological significance. Dromedaries (*Camelus dromedarius*) are not susceptible to *infection* with FMDV while South American camelids are not considered to be of epidemiological significance.
- 2) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of 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 an susceptible animal ~~listed in point 2~~; or
 - b) antigen or nucleic acid specific to FMDV has been detected in a sample from an 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 an 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 WOAHA 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, 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;

EU comment

In relation to the importation of vaccinated animals, the report of the Code Commission refers to Article 8.8.2. indicating that “*The Commission reminded Members that the risk mitigation measures provided in the relevant articles for importation are sufficient for such animals to be considered safe and consequently this introduction implies no additional risk. Regarding a comment that these changes would impose an additional burden on importing countries that are free without vaccination such as increased surveillance and traceability and identification of imported animals, the Commission reminded Members that the implementation of the standards at the national level is the prerogative of each Member*”. The EU would like to refer to a comment already submitted previously: if the WOA standard does not recognise an increased risk and allows for importation of vaccinated animals into a country or zone free from FMD where vaccination is not practiced, then Member Countries that prefer not to import such animals would need to provide an import risk analysis demonstrating why they deviate from the WOA standards (in line with WTO SPS principles).

The SCAD (in its February 2023 meeting report) stated the following: “*The Commission reiterated its disagreement with comments that importing vaccinated animals from ‘FMD-free country/zones/compartments with vaccination’ entails an increased risk. The Commission acknowledged that the importation of vaccinated animals might require adjusting the surveillance strategy of the importing country*”. This statement acknowledges the need to adapt surveillance in case vaccinated animals are imported, i.e. an additional risk mitigating measure is needed with the requirement to differentiate the surveillance in the vaccinated from the surveillance in the non-vaccinated populations.

In addition, the recommendations of the SCAD (in its February 2022 meeting report) stated that “*To further assist Members on this issue, the Commission recommended the OIE to develop FMD surveillance guidelines*”. To our knowledge this recommendation still needs to be addressed as these guidelines have not been made available to Members yet.

The EU therefore questions the change in the level of risk and the related risk mitigating measure that is added to compensate for such new risk. The EU expresses important

reservations on this draft chapter and invites the Code Commission and the SCAD to consider the following fact in case the proposed changes to this chapter are adopted:

The Member Countries which have an official status “FMD free where vaccination is not practised” would be exposed to a different level of risk once the changes to this chapter are adopted. This means that these Member Countries would have to undertake *one of the following*:

- a) increase administrative burden by setting up a separate surveillance scheme for imported vaccinated animals and communicate this to WOAHP in a structured and clear manner to ensure the annual reconfirmation of their status is granted, or
- b) perform an import risk analysis (scientifically sound and in line with WTO principles) to justify why they deviate from WOAHP Terrestrial Code standards and do not accept the importation of vaccinated animals, or
- c) accept the increase in risk when importing vaccinated animals and ultimately lose their WOAHP recognised FMD free status because they would not comply with a).

The first two options imply significantly more work for the importing country, while the third option would be non-viable in a realistic scenario.

To conclude: the EU invites the Code Commission and the SCAD to propose amendments to Chapter 1.11. to significantly simplify the data required for annual reconfirmation of official status in order not to overburden countries which have already demonstrated being able to maintain freedom from FMD without vaccination.

- 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*; ~~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.;~~

EU comment

The EU queries whether as a consequence of the deletion of the above text, vaccinated animals may be imported into a country free from FMD without vaccination from any country, no matter the FMD freedom or vaccination status, in accordance with the articles of this chapter (i.e. including from infected countries).

It is noted that the Commission’s report refers to changes in Article 8.8.8., but it would be helpful to clarify how the change applied above impacts imports from other countries with a different health status.

- 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 WOAAH 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 *populations* 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 WOAAH.

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 WOAHA 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 WOAHA as such, wishes to change its status to country or *zone* free from FMD where *vaccination* is not practised, it should notify WOAHA 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 WOAHA. If the application for the new status is not provided within 24 months of the cessation or if the compliance is not approved by WOAHA, 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 WOAHA as such, wishes to change its status to country or *zone* free from FMD where *vaccination* is practised, it should provide WOAHA 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 WOAHA. As soon as it is recognised as free from FMD where *vaccination* is practised, the country or *zone* ~~will~~ should begin the *vaccination*. ~~Then~~ Then the Member Country should provide evidence within six months that it has ~~complied~~ 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 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, 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 WOAAH, 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 WOAAH 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 WOAAH.

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 WOAAH.

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 WOAAH.

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 and~~ serological tests for FMD with negative results on samples 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*, FMD did not occur within a 10-kilometre radius of the *establishment* during that period, and all animals in isolation were subjected to diagnostic virological and serological tests for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period;

-
- 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 for *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

-
- 1) 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) 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) have been vaccinated at least twice with the last vaccination not more than six months, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to slaughter;
- c) were kept for the past 30 days in:
 - a quarantine station; or
 - an establishment, within a 10-kilometre radius of which FMD has not occurred during that period;
- d) have been transported, in a vehicle which was ~~cleaned~~ cleansed and disinfected before ~~the bovines and water buffaloes were loaded~~, directly from the establishment of origin or quarantine station to the approved slaughterhouse/abattoir without coming into contact with other FMD susceptible animals which do not fulfil the required conditions for export;
- e) have been slaughtered in an approved slaughterhouse/abattoir:
 - i) which is officially designated for export;
 - ii) in which no FMD has been detected during the period between the last disinfection carried out before slaughter and the shipment for export has been dispatched;
- f) were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., with favourable results;

- 2b) comes from deboned carcasses:

- a) from which feet, head, viscera and the major lymphatic nodes have been removed;
- b) which, prior to deboning, have been submitted to maturation at a temperature greater than + 2°C for a minimum period of 24 hours following slaughter and in which the pH value was less than 6.0 when tested in the middle of both the longissimus dorsi muscle.

Article 8.8.22bis.

Recommendations for importation of fresh meat of ~~domestic~~ pigs from countries or zones infected with FMDV, where an official control programme exists

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 loaded~~, directly from the establishment of origin or quarantine station to the approved slaughterhouse/abattoir without coming into contact with other FMD susceptible animals that do not fulfil the conditions required for export, either during transport or at the slaughterhouse/abattoir;
- 3) the ~~animals~~ 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* which at the time of *milk* collection were not infected or suspected of being infected with FMD; and
 - 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
ii) comes from milk that has been tested for FMDV with negative results, and heated at a minimum temperature of 72 C for at least 15 seconds;
- 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 have been imported from a country, *zone* or *compartment* free from FMD.

Article 8.8.30.

Recommendations for importation of skins and trophies derived from susceptible 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 (Aw) 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 (Na₂CO₃).

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 (Na₂CO₃) maintained at pH 11.5 or greater for at least 48 hours; or
- 4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at pH less than 3.0 for at least 48 hours; wetting and dressing agents may be added; or
- 5) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na₂CO₃).

Article 8.8.38.

Procedures for the inactivation of FMDV in casings of ruminants and pigs

For the inactivation of FMDV present in casings of ruminants and pigs, the following procedures should be used: treating for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl, a_w< 0.80), or with phosphate supplemented salt containing 86.5% NaCl, 10.7% Na₂HPO₄ and 2.8% Na₃PO₄ (weight/weight/weight), either dry or as a saturated brine (a_w< 0.80), and kept at a temperature of greater than 12°C during this entire period.

Article 8.8.39.

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 WOA, 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 WOAHP 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 WOAHP 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 WOAHP 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 animals should be considered in the strategy and design of the *surveillance* programme.

EU comment

Reference is made to the EU comment included in Article 8.8.2.

A Member Country wishing to substantiate FMD freedom where *vaccination* is practised should demonstrate that FMDV has not been transmitted in any susceptible *populations*. Within vaccinated *populations*, serological surveys to demonstrate no evidence of 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 WOAHP 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 WOAHP 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 movement of animals, epidemiological links to infected *herds*, species, production management systems and *herd* size;
 - ii) random serological *surveillance* in vaccinated *herds* with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level) in each emergency *vaccination* area;
 - iii) intensified clinical and *slaughterhouse/abattoir surveillance*;
 - iv) for non-vaccinated susceptible species that do not show reliable clinical signs or husbandry systems that do not allow sufficient observation, serological surveys with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level);
 - v) virological *surveillance* to investigate the status of vaccinated *herds* may also be conducted to contribute to additional confidence in demonstrating freedom.
- c) Vaccine efficacy and *vaccination* effectiveness of the emergency *vaccination* deployed have been demonstrated by documenting the following:
 - i) Vaccine efficacy
 - vaccine that provides high 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 movement of *animals*, epidemiological links to infected *herds*, species and age, production management systems, *herd* size;
- ii) random serological *surveillance* in vaccinated *herds* with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level);
- iii) intensified clinical and *slaughterhouse/abattoir surveillance*;
- iv) serological survey in non-vaccinated susceptible species that do not show reliable clinical signs or husbandry systems that do not allow sufficient observation with risk-based stratification according to factors such as proximity to the emergency *vaccination* area, *region/establishment* with numerous movement of *animals*, epidemiological links to infected *herds*, species, production management systems, *herd* size;

-
- v) virological *surveillance* to investigate the status of vaccinated *herds* may also be conducted to contribute to additional confidence in demonstrating freedom.

The efficacy of the routine vaccine against the virus that caused the *outbreak(s)* has been documented.

The entire investigative process should be documented within the *surveillance* programme.

All the epidemiological information should be substantiated, and the results should be collated in the final report.

Article 8.8.41.

Methods of surveillance

1. Clinical surveillance

Farmers and workers who have day-to-day contact with livestock, as well as *veterinary para-professionals*, *veterinarians* and diagnosticians, should report promptly any suspicion of FMD. The *Veterinary Services* 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 WOA Reference Laboratory.

Virological *surveillance* aims to:

- a) confirm clinically suspected *cases*;
- b) follow up positive serological results;
- c) characterise isolates for epidemiological studies and vaccine matching;
- d) monitor *populations* at risk for the presence and transmission of the virus.

3. Serological surveillance

Serological *surveillance* aims to detect antibodies resulting from *infection* or *vaccination* using 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 *populations*, SP tests may be used to screen sera for evidence of *infection* with FMDV or to detect the introduction of vaccinated *animals*. In vaccinated *populations*, 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.

CHAPTER 1.11.

**APPLICATION FOR OFFICIAL RECOGNITION BY WOAHP OF
FREE STATUS FOR FOOT AND MOUTH DISEASE**

EU comment

The EU thanks the Code Commission and in general supports the proposed changes to this chapter. However, it invites the Code Commission and the SCAD to review all the procedures for reconfirmation of official statuses (not only for FMD). Such revision should result in a reduction in administrative burden every year for indicating that there were no significant changes from the previous year.

Timing in adopting the changes to this chapter is essential as it should be adopted at the same time as the revised Chapter 8.8.

While Comments are provided in the text below, it should be noted that the Union still seeks clarifications on several important aspects of Chapter 8.8.; the feedback received will determine the Union's position also for chapter 1.11.

[...]

EU comment

The EU queries why changes similar to those brought in for Article 1.11.3. are not also proposed for Article 1.11.1. (Country free from infection with foot and mouth disease virus where vaccination is not practised)?

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 WOAHP 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 WOAHP 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 *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 WOAHP official languages. Weblinks to supporting documents in one of the official languages of WOAHP may also be provided, where they exist.

All annexes should be provided in one of the WOAHP 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 in previously vaccinated animals;
- 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. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?

EU comment

In order to match the requirements of point 3) of proposed new Article 8.8.2. see revised text:

“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 animals are considered in the strategy and design of the surveillance programme, if applicable.

EU comment

This additional text is closely related to the changes in Chapter 8.8. and its endorsement should be conditional to the endorsement of Chapter 8.8.

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 WOAHP 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 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.

[...]

CHAPTER 8.16.

INFECTION WITH RIFT VALLEY FEVER VIRUS

EU comment

The EU supports the proposed 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.

[...]

CHAPTER 8.18.

INFECTION WITH *TRICHINELLA* SPP.

EU comment

The EU in general supports the proposed changes to the chapter and invites the Code Commission to take this opportunity to review the case definition and align it with the approach taken in other disease chapters. A further comment is 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 adult parasite and the larval forms live in the small intestine and 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.~~

EU comment

Suggested revision: “The adult parasite and the L1 larval stage forms live in the small intestine and muscles (respectively) of many mammalian, avian and reptile host species.”

Only the L1 stage that’s found in muscle tissue, and not all larval forms as could be interpreted from the paragraph above. The other larval stages occur in the small intestine when there’s a series of larval moults to the adult stage (L1 to L5) after the L1 stage has been released from digested muscle tissue.

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*.

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).

~~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 comment**

The EU in general supports the proposed changes to this chapter. A comment is provided below.

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, do not play an epidemiologically significant role. 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*.

EU comment

The EU queries for the evidence that wild and feral animals do not play an epidemiologically significant role. Is there a citation for this?

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 comment

The EU would like to thank the Code Commission for taking into account previous comments. The EU, in general, supports this proposed new chapter. A comment is inserted in the text below.

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, Felidae; the orders Rodentia and Lagomorpha; and non-human primates.

EU comment

The EU would like to inquire why 'Cervidae' are not included as 'susceptible animals'.

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) 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.

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.126. to 8.Z.159. 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. to 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 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 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;~~

43) 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

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 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:
 - i) showed no clinical sign of surra on the day of shipment;
 - 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;
 - iii) 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 from *vectors* or any source of *T. evansi* by the application of effective *biosecurity*;
 - b) the equids were not subjected to any practice that may represent a risk of iatrogenic transmission of infection with *T. evansi* surra;
 - c) the equids are kept and transported individually in stalls and *vehicles/vessels* which are subsequently cleaned and disinfected 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;~~
- 32) the semen was collected, processed and stored in a *semen collection centre* 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 sustainability;~~
 - cb)** the collection and transport of samples from suspected *cases* to a *laboratory* for diagnosis or a procedure for the rapid diagnosis in the field;
 - dc)** 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*.
-

CHAPTER 11.5.

**INFECTION WITH *MYCOPLASMA*
MYCOIDES SUBSP. *MYCOIDES* SC
(CONTAGIOUS BOVINE PLEUROPNEUMONIA)**

EU comment

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

Article 11.5.1.

General provisions

~~1)~~ ~~For the purposes of this chapter, susceptible animals means domestic bovines (*Bos indicus*, *B. taurus*, *B. grunniens* and *Bubalus bubalis*).~~

~~121)~~ For the purposes of the *Terrestrial Code*, the ~~incubation period~~ for contagious bovine pleuropneumonia (CBPP) ~~shall be six months.~~

~~For the purpose of this chapter, is defined as an animal infected of susceptible animals bovines (*Bos indicus*, *B. taurus*, *B. grunniens* and *Bubalus bubalis*) with *Mycoplasma mycoides* subspecies *mycoides* SC (*Mmm-SC*), and freedom from CBPP means freedom from *Mmm-SC* infection.~~

~~For the purpose of this chapter, susceptible animals include bovids (*Bos indicus*, *B. taurus* and *B. grunniens*) and water buffaloes (*Bubalus bubalis*).~~

~~23)~~ ~~For the purposes of international trade~~ This chapter deals not only with the occurrence of clinical signs caused by *MmmSC*, but also with the presence of *infection* with *MmmSC* in the absence of clinical signs.

~~34)~~ The following defines the occurrence of *infection with MmmSC infection*:

- ~~1a)~~ *MmmSC* has been isolated and identified as such ~~in from an animal, embryos, oocytes or semen a sample from a susceptible animal bovine; or,~~ **or**
- ~~2b)~~ *Mmm* deoxyribonucleic acid **specific to *Mmm*** has been detected in a sample from a ~~susceptible animal bovine~~ showing pathological lesions consistent with an *infection* with *MmmSC*, **and or** epidemiologically **linked** to a confirmed case; **or**
- ~~c)~~ antibodies **specific to *MmmSC* antigens**, which are not the consequence of *vaccination*, **have been detected in a sample from a susceptible animal bovine showing pathological lesions consistent with an infection with *Mmm*, and or epidemiologically linked to a confirmed case or *MmmSC* deoxyribonucleic acid** have been identified in one or more animals showing pathological lesions consistent with *infection* with *MmmSC* with or without clinical signs, and epidemiological links to a confirmed *outbreak* of CBPP in susceptible animals.

~~45)~~ **For** ~~the purposes of the *Terrestrial Code*, the incubation period shall be six months.~~

~~When authorising import or transit of the commodities listed in this chapter, with the exception of those listed in Article 11.5.2., Veterinary Authorities should require the conditions prescribed in this chapter relevant to the CBPP status of the domestic bovids and water buffalo population of the exporting country, zone or compartment.~~

56) Standards for diagnosis, diagnostic tests and vaccines, as well as information on the epidemiology, are described in the *Terrestrial Manual*.

Article 11.5.2.

Safe commodities

When authorising the importation or transit of the following *commodities*, *Veterinary Authorities* should not require any CBPP-related conditions, regardless of the CBPP animal health status of the ~~domestic bovids~~ bovine and water buffalo population of the *exporting country, zone or compartment*:

- 1) *milk and milk products*;
- 2) *hides and skins*;
- 3) *meat and meat products* (excluding lung).

Article 11.5.3.

Country or zone free from CBPP free country or zone

A country or zone may be considered free from CBPP when the relevant provisions in point 2 of Article 1.4.6. have been complied with, and when within the proposed free country or zone for at least the past 24 months:

- 1) there has been no case of infection with Mmm;
- 2) the Veterinary Authority has current knowledge of, and authority over, all herds of susceptible animals bovines;
- 3) appropriate surveillance has been implemented in accordance with:
 - a) Article 1.4.6. where historical freedom can be demonstrated; or
 - b) Articles 11.5.13. and 11.5.14. where historical freedom cannot be demonstrated;
- 4) measures to prevent the introduction of the infection have been in place: in particular, the importations or movements of bovine commodities into the country or zone have been carried out in accordance with this chapter and other relevant chapters of the Terrestrial Code;
- 5) no vaccination or treatment against CBPP has been carried out;
- 6) no animal vaccinated or treated against CBPP have been introduced since the cessation of vaccination.

To qualify for inclusion in the existing list of CBPP free countries and zones, a Member Country should:

- 1) have a record of regular and prompt animal disease reporting;
- 2) send a declaration to WOAHP stating that:
 - a) there has been no *outbreak* of CBPP during the past 24 months;
 - b) no evidence of CBPP *infection* has been found during the past 24 months;
 - c) no *vaccination* against CBPP has been carried out during the past 24 months;and supply documented evidence that *surveillance* for CBPP in accordance with this chapter is in operation and that regulatory measures for the prevention and control of CBPP have been implemented;
- 3) not have imported since the cessation of *vaccination* any animals vaccinated against CBPP.

The country or *zone* will be included in the list of countries or zones free from CBPP in accordance with Chapter 1.6. only after the submitted evidence has been accepted by WOAH.

Retention on the list requires annual reconfirmation of compliance with all points above and the relevant provisions under point 4 of Article 1.4.6. that the information in points 2 a), 2 b), 2 c) and 3 above be re-submitted annually and Documented evidence should be resubmitted annually for points 1 to 4 above. Any changes in the epidemiological situation or other significant events should be reported notified to WOAH in accordance with the requirements in Chapter 1.1.

Article 11.5.46.

Compartment free from CBPP free compartment

The bilateral recognition of a CBPP free *compartment* should follow the principles laid down in this chapter and in Chapters 4.3. and 4.4.

A compartment free from CBPP can be established in any country or zone. In defining such a compartment the principles of Chapters 4.4. and 4.5. should be followed. Susceptible animals-Bovines in the compartment should be separated from any other susceptible animals-bovines by the effective application of a biosecurity plan.

A Member Country wishing to establish a compartment free from CBPP should:

- 1) have a record of regular and prompt animal disease reporting and, if not free, have an official control programme and a surveillance system for CBPP in place in accordance with Articles 11.5.13. and 11.5.14. that allows knowledge of the prevalence, distribution and characteristics of CBPP in the country or zone;
- 2) declare for the free compartment that:
 - a) ~~there has been no case of CBPP during the past 24 months;~~
 - ba) no infection with Mmm has been detected during the past 24 months;
 - eb) vaccination against CBPP is prohibited;
 - ec) no animal vaccinated or treated against CBPP within the past 24 months is in the compartment;
 - ed) animals, semen and embryos may only enter the compartment in accordance with relevant articles in this chapter;
 - fe) documented evidence shows that surveillance in accordance with Articles 11.5.13. and 11.5.14. is in operation;
 - gf) an animal identification and traceability system in accordance with Chapters 4.1. and 4.2. is in place;
- 3) describe in detail:
 - a) the animal subpopulation in the compartment;
 - b) the biosecurity plan to mitigate the risks identified by the surveillance carried out in accordance with point 1 notably to prevent the aerosol transmission of CBPP.

The compartment should be approved by the Veterinary Authority.

Article 11.5.5.

Country ~~of or~~ zone infected with Mmm CBPP infected country or zone

A country or zone shall be considered as infected with Mmm ~~When~~ the requirements for acceptance as a CBPP free country or zone free from CBPP are not fulfilled, a country or zone shall be considered as infected.

Article 11.5.5bis.

Establishment of a containment zone within a country or zone previously free from CBPP

In the event of outbreaks of CBPP-infection with Mmm within a country or zone previously free from CBPP, including within a protection zone, a containment zone, which includes all epidemiologically linked outbreaks, can may be established, in accordance with Article 4.4.7., to minimise the impact on the rest of 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 WOA, in addition to the requirements of Article 4.4.7., in support of the application, documented evidence that:

- 1) on suspicion, a strict standstill has been imposed on the suspected establishments, and in the country or zone animal movement control has been imposed and effective controls on the movement of animals and other relevant commodities are in place in the country or zone;
- 2) the infection has been confirmed and notified in accordance with Chapter 1.1.;
- 3) on confirmation, an the additional standstill and movement of susceptible animals has been imposed controls described in point 1 have been reinforced in the entire containment zone and the movement controls described in point 1 have been reinforced;
- 4) epidemiological investigations into the likely source of the outbreaks have been carried out;
- 5) a slaughter policy, with or without the use of emergency vaccination, has been applied;
- 6) surveillance in accordance with Articles 11.5.13. and 11.5.14. is in place in the containment zone and in the rest of the country or zone;
- 7) measures that prevent the spread of CBPP to the rest of the country or zone, taking into consideration physical and geographical barriers, are in place.

The free status of the areas outside the containment zone is suspended while the containment zone is being established. The free status of these areas outside the containment zone may be reinstated irrespective of the provisions of Article 11.5.4., once the containment zone has been approved by WOA as complying with Article 4.4.7. and points 1 to 7 above.

In the event of recurrence of infection with Mmm in the containment zone, established in accordance with point 4(a) of Article 4.4.7., the approval of the containment zone is withdrawn and the CBPP-free status of the whole country or zone is suspended until the relevant requirements of Article 11.5.46. are fulfilled.

In the event of occurrence of infection with Mmm in the outer zone of a containment zone established in accordance with point 4(b) of Article 4.4.7., the approval of the containment zone is withdrawn and the free status of the whole country or zone is suspended until the relevant requirements of Article 11.5.46. are fulfilled.

The recovery of the CBPP-free status of the containment zone should follow the provisions of Article 11.5.46.

Article 11.5.4.

Recovery of free status

Should an outbreak of CBPP occur in a previously free country or zone, its status may be recovered when surveillance in accordance with Articles 11.5.13. and 11.5.14. has been carried out with negative results, and 12 months after:

- 1) the disinfection of the last affected establishment, provided that a slaughter policy without vaccination has been implemented;
or
- 2) the disinfection of the last affected establishment and the slaughter of all vaccinated animals, provided that a slaughter policy with emergency vaccination and slaughter of vaccinated animals has been implemented.

When a CBPP outbreak occurs in a CBPP free country or zone, one of the following waiting periods is required to regain the status of CBPP free country or zone:

1) 12 months after the last case where a ~~stamping-out~~ policy and serological *surveillance* and strict movement control are applied in accordance with this chapter;

2) if ~~vaccination~~ was used, 12 months after the ~~slaughter~~ of the last vaccinated animal.

1) 12 months after the slaughter of the last case where a slaughter policy, without emergency vaccination, and surveillance are applied in accordance with Articles 11.5.13. and 11.5.14.; or

2) 12 months after the slaughter of the last case and of all vaccinated animals, whichever occurred last, where a slaughter policy, emergency vaccination and surveillance in accordance with Articles 11.5.13. and 11.5.14. are applied.

The country or zone will regain the status of CBPP free country or zone only after the submitted evidence, based on the provisions of Chapter 1.10., has been accepted by WOA.

Where a ~~stamping-out~~ slaughter policy is not practised, the above waiting periods do not apply but Article 11.5.3. applies.

Article 11.5.7.

Recommendations for importation of susceptible animals-bovines from CBPP free countries, ~~or zones,~~ or compartments free from CBPP free compartments

For domestic bovids and water buffaloes

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

1) showed no clinical sign of CBPP on the day of shipment;

2) were kept in a CBPP free country, zone or compartment since birth or for at least the past six months.

Article 11.5.8.

Recommendations for importation of susceptible animals-bovines from CBPP infected countries or zones infected with Mmm for immediate slaughter

For domestic bovids and water buffaloes for slaughter

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

1) showed no clinical sign of CBPP on the day of shipment;

2) originate from an establishment in which surveillance in accordance with Articles 11.5.13. and 11.5.14. demonstrates that where no case of CBPP had-has occurred was officially reported for during the past six months; and

3) are transported directly under the supervision of the Veterinary Authority in a vehicle/vessel, which was subjected to disinfection before loading, directly from the establishment of origin to the slaughterhouse/abattoir place of shipment in sealed vehicles without coming into contact with other susceptible animals bovines.

Article 11.5.9.

Recommendations for importation of bovine semen from CBPP free countries, ~~or zones,~~ or compartments free from CBPP free compartments

For bovine semen

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

1) the donor animals:

- a) showed no clinical sign of CBPP on the day of collection of the semen;
 - b) were kept in a CBPP free country, *zone* or *compartment* since birth or for at least the past six months;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.

Article 11.5.10.

Recommendations for importation of bovine semen from ~~CBPP infected countries~~ or zones infected with *Mmm*

For bovine semen

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

- 1) the donor animals:

~~a) were kept since birth, or for the past six months, in an establishment in which surveillance in accordance with Articles 11.5.13. and 11.5.14. demonstrates that no case of infection with *Mmm* has occurred during that period;~~

~~ab) showed no clinical sign of CBPP on the day of collection of the semen;~~

~~bc) were subjected to the complement fixation a serological test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each tests, the second test being performed within 14 days prior to collection;~~

~~ed) were isolated from other domestic bovids and water buffaloes susceptible animals-bovines that did not meet the same health requirements from the day of the first the complement fixation serological test until collection;~~

~~d) were kept since birth, or for the past six months, in an establishment in which surveillance in accordance with Articles 11.5.13. and 11.5.14. demonstrates that where no case of CBPP was reported had occurred during that period, and that the establishment was not situated in a CBPP infected zone;~~

e) AND EITHER:

i) have not been vaccinated against CBPP;

OR

ii) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than four months prior to collection; in this case, the condition laid down in point ~~(bc)~~ above is not required;

- 2) the semen:

~~a) was collected, processed and stored in accordance with Chapters 4.56. and 4.67.;~~

~~b) was subjected to a test for the identification detection of the agent.~~

Article 11.5.11.

Recommendations for importation of *in vivo* derived or *in vitro* produced oocytes or embryos of susceptible animals-bovines from ~~CBPP free countries, or zones, or compartments free~~ from CBPP free compartments

For *in vivo* derived or *in vitro* produced oocytes or embryos of domestic bovids and water buffaloes

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

- 1) the donor animals:

- a) showed no clinical sign of CBPP on the day of collection of the oocytes or embryos;
 - b) were kept in a CBPP free country, zone or compartment free from CBPP since birth or for at least the past six months;
- 2) the oocytes were fertilised with semen meeting the conditions of Articles 11.5.9. or 11.5.10.;
 - 3) the oocytes or embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.

Article 11.5.12.

Recommendations for importation of *in vivo* derived or *in vitro* produced oocytes or embryos of susceptible animals-bovines from CBPP infected countries or zones infected with *Mmm*

For *in vivo* derived or *in vitro* produced oocytes or embryos of domestic bovids and water buffaloes

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

- 1) the donor animals:
 - a) were kept since birth, or for the past six months, in an establishment in which surveillance in accordance with Articles 11.5.13. and 11.5.14. demonstrates that no case of infection with *Mmm* has occurred during that period.
 - ab) showed no clinical sign of CBPP on the day of collection of the embryos or oocytes;
 - bc) were subjected to ~~the complement fixation~~ a serological test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between ~~each test~~, the second test being performed within 14 days prior to collection;
 - ed) were isolated from other ~~domestic bovids and water buffaloes-bovines~~ that did not meet the same health requirements from the day of the first ~~the complement fixation~~ serological test until collection;
 - d) ~~were kept since birth, or for the past six months, in an establishment in which surveillance in accordance with Articles 11.5.13. and 11.5.14. demonstrates that where no case of CBPP was reported had occurred during that period, and that the establishment was not situated in a CBPP infected zone;~~
- e) AND EITHER:
 - i) have not been vaccinated against CBPP;
 - OR
 - ii) were vaccinated ~~using a vaccine complying with the standards described in the *Terrestrial Manual*~~ not more than four months prior to collection; in this case, the condition laid down in point (bc) above is not required;
- 2) the oocytes were fertilised with semen meeting the conditions of Articles 11.5.9. and or 11.5.10.;
- 3) the oocytes or embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.

Article 11.5.13.

Introduction to surveillance-General principles of surveillance

Surveillance aims at identifying infection in bovines. Articles 11.5.13. ~~to~~ and 11.5.14. define the principles and provide a guide for the surveillance of CBPP in accordance with Chapter 1.4. notably point ~~2(h)~~ 3 of Article 1.4.3. concerning quality assurance. They are applicable to Member Countries seeking establishment of freedom from CBPP. Guidance is provided for Member Countries seeking reestablishment, maintenance or recovery of freedom from CBPP for at the entire country, or for a zone, following an outbreak or compartment level or seeking endorsement by WOAHP of their official control programme for CBPP, in accordance with Article 11.5.13. Surveillance aims at identifying infection in bovines susceptible species as indicated in Article 11.5.1.

1. Early detection

A surveillance system for early detection should be in place in accordance with Chapter 1.4. under the responsibility of the Veterinary Authority.

2. Demonstration of freedom

The impact and epidemiology of CBPP differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from CBPP at an acceptable level of confidence should be adapted to the local situation. It is incumbent upon the applicant Member Country to submit a dossier to WOAHP in support of its application that not only explains the epidemiology of CBPP in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of science-scientifically based supporting data. Therefore, there is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that the absence of CBPP-infection with Mmm is assured at an acceptable level of confidence.

Surveillance for CBPP should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from CBPP-infection.

A Member Country wishing to substantiate freedom from CBPP should demonstrate absence of infection with Mmm in susceptible populations.

Article 11.5.14.

~~General conditions and methods for surveillance~~

3. WOAH endorsed official control programme

Surveillance strategies employed in support of a WOAHP endorsed official control programme should demonstrate evidence of the effectiveness of any control strategy used and of the ability to rapidly detect all outbreaks of infection with Mmm-CBPP.

Considerable latitude exists for Member Countries to design and implement surveillance to establish that the whole country or a zone is free from CBPP and to understand the epidemiology of CBPP as part of the official control programme.

The Member Country should submit an application-dossier to WOAHP in supported by a dossier of its application that explains the epidemiology of CBPP in the region concerned and demonstrates how all the risk factors are identified and managed. This should include provision of scientifically-science-based supporting data.

The entire investigative process should be documented within the surveillance programme. All the epidemiological information should be substantiated, and the results should be collated in the final report.

~~The entire investigative process should be documented within the surveillance system in accordance with Chapter 1.4. should be under the responsibility of the Veterinary Authority. A procedure should be in place for the rapid collection and transport of samples from suspect cases of CBPP to a laboratory for CBPP diagnoses.~~

2) ~~The CBPP surveillance programme should:~~

- a) ~~include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers (such as community animal health workers) who have day-to-day contact with livestock, meat inspectors as well as laboratory diagnosticians, should report promptly any suspicion of CBPP. They should be integrated directly or indirectly (e.g. through private veterinarians or veterinary para-professionals) into the surveillance system. All suspect cases of CBPP should be investigated immediately. Where suspicion cannot be resolved by the epidemiological and clinical investigation, samples should be taken and submitted to a laboratory. This requires that sampling kits information should be substantiated, and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in CBPP diagnosis and control;~~
- b) ~~implement, when relevant, regular and frequent clinical inspection and testing of high-risk groups of animals, such as those adjacent to a CBPP infected country or zone (for example, areas of transhumant production systems);~~

- e) ~~take into consideration additional factors such as animal movement, different production systems, geographical and socio-economic factors that may influence the risk of disease occurrence.~~

~~An effective surveillance system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is CBPP. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from CBPP infection should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.). should be collated in the final report.~~

Article 11.5.15.

4. Surveillance strategies

1. Introduction

~~The target population for surveillance aimed at identifying disease and infection should cover all the susceptible species (*Bos taurus*, *B. indicus*, *B. grunniens* and *Bubalus bubalis*) within the country or zone.~~

~~Given the limitations of the diagnostic tools available, the interpretation of serological surveillance results should be at the herd level rather than at the individual animal level.~~

Randomised surveillance may not be the preferred approach given the epidemiology of the disease (usually uneven distribution and potential for occult foci of infection in small populations) and the limited sensitivity and specificity of currently available tests. Targeted Risk-based surveillance (e.g. based on the increased likelihood of infection in particular localities or species, focusing on slaughter findings, and active clinical surveillance) may be the most appropriate strategy. The applicant Member Country should justify the surveillance strategy chosen as adequate to detect the presence of CBPP infection with Mmm in accordance with Chapter 1.4. and the epidemiological situation.

Targeted Risk-based surveillance may involve testing of the entire target subpopulation or a sample from it. In the latter case the sampling strategy should incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing should be large enough to detect infection if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant Member Country should justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular should be clearly based on the prevailing or historical epidemiological situation.

Regular and frequent clinical inspection and testing of high-risk groups of animals, such as those adjacent to a country or zone infected with Mmm (for example, areas of transhumant production systems), should be implemented when relevant.

Additional factors such as animal movement, different production systems, geographical and socio-economic factors that may influence the risk of disease introduction and occurrence should be taken into consideration.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. ~~Ideally, the sensitivity and specificity of the tests used should be validated.~~

5. Follow-up of suspected cases and interpretation of results

An effective surveillance system will identify suspected cases that require immediate follow-up and investigation to confirm or exclude that the cause of the condition is an infection with Mmm. Samples should be taken and submitted for diagnostic testing, unless the suspected case can be confirmed or ruled out by epidemiological and clinical investigation. Details of the occurrence of suspected cases and how they were investigated and dealt with should be documented. This should include the results of diagnostic testing and the measures applied to the animals concerned during the investigation.

~~Irrespective of the surveillance system employed, the design should anticipate the occurrence of false positive laboratory results reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following-up positives to ultimately determine, with a high level of confidence, whether or not they are indicative of infection or not. This should involve follow-up with~~

supplementary tests; ~~clinical and follow-up investigation and post-mortem examination in to collect diagnostic material from the original sampling epidemiological unit as well as and herds~~ which may be epidemiologically linked to it.

Laboratory results should be examined in the context of the epidemiological situation.

Article 11.5.14.

Methods of surveillance

1. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs of CBPP in a *herd* by ~~close a thorough~~ physical examination of ~~susceptible animals~~ bovines. Clinical inspection is an important component of CBPP *surveillance* contributing to reaching ing the desired level of confidence of detection of disease if a sufficiently large number of ~~clinically susceptible animals~~ bovines ~~is-are~~ examined.

~~Clinical *surveillance* and laboratory testing should always be applied in series to clarify the status of CBPP suspects detected by either of these complementary diagnostic approaches. Laboratory testing and post-mortem examination may contribute to confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should be classified as infected until contrary evidence is produced.~~

3. Pathological surveillance

Systematic pathological *surveillance* for CBPP is the most effective approach and should be conducted at ~~slaughterhouses/abattoirs and other slaughter facilities~~. Suspect pathological findings should be confirmed by agent identification. Training courses for *slaughter* personnel and *meat* inspectors are highly recommended.

4. Serological 3. Laboratory testing

Serological *surveillance* is not the preferred strategy for CBPP. However, in the framework of epidemiological investigations, serological testing may be used.

The limitations of available serological tests for CBPP make the interpretation of results difficult and useful only at the *herd* level. Positive findings should be followed up by clinical and pathological investigations and agent identification.

Clustering of seropositive reactions should be expected in CBPP infections and is usually accompanied by clinical signs. As clustering may signal field strain *infection*, the investigation of all instances should be incorporated into the *surveillance* strategy.

Following the identification of a CBPP infected *herd*, contact *herds* should be tested serologically. Repeated testing may be necessary to reach an acceptable level of confidence in *herd* classification.

5. Agent surveillance

Agent *surveillance* should be conducted to ~~follow up and~~ confirm or exclude infection with *Mmm*. ~~suspect cases. Isolates should be typed to confirm *Mmm*SC.~~

Article 11.5.16.

Countries or zones applying for recognition of freedom from CBPP

In addition to the general conditions described in this chapter, a Member Country applying for recognition of CBPP freedom for the country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme depend on the prevailing epidemiological circumstances and should be planned and implemented in accordance with general conditions and methods in this chapter, to demonstrate absence of CBPP *infection*, during the preceding 24 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of CBPP *infection*.

Article 11.5.17.

Countries or zones re-applying for recognition of freedom from CBPP following an outbreak

In addition to the general conditions described in this chapter, a Member Country re-applying for recognition of country or zone freedom from CBPP should show evidence of an active *surveillance* programme for CBPP, following the recommendations of this chapter.

Two strategies are recognised by WOAHP in a programme to eradicate CBPP infection following an outbreak:

- 1) *slaughter* of all clinically affected and in contact susceptible animals;
- 2) *vaccination* used without subsequent *slaughter* of vaccinated animals.

The time periods before which an application can be made for re-instatement of freedom from CBPP depends on which of these alternatives is followed. The time periods are prescribed in Article 11.5.4.

Article 11.5.15~~18~~.

WOAHP endorsed official control programme for CBPP

The overall objective of a WOAHP endorsed *official control programme* for CBPP is for Member Countries to progressively improve their situation and eventually attain CBPP free status. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined subpopulations.

A Member Country may, on a voluntary basis, apply for endorsement of their *its official control programme* for CBPP in accordance with Chapter 1.6., when they have it has implemented measures in accordance with this article.

For an *official control programme* for CBPP to be endorsed by WOAHP, the Member Country should provide a detailed *official control programme* for the control and eventual eradication of CBPP in the country or zone. This document should address and provide documented evidence on the following:

- 1) epidemiology:
 - a) the detailed epidemiological situation of CBPP in the country, highlighting the current knowledge and gaps;
 - b) the main production systems and movement patterns of susceptible animals-bovines and their products within and into the country and, where applicable, the specific zone;
- 2) surveillance and diagnostic capabilities:
 - a) CBPP surveillance in place, in accordance with Chapter 1.4. and Articles 11.5.13. and 11.5.14.;
 - b) diagnostic capability and procedures, including regular submission of samples to a laboratory that performs diagnostic testing and further characterisation of strains in accordance with the *Terrestrial Manual* including procedures to isolate and identify *Mmm*;
- 3) vaccination (if practised as part of the *official control programme* for CBPP):
 - a) vaccination is in accordance with Chapter 4.18. and compulsory in the target population;
 - b) detailed information on vaccination campaigns, in particular:
 - i) the strategy that is adopted for the vaccination campaign;
 - ii) target populations for vaccination;
 - iii) target geographical area for vaccination;
 - iv) monitoring of vaccination coverage, including serological monitoring of population immunity;

-
- v) the strategy to identify vaccinated animals;
 - vi) technical specification of the vaccines used and description of the vaccine licensing procedures in place;
 - vii) use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;
 - viii) the proposed strategy and work plan including the timeline for transition to the cessation of *vaccination*;
- 4) the measures implemented to prevent the introduction of the pathogenic agent and to ensure the rapid detection of all *CBPP outbreaks*;
 - 5) an emergency preparedness plan and an emergency response plan to be implemented in case of *CBPP outbreaks*;
 - 6) work plan and timelines of the *official control programme*;
 - 7) performance indicators for assessing the effectiveness of the control measures to be implemented;
 - 8) monitoring, evaluation and review of the *official control programme* to demonstrate the effectiveness of the strategies.
- 1) have a record of regular and prompt animal disease reporting in accordance with the requirements in Chapter 1.1.;
 - 2) submit documented evidence of the capacity of *Veterinary Services* to control CBPP; this evidence can be provided by countries following the WOAHPVS Pathway;
 - 3) submit a detailed plan of the programme to control and eventually eradicate CBPP in the country or zone including:
 - a) the timeline;
 - b) the performance indicators for assessing the efficacy of the control measures to be implemented;
 - c) submit documentation indicating that the *official control programme* for CBPP has been implemented and is applicable to the entire territory;
 - 4) submit a dossier on the epidemiology of CBPP in the country describing the following:
 - a) the general epidemiology in the country highlighting the current knowledge and gaps;
 - b) the measures to prevent introduction of *infection*, the rapid detection of, and response to, all *CBPP outbreaks* in order to reduce the incidence of *CBPP outbreaks* and to eliminate CBPP in at least one zone in the country;
 - c) the main livestock production systems and movement patterns of CBPP susceptible animals and their products within and into the country;
 - 5) submit evidence that CBPP *surveillance* is in place,
 - a) taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter;
 - b) have diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains in accordance with the *Terrestrial Manual* including procedures to isolate and identify *M. mycoides* subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC;
 - 6) where *vaccination* is practised as a part of the *official control programme* for CBPP, provide:
 - a) evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory;
 - b) detailed information on *vaccination* campaigns, in particular on:
 - i) target populations for *vaccination*;
-

-
- ii) ~~monitoring of vaccination coverage;~~
 - iii) ~~technical specification of the vaccines used and description of the licensing procedures in place;~~
 - iv) ~~the proposed timeline and strategy for the cessation of vaccination;~~

7) ~~provide an emergency preparedness and contingency response plan to be implemented in case of CBPP outbreaks.~~

~~The Member Country's official control programme for CBPP will be included in the list of programmes endorsed by WOAHP only after the submitted evidence has been accepted by WOAHP.~~

~~The country will be included in the list of countries having a WOAHP endorsed official control programme for CBPP in accordance with Chapter 1.6.~~

~~Retention on the list requires an annual update on the progress of the official control programme and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to WOAHP in accordance with the requirements in Chapter 1.1.~~

~~WOAHP may withdraw the endorsement of the official control programme if there is evidence of:~~

- ~~– non compliance with the timelines or performance indicators of the programme; or~~
 - ~~– significant problems with the performance of the Veterinary Services; or~~
 - ~~– an increase in the incidence of CBPP that cannot be addressed by the programme.~~
-

CHAPTER 11.X.

**INFECTION WITH BOVINE PESTIVIRUSES
(BOVINE VIRAL DIARRHOEA)**

EU comment

The EU cannot support the currently proposed case definition and seeks its re-evaluation. Important comments are inserted in the text below.

Article 11.X.1.

General provisions

For the purposes of the *Terrestrial Code*, bovine viral diarrhoea is defined as an *infection* of bovines (*Bos taurus*, *B. indicus* and *Bubalus bubalis*) ~~(hereafter ‘susceptible animals’)~~ with bovine viral diarrhoea virus type 1 (pestivirus A), type 2 (pestivirus B), and or type 3 (pestivirus H) (hereinafter ‘bovine pestiviruses’).

EU comment

The taxonomy of pestiviruses was revised by the International Committee on Taxonomy of Viruses (ICTV) and should be updated accordingly:

“For the purposes of the *Terrestrial Code*, bovine viral diarrhoea is defined as an infection of bovines (*Bos taurus*, *B. indicus* and *Bubalus bubalis*) with bovine viral diarrhoea virus type 1 (pestivirus bovis), type 2 (pestivirus tauri), or type 3 (pestivirus brazilense) (hereafter ‘bovine pestiviruses’).

The following defines the occurrence of *infection* with bovine pestiviruses:

- 1) bovine pestivirus, excluding vaccine strains, has been isolated and identified as such in a sample from a ~~susceptible animal~~ bovine; or
- 2) antigen or ribonucleic acid specific to bovine pestivirus, excluding vaccine strains, has been detected in a sample from a ~~susceptible animal~~ bovine.

EU comment

The EU thanks the Code Commission for considering the case definition in the September and February 2023 meetings as well as in the September 2021 meeting. The EU takes note of the expert opinion reported in these reports.

However, this case definition would not allow to consider as an outbreak the case when animals (maybe even sentinel animals) seroconverted to BVD. Bearing in mind the more

labour intensive surveillance required to identify antigen or nucleic acid, having in place serosurveillance appears fully justified.

The EU therefore needs to reiterate its earlier comment. The EU suggests adding a point 3, as follows:

“3) antibodies to bovine pestiviruses, that are not a consequence of vaccination, have been detected in a sample from a susceptible animal showing clinical signs consistent with bovine viral diarrhoea, or epidemiologically linked to a confirmed or suspected case of bovine viral diarrhoea.”

In addition, to make the Article work correctly, we should add “or” at the end of point 2 so that the case definition is met when fulfilling either point 1) or 2) or 3).

Standards for diagnosis, diagnostic tests and vaccines, as well as information on the epidemiology, are described in the *Terrestrial Manual*.

CHAPTER 12.1.

**INFECTION WITH
AFRICAN HORSE SICKNESS VIRUS**

EU comment

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

Article 12.1.1.

General provisions

For the purposes of the *Terrestrial Code*, African horse sickness (AHS) is defined as an *infection* of equids with African horse sickness virus (AHSV).

The following defines the occurrence of an *infection* with AHSV:

- 1) AHSV has been isolated and identified as such in a sample from an equid ~~or a product derived from that equid~~; or
- 2) ~~antigen or ribonucleic acid~~ specific to AHSV has been ~~identified~~ detected in a samples from an equid showing clinical signs or pathological lesions consistent with AHS, or epidemiologically linked to a confirmed or suspected ~~or confirmed~~ case; or
- 3) serological evidence of active *infection* with AHSV by detection of seroconversion due to recent exposure to with production of antibodies against structural or nonstructural proteins of AHSV, that are which is not a the consequence of vaccination, have ~~has~~ been ~~identified~~ detected in a paired samples from an equid ~~that either showing~~ clinical signs or pathological lesions consistent with AHS, or is epidemiologically linked to a confirmed or suspected ~~or confirmed~~ case.

For the purposes of the *Terrestrial Code*, the *infective period* for AHS is 40 days ~~for domestic horses. Although critical information is lacking for some species, this chapter applies to all Equidae.~~

All countries or *zones* adjacent to a country or *zone* not having free status should determine their AHSV status from an ongoing *surveillance* programme. ~~Throughout the chapter, *surveillance* is in all cases understood as being conducted as described in Articles 12.1.11. to 12.1.13.~~

Standards for diagnosis diagnostic tests and vaccines as well as information on the epidemiology, are described in the *Terrestrial Manual*.

Article 12.1.1bis.Safe commodities

When authorising the importation or transit of the following commodities, Veterinary Authorities should not require any AHS-related conditions regardless of the animal health status of the exporting country or zone:

1) milk and milk products;

2) meat and meat products;

3) hides and skins;

4) hooves;

5) gelatine and collagen;

6) sterile filtered horse serum;

Article 12.1.2.

AHS free eCountry or zone free from AHS

1) A country or *zone* may be considered free from AHS when the relevant provisions in point 2(a) of Article 1.4.6. have been complied with, and when within the proposed free country or zone: infection with AHSV is notifiable in the whole country, systematic vaccination is prohibited, importation of equids and their semen, oocytes or embryos are carried out in accordance with this chapter, and either:

1) for at least the past 24 months:

a) the Veterinary Authority has current knowledge of, and authority over, all domestic and captive wild equids in the country or zone;

b) the Veterinary Authority has current knowledge of the distribution, habitat and indication of disease occurrence through passive surveillance of wild and feral equids in the country or zone;

c) either:

i) ~~there has been no case of infection with AHSV and the country or zone is not adjacent to an infected country or zone;~~
or

ii) ~~a surveillance programme has demonstrated no evidence of Culicoides in accordance with Chapter 1.5.;~~

d) appropriate surveillance has been implemented in accordance with:

i) point 2(b) of Article 1.4.6. where historical freedom can be demonstrated; or

ii) Articles 12.1.11. to 12.1.13. where historical freedom cannot be demonstrated; or

iii) Chapter 1.5. where a surveillance programme has demonstrated no evidence of Culicoides.

e) if adjacent to an infected country or zone, includes an area in which surveillance is conducted in accordance with Articles 12.1.11. to 12.1.13.;

f) measures to prevent the introduction of the infection have been in place: in particular, the importations or movements of commodities into the country or zone have been carried out in accordance with this chapter and other relevant chapters of the Terrestrial Code;

2) no systematic vaccination against AHS has been carried out for at least the past 12 months.

a) historical freedom as described in Chapter 1.4. has demonstrated no evidence of AHSV in the country or zone; or

b) the country or zone has not reported any case of AHS for at least two years and is not adjacent to an infected country or zone; or

c) a surveillance programme has demonstrated no evidence of AHSV in the country or zone for at least two years; or

d) the country or zone has not reported any case of AHS for at least 40 days and a surveillance programme has demonstrated no evidence of Culicoides for at least two years in the country or zone.

-
- 2) An AHS free country or zone which is adjacent to an infected country or zone should include a zone in which *surveillance* is conducted in accordance with Articles 12.1.11. to 12.1.13., as relevant.
 - 3) An AHS free country or zone will not lose its free status through the importation of seropositive or vaccinated equids and their semen, oocytes or embryos from infected countries or zones, provided these imports are carried out in accordance with this chapter.
 - 4) To qualify for inclusion in the list of AHS free countries or zones, a Member Country should:
 - a) have a record of regular and prompt animal disease reporting;
 - b) send a declaration to the OIE stating:
 - i) the section under point 1) on which the application is based;
 - ii) no routine *vaccination* against AHS has been carried out during the past year in the country or zone;
 - iii) equids are imported in accordance with this chapter;
 - c) supply documented evidence that:
 - i) *surveillance* in accordance with Articles 12.1.11. to 12.1.13. is applied, unless historically free in accordance with Article 1.4.6.;
 - ii) regulatory measures for the early detection, prevention and control of *infection* with AHSV have been implemented.
 - 5) The Member Country will be included in the list only after the submitted evidence has been accepted by the OIE.

The country or zone will be included in the list of countries or zones free from AHS in accordance with Chapter 1.6.

Retention on the list requires annual reconfirmation of compliance with all points above and relevant provisions under point 4 of Article 1.4.6. that the information in points 4 b) ii) and iii) and 4 c) above be annually re-submitted and Documented evidence should be resubmitted annually for point 1 above. Any changes in the epidemiological situation or other significant events should be reported notified to WOAHP in accordance with the requirements in Chapter 1.1., and in particular, formally state that:

- a) there has been no *outbreak* of AHS during the past year in the country or zone;
- b) no evidence of *infection* with AHSV has been found during the past year in the country or zone.

Article 12.1.3.

AHS infected ~~e~~Country or zone infected with AHSV

A country or zone shall be considered as infected with AHSV. For the purposes of this chapter, an AHS infected country or zone is one that does not fulfil when the requirements for acceptance as a country or zone free from AHS are not fulfilled to qualify as AHS free.

Article 12.1.4.

Establishment of a containment zone within ~~a~~ an AHS free country or zone previously free from AHS

In the event of limited outbreaks of AHS within an AHS free country or zone previously free from AHS, including within a protection zone, a single containment zone, which includes all epidemiologically linked outbreaks, can may be established, in accordance with Article 4.4.7., for the purpose of to minimising the impact on the entire rest of the country or zone. Such a zone should include all cases and can be established within a protection zone.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should ~~provide~~ submit as soon as possible to WOA, in addition to the requirements of Article 4.4.7., in support of the application, documented evidence that:

- 1) ~~the outbreaks have been contained~~ are limited based on the following factors:
 - a) ~~immediately on suspicion, a rapid response has been implemented, including notification reporting, standstill of movements of equids and effective controls of the movements of equine commodities has been made~~ 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;
 - b) the infection has been confirmed and notified in accordance with Chapter 1.1.1.;
 - ~~c) standstill of movements of equids has been imposed, and effective controls on the movement of equids and their products specified in this chapter are in place~~ on confirmation, the standstill and movement controls described in point 1(a) have been reinforced;
 - e) epidemiological investigation (trace back, trace forward) has been completed;
 - ~~cd) the infection has been confirmed and notified in accordance with Chapter 1.1.1.;~~
 - ~~de) epidemiological investigations on~~ into the likely source of the *outbreak* have been carried out;
 - f) all cases have been shown to be epidemiologically linked;
 - ~~eg) no new cases have been found in the containment zone within a minimum of two infective periods as defined in Article 12.1.1.1.;~~
- 2) the equids within the containment zone are clearly identifiable as belonging to the containment zone;
- 2) increased passive and targeted surveillance in accordance with Articles 12.1.11. to 12.1.13. in the rest of the country or zone has not detected any evidence of infection;
- 3) ~~animal health~~ measures are in place to effectively prevent the spread of AHSV infection to the rest of the country or zone, taking into consideration the establishment of a protection zone within the containment zone, the seasonal vector conditions and existing physical, geographical and ecological barriers;
- 4) ongoing surveillance in accordance with Articles 12.1.11. to 12.1.13. is in place in the containment zone.

~~The free status of the areas outside the containment zone is suspended while the containment zone is being established in accordance with points 1) to 5) above. The free status of the areas of outside the containment zone is suspended while the containment zone is being established.~~ The free status of these areas outside the containment zone may be reinstated irrespective of Article 12.1.5. once the containment zone has been approved is recognised by the WOA as complying with points 1 to 4 above.

In the event of the recurrence of AHSV infection with AHSV in the containment zone, established in accordance with point 4(a) of Article 4.4.7., the approval of the containment zone is withdrawn and the AHS-free status of the whole country or zone is suspended until the relevant requirements of Article 12.1.5. are fulfilled.

In the event of occurrence of infection with AHSV in the outer zone of a containment zone established in accordance with point 4(b) of Article 4.4.7., the approval of the containment zone is withdrawn and the free status of the whole country or zone is suspended until the relevant requirements of Article 12.1.5. are fulfilled.

The recovery of the AHS free status of the *containment zone* should follow Article 12.1.5.

Article 12.1.5.

Recovery of free status

~~To regain free status when an AHS outbreak occurs in a country or zone previously free, Article 12.1.2. applies, irrespective of whether emergency vaccination has been applied or not.~~

Should an outbreak of AHS occur in a previously free country or zone, its status may be recovered in accordance with Article 12.1.2., irrespective of whether emergency vaccination has been applied or not.

The AHS free status of the country or zone will be reinstated only after the submitted evidence has been accepted by the WOAH.

Article 12.1.6.

Recommendations for importation of equids from AHS free countries or zones

For equids

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

- 1) showed no clinical sign of AHS on the day of shipment;
- 2) have not been vaccinated against AHS within the last 40 days;
- 3) were kept in an AHS free country or *zone* since birth or for at least 40 days prior to shipment;
- 4) either:
 - a) did not transit through an infected *zone* during transportation to the *place of shipment*; or
 - b) were protected from *Culicoides* attacks at all times when transiting through an infected *zone*.

Article 12.1.7.

Recommendations for importation of equids from AHS infected countries or zones

For equids

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

- 1) showed no clinical sign of AHS on the day of shipment;
- 2) have not been vaccinated against AHS within the last 40 days;
- 3) were held in isolation in a *vector-protected establishment*:
 - a) for a period of at least 28 days and a serological test to detect antibodies against ~~the AHSV group~~, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the *vector-protected establishment*; or
 - b) for a period of at least 40 days and serological tests to detect antibodies against AHSV were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after introduction into the *vector-protected establishment*; or
 - c) for a period of at least 14 days and an ~~agent identification~~ test for the identification-detection of the agent was carried out with a negative result on a blood sample collected not less than 14 days after introduction into the *vector-protected establishment*; or

-
- d) for a period of at least 40 days and were vaccinated, at least 40 days before shipment, against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 12.1.12. and 12.1.13., and were identified in the accompanying certification as having been vaccinated;
- 4) were protected from *Culicoides* attacks at all times during transportation (including transportation to and at the *place of shipment*).

Article 12.1.8.

Recommendations for the importation of equine semen

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

- 1) showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;
- 2) had not been ~~immunised~~ vaccinated against AHS with a live attenuated vaccine within 40 days prior to the day of collection;
- 3) were either:
 - a) kept in an AHS free country or *zone* for at least 40 days before commencement of, and during collection of the semen; or
 - b) kept in an AHS free *vector-protected artificial insemination centre* throughout the collection period, and subjected to either:
 - i) a serological test to detect antibodies against ~~the AHSV-group~~, carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of semen; or
 - ii) ~~agent identification tests for the identification of the agent~~ carried out with negative results on blood samples collected at commencement and conclusion of, and at least every seven days, during semen collection for this consignment.

Article 12.1.9.

Recommendations for the importation of *in vivo* derived equine oocytes or embryos

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

- 1) the donor animals:
 - a) showed no clinical sign of AHS on the day of collection of the oocytes or embryos and for the following 40 days;
 - b) had not been ~~immunised~~ vaccinated against AHS with a live attenuated vaccine within 40 days prior to the day of collection;
 - c) were either:
 - i) kept in an AHS free country or *zone* for at least 40 days before commencement of, and during collection of the oocytes or embryos, or
 - ii) kept in an AHS free *vector-protected collection centre* throughout the collection period, and subjected to either:
 - a serological test to detect antibodies against ~~the AHSV-group~~ carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of oocytes or embryos; or

-
- ~~agent identification tests for the identification-detection of the agent~~ carried out with negative results on blood samples collected at commencement and conclusion of, and at least every seven days during oocytes or embryos collection for this consignment;
- 2) the embryos were collected, processed and stored in accordance with Chapters 4.8. and 4.10., as relevant;
 - 3) the semen used to fertilise the oocytes complies at least with the requirements in Article 12.1.8.

Article 12.1.10.

Protecting animals from *Culicoides* attacks

1. Vector-protected establishment or facility

The *establishment* or facility should be approved by the *Veterinary Authority* and the means of protection should at least comprise the following:

- a) appropriate physical barriers at entry and exit points, for example double-door entry-exit system;
- b) openings of the building are *vector* screened with mesh of appropriate gauge impregnated regularly with an approved insecticide in accordance with the instructions of the manufacturer;
- c) *vector surveillance* and control within and around the building;
- d) measures to limit or eliminate breeding sites for *vectors* in the vicinity of the *establishment* or facility;
- e) Standard Operating Procedure, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of equids to the place of *loading*.

2. During transportation

When ~~equids are transported~~ ~~equids~~ through AHS infected countries or *zones*, *Veterinary Authorities* should require that they are strategies to protected animals from *Culicoides* attacks during transport, taking into account the local ecology of the *vector*.

a) Transport by road land

Potential *risk management* strategies include a combination of:

- i) treating animals with chemical repellents prior to and during transportation, in sanitized *vehicles* treated with appropriate residual contact insecticide;
- ii) *loading*, transporting and *unloading* animals at times of low *vector* activity (i.e. bright sunshine and low temperature);
- iii) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the *animals* are held behind insect proof netting;
- iv) darkening the interior of the *vehicle*, for example by covering the roof or sides of *vehicles* with shade cloth;
- v) surveillance for *vectors* at common stopping and offloading points to gain information on seasonal variations;
- vi) using historical, ongoing or modelling information on AHS to identify low risk ports and transport routes.

b) Transport by air

Prior to *loading* the equids, the crates, *containers* or jet stalls are sprayed with an insecticide approved in the country of dispatch.

Crates, *containers* or jet stalls in which equids are being transported and the cargo hold of the aircraft should be sprayed with an approved insecticide when the doors have been closed and prior to take off. All possible insect harbourage should be treated. The spray containers should be retained for inspection on arrival.

In addition, during any stopover in countries or zones not free from infected with AHSV, prior to the opening of any aircraft door and until all doors are closed, netting of appropriate gauge impregnated with an approved insecticide should be placed over all crates, *containers* or jet stalls.

Article 12.1.11.

Introduction to surveillance

Articles 12.1.11. to 12.1.13. define the principles and provide guidance on *surveillance* for AHS, complementary to Chapter 1.4. and, for *vectors*, complementary to Chapter 1.5.

AHS is a *vector-borne infection* transmitted by a limited number of some species of *Culicoides* insects. Unlike the related bluetongue virus, AHSV is so far geographically restricted to sub-Saharan Africa with periodic excursions into North Africa, southwest Europe, the Middle East and adjacent regions of Asia. An important component of AHSV epidemiology is vectorial capacity which provides a measure of disease *risk* that incorporates *vector* competence, abundance, seasonal incidence, biting rates, survival rates and the extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context.

According to this chapter, a Member Country demonstrating freedom from *infection* with AHSV for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented in accordance with general conditions and methods described in this chapter. This requires the support of a *laboratory* able to undertake identification of *infection* with AHSV through the virus detection tests for the detection of the agent and antibody detection tests.

Susceptible *captive wild, feral* and *wild* equine populations should be included in the *surveillance* programme.

The purpose of *surveillance* is to determine if whether a country or *zone* is free from AHS. *Surveillance* deals not only with the occurrence of clinical signs caused by AHSV, but also with evidence of *infection* with AHSV in the absence of clinical signs.

Article 12.1.12.

General conditions and methods for surveillance

- 1) A *surveillance* system should be under the responsibility of the *Veterinary Authority*. In particular the following should be in place:
 - a) a formal and ongoing system for detecting and investigating *outbreaks* of disease;
 - b) a procedure for the rapid collection and transport of samples from suspected cases of AHS to a *laboratory* for diagnosis;
 - c) a system for recording, managing and analysing diagnostic, epidemiological and *surveillance* data.
- 2) In a free country or *zone*, the *surveillance* programme for AHS should include an *early warning system* for reporting suspected cases. Persons who have regular contact with equids, as well as diagnosticians, should report promptly any suspicion of AHS to the *Veterinary Authority*. An effective *surveillance* system will periodically identify suspected cases that require follow-up and investigation to confirm or exclude that the cause of the condition is AHS. The rate at which such suspected cases are likely to occur will differ between among epidemiological situations and cannot therefore be predicted reliably. All suspected cases of

AHS should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment be available to those responsible for *surveillance*.

- 3) In a free country or zone bordering adjacent to an infected country or zone, surveillance based upon taking into account geography, climate, history of infection and other relevant factors should be carried out over an appropriate distance of at least 100 kilometres from the border with the infected country or zone; a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of AHSV.
- 4) In an AHS infected country or zone, random or targeted serological and virological *surveillance*, appropriate to the epidemiological situation, should be conducted in accordance with Chapter 1.4.

Article 12.1.13.

Surveillance strategies

The target population for *surveillance* aimed at identification of disease or *infection* should cover susceptible equids within the country or zone. Active and passive surveillance for infection with AHSV should be ongoing in all countries, while active surveillance should be ongoing in countries not having a free status or having identified specific risks of introduction. Surveillance should be composed of random or targeted approaches using virological, serological and clinical methods appropriate to the epidemiological situation.

A Member Country should justify the *surveillance* strategy chosen as appropriate to detect the presence of *infection* with AHSV in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular towards those species most likely to exhibit clinical signs (e.g. horses). Similarly, virological and serological testing may be targeted to towards species that rarely show clinical signs (e.g. donkeys).

In vaccinated populations serological and virological *surveillance* is necessary to detect the AHSV types circulating to ensure that all circulating types are included in the *vaccination* programme.

Serological or virological surveillance is also needed to detect subclinical infections in free countries or zones adjacent to countries or zones in which live attenuated AHS vaccines are used.

For random surveys, the design of the sampling strategy should incorporate epidemiologically appropriate design prevalence. The sample size selected for testing should be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size, expected prevalence and diagnostic sensitivity of the tests determine the level of confidence in the results of the survey. The Member Country should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence, in particular, should be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination* or *infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles for *surveillance* for disease or *infection* are technically well defined. *Surveillance* programmes to prove the absence of AHSV *infection* or transmission, should be carefully designed to avoid producing results that are insufficiently reliable to be accepted by WOAHP for official recognition of status. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

1. Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of AHS in equids particularly during a newly introduced *infection*. In horses, clinical signs may include pyrexia, oedema, hyperaemia of mucous membranes and dyspnoea.

Suspected cases detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

2. Serological surveillance

Serological *surveillance* of equine populations is an important tool to confirm absence of AHSV transmission in a country or *zone*. The species tested should reflect the local epidemiology of *infection* with AHSV, and the equine species available. Surveillance plans should include consideration of species that display clinical signs less commonly, such as donkeys or zebra. Management variables that may reduce the likelihood of *infection*, such as the use of insecticides and animal housing, should be taken into account when selecting equids to be included in the *surveillance* system.

Samples should be examined for antibodies against AHSV. Positive AHSV antibody tests results can have four possible causes:

- a) natural *infection* with AHSV;
- b) *vaccination* against AHS;
- c) maternal antibodies;
- d) lack of specificity of the test.

Sera collected for other purposes may be used for AHSV *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of *infection* with AHSV should not be compromised.

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

Serological *surveillance* in a free *zone* should target those areas that are at highest risk of AHSV transmission, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of AHSV, either random or targeted sampling is suitable to select *herds* or animals for testing.

~~Serological *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with an infected country or *zone*, based upon geography, climate, history of *infection* and other relevant factors. The *surveillance* should be carried out over a distance of at least 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of AHSV. An AHS free country or *zone* may be protected from an adjacent infected country or *zone* by a *protection zone*.~~

Serological *surveillance* in infected *zones* will identify changes in support the definition of the boundaries of the an infected *zone*, and can also be used to identify the AHSV types circulating. In view of the epidemiology of *infection* with AHSV, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis of AHSV from a proportion of infected animals is beneficial in terms of providing information on serotype and genetic characteristics of the viruses concerned.

Virological *surveillance* can be conducted:

- a) to identify virus transmission in ~~at at~~ risk populations;
- b) to confirm clinically suspected cases;

-
- c) to follow up positive serological results;
 - d) to better characterise the genotype of circulating virus in a country or *zone*.

4. Sentinel animals

Sentinel animals are a form of targeted *surveillance* with a prospective study design. They comprise groups of unexposed equids that have not been vaccinated and are managed at fixed locations and observed and tested regularly to detect new *infections* with AHSV.

The primary purpose of a sentinel equid programme is to detect *infections* with AHSV occurring at a particular place, for instance sentinel groups may be located on the boundaries of infected *zones* to detect changes in distribution of AHSV. In addition, sentinel equid programmes allow the timing and dynamics of *infections* to be observed.

A sentinel equid programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of AHSV in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting AHSV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid confounding factors sentinel groups should comprise animals selected to be of similar age and susceptibility to *infection* with AHSV. The only feature distinguishing groups of sentinels should be their geographical location. Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling should reflect the equine species used and the reason for choosing the sampling site. In endemic areas virus isolation will allow monitoring of the serotypes and genotypes of AHSV circulating during each time period. The borders between infected and non-infected areas can be defined by serological detection of *infection*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that *infections* with AHSV are not occurring unobserved. Here sampling prior to and after the possible period of transmission is sufficient.

Definitive information on AHSV circulating in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required sentinels should be sampled at sufficiently frequent intervals to ensure that some samples are collected during the period of viraemia.

5. Vector surveillance

AHSV is transmitted between equine hosts by species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential *vector* species accurately although many such species are closely related and difficult to differentiate with certainty.

Vector surveillance is aimed at demonstrating the absence of *vectors* or defining high, medium and low-risk areas and local details of seasonality by determining the various species present in an area, **and** their respective seasonal occurrence, and abundance. *Vector surveillance* has particular relevance to potential areas of spread. Long term *surveillance* can also be used to assess *vector* abatement measures or to confirm continued absence of *vectors*.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local *vector* species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to equids.

Vector surveillance should be based on scientific sampling techniques. The choice of the number and types of traps to be used in *vector surveillance* and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of *vector surveillance* sites at the same locations as sentinel animals is advisable.

The use of a *vector surveillance* system to detect the presence of circulating viruses is not recommended as a routine procedure ~~as because~~ the typically low *vector infection* rates mean that such detections can be rare. Animal-based *surveillance* strategies are preferred to detect virus transmission.

CHAPTER 13.2.

INFECTION WITH PATHOGENIC RABBIT LAGOVIRUSES
(RABBIT HAEMORRHAGIC DISEASE)

EU comment

The EU in general supports the proposed urgently needed changes to this chapter to create a case definition and clarify notification procedures.

The EU supports the approach proposed by the Code Commission to keep track of the comments already submitted by the EU and that these comments are taken into account when a full revision of the whole chapter will take place.

For ease of reference in the future revision of this chapter, the EU provides here the comments already submitted on the changes in Article 13.2.2.:

1) The free status should not include a vaccination ban as a prerequisite. Prophylactic vaccination against this deadly disease in free countries or especially in countries which have to restore a free status makes sense and should be possible. Serosurveillance can be performed in respect of vaccination data in domestic rabbits and investigations in wild rabbits.

Vaccination and biosafety measures are the tools of choice to fight the disease where prophylactic vaccination should be used in breeding facilities, as well as in pet animals worldwide to reduce the number of susceptible animals and to decrease the dramatic financial losses and the ecological damage even before the virus is actually introduced into certain regions or countries. This is also relevant for aspects of animal welfare.

In general, serological investigations play a very limited role in RHDV surveillance due to the peracute course of the disease and the cross-reactivity of possibly co-circulating apathogenic rabbit lagoviruses. Therefore, active and especially passive monitoring should be carried out, almost exclusively, by virological examinations. Sensitive PCR testing is not affected in vaccinated animals that die from RHD, because systemic virus replication as a cause of death will be detected without any diagnostic problems. In conclusion, PCR diagnostics and vaccination can be used side-by-side for RHD control. Serological surveillance is nevertheless feasible with ongoing vaccination campaigns, since unvaccinated animals can be selected for these analyses. Wild rabbits and hares e.g. do not come into contact with vaccines anyway and young animals that will lose their maternal antibodies very early at 4-6 weeks of age can be readily monitored for the presence of RHDV-induced antibodies.

Furthermore, documented recent vaccination in domestic and commercial rabbit holdings will exclude all affected animals from serological investigations, however the individual and usually patchy vaccination coverage will still enable sero-surveillance anyway which could then support a broad passive surveillance by real-time RT-PCR.

Therefore, we propose to review the text and exclude these words from the first para: “~~that no vaccination has been carried out in the past 12 months,~~”.

2) *The EU queries why 12 months have been chosen as a required period for demonstrating freedom from RHD.*

Possibly such period could be extended to allow capturing epidemiological waves that have gap periods longer than 12 months.

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.

[...]

CHAPTER 15.1.

INFECTION WITH AFRICAN SWINE FEVER VIRUS

EU comment

The EU, in general, supports the proposed changes and submits one comment.

[...]

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.

EU comment

The EU would welcome a clarification on the meaning of ‘extruded dry pet food’ and on the production process and heat treatments as provided by the GAPFA (as mentioned in the September 2023 meeting report).

Other *commodities* of suids can be traded safely if in accordance with the relevant articles of this chapter.

[...]

CHAPTER ~~X~~16.Z.

INFECTION WITH CAMELPOX VIRUS

EU comment

The EU supports this new chapter.

Article ~~X~~16.Z.1.

General provisions

For the purposes of the *Terrestrial Code*, *infection* with camelpox virus is defined as an *infection* of dromedary and bactrian camels (hereafter 'susceptible animals') with ~~e~~Camelpox virus of genus ~~Orthopoxvirus~~, family ~~Poxviridae~~.

The following defines the occurrence of *infection* with ~~e~~Camelpox virus:

- 1) ~~e~~Camelpox virus has been isolated and identified as such in a sample from a susceptible animal; or
- 2) characteristic orthopox virions have been observed in a sample from a susceptible animal showing clinical signs ~~suggestive of~~ consistent with *infection* with ~~e~~Camelpox virus or epidemiologically linked to a confirmed or suspected case; or
- 3) antigen or nucleic acid specific to ~~e~~Camelpox virus has been detected in a sample from a susceptible animal showing clinical signs ~~suggestive of~~ consistent with *infection* with ~~e~~Camelpox virus, or epidemiologically linked to a confirmed or suspected case; or
- 4) antibodies specific to ~~e~~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 ~~e~~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*.

TERMINOLOGY: USE OF THE TERMS
'COMPETENT AUTHORITY', 'VETERINARY AUTHORITY' AND
'VETERINARY SERVICES'

EU comment

The EU supports these proposed changes to the Code.

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 WOAHA 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 WOAHA 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 WOH endorment

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 Authorities* 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 Authorities* 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 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 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;

[...]

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.

[...]

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~~;

[...]

USER'S GUIDE

EU comment

The EU thanks the Code Commission for revising this guide. The EU supports the proposed changes to this guide, a comment is provided below.

A. Introduction

[...]

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 WOA 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 WOA 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 WOA 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 WOAHL 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 WOAHL aims to include a chapter for each WOAHL listed disease, not all WOAHL 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 definitions of disease and its occurrence;

EU comment

It is suggested to speak about ‘case definition’ rather than ‘define’ what a disease is.

A case definition is an epidemiological concept which allows for a common understanding of what a case is. In the case of the WOAHL Codes it has implication in notification, surveillance and trade aspects.

- Article on safe commodities;
- Articles on provisions for animal health status;
- Articles on recommendations for safe trade;
- Articles on inactivation of the pathogenic agents; and
- Articles on surveillance.

Not all disease-specific chapters include all these components and some chapters may include the first article on definition of occurrence for the purpose of notification to WOAHL. Each chapter includes only those provisions considered, at the time of adoption, relevant to address WOAHL 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 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 WOAHL aims to include a chapter for each WOAHL listed disease, not all WOAHL 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

[...]

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
<u>Class 'Insecta'</u>	=	<u>Family 'Apidae'</u>	<u>Sub-Family 'Apinae'</u> 'bees' means animals of <u>Sub-Family 'Apinae'</u>	<u>Including animals of Tribe:</u> • <u>'Apini'</u>	<u>Including animals of Genus:</u> • <u>'Apis'</u> 'honey bees' means animals of Genus <u>Apis</u> .
				<u>Including animals of Tribe:</u> • <u>'Bombini'</u>	<u>Including animals of Genus:</u> • <u>'Bombus'</u> 'bumble bees' means animals of Genus <u>Bombus</u> .
				<u>Including animals of Tribe:</u> • <u>'Meliponini'</u> 'stingless bees' means animals for Tribe <u>'Meliponini'</u>	=
<u>Class 'Aves'</u> 'avian' means <u>animals of class Aves</u>	<u>Order 'Galliformes'</u>	=	=	=	<u>Including animals of Genus:</u> • <u>'Gallus'</u> • <u>'Meleagris' etc.</u> 'chicken' means <u>Gallus gallus domesticus</u> . 'turkey' means <u>Meleagris gallopavo</u> .
	<u>Order 'Anseriformes'</u>	=	=	=	<u>Including animals of Genus:</u> • <u>'Anser'</u> • <u>'Branta'</u> • <u>'Anas' etc.</u> 'geese' means animals of Genera <u>Anser</u> and <u>Branta</u> . 'ducks' means <u>Anas platyrhynchos</u> . ('domestic ducks' means Anas platyrhynchos domesticus.)
'mammals' means animals of Class <u>'Mammalia'</u> 'ungulates' means animals	'ruminants' means <u>animals of Sub-order 'Ruminantia'</u>	'bovids' means <u>animals of Family 'Bovidae'</u>	'bovines' means animals of Sub-Family <u>'Bovinae'</u>	=	<u>Including animals of Genus:</u> • <u>'Bos'</u> • <u>'Bubalus'</u> • <u>'Bison'</u> • <u>'Syncerus' etc.</u>
			'caprines' means animals of Sub-Family <u>'Caprinae'</u>	=	<u>Including animals of Genus:</u> • <u>'Ovis'</u> • <u>'Capra', etc.</u>

<p>of Order 'Artiodactyla' (even-toed ungulates) and Order 'Perissodactyla' (odd-toed ungulates)</p> <p>'artiodactyls' means animals of Order 'Artiodactyla' (even-toed ungulates)</p>					<p>'sheep' means <i>Ovis aries</i>. 'goats' means <i>Capra hircus</i> (domestic goats) and <i>Capra aegagrus</i> (wild goats).</p>
			Sub-Family 'Antilopinae'	=	<p>Including animals of Genus:</p> <ul style="list-style-type: none"> 'Gazella' 'Antilope' 'Dibatag', etc.
		'cervids' means animals of Family 'Cervidae'	Sub-Family 'Cervinae'	=	<p>Including animals of Genus:</p> <ul style="list-style-type: none"> 'Cervus' 'Dama', etc.
			Sub-Family 'Capreolinae'	=	<p>Including animals of Genus:</p> <ul style="list-style-type: none"> 'Capreolus' 'Odocoileus' 'Rangifer', etc.
	Sub-Order 'Suina'	'suids' means animals of Family 'Suidae'	=	=	<p>Including animals of Genus:</p> <ul style="list-style-type: none"> 'Sus' 'Phacochoerus' 'Hylochoerus', etc. <p>'pigs' means <i>Sus scrofa</i> (domestic and wild).</p>
	Sub-Order 'Tylopoda'	'camelids' means animals of Family 'Camelidae'	Sub-Family 'Camelinae'	=	<p>Including animals of Genus:</p> <ul style="list-style-type: none"> 'Camelus' 'Lama' <p>'dromedary camels' means <i>Camelus dromedarius</i>. 'bactrian camels' means <i>Camelus bactrianus</i>. 'alpacas' means <i>Lama guanicoe pacos</i>. 'llamas' means <i>Lama guanicoe glama</i>. 'New World camelids' means alpacas and llamas.</p>
	Sub-Order 'Hippomorpha'	'equids' means animals of Family 'Equidae'	'equines' means animals of Sub-Family 'Equinae'	=	<p>Including animals of only Genus 'Equus'</p> <p>'horses' means <i>Equus ferus caballus</i>. 'donkeys' means <i>Equus africanus asinus</i>. 'mules' means <i>Equus africanus asinus</i> (male) × <i>Equus ferus caballus</i> (female). 'zebras' means animals of subgenus <i>Hippotigris</i>.</p>
	'lagomorphs' means animals of Order 'Lagomorpha'	'leporids' means animals of Family 'Leporidae'	=	=	<p>Including animals of Genus:</p> <ul style="list-style-type: none"> 'Oryctolagus' 'Lepus' 'Sylvilagus'

					<u>'rabbits'</u> means animals of Genus <i>Oryctolagus</i> . <u>'hares'</u> means animals of Genus <i>Lepus</i> . <u>'European hares'</u> means <i>Lepus europaeus</i> .
<u>'carnivores'</u> means animals of Order ' <u>Carnivora</u> '	<u>'canids'</u> means animals of Family ' <u>Canidae</u> '	Sub-Family ' <u>Caninae</u> '	=		Including animals of Genus: <ul style="list-style-type: none"> '<u>Canis</u>' <u>'dogs'</u> means <i>Canis lupus familiaris</i> .
	<u>'felids'</u> means animals of Family ' <u>Felidae</u> '	=	=		Including animals of Genus: <ul style="list-style-type: none"> '<u>Felis</u>' <u>'cats'</u> means <i>Felis catus</i> .
	Family ' <u>Mustelidae</u> '				Including animals of Genus: <ul style="list-style-type: none"> '<u>Mustela</u>' <u>'ferrets'</u> means <i>Mustela furo</i> .
<u>'rodents'</u> means animals of Family ' <u>Rodentia</u> '	=	=	=	=	=
<u>'bats'</u> means of animals of Order ' <u>Chiroptera</u> '	=	=	=	=	=
<u>'non-human primates'</u> means animals of Order ' <u>Primates</u> ' except for humans (Genus ' <u>Homo</u> ')	=	=	=	=	=

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*'.

GLOSSARY

EU comment

The EU in general supports the proposed changes to the glossary. Comments are provided below.

BIOSECURITY

means a set of management, behavioural and physical measures designed to reduce the *risk* of introduction, establishment and spread of pathogenic agents animal diseases, ~~infections or infestations~~ to, within and from ~~and within~~ an animal population.

EU comment

Can the Code Commission consider if the term “hazards” be more appropriate than “pathogenic agents”?

BIOSECURITY PLAN

means a ~~plan document or series of documents~~ that identifies potential pathways and factors for the introduction, establishment and spread of pathogenic agents ~~disease in a zone or compartment~~, and describes the corresponding biosecurity measures to be implemented and the mechanisms to evaluate its performance and to update it ~~which are being or will be applied to mitigate the disease risks~~, if applicable, in accordance with the recommendations in the *Terrestrial Code*.

BORDER INSPECTION POST

means any airport, or any port, railway station or road check point international point of entry for commodities ~~open to international trade of commodities, and associated facilities~~, where import-veterinary inspections can be is performed.

CONTAINER

means a non-self-propelled receptacle or other rigid structure ~~for holding animals to carry commodities~~ during transportation ~~a journey by one or several means of transport~~.

POINT OF EXIT

means any point from where commodities leave the territory of the exporting country.

QUARANTINE ~~STATION~~ CENTRE

means an *establishment* under the control of the *Veterinary Authority* where *animals* are maintained in isolation for observation during a specified length of time under biosecurity to with no direct or indirect ensure no contact with other animals and vectors when relevant, ~~to ensure so~~ that there is no transmission of specified pathogenic agents outside into nor out of the establishment while the *animals* are undergoing observation for a specified length of time and, if appropriate, testing or treatment.

EU comment

Suggested rewording for a more holistic approach: “so that there is no transmission of specified pathogenic agents into, within nor out of the establishment”.

SWILL

means food scraps or food waste, that contain or have been in contact with *animal products*, which may be used as *feed*.

VEHICLE/VESSEL

means any means of conveyance including train, truck, aircraft or ship that is used for carrying ~~animals~~ *commodities*.

UNOFFICIAL VERSION

SECTION 4.
DISEASE PREVENTION AND CONTROL

CHAPTER 4.X.
BIOSECURITY

EU comment

The EU in general supports this new chapter. However, it invites the Code Commission to revise it completely. In particular, the way how the Veterinary Authority is involved in biosecurity activities should be reviewed.

To be noted that the Veterinary Authority is not in charge of the development of the biosecurity plan. The development of the biosecurity plan is responsibility of the animal breeders, owners, keepers, transporters and/or feed producers.

Article 4.X.1.

Introduction

Biosecurity is the cornerstone of health programmes and as such should be implemented to prevent and control diseases. In addition to reducing the risk of disease, the benefits of *biosecurity* include a reduced need for *veterinary medicinal products*; reduced *killing of animals* for disease control purposes; reduced economic losses; protection of livelihoods; assurance of sustainability of animal production; improved food security and food safety; promotion of animal, human and environmental health, and assurance of safe trade and business continuity.

EU comment

It is suggested that the considerations of animal, human and environmental health, and assurance of safe trade and business continuity, also include *animal welfare* considerations.

Article 4.X.2.

Purpose and scope

The purpose of this chapter is to provide guidance to the *Veterinary Authority* and other relevant actors, as described in Article 4.X.5., on the principles, implementation and evaluation of *biosecurity* to support disease prevention and control programmes.

More specifically, this chapter aims to:

-
- Describe the general guiding principles of *biosecurity*;
 - Identify the roles and responsibilities of the different actors in *biosecurity*;
 - Describe the sources and pathways and factors for the transmission of pathogenic agents;
 - Describe the procedures and components of *biosecurity*;
 - Provide guidance on the design, application, *monitoring*, evaluation and training with regards to *biosecurity* and *biosecurity plans*.

The chapter applies to all animals including *wildlife*, to any type of animal gatherings and husbandry systems, to all components of animal production and commercial chains and to the interface between domesticated animals, humans and *wildlife*.

The chapter does not apply to laboratories, whose approaches to biosecurity are addressed in the *Terrestrial Manual*.

Article 4.X.3.

Definitions

For the purposes of this chapter:

All-in all-out is the management practice to remove all the *animals* prior to new *animals* entering a shared air space with the subsequent cleaning and decontamination of the space where the *animals* are housed to prevent the transmission of pathogenic agents between groups of *animals*.

EU comment

It is suggested to delete the word “air” as this could be understood as the animals share the same air, the understanding must be that they enter the same space.

Fomite is an inanimate object that can carry pathogenic agents.

External biosecurity also referred to as bio-exclusion or bio-containment, is a set of measures that aims at preventing pathogenic agents from entering or escaping a *population*.

Internal biosecurity also referred to as bio-management, is a set of measures that aims to reduce the spread of pathogenic agents within a *population*.

Article 4.X.4.

Guiding general principles

Biosecurity aims to break the cycle of *infection* by intervening at their source, during their transmission, or at the susceptible hosts. To achieve this, the following principles should be considered:

- 1) The *animal health status* of a *population* for which the *biosecurity* is being implemented should be known, to identify where improvements to the animal health and productivity may be required.
- 2) *Biosecurity* should be based upon *risk analysis* as described in Chapter 2.1. and be aligned with relevant legislative requirements.

EU comment

Chapter 2.1 "as is" describes the import risk analysis process, not biosecurity. Should chapter 2.1 be rephrased so it contemplates the use of the risk analysis process for biosecurity.

- 3) *Risk assessments* applied to *biosecurity* should identify the *hazards* and how and where these *pathogenic agents* are introduced, spread and established in the *population*. The frequency of certain activities, which influence the entry, spread and establishment of *pathogenic agents*, should be considered in the *risk assessment*.

EU comment

“pathogenic agents” refers to hazards which has a definition under the Glossary chapter, the EU suggests to use the word hazards instead of pathogenic agents, and add the words “pathogenic agents” to the definition of hazard.

- 4) *Biosecurity* should be based on scientific evidence and proportional to the *risk*.
- 5) *Biosecurity* should be sustainable, adaptable, monitored and subjected to a documented routine and ongoing evaluation and should include long-term planning.
- 6) A *biosecurity plan* is essential for ensuring consistent implementation of *biosecurity*.

EU comment

The terms “essential” might be exaggerated given that some biosecurity can be implemented by in a regular manner by some farmers based on experience and without the need for a formal biosecurity plane.

Therefore it is suggested to change the text like this “A biosecurity plan promotes is essential for ensuring consistent implementation of biosecurity”.

- 7) *Biosecurity* should be designed to account for human behaviour to maximise compliance.
- 8) Evaluation of compliance of *biosecurity* should be built into the day-to-day operations.
- 9) The socio-economic impacts of *biosecurity* and the context and size of the *population* to which the *biosecurity* is being applied should be considered.
- 10) Training of, and communication with, all actors involved in *biosecurity* is essential to successful outcomes.

Article 4.X.5.

Roles and responsibilities

The roles and responsibilities of different actors in *biosecurity* should be clearly defined and communicated with consideration made to the context (e.g. *establishment, compartment, zone, country level*), scale of operations, type of production and supply chain. Implementation of *biosecurity* requires engagement and collaboration amongst all actors involved.

- 1) **Veterinary Authority**, in collaboration with other *Competent Authorities*, should be responsible for the development and oversight of policy on and legislative frameworks of *biosecurity*. These policies should include the relative contribution and roles of *veterinarians* and *veterinary paraprofessionals* in both the private and public sectors. For international trade purposes, the *Veterinary Authority* should have an active role in the development, implementation, enforcement, oversight, and verification of *biosecurity* and *biosecurity plans*.

EU comment

The EU suggests amending this paragraph, as follows:

“Veterinary Authority, in collaboration with other Competent Authorities, should be responsible for the development and oversight of policy on and legislative frameworks of biosecurity. These policies should include the relative contribution and roles of veterinarians and veterinary paraprofessionals in both the private and public sectors. For international trade purposes, the Veterinary Authority should have an active role in the development,

implementation, enforcement, oversight, and verification of biosecurity and biosecurity plans while providing the necessary guidance for its development and implementation.”

Justification: As described in point number 4 the breeders, owners, keepers etc. are responsible for implementation and monitoring on the establishments and they should also be responsible for the development of the biosecurity plan not the veterinary authority while the Veterinary Authority should still provide guidance when needed.

- 2) **Veterinary Services** should execute and implement policies and legislation on *biosecurity* under the supervision of the *Veterinary Authorities*.
- 3) **Veterinarians and veterinary paraprofessionals and other animal health advisors** should give advice to animal breeders, owners, and keepers on *biosecurity* which may include the design, and evaluation of *biosecurity* and *biosecurity plans* and training. This advice should be aligned with the policies and legislation set by the *Veterinary Authority*.
- 4) **Animal breeders, owners, keepers, transporters, feed producers** should seek advice from *veterinarians* and *veterinary paraprofessionals* and other animal health advisors and are responsible for implementing and monitoring *biosecurity* and the *biosecurity plan*.

EU comment

In line with the previous comment for point 1 for Article 4.X.5 the EU suggests to amend this paragraph, as follows: “Animal breeders, owners, keepers, transporters, feed producers should seek advice from veterinarians and veterinary paraprofessionals and other animal health advisors and are responsible for development, implementing and monitoring biosecurity and the biosecurity plan.”

Justification: Animal breeders, owners, keepers, transporters, feed producers should also be responsible for the development of the biosecurity and plan for their establishment, based on advice of the veterinarian and/or veterinary paraprofessional.

- 5) **Training entities** should include training in *biosecurity* as part of the standard programmes and the training should be tailored for all actors. Coordination between the *Veterinary Authority*, the *Veterinary Statutory Body* and veterinary educational establishments may be required to ensure *biosecurity* training delivered to *veterinarians*, *veterinary paraprofessionals* and other advisors meets relevant standards.
- 6) **Farmer, veterinary and para-veterinary associations** should advocate and promote *biosecurity* among their members, including signposting to relevant training and advice.

Article 4.X.6.

Potential sources of pathogenic agents

Pathogenic agents can be spread through different sources of *infection* which should be considered when implementing *biosecurity* and developing a *biosecurity plan*. The main sources of pathogenic agents to be considered include:

- 1) *animals*,
- 2) *germinal products*,
- 3) *secretion and excretion*,

-
- 4) *animal products*,
 - 5) dead *animals* and parts thereof and afterbirth materials,
 - 6) arthropods such as mosquitoes, midges, flies, lice or ticks,
 - 7) fomites such as peoples' clothing, boots, *vehicles*, crates, bedding, or general farm equipment,
 - 8) *feed* and *feed ingredients* including forage, grazing pastures and swill,
 - 9) water, soil, surfaces and air,
 - 10) *biological products*,
 - 11) humans.

Article 4.X.7.

Transmission pathways

Transmission pathways of pathogenic agents should be considered when implementing *biosecurity* or developing a *biosecurity plan*. Transmission pathways are not mutually exclusive and include:

- 1) Direct transmission through *animal-to-animal* contact including their secretions and excretions without an intermediate. It includes contact between domesticated *animals* and *wildlife*.
- 2) Indirect transmission through an intermediate such as fomites, water, feed, germinal products and *animal* environment.

EU comment

Proposed addition:

“Indirect transmission through an intermediate such as humans, manure and bedding, fomites, water, feed, germinal products and animal environment.”

In addition the EU would like to have some clarifications for the meaning of “animal environment”.

- 3) Vertical transmission of pathogenic agents from parents to offspring in ovo, in utero or during birth.
- 4) Horizontal transmissions from one *animal* to another that are not vertical.

EU comment

It is proposed to delete paragraph 4) as it is covered by point 1.

Also, is it not horizontal transmission included under direct or indirect transmission?

- 5) Iatrogenic transmission through medical interventions.

EU comment

In order to clarify the text for the intended meaning and avoid too narrow interpretations, the EU suggests amending this paragraph, as follows:

“Iatrogenic transmission through medical interventions”.

- 6) Sexual transmission of pathogenic agents that are shed in reproductive secretions such as semen and vaginal fluids or transmitted directly between surfaces in contact during mating.

EU comment

It is proposed to delete 6) as it is covered by point 1.

- 7) Vector-borne transmission via *vectors* including blood-feeding arthropods such as mosquitoes, flies, ticks, fleas and lice. *Vectors* may be mechanical with no biological association between the *vector* and pathogenic agent or biological where the pathogenic agent undergoes a multiplication or a developmental change within the *vector*, necessary for survival, transmission or host infection.
- 8) Airborne or droplets transmission of pathogenic agents through particles suspended in the air. Pathogenic agents may travel in particles of multiple size ranges (droplets and droplet nuclei) that remain suspended in the air or deposited on surfaces. Airborne transmission may include short or long distances (which may be referred to as aerosol or wind-borne transmission, respectively).

Article 4.X.8.

Components of biosecurity

Biosecurity can be divided into: 1) external *biosecurity*, and 2) internal *biosecurity*. External *biosecurity* mainly focuses on interactions with elements outside the *population* (e.g. other farms, other regions) whereas internal *biosecurity* focuses on reducing risk of transmission between elements of the *population*. The distinction between external and internal *biosecurity* is not absolute and can vary depending on the scale considered (e.g. country, region, *herd*).

Several components of *biosecurity* may need to be applied to a *population* and *subpopulation* to address all transmission pathways, sources of *pathogenic agents* and unexpected *risks*. The components of *biosecurity* should be documented in a *biosecurity plan* when possible.

1) Components of external *biosecurity*:

- a) Introduction of *animals*, animal products and germinal products should be minimised as much as possible and if undertaken, the health status of the *animal* and their source *population* should be assessed.

EU comment

Introduction of humans should also be minimized and be part of the biosecurity plan. It is partially covered in d - but for example unauthorized access to the premises should be prevented.

- b) Whenever *animals* are introduced into a *population*, they should go through an isolation period of sufficient length, during which measures may be implemented to minimise the risk of transmission of pathogenic agents.

EU comment

An assessment is needed to ensure against which diseases the biosecurity measures need to be targeted. Suggested new text:

“Whenever animals are introduced into a population, they should go through an isolation period of sufficient length, during which measures may be implemented to minimise the risk of

transmission of pathogenic agents; such length could be tailored to the incubation period for the relevant pathogens".

- c) Direct contact between *populations* of unknown or different *animal health status* should be avoided through segregation using managerial measures, or physical or natural barriers.
- d) The contact between humans and *animals* should be limited where possible but when required precautionary measures should be used to reduce the *risk* such as wearing farm specific clothing and footwear, and hand hygiene.
- e) Equipment used to handle or care for *animals* should not be shared between different *populations*. If shared, equipment should undergo *disinfection*.
- f) Transport vehicles in direct and indirect contact with *animals* or their products should undergo *disinfection* after use.

EU comment

The EU suggests a thorough review of the text to harmonise “disinfection” (as in point 1-f above) with “cleaning and disinfection” (as mentioned in 1-l and 2-f below) while bearing in mind the definition of “disinfection”.

- g) Faeces or manure should be handled in a way to mitigate the spread of pathogenic agents.
- h) Dead animals and parts thereof should be handled and stored in specific containers, or in designated areas to avoid contact with or attraction of other *animals* in particular *wildlife* and arthropods.
- i) Feed should be produced, stored and transported in dedicated equipment only for the purpose of feeding *animals*. Feeding of untreated swill should be avoided. Water should originate from low-risk sources or be treated with pathogen inactivating agents prior to use. The safety of the water and feed should be checked regularly.
- j) Direct and indirect contact between rodents, birds, pets, *wildlife*, pests and the *population* should be avoided using mechanical or chemical control.

EU comment

Proposed revision of text in point j) given that rodents are pests. It is suggested to replace “pests” with “other pests”.

- k) Sufficient distance between *populations* and other possible sources of pathogenic agents should be considered. In some circumstances, air filtration might be considered when feasible and sufficient distance or other measures cannot be implemented to mitigate the risk of transmission.
- l) When cleaning and *disinfection* or other measures are not feasible or effectiveness is undetermined, an additional period of no contact between potential carriers of pathogenic agents (e.g. people, buildings, *vehicles*, equipment, materials, pastures and air spaces) and the population can be applied. The effectiveness of this measure will depend on the specific circumstances.

EU comment

Proposed harmonisation of text:

“(e.g. humans people, buildings, vehicles, equipment, materials, pastures and air spaces)”

2) Components of internal *biosecurity*:

EU comment

The EU believes that monitoring of animal health is a part of the biosecurity plan, and therefore suggests this component to be added to the list of “Components of internal biosecurity”.

- a) Diseased *animals* should be isolated to prevent other *animals* being exposed. Treatments should be administered safely to avoid iatrogenic transmission.
- b) All-in all-out management should be applied to all animals kept in the same air space.

EU comment

Can the meaning of “air space” be clarified?

Also, the EU proposes to add in the end of point b) “, when possible given the management system and type of production”.

- c) Stocking densities that may result in increased transmission rates of pathogenic agents or increased susceptibility to *infections* should be avoided.
- d) *Animals* with different characteristics such as age and immune status should be kept separately.

EU comment

EU proposes to add “, when applicable” at the end of the sentence of point d) since there are production forms with mothers and their offspring.

- e) It is advisable to organise the workflow according to disease risk starting at the lowest risk and ending with the highest risk. Whenever entering into contact with a new group or new animal category, *biosecurity* measures such as changing footwear and clothing and conducting hand hygiene should be considered. Dedicated equipment or material should be used in each group.

EU comment

Additional text suggested to clarify when the measure needs to take place.

“It is advisable to organise the workflow according to disease risk starting at the lowest risk and ending with the highest risk. Whenever entering into contact with a new group or new animal category, biosecurity measures such as changing footwear and clothing on coming into contact and leaving the group and conducting hand hygiene should be considered. Dedicated equipment or material should be used in each group.”

- f) Cleaning and *disinfection* of the equipment and surfaces should be applied between consecutive groups of *animals*.

EU comment

Additional text suggested to clarify when the measure needs to take place:

“f) Cleaning and disinfection of the equipment and surfaces should be applied after each use and in particular between consecutive groups of animals.

Additional text to ensure only authorised personnel access premises:

g) Prohibition should be applied to the entering of unauthorized persons or means of transports in the place where the animals are kept.”

Article 4.X.9.

Biosecurity plan

The purpose of a *biosecurity plan* is to document, organise and structure *biosecurity* including its evaluation.

A *biosecurity plan* should balance practicality, cost, and regulatory requirements and include necessary provisions for its maintenance.

The *biosecurity plan* should include the following sections:

a) Purpose and scope

This section should provide an overview of the plan, its purpose and scope. In addition, it should outline the goals and objectives of the plan, as well as the *population* characteristics, including animal husbandry systems, and context.

b) Roles and responsibilities

Design, implementation, and monitoring is a shared responsibility. Therefore, it is essential to describe the roles and responsibilities of all actors for ensuring adherence and compliance with *biosecurity*.

c) Hazard identification and risk assessment

This section should include a summary of the relevant parts of *risk assessment* e.g. identification of the potential pathogenic agents (i.e. *hazards*) and their transmission pathways.

EU comment

the biosecurity plan should be based on a risk assessment concerning routes of infection into and within the flock/herd rather than on the identification of specific pathogens as most biosecurity measures are general and generic.

d) Description of *biosecurity*

This section should outline the measures to reduce the risk of introduction, establishment and spread of pathogenic agents to, within and from the *population* in accordance with Article 4.X.8.

It should also include emergency and response procedures for animal health events.

e) Surveillance and monitoring of pathogenic agents

The *biosecurity plan* should include the procedures for *monitoring* and *surveillance* to detect the presence of pathogenic agents in accordance with Chapter 1.4.

f) Communication and reporting

This section should outline the procedures for communicating information about the *biosecurity plan* to actors. It should also include procedures for reporting incidents and sharing information with relevant authorities.

g) Training and education

This section should outline the training and education needs and identify programmes to ensure all relevant actors are aware of the *biosecurity plan* and clearly understand their responsibilities to implement and maintain the *biosecurity* and the consequences of non-compliance.

h) Supporting documents

This section should outline the standard operating procedures (SOPs), checklists, and record-keeping templates which describe routine management processes and ensure that responsibilities and duties are consistently fulfilled and documented.

i) Evaluation and improvement

This section should describe the procedures for *monitoring* and evaluation of the *biosecurity plan* in accordance with Article 4.X.10. *Biosecurity* incidents, and corrective actions taken should be documented. The *biosecurity plan* should be updated regularly.

EU comment

The EU suggests to amend this paragraph, as follows: “This section should describe the procedures for monitoring and evaluation of the biosecurity plan in accordance with Article 4.X.110. Biosecurity incidents, and corrective actions taken should be documented. The biosecurity plan should be updated regularly.”

Justification: This because article 4.X.10 is about Training and awareness.

Article 4.X.10.

Training and awareness

1) Training

Regular training on *biosecurity* should be undertaken according to the needs identified and should include all actors. Training should be provided by those with sufficient qualifications and experience. The training should be in line with legislative and policy frameworks. Such training may include:

- Principles of *biosecurity*,
- *Biosecurity risk assessment*,
- Application and monitoring of *biosecurity*, including emergency response and contingency planning,
- *Biosecurity* implementation and evaluation,
- Purpose, development, implementation, monitoring and evaluation of a *biosecurity plan*.

Competency-based training requirements should be identified and documented for each actor. The training achieved should be monitored to ensure the required level of competencies are obtained or maintained.

2) Awareness

The general public and those in industry should be made aware of the importance of *biosecurity* (and the *biosecurity plan* if appropriate) at strategic places (e.g. *border posts*, farm entrances, *markets*) and times (e.g. during disease outbreak, high risk season). This may be the responsibility of the *Veterinary Authority*, *Veterinary Services* or even farmers depending on the context and extent of the *risk*.

Article 4.X.11.

Evaluation and improvement

The implementation of *biosecurity*, the compliance with the *biosecurity plan* and the effectiveness of implemented measures should be subjected to evaluation for improvement.

- 1) The evaluation of implementation should be based on predefined scope and criteria, taking into consideration the expected scale of the operation and the characteristics of the *population* concerned. This will determine at which level of responsibility the evaluation should be conducted, and at which frequency. The frequency should be adapted to changing circumstances such as new animal health status, newly identified *hazards*, change in *risks*, previous evaluations, changes in production or changes in plan. The evaluation should determine the existence and level of implementation of *biosecurity*, through collected evidence that may include documentation of procedures and other routine records as well as interviews with personnel. Based on these findings, the evaluation may allow to establish a risk-based *biosecurity* score as a whole or for each measure.
- 2) Compliance with the *biosecurity plan* should be evaluated routinely or following a change in risks. Compliance should focus on critical control points as identified in the risk assessment and in the *biosecurity plan* itself. Documented evidence of compliance at these critical control points should be collected routinely and should be able to be provided for any evaluation, including formal audit. This could include checklists for routine procedures, log sheets, records of training and interviews with relevant actors. The evaluation of compliance to the *biosecurity plan* should be executed by an independent party.

EU comment

1) The EU believes that the use of the words “risk assessment” is incorrect. It is written that compliance should focus on critical control points, which is actually part of the Hazard Analysis and Critical Control Points (HACCP) procedure, which is different from the Import Risk Analysis described in Chapter 2.1 of the Code. Furthermore, this paragraph mentions that documented evidence of compliance for these critical control points include checklists, log sheets, records of training and interview, which are part of the HACCP principles and procedure.

HACCP and the Import Risk Analysis are two different processes use for prevention of disease occurrence. As it is described in this chapter, there is an external biosecurity and an internal biosecurity. The external biosecurity will use the principles of the Import Risk Analysis to identify transmission pathways for a hazard to enter the establishment and estimate its risk, on the other hand the HACCP system provides a tool for internal biosecurity by identifying critical control points and assess any deviation in order to take corrective measures and prevent any hazards from entering and spreading within the livestock production.

2) The EU, in line with the first comment made for this chapter, suggests that the Veterinary Authority can carry out the evaluation of the compliance of the compliance to the biosecurity plan, due to the fact that the Veterinary Authority is not responsible for the development of the biosecurity plan.

Suggested revised text:

“Compliance with the biosecurity plan should be evaluated routinely or following a change in risks. Compliance should focus on the Hazard Analysis Critical Control Point management

system and transmission pathways identified in the risk assessment as described ~~identified in the risk assessment and in the biosecurity plan itself~~. Documented evidence of compliance at these critical control points should be collected routinely and should be able to be provided for any evaluation, including formal audit. This could include checklists for routine procedures, log sheets, records of training and interviews with relevant actors. The evaluation of compliance to the biosecurity plan should be executed by ~~an independent party~~ the Veterinary Authority”

- 3) The effectiveness of the *biosecurity plan* should be evaluated routinely or following a change in risks, to ensure the *biosecurity plan* is complete, fit for purpose and up to date. The evaluation should be based on animal health data from within and outside the *population* (such as mortality or morbidity rates related to the targeted hazards, results of laboratory tests on *animals* in the *population*, levels of antimicrobial use, cell count trends), and on animal production performance data (such as milk yield, growth rates, egg production).

The outcomes of the evaluations should be communicated to all relevant actors and should inform which risk mitigation or corrective actions are needed so that the *biosecurity plan* can be updated accordingly.

CHAPTER 5.4.

MEASURES AND PROCEDURES APPLICABLE IN THE
EXPORTATION OF COMMODITIES**EU comment**

The EU in general supports the proposed new chapter.

However, our overall view is that the responsibilities of the Veterinary Authorities are very prominent in this Chapter, while the responsibilities of the exporter are underrepresented. Given that the authorities are acting at the request of the exporter, the exporters duties need to be more emphasized.

In addition, it needs to be clear that operators must cooperate with the Veterinary Authority in order to export (especially as they are "requesters" in case of export). If they do not cooperate, the Veterinary Authority is not in position to certify and the consignment cannot leave. However, this chapter might not be the best place where the relation between the Veterinary Authority and the operators should be detailed. The EU invites the Code Commission to assess if this should be better explained in SECTION 3 “QUALITY OF VETERINARY SERVICES” of the Terrestrial code. Indeed the role of operators is essential in several actions related to the management of animal health (e.g. traceability, access to the commodities, compliance with certification requirements, reporting of diseases, biosecurity).

With respect to the title it is suggested to consider if better spelling would be “TO IN THE EXPORTATION OF COMMODITIES”.

For specific suggestions see comments below.

Article 5.4.1.

Purpose and scope

This chapter provides general principles for measures and procedures that are applicable in the exportation of *commodities* to prevent the spread of pathogenic agents through *international trade of commodities*, without creating unjustified restrictions, covering from facilities of origin (such as *establishment, slaughterhouse/abattoir, semen collection centre*) to the *point of exit*.

EU comment

The EU proposes to add the following sentence to the paragraph:

“In the case of live animals, the chapter also addresses certain animal welfare aspects.”

Justification:

The current wording implies that animal welfare is not part of the purpose and scope.

This chapter provides *exporting countries* with recommendations on measures and procedures, roles and responsibilities of the *Veterinary Authority* or other *Competent Authorities*, and business operators, in addition to responsibilities that are described in Article 5.1.3. This chapter provides guidance to ensure the quality and performance of official controls for exportation.

This chapter applies to all *commodities*; some recommendations are specifically addressed to certain of those *commodities*.

Article 5.4.2.

General considerations

The *Veterinary Authority* of the *exporting country* should ensure that *importing country* requirements, including all information required for the agreed *international veterinary certificate*, in accordance with Article 5.1.1. and Chapter 5.3., are available to exporters.

The *Veterinary Authority* of the *exporting country* should be responsible for the performance of official controls in coordination with other relevant *Competent Authorities* in accordance with *veterinary legislation* to ensure that exported *commodities* can be traded safely and meet the requirements of the *importing country*. Its legal mandate, as described in Article 3.4.5. and 3.4.13., should include export control activities at any step and to request from the exporter any necessary information. Where appropriate, the *Veterinary Authority* may delegate certain tasks in accordance with point 2 of Article 3.4.5. Adequate human, technical and financial resources should be available in the *exporting country* to allow those official controls to be undertaken effectively and to properly apply the certification obligations and procedures laid down in Chapters 5.1. and 5.2., in accordance with the quality principles described in Article 3.2.2.

The *Veterinary Authority* should cooperate closely with customs authority and other authorities of the *exporting country* dealing with exports to ensure that official controls are performed effectively, to protect the status of the *commodities* without creating unjustified barriers to trade. This cooperation should also cover actions to prevent and combat fraud.

The *Veterinary Authority* should have procedures for certification of the *animal health status* of the *country, zone, compartment, or herd* as well as of the disease situation in *establishments* and other premises and communicate with the exporter regarding any additional documentary evidence that may be required to support such certification.

The *Veterinary Authority* in the *exporting country* should ensure that the certified *animal health status* of the *country, zone, compartment, herds or animals*, is based on appropriate *surveillance* and reporting in accordance with Chapter 1.4.

The *Veterinary Authority* in the *exporting country* should have procedures for registration and approval of *establishments* of origin, where applicable, and other facilities used for production and handling of consignments, to comply with the agreed *international veterinary certificate*. Operators should not hinder access by the *Veterinary Authority* to the *commodities*, the premises where they are located and the means by which they are transported. During official controls, operators should assist and cooperate with the *Veterinary Authority* and make available all information concerning the consignment.

The *Veterinary Authority* of the *exporting country* should ensure that appropriate identification of *commodities* is in place to support traceability for the consignment to comply with the agreed *international veterinary certificate*. *Animal identification* should be in accordance with Chapter 4.2. and Chapter 4.3.

Upon request from the *Veterinary Authority* of the *importing country* or from the *Veterinary Authority* of the *transit country*, the *Veterinary Authority* of the *exporting country* should provide additional information on the process to ensure compliance with the conditions included in the agreed *international veterinary certificate*, and give reasonable access for audit in case of repeated non-compliant consignments jeopardising the safety of trade. The *Veterinary Authority* of the *exporting country* should take the appropriate and necessary preventive measures to ensure that the status of the *commodities* is not jeopardised before and during transport. The *exporting country* should suspend the export of a *commodity* when there is reason to believe that it may present a risk for animal and public health or that it does not comply with the agreed *international veterinary certificate*.

The *Veterinary Authority* of the *exporting country* should promptly communicate to the *Veterinary Authority* of the *importing country*, any change or situation that may affect its capacity to fulfil the conditions of the agreed *international veterinary certificate*.

The *Veterinary Authority* of the *exporting country* should also inform without delay the *Veterinary Authority* of *importing country*, and where necessary the *transit country*, in the event that a particular issue affects the status of a *commodity* which has already left the *exporting country*.

The *Veterinary Authority* of the *exporting country* should carry out collaborative activities with other *Competent Authorities*, customs, other authorities and operators, and with *Veterinary Authorities* in other countries, to control the risk posed by the illegal cross-border movement of *commodities*, i.e. the international movement of *commodities* done in a way to expressly and intentionally avoid official controls.

Article 5.4.3.

General principles applicable to procedures for exportation

1. Preparation for exportation

Exporters should announce the export to the *Veterinary Authority* sufficiently in advance as to meet to conditions of the agreed *international veterinary certificate* and the administrative requirements of the *exporting, transit and importing countries*.

Exporters should provide to the *Veterinary Authority* as required details of the consignment. The *Veterinary Authority* should outline to the exporter the procedures, standards and timeframe for preparation of the consignment, and the documentary evidence required to demonstrate compliance with these requirements. Where relevant, the *Veterinary Authority* should identify eligible bodies or officers for performance and certification of procedures specified in the agreed *international veterinary certificate*.

The exporter and the *Veterinary Authority* should coordinate the implementation, and its documentation, of the conditions of the agreed *international veterinary certificate*. Implementation of these conditions and its documentation should be in accordance with the procedures and standards communicated by the *Veterinary Authority* of the *exporting country* and will form the basis upon which the *Official Veterinarian* will issue the *international veterinary certificate* for the consignment.

The *Veterinary Authority* should ensure that the facilities and operational procedures required for isolation of animals comply with the conditions of the agreed *international veterinary certificate*, including registration, approval, and inspection, in accordance with Chapters 4.6., 4.7. and 5.7. or other relevant chapters of the *Terrestrial Code*.

Testing of *commodities* required to fulfil the conditions of the agreed *international veterinary certificate* should be in accordance with Article 3.2.10. and with the *Terrestrial Manual*. The *Veterinary Authority* should define and communicate to the exporter the procedures for sample collection, identification and submission, the list of *approved laboratories* and the *approved* diagnostic tests.

The *Veterinary Authority* should define and communicate to the exporter the procedures for *vaccination* and treatment if required to fulfil the conditions of the agreed *international veterinary certificate*. The exporter should arrange for *vaccination* or treatment of animals, noting timeframes relevant to the scheduled date of exportation. *Vaccination* and treatment of animals should use *veterinary medicinal products* registered in the *exporting country*, in line with the conditions of the agreed *international veterinary certificate*.

The *Veterinary Authority* should define and communicate to the exporter the standards and procedures for *disinfection* and disinsection of *vehicles/vessels* and *containers* in accordance with Chapter 4.14., if required to fulfil the conditions of the agreed *international veterinary certificate*.

The exporter should also be able to provide to the *Veterinary Authority* a transport plan from the *point of exit* in the *exporting country* to the point of *unloading* in the *importing country*. In the case of animals, it should be in accordance with Chapters 7.2., 7.3. or 7.4. as relevant.

2. Procedures of exportation

a) Verification and certification

The exporter should cooperate with the *Veterinary Authority* to demonstrate that the conditions of the agreed *international veterinary certificate* have been met and that the consignment is eligible for certification and export. The exporter should provide all documentary evidence of compliance with the conditions of the agreed *international veterinary certificate* as required by the *Veterinary Authority*, including import permit where appropriate. There should be clear traceability and linkage, at every stage of preparation of animals and *animal product*, to the final consignment presented for export, as relevant to fulfil the conditions of the agreed *international veterinary certificate*.

The *Official Veterinarian* should review the preparation of the export consignment to confirm that animals and *animal products* have been clearly identified at every stage of their preparation, that the consignment complies with the conditions of the agreed *international veterinary certificate* and is in accordance with Chapters 5.1. and 5.2. of the *Terrestrial Code*. The *Official Veterinarian* should also review all transport arrangements for the consignment to ensure they support maintenance of the *commodity's* status and *animal welfare*.

EU comment

It is suggested to add “where applicable” at the end of the para above to provide the required flexibility.

Once satisfied that preparation and transport arrangements are appropriate and that the consignment is eligible for certification and export, the *Official Veterinarian* should issue the *international veterinary certificate*.

b) Domestic transportation of commodities

The *Veterinary Authority* should collaborate with other relevant authorities and stakeholders to ensure that management of the consignment pre-export and during transport is consistent with agreed processes and standards.

The exporter should ensure that the assembly, *loading* and crating of animals or other *commodities* is appropriate to preserving the status and *animal welfare* of the consignment from the *place of shipment*, including adequate *disinfection* and disinsection of the *vehicle/vessel* and *container*.

The *Veterinary Authority* in the *exporting country* may require health and welfare inspection of consignments of animals at the *point of exit*, which includes the possibility to deny permission to export if concerns are identified.

Article 5.4.4.

Specific recommendations depending on commodities

1. Animals

In the case of animals, the *Veterinary Authority* should ensure that *animal welfare* is maintained throughout the whole process of exportation, in accordance with Chapters 7.1., 7.2., 7.3. and 7.4. as relevant.

The exporter should ensure that *vehicles/vessels* used for transportation of animals throughout the whole process of exportation undergo adequate *disinfection*, and that measures are implemented to prevent and control vermin such as rodents or arthropods. These measures should be applied before every *loading* of animals. *Vehicles/vessels* should contain only animals of the same status.

Containers should be either new or cleaned and disinfected before every *loading* of animals, in accordance with Chapter 4.14., or be for single use.

The *Veterinary Authority* should ensure that, before leaving the *exporting country*, consignments of animals should be subjected to a visual examination, at an appropriate place and time according to the agreed *international veterinary certificate* and the

requirements of the *exporting country*. It should be ensured that, from the time of this visual inspection until the time of leaving the *exporting country*, the animals in the consignment are not in contact with other animals of a different status.

The *Veterinary Authority* in the *exporting country* may require welfare inspection of consignments of animals at the *point of exit*. Such inspections should be supported by *veterinary legislation*, which should also ascribe authority to deny permission to export if *animal welfare* concerns are identified.

2. Germinal products

Consignments of *germinal products* should be packed, dispatched, and transported in a way that preserves the viability of the products.

Consignments of *hatching eggs* should be dispatched from parental *flocks* that meet the conditions of the agreed *international veterinary certificate*. *Containers* should be either new or cleaned and disinfected before every use, in accordance with Chapter 4.14.

Cryogenic tanks for semen, oocytes, embryos should be dispatched from *semen collection centres* or *collection centres* that meet the conditions of the agreed *international veterinary certificate*. They should be single-use cryogenic tanks or be cleaned and disinfected before use in accordance with Chapter 4.14. and use new liquid nitrogen.

Consignments of semen, oocytes, embryos, should be identified in accordance with the relevant recommendations of Chapters 4.6. to 4.11.

The *Veterinary Authority* should ensure that, before leaving the *exporting country*, consignments of *germinal products* be subjected to a visual examination and documentary check and cryogenic tanks for semen, oocytes, embryos be sealed and marked, according to the agreed *international veterinary certificate* and the requirements of the *exporting country*.

3. Animal products

Containers used for transporting *animal products* should be suitable for the type of product, protect the *animal products* from contamination, and fulfil the conditions of the agreed *international veterinary certificate* and the requirements of the *exporting country*.

EU comment

It is suggested to review the text as follows to be more holistic: “protect the animal products from any damage or contamination”.

The *Veterinary Authority* should ensure that adequate measures are taken to clean and, where necessary after cleaning, to disinfect before use, *containers* and means of transportation in accordance with Chapter 4.14., particularly when conveying or transporting unpacked materials.

The *Veterinary Authority* should ensure that, before leaving the *exporting country*, consignments of *animal products* should be subjected to a visual examination and documentary check, according to the agreed *international veterinary certificate* and the requirements of the *exporting country*.

Article 5.4.5.

Emergency plan

The *Veterinary Authority* should develop a plan to address the occurrence within the *exporting country* after the *commodities* have been exported, of a *listed disease* or a disease referred to in the *importing country* requirements, which may have impacted the status of the exported *commodities*. The *Veterinary Authority* should be guided by *importing country* requirements in implementing the plan.

The *Veterinary Authority* should ensure that the exporter develops a plan to address emergencies which may impact the status of the *commodities* being exported, failure of transport arrangements, or rejection of the consignment by the *transit or importing country*. The emergency plan may be generic or specific to each consignment and should focus on preserving the status of the consignment and *animal welfare* in accordance with Chapters 7.2., 7.3. and 7.4.

The emergency plan should identify responsibility for development and communication of alternative transport arrangements when necessary. The relevant *Competent Authority* in the *transit and importing countries* should be consulted regarding revised transport arrangements to assess the implications for the status of the *commodities*. The *Veterinary Authority* in the *exporting country* should be consulted on alternative transport arrangements for consignments of *animals* to ensure that *animal welfare* is preserved.

The emergency plan should include procedures for managing exported consignments that fail to reach the designated *transit or importing countries* or are rejected by them.

CHAPTER 5.6.

MEASURES AND PROCEDURES APPLICABLE IN THE
IMPORTATION OF COMMODITIES**EU comment**

The EU in general supports the proposed new chapter.

In relation to ongoing work of the Code Commission on Chapter 5.7, it is suggested to consider the importance of biosafety measures at import control points (quarantine centres, border control posts, etc.), to prevent the spread of disease into the territory of the importing country. In case this will not be covered there, then it should be addressed in this chapter.

For specific suggestions, see comments below.

Article 5.6.1.

Purpose and scope

This chapter provides general principles for measures and procedures that are applicable in the importation of *commodities* to prevent the spread of pathogenic agents through *international trade of commodities*, without creating unjustified restrictions, covering from the time of arrival at the border of the *importing country* until clearance of *commodities*.

EU comment

The EU suggests adding the following sentence to the paragraph:

“This chapter also addresses specific animal welfare requirements with regard to the import procedure.”

Justification: The current wording implies that animal welfare is not part of the purpose and scope.

This chapter provides *importing countries* with recommendations on measures and procedures, roles and responsibilities of the *Veterinary Authority* and other *Competent Authorities*, and business operators, in addition to responsibilities that are described in Article 5.1.2. This chapter provides guidance to ensure the quality and performance of official controls for importation.

The *animal health status* of the *importing country or zone* is not affected by the presence of disease or infection in imported animals in a *quarantine centre* or at a *border inspection post*.

Article 5.6.2.

General considerations

The *Veterinary Authority* of the *importing country* should ensure that *importing country* requirements, including *international veterinary certificates*, and up-to-date information relevant to the import procedures, including a list of the *border inspection posts* designated for the import and transit of those *commodities* are made available.

The *Veterinary Authority* of the *importing country* should be responsible for the performance of official controls in accordance with *veterinary legislation* to ensure that imported *commodities* can be safely imported. Its legal mandate, as described in Articles 3.4.5. and 3.4.13., should include import control activities at any step and to request from the importer any necessary information. Where appropriate, the *Veterinary Authority* may delegate certain tasks in accordance with point 2 of Article 3.4.5. Adequate human, technical and financial resources should be available in the *importing country* to perform official inspection in accordance with the quality principles described in Article 3.2.2.

An *importing country* may require adequate advance notice or approval regarding the date of entry into its territory of *commodities*, stating the type of *commodity*, species, quantity, means of transport and the *border inspection post* to be used.

The *Veterinary Authority* or other *Competent Authorities* when relevant, should perform official inspection in accordance with Article 3.2.12. regularly, on a risk basis and with appropriate frequency to ensure compliance with the *importing country* requirements. By way of derogation, the *Veterinary Authority* or other *Competent Authorities* may exempt from the inspection, *safe commodities* or *commodities* posing a negligible risk and for which inspection is not considered necessary.

Biosecurity should be applied to prevent transmission of pathogenic agents from *commodities* throughout the import process.

An *importing country* may prohibit the introduction into its territory of *commodities* not complying with the *importing country* requirements.

Importers should be aware of the *importing country* requirements and import procedure before the importation and announce, in advance, to the *Competent Authorities* the arrival of consignments at the *border inspection post*, in accordance with *importing country* requirements. Importers should ensure that *commodities* are presented for official inspection at the *border inspection post*, together with the original official certificates or documents, or digital equivalents, which are required to accompany the consignments.

In case of animals, importers should ensure that *animal welfare* is maintained throughout the whole process of importation, in accordance with Chapters 7.1., 7.2., 7.3. and 7.4. as relevant.

The *Veterinary Authority* of the *importing country* should carry out collaborative activities with other *Competent Authorities*, customs, other authorities and operators, and with *Veterinary Authorities* in other countries, to control the risk posed by the illegal cross-border movement of *commodities*, i.e. international movement of *commodities* done in a way to expressly and intentionally avoid official controls.

Article 5.6.3.

General principles applicable to procedures for import control

Veterinary Authority or other *Competent Authorities* should take control of the imported *commodities* to decide whether or not the consignment complies with the *importing country* requirements.

EU comment

The EU suggests adding the following sentence:

“Live animal consignments should have priority and controls should be performed without unnecessary delay and in accordance with Articles 7.2.3 and 7.3.3.”

Justification:

It is of major importance to keep animal welfare aspects in mind at border controls. Measures and resources should be in place to avoid unnecessary waiting times.

Import control should be performed at an appropriate place which might include a *border inspection post*, a point of entry, quarantine centre, the place of destination, or premises of the operator responsible for the consignment. The consignment should remain under the control of the *Veterinary Authority* or other *Competent Authorities* until formal clearance.

1. In case of emergency, ships and aircrafts may be granted access to a port or airport which are not their intended destination. In those cases, they should be subjected to the animal health and welfare measures which the *Veterinary Authority* or other *Competent Authorities* may consider necessary. Official inspection

Where official inspections of *commodities* are performed, they should always include a documentary check and, depending on the risk to human and animal health and *animal welfare*, should also include identity checks and physical checks. When the *Veterinary Authority* or other *Competent Authorities* needs to have full access to the consignment for the purpose of identity checks or physical inspection, consignments should be partially or fully unloaded from the means of transport.

a) Documentary check

A documentary check should be performed on all consignments presented for official inspection to ensure that they meet the *importing country* requirements.

Documentary check should include examination of the *international veterinary certificate*, and possibly of laboratory reports or other documents, including those of a commercial nature, which are required to accompany the consignment.

When performing documentary check, the *Veterinary Authority* or other *Competent Authorities* should inspect the required documents, in original or their digital equivalents as agreed between the *importing* and *exporting country*, to ensure that:

- i) the *international veterinary certificate* has been issued by the *Official Veterinarian* of the *exporting country*; complies with relevant principles set out in Article 5.2.3. and corresponds to the model established by the *importing country* for that *commodity* and intended use, based on Chapters 5.10. to 5.13.; and
- ii) the information contained in the checked documents complies with the *importing country* requirements.

b) Identity check

Identity check should be performed upon arrival of consignment at the point of inspection, as a visual inspection to verify that the content and the labelling of a consignment, including the identification of *commodities*, seals and means of transport, correspond to the information declared in the *international veterinary certificate* and accompanying documents.

The frequency of checks, the quantity of *commodities* to be inspected as well as the criteria for sampling should be determined by the *Veterinary Authority* or other *Competent Authorities* of the *importing country* based on *risk assessment*.

c) Physical inspection

Physical inspection should include clinical examination of an animal for evidence of transmissible diseases and *animal welfare* issues and physical checks of *animal products* and *germinal products* and, as appropriate, checks on packaging, the means of transport, labelling and temperature records, the sampling for analysis, testing or diagnosis and any other check required by the *Veterinary Authority* or other *Competent Authorities* to verify compliance with the *importing country* requirements.

The frequency of inspection, the quantity of *commodities* to be inspected as well as the criteria for sampling should be determined by the *Veterinary Authority* or other *Competent Authorities* of the *importing country* based on *risk assessment*.

- i) Animals

The *Veterinary Authority* or other *Competent Authorities* of the *importing country* should determine the number of animals to be clinically examined in accordance with the overall number of animals in the consignment and the declared purpose of animals, which may be increased if the physical checks carried out have not been satisfactory.

For animals that are not required to be identified individually and animals considered to be dangerous, clinical examination should consist of observation of the state of health and behaviour of the entire group or of a representative number of animals.

If the clinical examination reveals an anomaly, a more thorough clinical examination may be carried out, including sampling and testing, where appropriate.

ii) Germinal products

The *Veterinary Authority* or other *Competent Authorities* should carry out physical checks of the consignment to verify the compliance of the transport conditions with *importing country* requirements, including temperature records when relevant and the integrity of the packaging material and cryogenic tanks.

The *Veterinary Authority* or other *Competent Authorities* of the *importing country* should determine the number of items to be checked, which may be increased if the checks carried out have not been satisfactory.

The *Veterinary Authority* or other *Competent Authorities* may carry out physical checks to verify that the labelling complies with *importing country* requirements.

Physical inspection may include laboratory testing of the *germinal products*.

If the physical checks reveal an anomaly, a more thorough inspection may be carried out.

iii) Animal products

The *Veterinary Authority* or other *Competent Authorities* should carry out physical checks of the consignment to verify the compliance of the transport conditions with *importing country* requirements, including temperature records when relevant and the integrity of the packaging material.

The *Veterinary Authority* or other *Competent Authorities* may carry out physical checks to verify that the labelling complies with *importing country* requirements.

Physical inspection may include sensory examination and laboratory testing of the *animal products*.

If the physical checks reveal an anomaly, a more thorough inspection may be carried out.

2. Sampling and testing

Sampling and testing of imported *commodities* with a view to checking compliance with the health requirements laid down in the *international veterinary certificate*, may be performed following a risk-based sampling plan or upon suspicion of non-compliance resulting from the documentary, identity or physical checks of *commodities*. Testing should be performed in an *approved laboratory*.

The *Veterinary Authority* or other *Competent Authorities* may develop a risk-based sampling plan for imported consignments, that should specify the percentage of consignments to be sampled, taking into account the species concerned, the nature and declared purpose of the *commodities*, the number of incoming consignments and the results of previous sampling.

Where no immediate danger to animal health or public health is suspected from *commodities* sampled in accordance with a sampling plan, a consignment may be released before the results of laboratory tests are available.

3. Sanitary measures at import

To meet the *importing country* requirements, in addition to the *sanitary measures* implemented in the *exporting countries*, the *Veterinary Authority* or other *Competent Authorities* of *importing country* may require *sanitary measures* to be

implemented at importation before release of the *commodities*. Measures may include *disinfection* and disinsection of *vehicles/vessels* and *containers* used in the transportation and unloading of *commodities*, in accordance with Chapter 4.14.

In the case of animals, measures may include *vaccination*, treatment or isolation. In the case of other *commodities*, measures may include a holding period or the application of physical or chemical treatment.

4. Release of consignments

Based on the performed import control, the *Veterinary Authority* or other *Competent Authorities of importing countries* should decide whether the consignment complies with the *importing country* requirements.

When the decision is made that the consignment complies with the *importing country* requirements, the *Veterinary Authority* or other *Competent Authorities* should notify the importer and the information should be made available to the customs authorities.

Article 5.6.4.

Further action for non-compliant commodities

Commodities identified as non-compliant based on the performed import controls should not be released by the *Veterinary Authority* or other *Competent Authorities* and should be isolated under appropriate conditions pending further decision by the *Competent Authority*.

Depending on the type of *commodity* and the *risk* the *commodity* represents to human and animal health, and environment, or due to *animal welfare* reasons, the *Veterinary Authority* or other *Competent Authorities*, should identify the options for the disposition of the *commodities* and notify the importer. Disposition of *commodities* may include:

- a) re-dispatching the *commodity* back to the *exporting country* or another country, with the agreement of the receiving *Competent Authority*;
- b) subjecting the *commodity* to treatment or to other risk mitigation measures necessary to allow importation;
- c) killing and disposal of *animals*, or destruction of other *commodities*.

Any action applied to consignments of *animals* should comply with Chapters 7.1 and 7.6.

EU comment

The EU suggests adding the following 2 sentences:

Actions in the event of a refusal to allow the completion of the journey should comply with Articles 7.2.11 and 7.3.11. Unloading animals and their secure holding at a quarantine facility of the importing country close to the border should be carried out until resolution.

Justification:

Animal welfare at borders, especially in the event of a refusal, needs to be ensured by the importing country. Consistent with Chapters 7.2. and 7.3 (specifically their Articles 7.2.11 and 7.3.11).

The *Veterinary Authority* or other *Competent Authorities* of the *importing country* should notify any decision to refuse entry of a *commodity* to the customs authorities and are encouraged to communicate it to the *Veterinary Authority* of the *exporting country*.

Following decisions taken in relation to non-compliant *commodities*, the *Veterinary Authority* or other *Competent Authorities* should supervise the effective disposition of the *commodities* and apply measures to prevent the introduction into the country of *commodities* which have been refused import, and the reuse of the *international veterinary certificate* that accompanied the consignment.

Article 5.6.5.

Emergency plan

The *Veterinary Authority* or other *Competent Authorities* of the *importing country* should develop a plan to address the occurrence, within the *exporting country* after the *commodities* have been exported or within the *transit country* after the *commodities* have transited, of a *listed disease* or a disease referred to in the *importing country* requirements which may have impacted the status of the exported *commodities*. The *Veterinary Authority* or other *Competent Authorities* may also develop a plan to address the occurrence of a *listed disease*, or a disease referred to in the *importing country* requirements, within the *importing country* before the animals have been released.

The *Veterinary Authority* or other *Competent Authorities* should ensure that the importer develops a plan to address emergencies which may impact the status of the *commodities* being imported, and non-compliant *commodities* described in Article 5.6.4. The emergency plan may be generic, or specific to each consignment, and should focus on preventing the introduction to the *importing country* of a *listed disease* or a disease referred to in the *importing country* requirements, and *animal welfare* in accordance with Chapters 7.2., 7.3. and 7.4. The emergency plan should identify responsibility and include procedures for actions taken for non-compliant commodities described in Article 5.6.4.

Article 5.6.6.

General recommendations applicable to vehicles/vessels and containers that transported infected animals

Vehicles/vessels and *containers* that transported *animals* found to be infected with a pathogenic agent of a *listed disease* or a disease referred to in the *importing country* requirements should be considered as contaminated, and the *Veterinary Authority* or other *Competent Authorities* should apply the following measures:

- a) treatment of the litter, forage and any other potentially contaminated material, by its removal from the *vehicle/vessels* and *containers* for immediate transportation to an establishment assigned in advance, where the animal health measures required by the *importing country* should be strictly applied;
- b) *disinfection* of all parts of the *vehicles/vessels* and *containers* which were used in the transport, feeding, watering, moving and *unloading* of the *animals*, as well as all baggage of travelling attendants, in accordance with Chapter 4.14.;
- c) *disinsection of vehicles/vessels and containers* in case of *vector* disease.

Article 5.6.7.

General principles applicable to disposal of international catering waste

International catering waste is a high-risk category of product and should therefore be subject to strict controls to minimise the risk of introduction of pathogenic agents.

The *Veterinary Authority* or other *Competent Authorities* should ensure that all international catering waste entering the country from the international means of transport is handled, collected and disposed of in a way to minimise the risk of introduction of pathogenic agents.

Article 5.6.8.

General recommendations on measures to address identified illegal movement of commodities at border inspection post

To control the *risks* posed by illegal cross-border movement at *border inspection posts*, the *Veterinary Authority* or other *Competent Authorities* should coordinate and cooperate closely with the customs authority to ensure that the official inspection of *commodities* entering the country is performed in accordance with the rules of this chapter and national legislation.

For that purpose, the *Veterinary Authority* or other *Competent Authorities* should ensure the timely exchange with the customs authority, including via electronic means, of information and decisions made relevant to the organisation and conduct of their

respective activities for *commodities* entering the country. The *Veterinary Authority* or other *Competent Authorities* should collaborate with the customs authority to ensure immediate notification to the *Veterinary Authority* or other *Competent Authorities* of circumstances where a declaration is submitted to the customs authority for a consignment of the categories of *commodities* subject to official inspection but with no evidence of an official inspection having been conducted.

The *Veterinary Authority* or other *Competent Authorities*, in collaboration with custom authorities, should have practical arrangements in place to ensure the implementation of the measures described in Article 5.6.4. in case of detection of illegal cross-border movement of *commodities* at a *border inspection post*.

Article 5.6.9.

General recommendations on measures to address identified illegal movement of commodities outside border inspection posts

To control the *risks* posed by the illegal cross-border movement of *commodities* outside of *border inspection posts*, the *Veterinary Authority* or other *Competent Authorities* should:

- 1) coordinate with border authorities (police, customs, transport, immigration) to provide technical support for identification of illegal cross border movement of *commodities*;
 - 2) develop practical mechanisms to address illegal cross border movement of *commodities* and implementation thereof in close collaboration with border authorities.
-

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR
ANIMAL WELFARE

EU comment

The EU thanks WOAAH and welcomes the revision of this Chapter along the “five domains” approach.

The EU would like to share few 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 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 suggests keeping the previous wording:

“An *animal* experiences good welfare if the *animal* is healthy, comfortable, well nourished, safe, is not suffering severely or for a long time from unpleasant states such as pain, fear and distress, and is able to express behaviours that are important for its physical and mental state.”

Justification:

The EU believes that that the previous wording was better and more straight forward. Suffering does not need to be quantified in terms of severity and duration in the context of a good welfare experience. Suggested changes risk to weaken the current formulation and understanding of a good welfare. We should avoid limiting the good welfare experience only to the lack of severe and long terms suffering.

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~~The 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, 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~~ lImprovements 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” listed above.~~
- 2) The scientific assessment of *animal welfare* has ~~progressed rapidly in recent years and forms~~ the basis of these recommendations.
- 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 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 WOAHA 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 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.~~

EU comment

Suggestion to keep the text below:

“Although, in some circumstances, it may be necessary to recommend specific conditions of the animals' environment and management.”

Justification:

Focusing standards merely on “consequences” will not sufficiently guarantee animal welfare and is also not efficient.

- 2) For each principle listed in Article 7.1.5., the most relevant criteria (or measurable), 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 and The use of any of these three 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.

EU comment

The EU would like to ask WOAH to provide clearer wording of the first sentence of paragraph 4. More concretely we propose to reconsider the use of “one may use” and “evaluation”.

- 5) ~~Users of the standard~~ Members should select the most ~~appropriate animal-based~~ relevant measures for their farming system or environment, from among those listed in the standard. Welfare ~~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.

EU comment

The EU propose the keep the previous wording at the beginning of the paragraph:

“Users of the standard ~~Members~~ should select relevant measures for their farming system or environment, from among those listed in the standard.”

Justification:

The section talks about 'their farming system'. It seems to relate to a farming system of an individual farmer and there are more than one farming system in a member country.

- 6) Whatever the basis of the measure, if welfare outcomes are unsatisfactory, ~~users~~ Members should consider what changes to resources or management are necessary 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 and able to adapt to local 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*.

-
- 4) The physical environment should allow comfortable resting, safe and comfortable movement including normal postural changes, and the opportunity to perform ~~types of~~ natural behaviour that *animals* are motivated to perform.
 - 5) Social grouping of *animals* should be managed to allow positive social behaviour and minimise injury, distress and chronic fear.
 - 6) For housed *animals*, air quality, temperature and humidity should not be aversive and should support good animal health ~~and not be aversive~~. Where extreme 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) 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 skill and knowledge to ensure that *animals* are treated in accordance with these principles.
-

CHAPTER 8.Y.

INFECTION WITH NIPAH VIRUS

EU comment

The EU in general supports the proposed new chapter provided the comments below are considered.

Note also the reference to the EU comment on draft Chapter 1.3. where it is suggested to move Nipah virus into the list of diseases affecting multiple species.

Article 8.Y.1.

General provisions

For the purposes of the *Terrestrial Code*, infection with Nipah virus is defined as an *infection* of horses and pigs (hereafter 'susceptible animal') with Nipah virus.

EU comment

Nipah virus infection is described above as a disease in “horses and pigs”. However, the infection of pigs is much more common. We suggest considering if it should be changed into “pigs and horses”.

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

Point 3 appears to be not in line with other case definitions where the presence of antibodies should be epidemiologically linked to other Nipah occurrences or suspicious.

It is proposed to delete point 3).

Standards for diagnosis and vaccines, as well as information on the epidemiology, are described in the *Terrestrial Manual*.

CHAPTER 14.8.

SCRAPIE**EU comment**

The EU in general supports the proposed changes to this chapter as regards “greaves”.

On the other hand, the EU has taken note of WOAAH decision not to assess scrapie against the listing criteria. In these circumstances and based on the reopening of Chapter 14.8. to comments, the EU would like to take this opportunity and reiterate the comments it made previously on this Chapter. In particular, it would like to point out the following:

1. Like BSE, scrapie is a prion disease characterized by a long incubation period, a lack of approved in vivo diagnostic method, and a real potential for sporadic occurrence. It therefore appears that, just as for BSE, the notion of negligible risk should be preferred to scrapie freedom. The EU proposes that Chapter 14.8. is revised accordingly, and more particularly Articles 14.8.3., 14.8.4. and 14.8.5.

2. It is scientifically recognised that some polymorphisms of the PRNP gene are associated with differences in the phenotypic expression of prion diseases in sheep and goats. This has led to the implementation at EU level of eradication/control measures in scrapie infected flocks and herds based on a selective elimination of genetically susceptible animals and the exemption of application of some regular movement restrictions to the genetically resistant animals. The appropriateness of these measures has been confirmed in the EFSA opinions on the breeding program for TSE resistance in sheep of 13 July 2006, and on genetic resistance to transmissible spongiform encephalopathies (TSE) in goats of 5 July 2017. The EU considers that Chapter 14.8. should acknowledge the genetic susceptibility/resistance to scrapie in sheep and goats as a valid additional tool to manage the risk associated with movements of such animals and their germinal products.

3. Reference is made throughout Chapter 14.8. to compliance with the seven-year rule for scrapie free status (or negligible risk). This may have been chosen by analogy with the BSE Chapter recommendations. The EU therefore suggests that consideration should be given to clarify the seven-year rule for scrapie free status (or negligible risk).

4. Whereas the provision in several articles of Chapter 14.8. to have in place a formal programme of surveillance makes sense to be considered free from scrapie (or negligible risk), the EU considers that clarification should also be included on how continued surveillance should be designed once freedom (or negligible risk) status is reached taking into account the merit of reducing the required level of surveillance once such status is recognised.

5. Article 14.8.6. lays down similar recommendations for the importation from countries or zones not considered free from scrapie of sheep and goats for breeding as well as for rearing purposes. Whereas these stringent recommendations make sense for breeding animals, the EU considers that applying the same conditions to animals intended for rearing, including fattening

for a limited period before slaughter, is overly restrictive and disproportionate. Since animals for fattening will not breed or give birth, the EU considers that article 1.8.6. should cover breeding and rearing animals other than for fattening, and that importation of animals for fattening should be examined and revised.

6. According to EFSA opinion of 6 January 2010 (Scientific Opinion on Risk of transmission of TSEs via semen and embryo transfer in small ruminants (sheep and goats), the risk of TSE transmission associated with semen and embryos collected from classical scrapie incubating sheep and goats ranges from negligible to low. The EU therefore proposes to review and incorporate latest science regarding scrapie transmission with respect to germinal products and amend Articles 14.8.8. and 14.8.9. as follows:

- to modify the introductory phrase of Article 14.8.9. to cover all embryos, not only in vivo derived goat embryos.
- to amend article 14.8.8. to apply to semen similar provisions as laid down in 14.8.9. for embryos.

Article 14.8.1.

General provisions and safe commodities

Scrapie is a neurodegenerative disease of sheep and goats. The main mode of transmission is from mother to offspring immediately after birth and to other susceptible neonates exposed to the birth fluids and tissues of an infected animal. Transmission occurs at a much lower frequency to adults exposed to the birth fluids and tissues of an infected animal. A variation in genetic susceptibility of sheep has been recognised. The *incubation period* of the disease is variable; however, it is usually measured in years. The duration in *incubation period* can be influenced by a number of factors including host genetics and strain of agent.

Scrapie is not considered to pose a risk to human health. The recommendations in this chapter are intended to manage the animal health risks associated with the presence of the scrapie agent in sheep and goats. The chapter excludes so-called 'atypical' scrapie because this condition is clinically, pathologically, biochemically and epidemiologically unrelated to 'classical' scrapie, may not be contagious and may, in fact, be a spontaneous degenerative condition of older sheep.

- 1) When authorising import or transit of the following *commodities* derived from sheep or goats and any products made from these *commodities* and containing no other tissues from sheep or goats, *Veterinary Authorities* should not require any scrapie-related conditions, regardless of the scrapie risk status of the sheep and goat populations of the *exporting country, zone or compartment*:
 - a) *in vivo* derived sheep embryos handled in accordance with Chapter 4.8.;
 - b) *meat* (excluding materials as referred to in Article 14.8.12.);
 - c) hides and skins;
 - d) gelatine;
 - e) collagen prepared from hides or skins;
 - f) tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;
 - g) dicalcium phosphate (with no trace of protein or fat);
 - h) wool or fibre.

-
- 2) When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the scrapie risk status of the sheep and goat populations of the *exporting country, zone or compartment*.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 14.8.2.

Determination of the scrapie status of the sheep and goat populations of a country, zone, compartment or establishment

The scrapie status of the sheep and goat populations of a country, *zone, compartment or establishment* should be determined on the basis of the following criteria:

- 1) the outcome of a *risk assessment* identifying all potential factors for scrapie occurrence and their historic perspective, in particular the:
 - a) importation or introduction of sheep and goats or their semen, *in vivo* derived goat embryos or *in vitro* processed sheep and goat oocytes or embryos potentially infected with scrapie;
 - b) extent of knowledge of the population structure and husbandry practices of sheep and goats;
 - c) feeding practices, including consumption of *protein meal or greaves* derived from ruminants;
 - d) importation of *milk and milk products* of sheep or goats origin intended for use in feeding of sheep and goats;
- 2) an ongoing awareness programme for *veterinarians*, farmers, and workers involved in transportation, marketing and *slaughter* of sheep and goats to facilitate recognition and encourage reporting of all animals with clinical signs compatible with scrapie;
- 3) a *surveillance* and monitoring system including the following:
 - a) official veterinary *surveillance*, reporting and regulatory control in accordance with Chapter 1.4.;
 - b) a *Veterinary Authority* with current knowledge of, and authority over, all *establishments* which contain sheep and goats in the whole country;
 - c) compulsory notification and clinical investigation of sheep and goats showing clinical signs compatible with scrapie;
 - d) examination, in accordance with the *Terrestrial Manual*, in a *laboratory* of appropriate material from sheep and goats older than 18 months displaying clinical signs compatible with scrapie;
 - e) maintenance of records including the number and results of all investigations for at least seven years.

Article 14.8.3.

Scrapie free country or zone

Countries or *zones* may be considered free from scrapie if within the said territory:

- 1) a *risk assessment*, as described in point 1 of Article 14.8.2., has been conducted, and it has been demonstrated that appropriate measures are currently in place and have been taken for the relevant period of time to manage any *risk* identified and points 2 and 3 have been complied with for the preceding seven years;

AND

- 2) one of the following conditions should be met:
 - a) the country or the *zone* has demonstrated historical freedom as follows:

-
- i) scrapie has been notifiable for at least 25 years; and
 - ii) a formal programme of targeted *surveillance* and monitoring, which includes testing of sheep and goats displaying clinical signs compatible with scrapie and those over 18 months of age slaughtered, culled or found dead on farm, can be documented as having been in place for at least 10 years; and
 - iii) appropriate measures to prevent scrapie introduction can be documented as having been in place for at least 25 years; and
 - either scrapie has never been reported; or
 - no case of scrapie has been reported for at least 25 years;
 - b) for at least seven years, sheep and goats displaying clinical signs compatible with scrapie have been tested. Also a sufficient number of sheep and goats over 18 months of age, representative of slaughtered, culled or found dead on farm, have been tested annually, to provide a 95% level of confidence of detecting scrapie if it is present in that population at a prevalence rate exceeding 0.1% and no case of scrapie has been reported during this period; or
 - c) all *establishments* containing sheep or goats have been accredited free as described in Article 14.8.5.;

AND

- 3) the feeding to sheep and goats of *protein meal* ~~or greaves~~ of ruminant origin has been banned and effectively enforced in the whole country for at least seven years;

AND

- 4) introductions of sheep and goats or their semen, *in vivo* derived goat embryos or *in vitro* processed sheep and goat oocytes or embryos from countries or *zones* not free from scrapie are carried out in accordance with Articles 14.8.6., 14.8.7., 14.8.8. or 14.8.9., as relevant.

Article 14.8.4.

Compartment free from scrapie

To qualify as a *compartment* free from scrapie, all sheep and goats in a *compartment* should be certified by the *Veterinary Authority* as satisfying the following requirements:

- 1) all *establishments* within the *compartment* are free from scrapie in accordance with Article 14.8.5.;
- 2) all *establishments* within the *compartment* are managed under a common *biosecurity plan* protecting them from introduction of scrapie, and the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.4. and 4.5.;
- 3) introductions of sheep and goats are allowed only from free *establishments* or free countries;
- 4) introductions of *in vivo* derived goat embryos and *in vitro* processed sheep and goat oocytes or embryos are allowed either from free *establishments* or in accordance with Article 14.8.9.;
- 5) sheep and goat semen should be introduced into the *compartment* in accordance with Article 14.8.8.;
- 6) sheep and goats in the *compartment* should have no direct or indirect contact, including shared grazing, with sheep or goats from *establishments* not within the *compartment*.

Article 14.8.5.

Scrapie free establishment

To qualify as free from scrapie, an *establishment* of sheep and goats should satisfy the following requirements:

-
- 1) in the country or *zone* where the *establishment* is situated, the following conditions are fulfilled:
 - a) the disease is compulsorily notifiable;
 - b) an awareness, *surveillance* and monitoring system as referred to in Article 14.8.2. is in place;
 - c) affected sheep and goats are killed and completely destroyed;
 - d) the feeding to sheep and goats of *protein meal* ~~or *greaves*~~ of ruminant origin has been banned and effectively enforced in the whole country for at least seven years;
 - e) an official accreditation scheme is in operation under the supervision of the *Veterinary Authority*, including the measures described in point 2 below;

 - 2) in the *establishment* the following conditions have been complied with for at least seven years:
 - a) sheep and goats are permanently identified and records maintained, to enable trace back to their *establishment* of birth;
 - b) records of movements of sheep and goats in and out of the *establishment* are maintained;
 - c) introductions of sheep and goats are allowed only from free *establishments* or *establishment* at an equal or higher stage in the process of accreditation;
 - d) introduction of *in vivo* derived goat embryos and *in vitro* processed sheep and goat oocytes or embryos should comply with Article 14.8.9.;
 - e) sheep and goat semen should be introduced into the *establishment* in accordance with Article 14.8.8.;
 - f) an *Official Veterinarian* inspects sheep and goats in the *establishments* and audits the records at least once a year;
 - g) no *case* of scrapie has been reported;
 - h) sheep and goats of the *establishments* should have no direct or indirect contact, including shared grazing, with sheep or goats from *establishments* of a lower status;
 - i) all culled sheep and goats over 18 months of age are inspected by an *Official Veterinarian*, and a proportion of those exhibiting wasting signs and all those exhibiting neurological signs are tested in a *laboratory* for scrapie. The selection of the sheep and goats to be tested should be made by the *Official Veterinarian*. Sheep and goats over 18 months of age that have died or have been killed for reasons other than routine *slaughter* should also be tested (including 'fallen' stock and those sent for emergency *slaughter*).

Article 14.8.6.

Recommendations for importation from countries or zones not considered free from scrapie

For sheep and goats for breeding or rearing

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals come from an *establishment* free from scrapie as described in Article 14.8.5.

Article 14.8.7.

Recommendations for importation from countries or zones not considered free from scrapie

For sheep and goats for slaughter

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

-
- 1) in the country or *zone*:
 - a) the disease is compulsorily notifiable;
 - b) an awareness, *surveillance* and monitoring system as referred to in Article 14.8.2. is in place;
 - c) affected sheep and goats are killed and completely destroyed;
 - 2) the sheep and goats selected for export showed no clinical sign of scrapie on the day of shipment.

Article 14.8.8.

Recommendations for importation from countries or zones not considered free from scrapie

For semen of sheep and goats

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

- 1) the donor animals:
 - a) are permanently identified to enable trace back to their *establishment* of origin;
 - b) showed no clinical sign of scrapie at the time of semen collection;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.

Article 14.8.9.

Recommendations for importation from countries or zones not considered free from scrapie

For *in vivo* derived goat embryos and *in vitro* processed sheep and goat oocytes or embryos

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

- 1) in the country or *zone*:
 - a) the disease is compulsorily notifiable;
 - b) an awareness, *surveillance* and monitoring system as referred to in Article 14.8.2. is in place;
 - c) affected sheep and goats are killed and completely destroyed;
 - d) the feeding to sheep and goats of *protein meal* or ~~*greaves*~~ of ruminant origin has been banned and effectively enforced in the whole country;
- 2) the donor animals either have been kept since birth in a free *establishment*, or meet the following conditions:
 - a) are permanently identified to enable trace back to their *establishment* of origin;
 - b) have been kept since birth in *establishments* in which no *case* of scrapie had been confirmed during their residency;
 - c) showed no clinical sign of scrapie at the time of oocyte or embryo collection;
- 3) the oocytes or embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.

Article 14.8.10.

Recommendations for importation from countries or zones not considered free from scrapie

For milk and milk products of sheep or goat origin intended for use in feeding of sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *milk and milk products* come from scrapie free *establishments*.

Article 14.8.11.

Recommendations on protein meal

Protein meal containing any sheep or goat protein, or any feedstuffs containing that type of *protein meal*, which originate from countries not considered free from scrapie should not be traded between countries for ruminant feeding.

Article 14.8.12.

Recommendations for importation from countries or zones not considered free from scrapie

For skulls including brains, ganglia and eyes, vertebral column including ganglia and spinal cord, tonsils, thymus, spleen, intestine, adrenal gland, pancreas, or liver, and protein products derived therefrom, from sheep and goats

- 1) These *commodities* should not be traded for use in ruminant *feed*.
- 2) For purposes other than ruminant feeding, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:
 - a) in the country or *zone*:
 - i) the disease is compulsorily notifiable;
 - ii) an awareness, *surveillance* and monitoring system as referred to in Article 14.8.2. is in place;
 - iii) affected sheep and goats are killed and completely destroyed;
 - b) the materials come from sheep and goats that showed no clinical sign of scrapie on the day of *slaughter*.

Article 14.8.13.

Recommendations for the importation of ovine and caprine materials destined for the preparation of biologicals

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products originate from sheep and goats born and raised in a scrapie free country, *zone* or *establishment*.
