Report of the Meeting of WOAH Terrestrial Animal Health Standards Commission

7 to 17 February 2023 Paris

Introduction and Member contribution

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

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

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

Status of annexes

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

How to submit comments

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

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

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

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



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

Deadline for comments

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

Where to send comments

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

Date of the next meeting

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

Table of Contents

1.	Welcome				
	1.1.	Depu	ty Director General-International Standards and Science	8	
	1.2.	Direct	tor General	9	
	1.3.	Upda	tes from WOAH Headquarters	9	
		1.3.1.	WOAH Specialist Commission reports	9	
		1.3.2.	Pre-General Session	10	
		1.3.3.	Use of the acronym 'WOAH' in the <i>Terrestrial Code</i>	10	
2.	Add	option o	f the agenda	11	
3.	Cooperation with other Specialist Commissions				
	3.1.	Scien	tific Commission for Animal Diseases	11	
	3.2.	Biolog	gical Standards Commission	13	
	3.3.	Aqua	tic Animals Health Standards Commission	15	
4.	WO	AH Terr	estrial Standards Coordination	15	
5.	Wo	rk Progi	ramme and priorities	16	
	5.1.	Comr	nents received on the Code Commission Work Programme	16	
	5.2.	Ongo	ing priority topics (other than texts circulated for comments)	16	
		5.2.1.	Wildlife health	16	
		5.2.2.	Inclusion of the 'Five Domains' concept in Section 7	17	
		5.2.3.	Animal health status and pathogenic agents held in laboratories.	18	
		5.2.4.	Revision of Chapter 4.4. Zoning and compartmentalisation	18	
		5.2.5.	New chapter on biosecurity (Chapter 4.X.)	19	
		5.2.6.	Revision of Chapters 5.4. to 5.7.	19	
		5.2.7.	Revision of Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine	20	
		5.2.8.	New chapter on Animal welfare and laying hen production systems (Chapter 7.Z.)	21	
		5.2.9.	Revision of Chapter 7.2. Transport of animals by land and Chapter 7.3. Transport of animals by sea	22	
		5.2.10.	Revision of Chapter 10.5. Avian mycoplasmosis	22	
		5.2.11.	Terminology: Use of terms "animal-based measures', 'animal-based measurables', 'resource-based measures', 'management-based measures' and 'outcome'	23	
	5.3.	Items	under consideration for inclusion in the work programme	23	
		5.3.1.	Infection with Theileria annulata, T. orientalis and T. parva (Chapter 11.10.)	23	
	5.4.	New	proposals and requests for inclusion in the work programme	24	
		5.4.1.	New chapter on turkey rhinotracheitis	24	
		5.4.2.	Chapter 14.9. Sheep pox and goat pox	24	
		5.4.3.	Chapter 5.8. International transfer and Laboratory containment of animal pathogenic agents	24	
		5.4.4.	Chapter 7.7. Dog population management	24	

	Ę	5.4.5. Chapter 15.1. Infection with African swine fever virus	. 24				
	5.5.	Prioritisation of items on the work programme	. 24				
6.	Texts proposed for adoption in May 2023 (Annexes Part A)						
	6.1.	User's Guide	. 26				
	6.2.	Glossary	. 26				
	6.3.	Diseases, infections and infestations listed by WOAH (Chapter 1.3.)	. 27				
	6.4.	Infection with foot and mouth disease virus (Chapter 8.8.)	. 28				
	6.5.	Infection with rabies virus (Articles 8.14.6bis. and 8.14.7. and 8.14.11bis. of Chapter 8.14)	34				
	6.6.	Infection with Rift Valley fever virus (Chapter 8.15.)	. 35				
	6.7.	Infection with Newcastle disease virus (Article 10.9.1. of Chapter 10.9.)	. 37				
	6.8.	Bovine spongiform encephalopathy (Chapter 11.4.; Chapter 1.8.; Glossary definitions for 'prote meal' and 'meat-and-bone meal')					
	6.9.	Contagious equine metritis (Chapter 12.2.)	. 44				
	6.10.	Infection with equine influenza virus (Chapter 12.6.)	. 46				
	6.11.	Equine piroplasmosis (Chapter 12.7.)	. 47				
	6.12.	Infection with Theileria lestoquardi, T. luwenshuni and T. uilenbergi (New Chapter 14.X.)	50				
	6.13.	Middle East Respiratory Syndrome Coronavirus (MERS-CoV) (New Chapter 16.1.)	51				
	6.14.	Infection with Leishmania spp. (leishmaniosis) (New Chapter 8.Y.)	. 52				
	6.15.	Terminology: Use of terms 'fetal', 'foetal', 'fetus' and 'foetus'	. 52				
	6.16.	Terminology: Use of terms 'bovid', 'bovidae', 'bovine' and 'cattle'	. 53				
	6.17.	Terminology: Use of terms 'enzootic', 'endemic', 'epizootic' and 'epidemic'	53				
7.	Texts	Texts circulated for comments (Annexes Part B)					
	7.1.	New Glossary definitions for 'animal products', 'product of animal origin' and 'animal by-produc					
	7.2.	General hygiene in semen collection and processing centres (Chapter 4.6.)	. 55				
	7.3.	Slaughter of animals (Chapter 7.5.) and associated Glossary definitions	. 58				
	7.4.	Infection with Coxiella burnetii (Q fever) (New Chapter 8.X.)	. 60				
	7.5.	New chapter on infection with Trypanosoma evansi (New Chapter 8.Z.)	. 61				
	7.6.	Infection with <i>Mycoplasma mycoides</i> subsp. <i>mycoides SC</i> (Contagious bovine pleuropneumor (Chapter 11.5.)					
	7.7.	Infection with bovine pestiviruses (bovine viral diarrhoea) (New Chapter 11.X.)	63				
	7.8.	Infection with African horse sickness virus (Chapter 12.1.)	. 65				
	7.9.	Revision of Articles 13.2.1. and 13.2.2. of Chapter 13.2. Rabbit haemorrhagic disease	67				
	7.10.	Infection with Camelpox virus (New Chapter 16.Z.)	. 68				
	7.11.	Terminology: Use of terms 'Competent Authority', 'Veterinary Authority' and 'Veterinary Servic					
8.	Upda	tes on WOAH initiatives relevant to the Code Commission	70				
	8.1.	WOAH Observatory	70				
	8.2.	Global Burden of Animal Diseases (GBADs)	. 70				
	8.3.	WOAH Global Animal Welfare Strategy	71				

	8.4.	.4. WOAH Scientific and Technical review Vol. 41(1) 2022 'Safety, regulatory and environmental issues related to international trade of insects'		
	8.5.	Terre	strial Code data standardisation	. 72
	8	8.5.1.	Framework for Terrestrial Code standards	. 72
	8	8.5.2.	Commodities	. 72
9.	Upda	ate on f	he other standard-setting bodies and international organisations	. 73
	9.1.	1. Update on IATA collaboration		. 73
	9.2.	Updat	e on collaboration with the International Embryo Technology Society (IETS)	. 73

List of Annexes

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

Texts proposed for adoption (PART A)

- Annex 4. User's Guide
- Annex 5. Glossary
- Annex 6. Chapter 7.8. (definitions)
- Annex 7. Chapter 1.3. Diseases, infections and infestations listed by WOAH
- Annex 8. Chapter 8.8. Infection with foot and mouth disease virus
- Annex 9. Chapter 8.14. Infection with rabies virus
- Annex 10. Chapter 8.15. Infection with Rift Valley fever virus
- Annex 11. Chapter 10.9. Infection with Newcastle disease virus
- Annex 12. Chapter 11.4. Bovine spongiform encephalopathy
- Annex 13. Chapter 1.8. Application for official recognition by WOAH of risk status for bovine spongiform encephalopathy
- Annex 14. Chapter 12.2. Contagious equine metritis
- Annex 15. Chapter 12.6. Infection with equine influenza virus
- Annex 16. Chapter 12.7. Equine piroplasmosis
- Annex 17. Chapter 14.X. Infection with Theileria lestoquardi, T. luwenshuni and T. uilenbergi
- Annex 18. Chapter 16.1. Infection with Middle East respiratory syndrome coronavirus
- Annex 19. Chapter 8.Y. Infection with *Leishmania* spp. (Leishmaniosis)
- Annex 20. Terminology: Use of terms 'fetal', 'foetal', 'fetus' and 'foetus'
- Annex 21. Terminology: Animal categories (section titles)
- Annex 22. Terminology: Use of terms 'enzootic', 'endemic', 'epizootic' and 'epidemic'

Texts for comments (PART B)

- Annex 3. Work programme
- Annex 23. Glossary: 'animal product', 'commodity', 'germinal products'
- Annex 24. Chapter 4.6. General hygiene in semen collection and processing centres
- Annex 25. Chapter 7.5. Slaughter of animals
- Annex 26. Glossary: definitions related to Chapter 7.5.
- Annex 27. Chapter 8.X. Infection with Coxiella burnetii (Q Fever)
- Annex 28. Chapter 8.Z. Infection with Trypanosoma evansi
- Annex 29. Chapter 11.5. Infection with *Mycoplasma mycoides* subsp. *Mycoides* SC (Contagious bovine pleuropneumonia)
- Annex 30. Chapter 11.X. Infection with bovine pestiviruses (Bovine viral diarrhoea)

- Annex 31. Chapter 12.1. Infection with African horse sickness virus
- Annex 32. Chapter 13.2. Rabbit haemorrhagic disease
- Annex 33. Chapter 16.Z. Infection with Camelpox virus
- Annex 34. Terminology: Use of terms 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'

1. Welcome

1.1. Deputy Director General-International Standards and Science

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

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

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

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

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

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

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

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

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

1.2. Director General

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

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

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

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

The Code Commission thanked Dr Eloit for these updates.

1.3. Updates from WOAH Headquarters

1.3.1. WOAH Specialist Commission reports

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

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

1.3.2. Pre-General Session

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

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

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

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

Background

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

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

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

Discussion

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

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

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

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

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

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

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

2. Adoption of the agenda

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

3. Cooperation with other Specialist Commissions

3.1. Scientific Commission for Animal Diseases

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

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

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

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

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

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

Consideration of the listing criteria in Chapter 1.2.

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

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

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

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

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

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

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

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

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

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

Categorisation used in Chapter 1.3. of the Terrestrial Code

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

In conclusion, the Code Commission summarised that:

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

- placement of a disease under a given category in Chapter 1.3. (i.e., article) and the corresponding Section of Volume II, should be based on the content of the relevant disease-specific chapter, notably the case definition, which should be science based and indicate the precise species (the epidemiologically significant ones) that should be targeted for the purpose of notification to WOAH; and
- changes in the animal species included in the case definition of a chapter must be supported by an assessment based on Chapter 1.2. and could result in a change of the categorisation of the disease within Chapter 1.3. as a consequence.

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

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

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

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

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

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

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

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

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

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

3.2. Biological Standards Commission

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

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

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

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

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

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

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

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

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

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

- Chapter 3.4.12. Lumpy skin disease

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

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

3.3. Aquatic Animals Health Standards Commission

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

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

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

4. WOAH Terrestrial Standards Coordination

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

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

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

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

5. Work Programme and priorities

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

5.1. Comments received on the Code Commission Work Programme

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

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

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

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

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

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

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

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

5.2.1. Wildlife health

Background

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

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

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

Discussion

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

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

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

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

Background

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

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

Discussion

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

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

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

Background

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

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

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

Discussion

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

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

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

5.2.4. Revision of Chapter 4.4. Zoning and compartmentalisation

Background

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

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

Discussion

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

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

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

Background

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

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

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

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

Discussion

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

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

5.2.6. Revision of Chapters 5.4. to 5.7.

Background

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

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

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

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

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

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

Discussion

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

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

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

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

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

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

Background

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

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

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

Discussion

The Code Commission appreciated the large number of comments received.

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

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

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

Background

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

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

Discussion

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

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

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

The Commission reminded Members that the final objective of the WOAH standard setting process is the development of recommendations that are agreed by its Membership to achieve the goal of improving animal health and welfare worldwide, and to which Members could commit on a progressive implementation, and not to impose any regulatory framework. Nevertheless, the Commission clarified that the explicit inclusion of text within the chapter indicating that some provisions could be implemented in a progressive way was not appropriate, and it would not be in line with the approach of WOAH Standards texts. The Commission noted that such an explanation was of general nature and could rather be included in the User's Guide. The Commission agreed that there was no agreement among Members about how to progress this work and that there were other priorities and ongoing work, hence it agreed to remove this item from its work programme. Nonetheless, the Commission agreed to consider this topic again for inclusion in its work programme if Members showed that it would be feasible to develop a draft chapter that could reach consensus. The Commission invited Members to provide their proposals as to how to progress in that direction.

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

Background

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

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

Discussion

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

5.2.10. Revision of Chapter 10.5. Avian mycoplasmosis

Background

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

Discussion

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

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

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

Background

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

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

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

Discussion

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

5.3. Items under consideration for inclusion in the work programme

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

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

Background

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

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

Discussion

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

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

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

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

5.4.1. New chapter on turkey rhinotracheitis

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

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

5.4.2. Chapter 14.9. Sheep pox and goat pox

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

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

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

5.4.4. Chapter 7.7. Dog population management

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

5.4.5. Chapter 15.1. Infection with African swine fever virus

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

5.5. Prioritisation of items on the work programme

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

Added items:

- Consider 'extruded dry pet food' and 'heat-treated meat products in a hermetically sealed container with an F0 value of 3 or above' for listing as 'Safe commodities' in disease-specific chapters (when revised)
- Consider 'extruded dry pet food' for listing as 'Safe commodities' in Chapter 15.1. Infection with African swine fever virus
- Revision of disease names and animal categories (in Chapter 1.3. Diseases, infections and infestations listed by WOAH)
- Chapter 14.9. Sheep pox and goat pox

Removed items:

- Glossary definition for 'poultry'
- Chapter 7.Z. New chapter on animal welfare and laying hen production systems

The Code Commission updated its work programme accordingly.

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

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

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

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

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

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

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

6.1. User's Guide

Comments were received from Norway, Switzerland and the EU.

Background

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

Discussion

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

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

6.2. Glossary

a) 'poultry'

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

Background

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

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

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

Discussion

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

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

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

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

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

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

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

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

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

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

Background

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

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

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

Discussion

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

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

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

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

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

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

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

Background

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

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

Discussion

General Comments

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

The Commission acknowledged comments expressing concerns about the proposed amendments that would give the possibility for countries or zones free from FMD where vaccination is not practised to introduce vaccinated animals without having their animal health status affected. The Members considered

that these changes would impose an additional burden on importing countries that are free without vaccination. The Commission reminded Members that the proposed new provisions are based on the safety of such vaccinated animals if imported in compliance with the recommendations of the chapter. The Commission answered the specific concerns in each of the relevant articles.

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

Article 8.8.1.

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

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

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

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

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

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

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

Article 8.8.1bis.

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

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

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

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

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

Article 8.8.2.

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

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

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

In response to a comment requesting more information on the format and level of details that the Veterinary Authority should provide to WOAH for the demonstration of freedom, the Code Commission noted that Members can find this in the specific guidance on the WOAH Official Status recognition procedures, which is available on <u>WOAH webpage on official status</u>.

In point 5, the Code Commission acknowledged comments expressing concerns on the proposed amendments that would give the possibility for FMD-free countries or zones where vaccination is not practised to introduce vaccinated animals without affecting their animal health status. Noting that this

introduction only refers to animals coming from countries, zones or compartments free from FMD and compliant with the provisions in articles 8.8.11. and 8.8.11bis., referring to the demonstration of the absence of FMDV infection in the animals to be introduced, the Commission, in agreement with <u>the opinion of the Scientific Commission</u>, considered that the disease incursion risk from such introduced animals would be negligible. The consequence of such introduction on the surveillance programmes of the importing countries or zones is another issue that is up to those countries to take into consideration when they choose to import. The Commission amended the text for clarity.

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

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

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

Article 8.8.3bis.

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

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

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

Article 8.8.5bis.

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

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

Article 8.8.6.

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

Article 8.8.8.

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

Article 8.8.10.

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

Article 8.8.11.

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

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

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

Article 8.8.11bis.

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

Article 8.8.12.

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

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

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

Article 8.8.18.

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

Article 8.8.21.

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

Article 8.8.22.

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

Articles 8.8.22bis.

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

Article 8.8.22ter.

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

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

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

Article 8.8.24.

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

Article 8.8.25.

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

Article 8.8.27.

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

Articles 8.8.29.

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

Article 8.8.31.

In response to a comment suggesting that the measures provided in this chapter would also apply to pet food, the Code Commission noted that these measures were not targeting any specific end-use of the

meat and meat products, but rather to ensure the inactivation of the virus, irrespective of the end use, so that the commodity is rendered safe.

Article 8.8.35.

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

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

Article 8.8.40.

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

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

Article 8.8.41.

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

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

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

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

Background

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

At its September 2020 meeting, the Code Commission considered the advice of the *ad hoc* Group (<u>October 2019</u>) on Rabies and the Scientific Commission and agreed to add a new Article 8.14.6bis. on recommendations for the importation of dogs from countries or zones infected with rabies virus and amend the title of Article 8.14.7. and circulate the amended articles for comments.

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

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

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

Discussion

Article 8.14.6bis.

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

Article 8.14.11bis.

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

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

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

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

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

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

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

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

Background

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

An *ad hoc* Group meeting was convened in June 2021 to develop guidance for RVF surveillance during epidemic and inter-epidemic periods, as well as the consideration of other issues such as the development

of provisions for the recovery of freedom in a country or zone previously free from RVF. The report of the meeting was endorsed by the Scientific Commission at its September 2021 meeting.

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

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

Discussion

General

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

Article 8.15.1.

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

Article 8.15.2.

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

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

Article 8.15.5.

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

Article 8.15.8.

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

Commission agreed that this issue should be addressed horizontally across the disease-specific chapters at a future meeting.

Article 8.15.11.

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

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

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

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

Comments were received from Switzerland and the EU.

Background

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

While acknowledging that Chapter 10.9. may benefit from other updates, the Commission informed Members that the current revision would be limited to addressing this change for consistency with other chapters, and that a review of other aspects of the chapter would be considered for prioritisation in the future.

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

Discussion

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

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

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

Background

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

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

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

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

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

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

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

Discussion

a) Chapter 11.4. Bovine spongiform encephalopathy

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

General comments

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

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

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

The Code Commission clarified that, when applying for an official recognition of BSE risk status, Members will need to submit data on the BSE risk assessment as well as data on the ongoing implementation of a

surveillance programme for BSE (described in point 2 of Article 11.4.2. and point 2 of Article 11.4.3.), and on the history of occurrence and management of cases of BSE and bovines affected by atypical BSE (described in point 3 of Article 11.4.2. and points 3 and 4 of Article 11.4.3.). The Code Commission emphasised that the provisions on atypical BSE are essential because the potential for recycling of atypical BSE cannot be ruled out and thus should be avoided. The Commission encouraged Members to refer to the details explained by the Scientific Commission in its September 2022 meeting report.

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

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

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

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

Similarly, in response to a comment querying when the revised annual reconfirmation form for maintenance of BSE risk status will be re-circulated to Members, the Code Commission encouraged Members to refer to the September 2022 Scientific Commission report where the latest version was shared. The final version, to be used for the annual reconfirmation in 2024, will be finalised after the adoption of the revised chapters and shared with Members in the September 2023 meeting report of the Scientific Commission.

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

Article 11.4.1.

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

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

Article 11.4.2.

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

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

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

Article 11.4.3.

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

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

In point 4, the Code Commission did not agree with a comment to replace 'animal feed chain' with 'ruminant feed chain' as it considered that 'completely destroyed or disposed of' noted in this point would ensure that they do not enter any feed chain. Nevertheless, the Commission agreed to delete 'animal' as it considered it to be redundant given that 'feed' is a defined term in the Glossary of the *Terrestrial Code*.

Article 11.4.4.

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

Article 11.4.5bis.

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

The Code Commission did not agree with a comment to add 'classical' before 'BSE' based on the similar rationale described above (point 1(d) of Article 11.4.2.). The Commission also emphasised that, as described in September 2022 Scientific Commission report, the control measures in place for mitigating

the risk of classical BSE would also be relevant to prevent any potential recycling and amplification of atypical BSE in a bovine population.

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

Article 11.4.7.

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

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

Article 11.4.10.

The Code Commission did not agree with a comment to add 'enabling it to be traced throughout its lifetime'. The Commission explained that, unlike Article 11.4.8. on recommendations for live bovines, the provision 'throughout its lifetime' is not relevant for animal products. The Commission noted that this response also applies to similar comments submitted for Articles 11.4.11., 11.4.12. and 11.4.13.

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

Article 11.4.11.

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

Article 11.4.14.

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

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

Article 11.4.17.

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

Article 11.4.18.

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

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

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

In points 2(a) to 2(d), in response to comments to clarify, the Code Commission, in agreement with the <u>Scientific Commission</u>, agreed to make necessary amendments as it considered that the term 'ruling out' implies the need to test for multiple causes of behavioural or neurological signs. The Commission explained that only animals whose clinical presentation cannot be attributed to these causes should be followed up with appropriate laboratory testing in accordance with the *Terrestrial Manual* to accurately confirm or rule out the presence of BSE agents, including discrimination between atypical and classical BSE strains.

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

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

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

General comments

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

In response to a comment asking if the risk assessment could be reviewed prior to the submission of the entire dossier for application for a BSE risk status, the Code Commission encouraged Members to refer to the <u>February 2023 Scientific Commission report</u>. The Code Commission agreed with the Scientific

Commission that the risk assessment is only one of the criteria for official recognition of BSE risk status as specified in Article 11.4.3.

Article 1.8.1.

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

Article 1.8.5.

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

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

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

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

Article 1.8.6.

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

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

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

response to a comment to reinstate 'classical and atypical', the Commission explained that the proposed amendment would address this comment.

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

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

Article 1.8.6bis. (moved from Article 1.8.2.)

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

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

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

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

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

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

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

6.9. Contagious equine metritis (Chapter 12.2.)

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

Background

At its February 2019 meeting, the Code Commission agreed to amend Chapter 12.2. Contagious equine metritis, to include requirements for the temporary movement of horses and to undertake a comprehensive revision. The Commission requested that experts be convened to undertake this work.

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

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

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

Discussion

Article 12.2.1.

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

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

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

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

Article 12.2.2.

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

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

Article 12.2.3.

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

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

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

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

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

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

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

Article 12.2.4.

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

Article 12.2.5.

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

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

Article 12.2.6.

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

Article 12.2.7.

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

Article 12.2.8.

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

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

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

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

Background

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

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

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

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

Discussion

The Code Commission considered the comments received.

Article 12.6.1.

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

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

In the seventh paragraph, in response to the Biological Standards Commission's opinion on the length of the infective period, the Commission did not agree with the proposal to keep the suggested 21 days. The Biological Standards Commission explained that the infective period of 10 days was based on the virus isolation in embryonated eggs, which is not a sensitive method, thus recommended keeping the 21 days as precautionary measures. The Commission agreed with the need for a precautionary approach given the impact of the introduction of the disease, especially in naïve countries but agreed that 21 days was unnecessarily long. Therefore, the Commission proposed a period of 14 days to take into account the latent period of up to 4 days and the fact that infected horses have been found to shed the virus for up to 10 days via nasal discharge. This change has been applied throughout the chapter for consistency.

Article 12.6.2.

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

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

Article 12.6.4.

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

Article 12.6.4bis.

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

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

6.11. Equine piroplasmosis (Chapter 12.7.)

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

Background

At its February 2019 meeting, the Code Commission agreed to amend Chapter 12.7. Equine piroplasmosis to include requirements for the temporary movement of horses and it agreed that given this chapter had not been reviewed for some time, a comprehensive revision should be undertaken. The Commission requested that experts be convened to undertake this work.

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

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

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

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

Discussion

The Code Commission considered the comments received.

Article 12.7.1.

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

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

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

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

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

Article 12.7.2.

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

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

Article 12.7.3.

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

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

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

Article 12.7.4.

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

Article 12.7.5.

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

Article 12.7.6.

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

Article 12.7.8.

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

Article 12.7.9.

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

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

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

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

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

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

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

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

Background

A new Chapter 14.X. Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* was first circulated for comment in the Code Commission's September 2017 report, following the work of the *ad hoc* Group on Theileriosis that met in February 2017. At the Code Commission's February 2018 meeting, in response to comments which questioned the listing of some *Theileria* spp., the Commission agreed to seek expert advice regarding listing and to put on hold the review of comments received.

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

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

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

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

Discussion

General Comments

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

Article 14.X.1.

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

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

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

Article 14.X.2.

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

Article 14.X.3.

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

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

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

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

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

Background

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

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

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

Discussion

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

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

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

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

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

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

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

Background

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

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

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

Discussion

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

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

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

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

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

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

Comments were received from Switzerland and the EU.

Background

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

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

Discussion

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

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

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

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

Background

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

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

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

Discussion

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

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

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

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

Background

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

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

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

Discussion

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

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

7. Texts circulated for comments (Annexes Part B)

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

7.1. New Glossary definitions for 'animal products', 'product of animal origin' and 'animal byproduct'

Background

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

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

Discussion

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

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

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

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

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

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

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

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

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

Background

At its September 2019 meeting, the Code Commission requested that an *ad hoc* Group be convened to revise Chapter 4.6. General hygiene in semen collection and processing centres, and Chapter 4.7. Collection and processing of bovine, small ruminant and porcine semen, as well as provisions in relevant disease-specific chapters of the *Terrestrial Code* and the *Terrestrial Manual*. This work had been requested to resolve inconsistencies among the chapters and to ensure that the texts reflect the latest scientific evidence and best practices regarding risk mitigation measures in the collection and processing of semen of animals. The *ad hoc* Group was also requested to consider the inclusion of provisions to address equine semen in relevant chapters.

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

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

Discussion

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

General comments

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

Article 4.6.1.

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

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

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

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

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

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

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

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

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

Article 4.6.2.

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

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

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

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

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

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

In point 3, the Code Commission did not agree with a comment to delete 'at least four weeks prior to entry into the pre-entry isolation facility' as it considered the information of natural mating to be necessary before

entering the facility; nonetheless the Commission amended the text for clarity. In addition, the Commission replaced 'four weeks' with '30 days' for alignment with other chapters in the Code.

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

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

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

Article 4.6.3.

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

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

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

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

Article 4.6.4.

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

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

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

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

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

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

Article 4.6.5.

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

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

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

Article 4.6.6.

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

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

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

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

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

Background

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

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

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

Discussion

a) Animal welfare during slaughter (Chapter 7.5.)

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

Article 7.5.13.

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

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

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

Article 7.5.15.

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

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

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

Article 7.5.17.

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

Article 7.5.18.

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

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

Article 7.5.22.

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

Article 7.5.23.

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

Article 7.5.25.

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

Article 7.5.27.

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

Article 7.5.33.

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

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

Discussion

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

'death' and 'suffering'

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

'distress' and 'pain'

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

'euthanasia'

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

'slaughter'

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

'stunning'

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

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

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

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

Background

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

Discussion

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

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

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

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

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

Background

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

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

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

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

In September 2022, the Code Commission reviewed the draft new Chapter 8Z. and <u>the ad hoc Group</u> <u>report</u>, together with the opinion of the Scientific Commission. The Code Commission identified a number of critical points that were not clearly explained in the supporting reports, and agreed not to circulate the proposed text for comments and requested that the draft text be further reviewed by addressing the points of concern. The Commission agreed to review this revised draft together with additional information from the experts, at its next meeting.

Discussion

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

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

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

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

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

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

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

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

Background

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

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

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

Discussion

Title

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

Article 11.5.1.

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

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

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

Article 11.5.2.

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

Article 11.5.3.

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

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

Article 11.5.5bis.

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

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

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

Article 11.5.8.

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

Article 11.5.12.

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

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

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

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

Background

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

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

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

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

Discussion

Article 11.X.1.

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

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

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

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

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

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

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

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

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

Background

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

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

Discussion

General

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

Article 12.1.1.

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

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

In point 2) the Code Commission did not agree with a comment to include reference to antigen detection because although Chapter 3.6.1. of the *Terrestrial Manual* refers to such techniques in the 'Summary' section, it provides no description of any specific technique, and in the absence of an international standard, they cannot be considered definitive for the confirmation of the occurrence of a case.

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

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

Article 12.1.2.

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

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

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

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

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

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

Article 12.1.3.

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

Article 12.1.4.

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

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

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

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

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

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

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

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

Article 12.1.5.

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

Article 12.1.6.

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

Article 12.1.8.

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

Article 12.1.10.

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

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

Article 12.1.11.

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

Article 12.1.12.

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

Article 12.1.13.

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

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

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

Background

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

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

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

Discussion

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

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

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

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

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

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

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

Background

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

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

including the definition of its occurrence. The Code Commission also agreed to amend the name of the listed disease in Article 1.3.2. to 'Infection with Camelpox virus' but to circulate this amendment closer to adoption, after considering the comments on the proposed new disease-specific chapter. The proposed new Chapter X.Z. Infection with Camelpox virus, was circulated for comments.

Discussion

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

General Comment

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

Article 16.Z.1.

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

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

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

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

Background

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

In September 2022, the Code Commission considered the use of the terms 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' in the *Terrestrial Code* (2022 edition), based on the rationale for the use of these terms provided by the Code Commission in its September 2021 report, and agreed on several amendments that would need to be addressed. Before proposing these amendments for comments, the Commission wished to discuss its conclusions with the Aquatic Animals Commission to ensure alignment with proposed changes for the use of corresponding terms in the Aquatic Code. The two Commissions agreed to circulate proposed amendments in their respective February 2023 report to allow Members to consider them at the same time. The Commission also agreed to propose amendments to the use of these terms in the User's Guide.

Discussion

The Commission reviewed the proposed amendments to harmonise the use of the revised definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' in the *Terrestrial Code* discussed

at their September 2022 meeting and also considered the conclusions of the Aquatic Animals Commission February 2023 meeting regarding the use of the terms 'Competent Authority', 'Veterinary Authority' and 'Aquatic Animal Health Services' in the *Aquatic Code*, as well as the amendments it considered necessary in the *Aquatic Code*.

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

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

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

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

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

8. Updates on WOAH initiatives relevant to the Code Commission

8.1. WOAH Observatory

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

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

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

8.2. Global Burden of Animal Diseases (GBADs)

The Code Commission was updated on the progress of the programme since the September 2022 Commission meeting. The Secretariat reported that several key milestones have been met in developing, refining, and testing GBADs methodologies and informatics. The focus has been on deriving burden estimates in Ethiopia, implementing the Ethiopia stakeholder workshop, and obtaining initial user feedback for the various dashboards developed thus far. In the coming months, the work plan will focus on: (i) completing the scientific validation process of the GBADs approach, (ii) demonstrating the utility of GBADs in Ethiopia, and (iii) updating the knowledge engine prototype build to align with overall progress to move GBADs out of the proof-of-concept phase. These activities will ensure that the GBADs approach is flexible enough to account for differences in data availability, diseases of concern and regional characteristics while still providing comparable estimates for decision-makers.

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

8.3. WOAH Global Animal Welfare Strategy

Background

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

Discussion

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

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

<u>Update</u>

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

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

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

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

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

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

8.5. Terrestrial Code data standardisation

8.5.1. Framework for Terrestrial Code standards

Background

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

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

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

Discussion

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

8.5.2. Commodities

Background

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

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

Discussion

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

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

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

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

9.1. Update on IATA collaboration

Background

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

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

Discussion

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

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

Background

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

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

Discussion

The Code Commission President, Dr Etienne Bonbon, reported that the IETS HASAC discussed the important developments in the technologies and use of *in-vitro* produced embryos, as well as its relevance in the context of international trade. The IETS HASAC also expressed interest in contributing to the update of the international standards and in the development of recommendations on disease risk mitigation measures for *in-vitro*-produced embryos. However, it also recognised that there was still not sufficient standardisation of the practices nor consolidated data on *in-vitro* produced embryos while there is a lot of empirical information, which needs to be collated in a systematic way to allow for interpretation and use.

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

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

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

.../Annexes

Annex 1. Adopted Agenda

MEETING OF THE WOAH TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 7 to 17 February 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.** Listing assessments forwarded to TAHSC (SOP Step 3 conclusions): *Theileria mutans*, Strangles
 - 3.1.2. Emerging diseases SOP:
 - **3.1.2.1.** Annual reassessment of emerging diseases (SOP Step 5.1): Infection with SARS-CoV-2
 - 3.1.2.2. New assessments: Monkeypox, Avian influenza (H3N8)
 - **3.1.2.3.** Consideration of stable events that previously were submitted to WAHIS as emerging disease events
 - **3.1.3.** Consideration of the listing criteria in Chapter 1.2.
 - **3.1.4.** Categorisation used in Chapter 1.3.
- 3.2. Biological Standards Commission
 - 3.2.1. Biological Standards Commission's recommendations to the Terrestrial Code
 - **3.2.2.** Consideration of terms used in provisions to define the occurrence of a disease (Article X.X.1. of disease-specific chapters)
- 3.3. Aquatic Animals Commission
- 3.4. Terrestrial Standards Coordination

4. Code Commission's work programme not including texts proposed for comments or adoption

4.1. Ongoing work items (not in order of priority)

- 4.1.1. Wildlife health
- 4.1.2. Inclusion of the 'Five Domains' concept in Section 7
- **4.1.3.** New Glossary definitions for 'animal products', 'product of animal origin' and 'animal by-product'
- **4.1.4.** Revision of Chapter 1.6. Procedures for official recognition of animal health status, endorsement of an official control programme, and publication of a self-declaration of animal health status, by WOAH
- **4.1.5.** Revision of Chapter 4.4. Zoning and compartmentalisation
- 4.1.6. New chapter on biosecurity (Chapter 4.X.)
- **4.1.7.** Revision of Chapters 5.4. to 5.7.
- **4.1.8.** New chapter on Animal welfare and laying hen production systems (Chapter 7.Z.)
- **4.1.9.** Revision of Chapter 7.2. Transport of animals by land and Chapter 7.3. Transport of animals by sea

- 4.1.10. New chapter on infection with Trypanosoma evansi (Chapter 8.X.)
- 4.1.11. Revision of Chapter 10.5. Avian mycoplasmosis
- **4.1.12.** Revision of Chapter 13.2. Rabbit haemorrhagic disease
- 4.1.13. Terminology: Use of terms 'animal-based measures' and 'measurables'
- **4.1.14.** Terminology: Use of terms 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'

4.2. Items under consideration for inclusion in work programme

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

4.3. New proposals and requests for inclusion in work programme

- **4.3.1.** Revision of chapters on diseases for which WOAH grants official recognition of animal health status
- 4.3.2. New chapter on turkey rhinotracheitis

4.4. Prioritisation of items in work programme

5. Texts proposed for adoption in May 2023

- 5.1. User's Guide
- 5.2. Glossary definition for 'Poultry'
- 5.3. Infection with foot and mouth disease virus (Chapter 8.8.)
- 5.4. Infection with rabies virus (Articles 8.14.6bis., 8.14.7. and 8.14.11bis. of Chapter 8.14.)
- 5.5. Infection with Rift Valley fever virus (Chapter 8.15.)
- 5.6. Infection with Newcastle disease virus (Article 10.9.1. of Chapter 10.9.)
- **5.7.** Bovine spongiform encephalopathy (Chapter 11.4.), Application for official recognition by WOAH of risk status for bovine spongiform encephalopathy (Chapter 1.8.) and Glossary definitions ('protein meal' and 'meat-and-bone meal')
- 5.8. Contagious equine metritis (Chapter 12.2.)
- 5.9. Infection with equine influenza virus (Chapter 12.6.)
- 5.10. Equine piroplasmosis (Chapter 12.7.)
- 5.11. Infection with Theileria lestoquardi, T. luwenshuni and T. uilenbergi (New Chapter 14.X.)
- 5.12. Infection with Middle East respiratory syndrome coronavirus (New Chapter X.X.)
- 5.13. Infection with Leishmania spp. (New Chapter X.Y.)
- **5.14.** Revision of Chapter 1.3.: Article 1.3.3. (Infection with *Theileria lestoquardi, T. luwenshuni* and *T. uilenbergi*) and Article 1.3.9. (Infection of dromedary camels with Middle East respiratory syndrome coronavirus and Leishmaniosis)
- 5.15. Terminology: Use of terms 'fetal', 'foetal', 'fetus' and 'foetus'
- 5.16. Terminology: Use of terms 'bovid', 'bovidae', 'bovine' and 'cattle'
- 5.17. Terminology: Use of terms 'enzootic', 'endemic', 'epizootic' and 'epidemic'

6. Texts circulated for comments

6.1. In September 2022 Report

- 6.1.1. Collection and processing of semen of animals (Chapter 4.6.)
- 6.1.2. Responsible and prudent use of antimicrobial agents in veterinary medicine (Chapter 6.10.)
- 6.1.3. Infection with Coxiella burnetii (Q fever) (New Chapter 8.X.)
- **6.1.4.** Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia) (Chapter 11.5.)
- 6.1.5. Infection with bovine pestiviruses (Bovine viral diarrhoea) (New Chapter 11.X.)
- **6.1.6.** Infection with African horse sickness virus (Chapter 12.1.)
- 6.1.7. Infection with camelpox virus (New Chapter X.Z.)

6.2. Previously circulated

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

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

- 7.1. WOAH Observatory
- 7.2. GBADs
- 7.3. WOAH Global Animal welfare strategy
- **7.4.** WOAH Scientific and technical review Vol. 41(1) 2022 'Safety, regulatory and environmental issues related to international trade of insects'
- 7.5. Terrestrial Code data standardisation
 - 7.5.1. Framework for Terrestrial Code standards
 - 7.5.2. Commodities
 - 7.5.3. Code navigation tool
- 7.6. WOAH Rebranding

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

- 8.1. Updated on IATA collaboration
- 8.2. Update on collaboration with IETS (International Embryo Technology Society)
- 9. Meeting review
- 10. Date of next meeting

Annex 2. List of Participants

MEETING OF THE WOAH TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 7 to 17 February 2023

MEMBERS OF THE COMMISSION

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

Dr Bernardo Todeschini

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

Dr Salah Hammami

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

Dr Kiyokazu Murai

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

Dr Gaston Maria Funes

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

Dr Lucio Ignacio Carbajo Goñi (member)

Agricultural Attaché, Ministry of Agriculture, Food and Environment, Béjar (Salamanca) SPAIN

WOAH HEADQUARTERS

Dr Gillian Mylrea Head Standards Department

Dr Leopoldo Stuardo Chargé de Mission Standards Department **Dr Francisco D'Alessio** Deputy Head Standards Department

Ms Elizabeth Marier Chargée de mission Standards Department **Dr Yukitake Okamura** Chargé de mission Standards Department

Dr Serin Shin 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.

	Issues		Status	- February 2023	
Chapter		Summary of the work	Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
	Wildlife Health	Overarching consideration on how wildlife animal health is addressed in the <i>Terrestrial Code</i>	Preliminary discussions	Noted in Feb 2023 TAHSC report	3
	Five domains concept	Impact assessment for the inclusion of the concept in the <i>Terrestrial Code</i> (revision of Ch 7.1. as well)	Preparatory work	Noted in Feb 2023 TAHSC report	2
General	Pet-food commodities	Consider the inclusion of 'extruded dry pet food' and 'heat-treated meat products in a hermetically sealed container with an F0 value of 3 or above' in the list of safe commodities of chapters (when revised).	Preparatory work	Refer to Sep 2022 TASHC report	2
		In Chapter 15.1. Infection with African swine fever virus	Preparatory work	Noted in Feb 2023 TASHC report	2
Use of	Use of terms: disease / infection / infestation	Review use of the terms across the Code for consistency	Preparatory work	Refer to Feb 2020 TAHSC report	2
terms	Use of terms: animal health status	Review use of the terms across the Code for consistency	Preparatory work	Refer to Feb 2020 TAHSC report	3

WORK PROGRAMME FOR THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

	Use of terms: animal-based measures / measurables	Review use of the terms across the Code for consistency Develop a policy for their use	Preparatory work	Noted in Feb 2023 TAHSC report	2
	Use of terms: enzootic / endemic / epizootic / epidemic	To consider replacing 'enzootic' with 'endemic' and 'epizootic' with 'epidemic' throughout the Code	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Sep 2022/2)	1
	Use of terms: notify / notifiable disease / report / reportable disease	Review use of the terms across the Code for consistency. Develop a policy for their use	Preparatory work	Refer to Feb 2019 TAHSC report	2
	Use of terms: Competent Authority / Veterinary Authority / Veterinary Services	Review use of the terms across the Code for consistency	Circulated for comments	Noted in Feb 2023 TAHSC report (Feb 2023/1)	1
	Use of terms: fetal / foetal / fetus / foetus	Review use of the terms across the Code for consistency	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Sep 2022/2)	1
	Use of terms: bovid / bovidae / bovine / cattle	Review use of the terms across the Code for consistency Develop a policy for their use	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Sep 2022/2)	1
User's guide	Revision of the Users' guide (standing item)	Amendments related to use of terms: Competent Authority / Veterinary Authority / Veterinary Services and bovid / bovidae / bovine / cattle	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Sep 2022/2)	1
	'Death', 'euthanasia', 'slaughter' and 'stunning'	In-depth revision in relation to work on Ch 7.5-7.6	Expert consultation	Noted in Sep 2022 TAHSC report (Sep 2019/3)	1
Glossary	New definition for 'protein meal'	Develop the new definition as a result of discussion on revision of Ch 11.4.	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Feb 2021/5)	1

	New definitions for 'distress' and 'pain'	Develop the new definitions as a result of discussion on revision of Ch 7.5. (to remove them from Ch 7.8.)	Circulated for comments (proposed for adoption in May 2023)	Refer to Sep 2022 TAHSC report (Sep 2019/2)	1
	New definitions for 'animal products', 'product of animal origin' and 'animal by-product'	Review use of the terms across the Code for consistency. Develop a policy for their use and draft definitions.	Circulated for comments	Noted in Feb 2023 TAHSC report (Feb 2023/1)	2
	New definition for 'swill'	Review use of the term across the Code. Develop a policy for its use and consider developing a definition. (connected to biosecurity work)	Preparatory work	Noted in Feb 2023 TAHSC report	2
	Use of terms 'meat-and-bone	Review use of the term 'meat-and- bone meal' across the Code and consider replacing the term with 'protein meal' after adoption of new definition	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Sep 2022/2)	1
	meal' and 'greaves'	Review use of the term 'greaves' across the Code and consider replacing the term with 'protein meal' after adoption of new definition	Preparatory work	Refer to Sep 2022 TAHSC report	2
Section 1					
4.2	Listing of Infection with <i>T.</i> <i>lestoquardi</i> , <i>T. luwenshuni</i> and <i>T. uilenbergi</i> (Article 1.3.3.)	Consider listing based on the conclusion that the disease meets the criteria for listing	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Feb 2022/3)	1
1.3.	Revision of disease names: Infection of dromedary camels with Middle East respiratory syndrome coronavirus, Leishmaniosis	Partial revision to align disease names with the title of corresponding disease-specific chapters	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Feb 2023/1)	1

	Revision of animal categories	Partial revision of the animal categories referred to in each article	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TASHC report (Feb 2023/1)	1
1.6.	Procedures for official recognition of animal health status, endorsement of an official control programme, and publication of a self-declaration of animal health status, by WOAH	Partial revision to improve clarity on the ability for Members to hold pathogenic agents within laboratories without affecting their animal health status	Circulated for comments	Noted in Feb 2023 TAHSC report (Feb 2023/1)	2
1.8.	Application for official recognition by WOAH of free status for bovine spongiform encephalopathy	Full revision of chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Sep 2019/7)	1
Section	4				
4.4.	Zoning and compartmentalisation	Partial revision to define a time limit for containment zones	Preparatory work	Refer to Sep 2021 TAHSC report	1
4.6.	Collection and processing of semen of animals	Comprehensive revision of chapter	Circulated for comments	Noted in Feb 2023 TAHSC report (Sep 2022/2)	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.	3
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	Preparatory work	Refer to Feb 2022 TAHSC report	2
4.X.	New chapter on biosecurity	Develop a new chapter	Expert consultation	Noted in Feb 2023 TAHSC report	1
Section 5					
General	Revision of Section 5 Trade measures, import/export procedures and veterinary certification (especially Chs 5.4. to 5.7.)	Comprehensive revision of Chs 5.4. to 5.7.	Expert consultation	Noted in Feb 2023 TAHSC report	1
5.2.	Certification procedures	Partial revision to review provisions on electronic certification	Expert consultation	Refer to Sep 2022 TAHSC report	3
5.11.	Model veterinary certificate for international movement of dogs, cats and ferrets originating from countries considered infected with rabies	Consequential revision due to revision of Ch 8.14.	Preparatory work	Pending progress of the work on Ch 8.14.	3
5.12.	Model passport for international movement of competition horses	Update the relevant chapters on equine diseases to take into account proposals made by the AHG on HHP Horses Veterinary Certificates	Preparatory work	Pending progress of the works on Chs on horse diseases	3
Section 6					
6.2.	The role of the Veterinary Services in food safety systems	Review the chapter based on the revised Glossary definitions for 'CA', 'VA' and 'VS'	Preparatory work	Refer to Sep 2022 TAHSC report	3
6.3.	Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection	Revision to avoid duplication with Ch 6.2., to simplify and to refer to relevant Codex GLs more	Not started	-	3

6.10.	Responsible and prudent use of antimicrobial agents in veterinary medicine	Comprehensive revision of chapter	Circulated for comments	Noted in Feb 2023 TAHSC report (Sep 2022/1)	1
6.12.	Zoonoses transmissible from non-human primates	Consider possible inclusion of SARS-CoV-2 in this chapter, possible inclusion of Macacine Herpesvirus 1 and the revision of test schedule and animal species to be tested for tuberculosis (Origin Member requests)	Not started	Refer to Feb 2022 TAHSC report	3
Section 7					
7.2., 7.3.	Transport of animals by land and sea	Comprehensive revision of chapters	Expert consultation	Noted in Feb 2023 TAHSC report	2
7.4.	Transport of animals by air	Comprehensive revision of chapter	Preparatory work	Refer to Sep 2022 TAHSC report	3
7.5.	Slaughter of animals	Comprehensive revision of chapter	Expert consultation	Refer to Sep 2022 TAHSC report (Feb 2021/2)	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 2023)	Noted in Feb 2023 TAHSC report (Sep 2015/5)	1
8.10.	Japanese encephalitis	Comprehensive revision of chapter (related to works on Chs 12.4. and 12.11.)	Expert consultation	Noted in Feb 2023 TAHSC report	2
8.11.	Infection with <i>Mycobacterium tuberculosis</i> complex	Partial revision - to add recommendations for camelids and goats	Not started	Refer to Feb 2022 TAHSC report	3

		- to clarify point 1(b) of Article 8.11.4.			
8.13.	Paratuberculosis	Consider amendments to ensure alignment with recently revised Manual chapter	Not started	Refer to Sep 2020 TAHSC report	4
8.14.	Infection with rabies virus	 Partial revision to amend the provisions for the importation of vaccinated dogs from infected countries or zones to add provisions for the implementation of a rabies vaccination programme for dogs 	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Sep 2020/4)	1
		Partial revision - to add recommendations on wildlife-mediated rabies	Preparatory work	Refer to Sep 2022 TAHSC report	3
8.15.	Infection with Rift Valley fever virus	Comprehensive revision of chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Feb 2019/6)	1
8.X.	New Chapter on Infection with <i>Coxiella burnetiid</i> (Q fever)	Develop a new chapter	Circulated for comments	Noted in Feb 2023 TAHSC report (Sep 2022/2)	2
8.Y.	New Chapter on infection with <i>Leishmania</i> spp. (Leishmaniosis)	Develop a new chapter following Manual chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Feb 2022/3)	1
8.Z.	New Chapter on Surra	Develop a new chapter	Circulated for comments	Noted in Feb 2023 TAHSC report (Feb 2023/1)	2

Section 1	10				
10.3.	Avian infectious laryngotracheitis	Consider amendments to ensure alignment with recently revised Manual chapter	Not started	Refer to Sep 2020 TAHSC report	4
10.5.	Infection with <i>Mycoplasma gallisepticum</i> (Avian mycoplasmosis)	Full update of the chapter (content and structure) based on the recent update of the <i>Manual</i> Chapter. Consider inclusion of <i>M. synoviae</i> into a single chapter (and listed disease).	Preparatory work	Noted in Feb 2023 TAHSC report	3
10.9.	Infection with Newcastle disease virus	Remove the definition of poultry	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Feb 2022/3)	1
		Revision to align with recent revision of Ch 10.4.	Not started	Refer to Feb 2022 TAHSC report	3
Section 1	11				
11.4.	Bovine spongiform encephalopathy	Comprehensive revision of chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Sep 2019/7)	1
11.5.	Infection with <i>Mycoplasma</i> <i>mycoides</i> subsp. <i>mycoides</i> SC (Contagious bovine pleuropneumonia)	Harmonisation of chapters with official status recognition	Circulated for comments	Noted in Feb 2023 TAHSC report (Sep 2022/2)	2
11.11.	Trichomonosis	Comprehensive revision of chapter	Expert consultation	Refer to Feb 2022 TAHSC report (Sep 2020/2)	3
11.X.	New Chapter on Infection with bovine pestivirus (bovine viral diarrhoea)	Develop a new chapter	Circulated for comments	Noted in Feb 2023 TAHSC report (Sep 2022/2)	2

Section 1	2				
12.1.	African horse sickness	Harmonisation of chapters with official status recognition Proposals from AHG on AHS and SCAD	Circulated for comments	Noted in Feb 2023 TAHSC report (Sep 2022/2)	2
12.2.	Contagious equine metritis	Comprehensive revision of chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Sep 2020/4)	1
12.3.	Dourine	Comprehensive revision of chapter	Expert consultation	Noted in Feb 2023 TAHSC report	2
12.4.	Equine encephalomyelitis (Eastern and Western)	Comprehensive revision of chapter (related to works on Chs 8.10. and 12.11.)	Expert consultation	Noted in Feb 2023 TAHSC report	2
12.6.	Infection with equine influenza virus	 Partial revision to add a case definition to revise Article 12.6.6. based on the outcomes of work to evaluate equine influenza vaccination protocols prior to shipment of horses coordinated by a WOAH Reference Laboratory to consider the consequential amendments to the chapter 	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Feb 2019/6)	1
12.7.	Equine piroplasmosis	Comprehensive revision of chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Sep 2020/4)	1
12.11.	Venezuelan equine encephalomyelitis	Comprehensive revision of chapter (related to works on Chs 8.10. and 12.4.)	Expert consultation	Noted in Feb 2023 TAHSC report	2

13.2.	Rabbit haemorrhagic disease	 Partial revision to add a case definition to add a new article on recovery of free status to revise other articles, as appropriate 	Circulated for comments	Noted in Feb 2023 TAHSC report (Feb 2023/1)	3
Section	14				
14.8.	Scrapie	Comprehensive revision of chapter	Preparatory work	Noted in Feb 2023 TAHSC report	2
14.9.	Sheep pox and goat pox	(Not defined yet)	Not started	Noted in Feb 2023 TAHSC report	3
14.X.	New Chapter on infection with <i>Theileria</i> in small ruminants	Develop a new chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Sep 2017/4)	1
Section	15				
15.3.	Infection with porcine reproductive and respiratory syndrome virus (Article 15.3.9.)	Partial revision to address a concern that the testing regime in relation to semen collection centres is not sufficient to prevent the introduction of the virus through semen from countries that are not free from PRRS	Not started	Refer to Feb 2018 TAHSC report	4
Others					
X.X.	New Chapter on Crimean Congo haemorrhagic fever	Develop a new chapter	Preparatory work	Noted in Feb 2023 TAHSC report Pending ongoing work on case definition	2
16.1.	New Chapter on infection with Middle East respiratory syndrome coronavirus	Develop a new chapter following listing and Manual chapter	Circulated for comments (proposed for adoption in May 2023)	Noted in Feb 2023 TAHSC report (Feb 2022/3)	1

16.Z.	New Chapter on Camelpox	Develop a new chapter	Circulated for comments	Noted in Feb 2023 TAHSC report (Sep 2022/2)	2	
-------	-------------------------	-----------------------	-------------------------	---	---	--

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

List of abbreviations	
AHG	Ad hoc Group
BSC	Biological Standards Commission
Ch	Chapter
HQ	WOAH Headquarters
IETS	International Embryo Technology Society
SCAD	Scientific Commission for Animal Diseases
TAHSC	Terrestrial Animal Health Standard Commission

Annex 4

USER'S GUIDE

[...]

B. Terrestrial Code content

[...]

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

[...]

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

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

[...]

C. Specific issues

[...]

5. <u>Trade requirements</u>

[...]

WOAH aims to include an article listing the commodities that are considered safe for trade without the need for risk mitigation measures specifically directed against a particular listed disease, infection or infestation, regardless of the status of the country or zone of origin for the agent in question, at the beginning of each listed disease-specific chapter in Sections 8 to <u>45.16</u>. This is work in progress and some chapters do not yet contain articles listing safe commodities. When a list of safe commodities is present in a chapter, importing countries should not apply trade restrictions to such commodities with respect to the agent in question. Chapter 2.2. describes the criteria used to assess the safety of commodities.

6. International veterinary certificates

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

[...]

Annex 5

GLOSSARY

[...]

<u>DISTRESS</u>

<u>means the state of an animal, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.</u>

[...]

MEAT-AND-DONE MEAL

means the solid protein products obtained when animal tissues are rendered, and includes any intermediate protein product other than peptides of a molecular weight less than 10,000 daltons and amino-acids.

[...]

<u>PAIN</u>

means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

[...]

PROTEIN MEAL

means any final or intermediate solid protein-containing product, obtained when animal tissues are rendered, excluding <u>+ blood and blood products, peptides of a molecular</u> weight-mass less than 10,000 daltons and amino-acids.

[...]

Annex 6

CHAPTER 7.8.

USE OF ANIMALS IN RESEARCH AND EDUCATION

[...]

Article 7.8.1.

Definitions

For the purposes of this chapter the following definitions apply:

Biocontainment means the system and procedures designed to prevent the accidental release of biological material including allergens.

Bioexclusion means the prevention of the unintentional transfer of adventitious organisms with subsequent infection of animals, resulting in adverse effects on their health or suitability for research.

Biosecurity means a continuous process of risk assessment and risk management designed to minimise or eliminate microbiological infection with adventitious organisms that can cause clinical disease in the infected animals or humans, or make animals unsuitable for biomedical research.

Cloned animal means a genetic copy of another living or dead animal produced by somatic cell nuclear transfer or other reproductive technology.

Distress means the state of an animal, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

Endangered species means a population of organisms which is at risk of becoming extinct because it is either few in numbers, or threatened by changing environmental or predation parameters.

Environmental enrichment means increasing the complexity (e.g. with toys, cage furniture, foraging opportunities, social housing, etc.) in a captive animal's environment to foster the expression of non-injurious species-typical behaviours and reduce the expression of maladaptive behaviours, as provide cognitive stimulation.

Ethical review means consideration of the validity and justification for using animals including: an assessment and weighing of the potential harms for animals and likely benefits of the use and how these balance (see harm-benefit analysis below); and consideration of experimental design; implementation of the Three Rs; animal husbandry and care and other related issues such as personnel training. Ethical judgements are influenced by prevailing societal attitudes.

Harm-benefit analysis means the process of weighing the likely adverse effects (harms) to the animals against the benefits likely to accrue as a result of the proposed project.

Humane endpoint means the point in time at which an experimental animal's pain and/or distress is avoided, terminated, minimised or reduced, by taking actions such as giving treatment to relieve pain and/or distress, terminating a painful procedure, removing the animal from the study, or humanely killing the animal.

Laboratory animal means an animal that is intended for use in research. In most cases, such animals are purpose-bred to have a defined physiological, metabolic, genetic or pathogen free status.

Operant conditioning means the association that an animal makes between a particular response (such as pressing a bar) and a particular reinforcement that may be positive (for example, a food reward) or negative (e.g. a mild electric shock). As

a result of this association, the occurrence of a specific behaviour of the animal can be modified (e.g. increased or decreased in frequency or intensity).

Pain means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species specific traits of behaviour, including social behaviour.

Project proposal (sometimes called protocol) means a written description of a study or experiment, programme of work, or other activities that includes the goals of the work, characterises the use of the animals, and includes ethical considerations.

Suffering means an unpleasant, undesired state of being that is the outcome of the impact on an animal of a variety of noxious stimuli and/or the absence of important positive stimuli. It is the opposite of good welfare.

[...]

Annex 7

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY WOAH

Preamble

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

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

Article 1.3.1.

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

- Anthrax
- Crimean Congo hemorrhagic fever
- Equine encephalomyelitis (Eastern)
- Heartwater
- Infection with Trypanosoma brucei, Trypanosoma congolense, Trypanosoma simiae and Trypanosoma vivax
- Infection with Aujeszky's disease virus
- Infection with bluetongue virus
- Infection with Brucella abortus, Brucella melitensis and Brucella suis
- Infection with Echinococcus granulosus
- Infection with Echinococcus multilocularis
- Infection with epizootic hemorrhagic disease virus
- Infection with Leishmania spp. (Leishmaniosis)
- Infection with Mycobacterium tuberculosis complex
- Infection with rabies virus
- Infection with Rift Valley fever virus
- Infection with rinderpest virus
- Infection with *Trichinella* spp.
- Japanese encephalitis
- New World screwworm (Cochliomyia hominivorax)
- Old World screwworm (Chrysomya bezziana)

- Paratuberculosis
- Q fever
- Surra (Trypanosoma evansi)
- Tularemia
- West Nile fever.

Article 1.3.2.

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

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

Article 1.3.3.

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

- Caprine arthritis/encephalitis
- Contagious agalactia
- Contagious caprine pleuropneumonia
- Infection with Chlamydia abortus (Enzootic abortion of ewes, ovine chlamydiosis)
- Infection with peste des petits ruminants virus
- Infection with Theileria lestoquardi, Theileria luwenshuni and Theileria uilenbergi
- Maedi–visna
- Nairobi sheep disease
- Ovine epididymitis (Brucella ovis)

- Salmonellosis (S. abortusovis)
- Scrapie
- Sheep pox and goat pox.

Article 1.3.4.

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

- Contagious equine metritis
- Dourine
- Equine encephalomyelitis (Western)
- Equine infectious anaemia
- Equine piroplasmosis
- Infection with Burkholderia mallei (Glanders)
- Infection with African horse sickness virus
- Infection with equid herpesvirus-1 (Equine rhinopneumonitis)
- Infection with equine arteritis virus
- Infection with equine influenza virus
- Venezuelan equine encephalomyelitis.

Article 1.3.5.

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

- Infection with African swine fever virus
- Infection with classical swine fever virus
- Infection with porcine reproductive and respiratory syndrome virus
- Infection with Taenia solium (Porcine cysticercosis)
- Nipah virus encephalitis
- Transmissible gastroenteritis.

Article 1.3.6.

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

- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis

- Duck virus hepatitis
- Fowl typhoid
- Infection with high pathogenicity avian influenza viruses
- Infection of birds other than poultry, including wild birds, with influenza A viruses of high pathogenicity
- Infection of domestic and *captive wild* birds with low pathogenicity avian influenza viruses having proven natural transmission to humans associated with severe consequences
- Infection with Mycoplasma gallisepticum (Avian mycoplasmosis)
- Infection with Mycoplasma synoviae (Avian mycoplasmosis)
- Infection with Newcastle disease virus
- Infectious bursal disease (Gumboro disease)
- Pullorum disease
- Turkey rhinotracheitis.

Article 1.3.7.

The following are included within the category of lagomorph leporids diseases and infections:

- Myxomatosis
- Rabbit haemorrhagic disease.

Article 1.3.8.

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

- Infection of honey bees with Melissococcus plutonius (European foulbrood)
- Infection of honey bees with Paenibacillus larvae (American foulbrood)
- Infestation of honey bees with Acarapis woodi
- Infestation of honey bees with *Tropilaelaps* spp.
- Infestation of honey bees with Varroa spp. (Varroosis)
- Infestation with Aethina tumida (Small hive beetle).

Article 1.3.9.

The following are included within the category of other camelids diseases and infections:

- Camelpox
- Infection of dromedary camels with Middle East respiratory syndrome coronavirus
- <mark>Leishmaniosis.</mark>

Annex 8

CHAPTER 8.8.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

Article 8.8.1.

General provisions

- 1) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with foot and mouth disease virus (FMDV). Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contacts between them. Amongst *Camelidae*, only Bactrian camels (*Camelus bactrianus*) are sufficiently susceptible to have potential for epidemiological significance. Dromedaries (*Camelus dromedarius*) are not susceptible to *infection* with FMDV while South American camelids are not considered to be of epidemiological significance.
- 2) For the purposes of the Terrestrial Code, foot and mouth disease (FMD) is defined as an infection of animals of the suborder ruminantia and of the familyies Suidae and the subfamilies bovinae, caprinae and cervidaeCervidae, the subfamilies bovinae, and caprinae and antilopinae of the family Bovidae, order Artiodactyla, and Camelus bactrianus with FMDV (hereafter 'susceptible animals').

2bis) For the purposes of this chapter, 'cattle' a 'bovine' means an animals 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 animal listed in point 2; or
 - b) viral antigen or viral ribonucleic <u>nucleic</u> acid specific to FMDV has been identified <u>detected</u> in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed or <u>suspected</u> outbreak <u>case</u> of FMD, or giving cause for suspicion of previous association or contact with FMDV; or
 - c) antibodies to structural <u>proteins (SP)</u> or non-structural proteins <u>(NSP)</u> of FMDV, that are not a consequence of vaccination, have been <u>identified detected</u> in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed <u>or suspected</u> outbreak <u>case</u> of FMD, or giving cause for suspicion of previous association or contact with FMDV.
- 4) Transmission of FMDV in a vaccinated *population* is demonstrated by change in virological or serological evidence indicative of recent *infection*, even in the absence of clinical signs or any cause for suspicion of previous association or contact with FMDV. Transmission of FMDV shall be notified to WOAH as occurrence of infection.
- 5) For the purposes of the Terrestrial Code, the incubation period of FMD shall be 14 days.
- 6) Infection with FMDV can give rise to disease of variable severity and to FMDV transmission of FMDV. FMDV may persist in the pharynx and associated lymph nodes of ruminants for a variable but limited period of time beyond 28 days <u>after infection</u>. Such animals have been termed carriers. However, The only persistently infected species from for which transmission of FMDV has been proven from persistently infected individuals is the African buffalo (Syncerus caffer). However, transmission from this species African buffalo to domestic livestock is rare.
- 7) This chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of *infection* with, FMDV and transmission <u>of FMDV</u> in the absence of clinical signs.

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

Article 8.8.1bis.

Safe commodities

When authorising the importation or transit of the following *commodities*, *Veterinary Authorities* should not require any type of FMD-related conditions, regardless of the <u>FMD-animal health</u> status of the exporting country or zone:

- 1) UHT milk and derivatives thereof;
- 2) <u>heat-treated meat products in hermetically sealed container with a F₀ value of 3 or above;</u>
- 3) *meat* and bone meal and blood protein meal;
- 4) gelatine;
- 5) in vivo derived bovine embryos collected, processed and stored in accordance with Chapter 4.8.;
- 6) limed hides, pickled pelts, and semi-processed leather;
- 7) extruded dry pet food.

Other commodities of susceptible species animals can be traded safely if in accordance with the relevant articles in this chapter.

Article 8.8.2.

FMD free Country or zone free from FMD where vaccination is not practised

In defining a zone where vaccination is not practised the principles of Chapter 4.34. should be followed.

Susceptible animals in the FMD free country or zone <u>free from FMD</u>, where vaccination is not practised should be protected by the application of *biosecurity* measures that prevents the entry of FMDV into the free country or zone.

Taking into consideration physical or geographical barriers with any neighbouring infected country or zone, these measures may include a protection zone.

<u>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:</u>

To qualify for inclusion in the list of FMD free countries or zones <u>free from FMD</u>, where vaccination is not practised, a Member Country should:

- 1) have a record of regular and prompt animal disease reporting;
- 2) send a declaration to the OIE stating that during the past 12 months, within the proposed FMD free country or zone:
- 1) a) there has been no case <u>of infection with FMDV</u>;
- 2) <u>the Veterinary Authority has current knowledge of, and authority over, all herds of domestic and captive wild</u> susceptible animals in the country or zone;
- 3) <u>the Veterinary Authority has current knowledge of the distribution, and habitat and indication of disease occurrence</u> <u>through passive surveillance of wild and feral susceptible animals in the country or zone;</u>
- 4) appropriate surveillance has been implemented in accordance with:

- a) Article 1.4.6. where historical freedom can be demonstrated; or
- b) no vaccination against FMD has been carried out;
- 3) supply documented evidence that for the past 12 months:
 - a) surveillance in accordance with Articles 8.8.40. to 8.8.42. where historical freedom cannot be demonstrated which includes the has been implemented to detection of clinical signs of FMD and demonstrate no evidence of:
 - i) <u>no</u> infection with FMDV in unvaccinated animals;
 - ii) <u>no FMDV</u> transmission <u>of FMDV</u> in previously vaccinated animals when the FMD free country or zone where vaccination is practised is seeking to become one where vaccination is not practised;
- 5) d) measures to prevent the introduction of the infection have been in place: in particular, the importations or movements of commodities into the country or zone have been carried out in accordance with this chapter and other relevant chapters of the Terrestrial Code. Introduction of vaccinated animals have only been carried out either:
 - a) <u>from countries or zones free from FMD where vaccination is practised</u> in accordance with Articles 8.8.11. or <u>8.8.11bis</u>, or <u>+</u> the control of the movement of susceptible animals, their meat and other products, <u>and fomites</u> into the proposed FMD free country or zone, in particular the measures described in Articles 8.8.8., 8.8.9. and to 8.8.12. has been effectively implemented and supervised;

<u>measures to prevent the introduction of</u> no vaccinated animal<u>s</u> has been introduced, except in accordance with Articles 8.8.8. and 8.8.9., <u>8.8.9bis., 8.8.11. and 8.8.11bis. have been effectively implemented and supervised. Any</u> <u>vaccinated aAnimals introduced</u>

- b) for direct slaughter in accordance with Articles 8.8.8, and 8.8.9.bis and 8.8.11bis, were should be subjected to ante- and post-mortem inspections in accordance with Chapter 6.32. with favourable results; .FfF or ruminants, the head, including the pharynx, tongue and associated lymph nodes, was either destroyed or treated in accordance with Article 8.8.31.;
- 6) vaccination against FMD is prohibited and the prohibition has been effectively implemented and supervised.

The <u>country</u> Member Country or the proposed free <u>or</u> zone will be included in the list of FMD free countries or zones <u>free</u> <u>from FMD</u>, where vaccination is not <u>practised in accordance with Chapter 1.6.</u> only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Retention on the list requires <u>annual reconfirmation of compliance with all points above and relevant</u> provisions under point <u>4 of Article 1.4.6.</u> Documented evidence should be resubmitted that the information in points 2, 3 and 4 above be resubmitted annually for all points above. And <u>Any</u> changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported <u>notified</u> to WOAH in accordance with the requirements in Chapter 1.1.

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

Provided the conditions of points 1 to 43 <u>4</u> are <u>is are</u> 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 country²/₂s contingency plan for FMD;
- appropriate biosecurity measures are in place, including effective separation from other susceptible domestic populations or wildlife;

- the animals are identified as belonging to the collection and any movements can be traced;
- the vaccine used complies with the standards described in the Terrestrial Manual;
- vaccination is conducted under the supervision of the Veterinary Authority;
- the zoological collection is placed under surveillance for at least 12 months after vaccination.

In the event of the application for the status of a <u>new</u> FMD free zone where vaccination is not practised to be assigned to a new zone <u>being</u> adjacent to another FMD free zone <u>of the same status</u> where vaccination is not practised, it should be stated if the new zone is being merged with the adjacent zone to become one enlarged zone. If the two zones remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate zones and particularly on the identification and the control of the movement of animals between the zones of the same status in accordance with Chapter 4.3.

In the case of an incursion of stray African buffalo, a protection zone according to Article 4.4.6. should be established to manage the threat and maintain the free status of the rest of the country.

If Aa protection zone used is established, to preserve the status of a free country or zone from a newly identified likelihood of introduction of FMDV it should comply with Article 4.43.6. If vaccination is implemented in the protection zone, this will not affect the freedom of the rest of the country or zone the animal health status of the rest of the country or zone is not affected.

A country or zone free from FMD where vaccination is not practised may maintain its free status despite an incursion of African buffalo from a neighbouring infected country or zone provided that it is demonstrated that the relevant conditions are provisions in this article continue to be met and documented evidence has been submitted to and accepted by WOAH.

Article 8.8.3.

FMD free Country or zone free from FMD where vaccination is practised

In defining a zone where vaccination is practised the principles of Chapter 4.3. should be followed.

Susceptible animals in the FMD free country or zone free from FMD where vaccination is practised should be protected by the application of biosecurity measures that prevent the entry of FMDV into the free country or zone. Taking into consideration physical or geographical barriers with any neighbouring infected country or zone, these measures may include a protection zone.

Based on the epidemiology of FMD in the country, it may be decided to vaccinate only a defined subpopulation comprised of certain species or other subsets of the total susceptible population.

<u>A country or zone may be considered free from FMD where vaccination is practised when the relevant provisions in point</u> 2 of Article 1.4.6. have been complied with, and when within the proposed free country or zone To qualify for inclusion in the list of FMD free countries or zones free from FMD where vaccination is practised, a Member Country should:

- 1) have a record of regular and prompt animal disease reporting; for at least the past 12 months:
- 2) send a declaration to the OIE stating that, based on the surveillance described in point 3, within the proposed FMD free country or zone:
 - a) there has been no case of FMD during the past two years;
 - ba) there has been no evidence of FMDV transmission of FMDV during the past 12 months;
 - b) there has been no infection of FMDV in the unvaccinated subpopulations case with clinical sign of FMD during the past 12 months:

- c) the Veterinary Authority has current knowledge of, and authority over, all herds of domestic and captive wild susceptible animals in the country or zone:
- d) the Veterinary Authority has current knowledge of the distribution, and habitat and indication of disease occurrence through passive surveillance of wild and feral susceptible animals in the country or zone;
- e) compulsory systematic vaccination in the target population has been carried out to achieve adequate vaccination coverage and population immunity; based on the epidemiology of FMD in the country or zone, it may be decided to vaccinate only a defined subpopulation comprised of certain species or other subsets of the total susceptible population.
- <u>f)</u> <u>vaccination has been carried out following appropriate vaccine strain selection;</u>
- g) <u>measures to prevent the introduction of infection have been in place; in particular, the importations or</u> <u>movements of commodities into the country or zone have been carried out in accordance with this chapter and</u> <u>other relevant chapters of the Terrestrial Code;</u>
- 23) for the past 24 months supply documented evidence that:
 - appropriate surveillance to detect clinical signs of FMD-has been implemented in accordance with Articles 8.8.40. to 8.8.42. has been implemented to detect clinical signs of FMD for the past two years and demonstrates points 1 a) and 1 b) above. No evidence of that there has been no:
 - i) infection with FMDV in unvaccinated animals for the past two years 12 months;
 - ii) FMDV transmission of FMDV in vaccinated animals for the past 12 months;
 - b) regulatory measures for the prevention and early detection of FMD have been implemented for the past 12 months two years;
 - c) compulsory systematic vaccination in the target population has been carried out to achieve adequate vaccination coverage and population immunity for the past 12 months two years;
 - d) vaccination has been carried out following appropriate vaccine strain selection for the past 12 months two years;
- 4) describe in detail and supply <u>provide</u> documented evidence that <u>for the past 12 months</u> the following have been properly implemented and supervised:
 - a) in case of FMD free zone, the boundaries of the proposed FMD free zone <u>have been established and effectively</u> <u>supervised</u>;
 - b) the boundaries and <u>biosecurity</u> measures of any protection zone, if applicable <u>have been established and</u> <u>effectively supervised</u>;
 - c) the system for preventing the entry of FMDV into the proposed FMD free country or zone, in particular the measures described in Articles 8.8.9. and 8.8.12. <u>has been established and effectively supervised;</u>
 - d) the control of the movement of susceptible animals and their products into the proposed FMD free country or zone has been effectively implemented and supervised.

The <u>country</u> Member Country or the proposed free zone will be included in the list of FMD free countries or zones <u>free from</u> <u>FMD</u> where vaccination is practised <u>in accordance with Chapter 1.6.</u> only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Retention on the list requires <u>annual reconfirmation of compliance with all points above and relevant provisions under point</u> <u>4 of Article 1.4.6. Documented evidence should be resubmitted that the information in points 2, 3 and 4 above be resubmitted annually for all points above. And Any changes in the epidemiological situation or other significant events</u> including those relevant to points 3b) and 4 should be reported <u>notified</u> to WOAH in accordance with the requirements in Chapter 1.1.

Article 8.8.3bis.

Transition of vaccination status in a country or zone free from FMD

As recommended in Article 4.18.10., vaccination programmes may include an exit strategy.

If a Member Country that meets the requirements of a FMD free country or zone free from FMD where vaccination is practised and is recognised by WOAH as such, wishes to change its status to FMD free country or zone free from FMD where vaccination is not practised, it should notify WOAH in advance of the intended date of cessation of vaccination and apply for the new status within 24 months of the cessation. The status of this country or zone remains unchanged until compliance with Article 8.8.2. is approved by WOAH. If the dessier application for the new status is not provided within 24 months of the cessation or the compliance is not approved by WOAH, then the status of the country or zone as being free with vaccination from FMD where vaccination is practised will be suspended. If the country or zone does not comply with requirements of Article 8.8.2., evidence should be provided within three months that it complies with Article 8.8.3. Otherwise the status will be withdrawn suspended.

If a Member Country that meets the requirements of a country or zone free from FMD where vaccination is not practised and is recognised by WOAH as such, wishes to change its status to country or zone free from FMD where vaccination is practised, it should provide WOAH with an application and a plan following the structure of the Questionnaire of Article 1.6.6., indicating the intended date of beginning of vaccination. The status as country or zone free from FMD where vaccination is not practised of this country or zone remains unchanged until the application and plan are approved by WOAH. As soon as it is recognised free from FMD where with vaccination is practiced, the country or zone will begin the vaccination. The Member Country should provide evidence within six months that it complies with Article 8.8.3. for this time period. Otherwise the status will be withdrawn suspended.

If a country needs to define a protection zone lin accordance with Article 4.34.6. in response to an increased risk, including by the application of vaccination, once a the protection zone has been approved by the OIE, the freedom of the rest of the country or zone remains unchanged.

In the event of the application for the status of a <u>new</u> FMD free <u>free</u> zone where vaccination is practised to be assigned to a new zone <u>being</u> adjacent to another FMD free zone <u>of the same status</u> where vaccination is practised, it should be stated if the new zone is being merged with the adjacent zone to become one enlarged zone. If the two zones remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate zones and particularly on the identification and the control of the movement of animals between the zones of the same status in accordance with Chapter 4.3.

Article 8.8.4.

FMD free Compartment free from FMD where vaccination is not practised

A FMD free compartment free from FMD where vaccination is not practised can be established in either a FMD free any country or zone or in an infected country or zone. In defining such a compartment the principles of Chapters 4.34. and 4.45. should be followed. Susceptible animals in the FMD free compartment should be separated from any other susceptible animals by the effective application of an effective biosecurity plan management system.

A Member Country wishing to establish a FMD free compartment free from FMD where vaccination is not practised should:

- 1) have a record of regular and prompt animal *disease* reporting and, if not FMD free, have an official control programme and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;
- 2) declare for the FMD free compartment that:
 - a) there has been no case of FMD during the past 12 months;

- ab) no evidence of infection with FMDV has been found detected occurred during the past 12 months;
- eb) vaccination against FMD is prohibited;
- dc) no animal vaccinated against FMD within the past 12 months is in the compartment;
- <u>ed</u>) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;
- fe) documented evidence shows that surveillance in accordance with Articles 8.8.40. to 8.8.42. is in operation;
- gf) an animal identification and traceability system in accordance with Chapters 4.21. and 4.32. is in place;
- 3) describe in detail:
 - a) the animal subpopulation in the compartment;
 - b) the biosecurity plan to mitigate the risks identified by the surveillance carried out in accordance with point 1.

The compartment should be approved by the Veterinary Authority. The first approval should only be granted when no <u>infection</u> case or transmission of FMDV has occurred within a <u>10 ten-kilometre</u> radius of the compartment during the past three months prior to the effective establishment of the biosecurity plan.

Article 8.8.4bis.

Compartment free from FMD where vaccination is practised

<u>A compartment free from FMD where vaccination is practised can be established in either a free country or zone where vaccination is practised or in an infected country or zone. In defining such a compartment the principles of Chapters 4.34.</u> and 4.45. should be followed. Susceptible animals in the free compartment should be separated from any other susceptible animals by the application of an effective biosecurity plan.

A Member Country wishing to establish a compartment free from FMD where vaccination is practised should:

- 1) <u>have a record of regular and prompt animal disease reporting and, if not free, have an official control programme and</u> <u>a surveillance system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the</u> <u>prevalence, distribution and characteristics of FMD in the country or zone:</u>
- 2) declare for the free compartment where vaccination is practised that:
 - a) there has been no case of FMD during the past 12 months;
 - <u>ab)</u> <u>no evidence of infection with infection or transmission of FMDV has been found occurred during the past 12</u> <u>months;</u>
 - be) compulsory systematic vaccination is carried out using a vaccine that complies with the standards described in the Terrestrial Manual, including appropriate vaccine strain selection. The vaccination coverage and population immunity are closely monitored:
 - <u>cel</u> <u>animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant <u>articles in this chapter;</u></u>
 - <u>de)</u> <u>documented evidence shows that regular clinical, serological and virological surveillance in accordance with</u> <u>Articles 8.8.40. to 8.8.42. is in operation, so as to detect infection at an early stage with a high level of confidence;</u>
 - ef) an animal identification and traceability system in accordance with Chapters 4.12. and 4.23. is in place;

3) describe in detail:

- <u>a) the animal subpopulation in the compartment;</u>
- b) the biosecurity plan to mitigate the risks identified by the surveillance carried out according to point 1 and the vaccination plan:
- <u>c)</u> implementation of points 2 be), 2 de) and 2 ef).

<u>The compartment should be approved by the Veterinary Authority. The approval should only be granted when no infection</u> case or transmission of FMDV has occurred within a 10-kilometre radius of the compartment during the three months prior to the effective establishment of the biosecurity plan.

Article 8.8.5.

FMD infected Country or zone infected with FMDV

For the purposes of this chapter, a<u>A</u> FMD infected country or zone <u>shall be considered as infected with FMDV</u> is one that does not fulfil when the requirements for acceptance to qualify as a country or zone free from FMD either FMD free where vaccination is not practised or FMD free where vaccination is practised are not fulfilled.

Article 8.8.5bis.

Establishment of a protection zone within a country or zone free from FMD

Susceptible animals in the a country or zone free from FMD should be protected by the application of biosecurity that prevents the entry of FMDV into the free country or zone. Taking into consideration physical or geographical barriers with any neighbouring infected country or zone, these measures may include a protection zone.

A protection zone may be established, in response to an increased risk of FMD, in accordance with Article 4.4.6. The Veterinary Authority should submit as soon as possible to WOAH, in addition to the requirements of Article 4.4.6. in support of the application, documented evidence that, in addition to the requirements of Article 4.4.6.:

- 1) the susceptible animal populations within the protection zone are clearly identified as belonging to the protection zone:
- 2) <u>strict movement control of susceptible animals and their products is in place in line with the relevant provisions of this chapter;</u>
- 3) <u>enhanced surveillance in accordance with Articles 8.8.40. to 8.8.42. is in place in the protection zone and in the rest</u> of the country or zone;
- <u>4)</u> <u>intensified biosecurity in the rest of the country protection zone is in place;</u>
- 5) <u>awareness campaigns aimed at the general public, breeders, traders, veterinarians and other relevant stakeholders</u> <u>are implemented;</u>
- 6) <u>a biosecurity plan including the implementation of emergency vaccination is in place, in particular when the protection zone is established in a country or zone free from FMD where vaccination is not practised.</u>

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 whileand 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, Schould the Member Country wish to maintain vaccination in the protection zone, Article 8.8.3bis applies.

In the event of an outbreak within a previously free protection zone, the free status of the protection zone is suspended and the status of the protection zone can be recovered following Article 8.8.7., while the free status of the rest of the country or zone is not affected. For the establishment of Alternatively, if the Veterinary Authority establishes a containment zone after an outbreak in the protection zone, an application in accordance with Articles 4.4.7. and 8.8.6 should be submitted as soon as possible. In particular, when applying for a containment zone, it should be stated whether the boundaries would be the same as the boundaries of the protection zone or within the boundaries of the protection zone.

A protection zone, in which the free status has remained unchanged, should be limited to less than 24 months from the date of its approval by WOAH. The Member Country should either apply for the removal of the protection zone or official recognition of the protection zone as a separate zone within 24 months from the date of its approval by WOAH.

Article 8.8.6.

Establishment of a containment zone within a FMD free country or zone previously free from FMD

In the event of limited outbreaks within a FMD free country or zone previously free from FMD where vaccination is either practised or not, including within a protection zone, with or without vaccination, a singlecontainment zone, which includes all epidemiologically linked outbreaks, may be established, in accordance with Article 4.4.7., for the purpose of minimising to minimise the impact on the entire rest of the country or zone in accordance with Article 4.4.7.

For this to be achieved and for the Member Country to take full advantage of this process, the Veterinary Authority should submit as soon as possible to WOAH, in addition to the requirements of Article 4.4.7. in support of the application, documented evidence that:

- on suspicion, a strict standstill has been imposed on the suspected establishments and in the country or zone animal movement control has been imposed and effective controls on the movement of animals and other commodities mentioned in this chapter are in place in the country or zone;
- on confirmation, an additional-the standstill and movement controls described in point 1 have been reinforced of susceptible animals has been imposed in the entire containment zone and the movement controls described in point 1 have been reinforced;
- 3) the definitive boundaries of the containment zone have been established after an epidemiological investigation (trace-back, trace-forward) has demonstrated that the outbreaks are epidemiologically related and limited in number and geographic distribution;
- <u>34</u>) <u>epidemiological</u> investigations into the likely source of the *outbreaks* have been carried out;
- 5 a stamping-out policy, with or without the use of emergency vaccination, has been applied;
- 6) no new cases have been found in the containment zone within a minimum of two incubation periods as defined in Article 8.8.1. after the application of a stamping out policy to the last detected case;
- 7) the susceptible domestic and captive wild animal populations within the containment zone are clearly identified as belonging to the containment zone;
- <u>48</u>) 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;
- <u>5</u>9) measures that prevent the spread of FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place.

The free status of the areas outside the containment zone is suspended while the containment zone is being established. <u>The free status of the areas outside the containment zone is suspended while the containment zone is being established.</u> The free status of <u>the these</u> areas <u>outside the containment zone</u> may be reinstated irrespective of the provisions of Article 8.8.7., once the containment zone has been approved by WOAH as complying with points 1 to 59 above.

Commodities from susceptible animals for international trade should be identified as to their origin, either from inside or outside the containment zone.

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

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

The recovery of the FMD free status of the *containment zone* should be achieved within <u>1218-24</u> months of its approval and follow the provisions of Article 8.8.7.

Article 8.8.7.

Recovery of free status (see Figures 1 and 2)

- 1) When a <u>infection with FMDV</u> case occurs in a FMD free country or zone <u>previously free from FMD</u> where vaccination is not practised, one of the following waiting periods is required to regain this free status:
 - a) three months after the disposal of the last animal killed where a *stamping-out policy*, without emergency *vaccination*, and *surveillance* are applied in accordance with Articles 8.8.40. to 8.8.42.; or
 - b) three months after the disposal of the last animal killed or the *slaughter* of all vaccinated animals, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied; or
 - c) six months after the disposal of the last animal killed or the last vaccination, whichever occurred last, where a stamping-out policy, emergency vaccination not followed by the slaughtering of all vaccinated animals, and surveillance in accordance with Articles 8.8.40. to 8.8.42. are applied. However, this requires a serological survey based on the detection of antibodies to non-structural proteins <u>NSP</u> of FMDV to demonstrate no evidence of infection transmission of FMDV in the remaining vaccinated population. This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of infection in the non-vaccinated population, and absence of transmission in the emergency vaccinated population based on the provisions of point 7 of Article 8.8.40. effectiveness of vaccination is demonstrated by a serological survey and serological surveillance for antibodies to nonstructural proteins is carried out in all vaccinated herds by sampling all vaccinated ruminants and their unvaccinated offspring, and a representative number of FMD susceptible animals of other species.

The country or *zone* will regain the <u>its free</u> status of FMD free country or *zone* where vaccination is not practised only after the submitted evidence, based on the provisions of Article Chapter 1.116.6., has been accepted by WOAH.

The time periods in points 1 a) to 1 c) are not affected if official emergency *vaccination* of zoological collections has been carried out following the relevant provisions of Article 8.8.2.

Where a stamping-out policy is not practised, the above waiting periods do not apply, and Article 8.8.2. applies.

2) When a FMD case of infection with FMDV occurs in a FMD free country or zone previously free from FMD where vaccination is not practised, the following waiting period is required to gain the status of FMD free country or zone free from FMD where vaccination is practised: six months after the disposal of the last animal killed where a stamping-out policy has been applied and a continued vaccination policy has been adopted, provided that surveillance is applied in accordance with Articles 8.8.40. to 8.8.42., and a serological survey based on the detection of antibodies to nonstructural proteins NSP of FMDV demonstrates no evidence of FMDV transmission of FMDV.

The country or *zone* can gain the status of FMD free country or *zone* <u>from FMD</u> where *vaccination* is practised only after the submitted evidence, based on the provisions of <u>Article Chapter</u> 1.<u>11</u>6.6. has been accepted by WOAH.

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

- 3) When a case of <u>infection with FMDV or transmission of FMDV</u> occurs in a FMD free country or zone <u>previously free</u> from FMD where vaccination is practised, one of the following waiting periods is required to regain this free status:
 - a) six months after the disposal of the last animal killed where a stamping-out policy, with emergency vaccination, and surveillance in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological surveillance based on the detection of antibodies to nonstructural proteins <u>NSP</u> of FMDV demonstrates no evidence of virus transmission <u>of FMDV</u>. This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of infection in the non-vaccinated population and absence of transmission of FMDV in the vaccinated population based on the provisions of points 7 and 8 of Articles 8.8.40. as appropriate; or
 - b) 12 months after the detection of the last case where a stamping-out policy is not applied, but where emergency vaccination and surveillance in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological surveillance based on the detection of antibodies to nonstructural proteins <u>NSP</u> of FMDV demonstrates no evidence of virus transmission of FMDV.

The country or zone will regain its free status only after the submitted evidence, based on the provisions of Article 1.6.6 Chapter 1.11., has been accepted by WOAH.

Whenre emergency vaccination is not applied, the above waiting periods do not apply, and Article 8.8.3. applies.

The country or zone will regain the status of FMD free country or zone where vaccination is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

- When a FMD case of infection with FMDV occurs in a FMD free compartment free from FMD, Article 8.8.4. or Article 8.8.4bis. applies.
- 5) Member Countries applying for the recovery of status should do so only when the respective requirements for the recovery of status are met. When a *containment zone* has been established, the restrictions within the *containment zone* should be lifted in accordance with the requirements of this article only when the *disease* <u>FMD</u> 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<u>of status</u>, the provisions of Article 8.8.2., Article 8.8.3. or <u>Article 8.8.4. or Article 8.8.4. bis</u> apply.

Article 8.8.8.

Direct transfer within a country of FMD susceptible animals from an infected zone, including containment zone, for slaughter in a free zone (whether vaccination is practised or not)

In order not to jeopardise the status of a free *zone*, FMD susceptible animals should only leave the infected *zone* if transported directly to <u>for</u> 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;

- the animals should be <u>are</u> transported under the supervision of the Veterinary Authority in a vehicle, which was cleansed and disinfected before *loading*, directly from the establishment of origin to the slaughterhouse/abattoir without coming into contact with other susceptible animals;
- 5) such a the slaughterhouse/abattoir is not approved for the export of fresh meat during the time it is handling the meat of animals from the infected zone;
- 6) vehicles and the slaughterhouse/abattoir should be <u>are</u> subjected to thorough cleansing and disinfection immediately after use.

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

Article 8.8.9.

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

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

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

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

Article 8.8.9bis.

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

In order not to jeopardise the status of a free zone where vaccination is not practised, FMD vaccinated animals should only leave the free zone if transported directly for slaughter in the a nearest designated slaughterhouse/abattoir under the following conditions:

- 1) <u>no animal in the establishment of origin has shown clinical signs of FMD for at least 30 days prior to movement;</u>
- 2) the animals were kept in the country or zone of origin for at least three months prior to movement;
- 3) the animals are transported under the supervision of the Veterinary Authority in a vehicle, directly from the establishment of origin to the slaughterhouse/abattoir;

<u>4)</u> <u>if transiting an infected zone, the animals were not exposed to any source of FMDV during transportation to the place</u> <u>of shipment.</u>

Article 8.8.10.

Recommendations for importation <u>of susceptible animals</u> from FMD free countries, or zones <u>or compartments free from</u> <u>FMD</u> where vaccination is not practised or FMD free compartments <u>free from FMD</u>

For FMD susceptible animals

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

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept since birth or for at least the past three months in a FMD free country. or zone or compartment free from FMD where vaccination is not practised or a FMD free compartment free from FMD;
- 3) if transiting an infected *zone*, were not exposed to any source of FMDV during transportation to the *place* of *shipment*.
- 4) if previously vaccinated, comply with point 4 of Article 8.8.11.

Article 8.8.11.

Recommendations for importation <u>of domestic ruminants and pigs</u> from FMD free countries, or zones <u>or compartments</u> <u>free from FMD</u> where vaccination is practised

For domestic ruminants and pigs

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

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept since birth or for at least the past three months in a FMD free country, or zone or compartment free from <u>FMD</u> where vaccination is practised;
- <u>if not vaccinated</u> were subjected to <u>a virological and serological</u> test<u>s</u> for FMD with negative results <u>on samples</u> <u>collected not earlier than 14 days before the shipment;</u>
- <u>if vaccinated were subjected to virological and NSP serological tests for FMD with negative results on samples</u> <u>collected not earlier than 14 days before the shipment;</u>
- <u>5)</u> if transiting an infected *zone*, were not exposed to any source of FMDV during transportation to the *place* of *shipment*;
- 6) if transiting a free zone where vaccination is not practised, were not in contact with any FMD susceptible animal during transportation to the place of shipment.

Article 8.8.11bis.

Recommendations for the importation of vaccinated animals destined for slaughter from a free country, zone or compartment free from FMD where vaccination is practised

For vaccinated animals destined for slaughter

<u>Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate</u> <u>attesting that:</u>

- 1) <u>no animal in the establishment of origin has shown clinical signs of FMD for at least 30 days prior to shipment:</u>
- 2) <u>the animals were kept in the country, zone or compartment of origin since birth or for at least three months prior to shipment;</u>
- 3) the animals were transported under the supervision of the Veterinary Authority directly from the establishment of origin in sealed vehicles/vessels:
- <u>4)</u> <u>if transiting an infected zone, the animals were not exposed to any source of FMDV during transportation to the place</u> <u>of shipment.</u>

Article 8.8.12.

Recommendations for importation <u>of domestic ruminants and pigs</u> from FMD infected countries or zones <u>infected with</u> <u>FMDV</u>, where an official control programme exists

For domestic ruminants and pigs

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

- 1) the animals showed no clinical sign of FMD on the day of shipment;
- 2) pigs have not been fed swill not complying with Article 8.8.31bis.;
- $\underline{32}$) 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*;
- <u>43</u>) <u>the establishment of origin is covered by the official control programme and</u> FMD has not occurred within <u>it</u> the establishment of origin for the relevant period as defined in points 2<u>3</u> a) and 2<u>3</u> b) above;
- 54a) the animals were isolated for the 30 days prior to shipment:
 - <u>a)</u> in an establishment <u>or a quarantine station</u> for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic virological and serological tests for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period, and or
 - b) <u>if the animals were isolated in an establishment that is not a quarantine station, that</u> FMD did not occur within a 10-kilometre radius of the establishment during that period, and all animals in isolation were subjected to diagnostic virological and serological tests for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period, or the establishment is a quarantine station;
- <u>6</u>5) the animals were not exposed to any source of FMDV during their transportation from the establishment to the place of shipment.

Article 8.8.13.

Recommendations for importation from FMD free countries, or *zones* <u>free from FMD</u> where vaccination is not practised or FMD free compartments <u>free from FMD</u>

For fresh semen of domestic ruminants and pigs

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

1) the donor males:

- a) showed no clinical sign of FMD on the day of collection of the semen;
- b) were kept for at least three months prior to collection in a FMD free country, or zone <u>free from FMD</u> where vaccination is not practised or FMD free compartments <u>free from FMD</u>;
- c) were kept in an artificial insemination centre where none of the animals had a history of infection with FMDV;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.8.14.

Recommendations for importation <u>of fresh and frozen semen of domestic ruminants and pigs</u> from FMD free countries, or compartments free from FMD where vaccination is not practised or FMD free compartments free from FMD

For fresh and frozen semen of domestic ruminants and pigs

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

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least three months prior to collection in a FMD free country, or zone or compartment free from FMD where vaccination is not practised or FMD free compartments free from FMD;
 - c) were kept in an artificial insemination centre;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.56. and 4.67.

Article 8.8.15.

Recommendations for importation <u>of frozen semen of domestic ruminants and pigs</u> from FMD free countries or, zones <u>or compartments free from FMD</u> where vaccination is practised

For frozen semen of domestic ruminants and pigs

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

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least three months prior to collection in a FMD free country, or zone or compartment free from FMD where vaccination is practised;
 - c) either
 - i) have been vaccinated at least twice, with the last vaccination not less <u>more</u> than one <u>six</u> months and not more than six months prior to collection, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;

or

ii) <u>have not been vaccinated and</u> were subjected, not less than 21 days <u>and not more than 60 days</u> after collection of the semen, to tests for antibodies against FMDV, with negative results;

2) the semen:

- a) was collected, processed and stored in accordance with Chapters 4.56. and 4.67.;
- b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor animals <u>males</u> were kept showed any <u>clinical</u> sign of FMD.

Article 8.8.16.

Recommendations for importation of <u>frozen semen of domestic ruminants and pigs</u> from FMD infected countries or zones <u>infected with FMDV</u>

For frozen semen of domestic ruminants and pigs

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

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept in an artificial insemination centre where to which no animal had been added in the 30 days before collection, and within a 10-kilometre radius of which, that FMD has not occurred within a 10 kilometre radius of the artificial insemination centre for in the 30 days before and after collection;
 - c) either
 - i) have been vaccinated at least twice, with the last vaccination not less <u>more</u> than one <u>six</u> months and not more than six months prior to collection, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;
 - or
 - ii) <u>have not been vaccinated and</u> were subjected, not less than 21 days <u>and not more than 60 days</u> after collection of the semen, to tests for antibodies against FMDV, with negative results;
- 2) the semen:
 - a) was collected, processed and stored in accordance with Chapters 4.56. and 4.67.;
 - b) was subjected, with negative results, to a test for evidence of FMDV if the donor male has been vaccinated within the 12 months prior to collection;
 - c) was stored in the country of origin for a period of at least one month following collection, and that during this period no animal on the *establishment* where the donor males were kept showed any sign of FMD.

Article 8.8.17.

Recommendations for the importation of in vivo derived embryos of bovines cattle

Irrespective of the FMD status of the exporting country, zone or compartment, Veterinary Authorities should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of <u>bovines</u> cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in accordance with <u>the relevant provisions of</u> Chapters 4.7. and 4.9., as relevant.

Article 8.8.18.

Recommendations for importation <u>of *in vitro* produced bovine embryos</u> from FMD free countries— $or_{\underline{i}}$ zones <u>or</u> <u>compartments free from FMD</u> where vaccination is not practised or FMD free compartments <u>free from FMD</u>

For in vitro produced embryos of bovines cattle

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

- 1) the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the oocytes;
 - b) were kept for at least three months prior to collection in a FMD free country, or zone or compartment free from FMD where vaccination is not practised or FMD free compartments free from FMD;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in accordance with Chapters 4.8.<u>and</u> 4.9., <u>and 4.10.</u> as relevant.

Article 8.8.19.

Recommendations for importation <u>for *in vitro* produced bovine embryos</u> from FMD free countries-or, zones <u>or</u> <u>compartments free from FMD</u> where vaccination is practised

For in vitro produced embryos of bovines cattle

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

- 1) the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the oocytes;
 - b) were kept for at least three months prior to collection in a FMD free country, or zone or compartment free from <u>FMD</u> where vaccination is practised;
 - c) either
 - have been vaccinated at least twice, with the last vaccination not less more than one six months and not more than six months prior to collection, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;
 - or
 - ii) were subjected, not less than 21 days <u>and not more than 60 days</u> after collection, to tests for antibodies against FMDV, with negative results;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in accordance with Chapters 4.8.<u>_and</u> 4.9., <u>and 4.10.</u> as relevant.

Article 8.8.20.

Recommendations for importation <u>of fresh meat or meat products of susceptible animals</u> from FMD free countries-or<u>,</u> zones <u>or compartments free from FMD</u> where vaccination is not practised or FMD free compartments <u>free from FMD</u>

For fresh meat or meat products of FMD susceptible animals

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

- have been kept in a FMD free country or <u>arcompartment</u> free from FMD where vaccination is not practised or FMD free compartment free from FMD, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 8.8.21.

Recommendations for importation <u>of fresh meat and meat products of ruminants and pigs from</u> FMD free countries or, zones <u>or compartments free from FMD</u> where vaccination is practised

For fresh meat and meat products of ruminants and pigs

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

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

Article 8.8.22.

Recommendations for importation <u>of fresh meat of bovines and water buffaloes (Bubalus bubalis)(excluding feet, head</u> <u>and viscera)</u> from FMD infected countries or zones <u>infected with FMDV</u>, where an official control programme exists

For fresh meat of bovines cattle and water buffaloes (Bubalus bubalis) (excluding feet, head and viscera)

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

- 1) comes from animals which:
 - have remained, for at least three months prior to slaughter, in a zone of the exporting country where <u>bovines</u> <u>cattlecattle_bovines</u> 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:
 - <u>a quarantine station; or in</u>
 - an establishment, within a ten 10-kilometre radius of which and that FMD has not occurred within a 10 kilometre radius of the establishment during that period, or the establishment is a quarantine station;

- have been transported, in a vehicle which was cleansed and disinfected before the <u>bovines cattlecattle bovines</u> 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 <u>FMD susceptible</u> animals which do not fulfil the required conditions for export;
- e) have been slaughtered in an approved slaughterhouse/abattoir:
 - i) which is officially designated for export;
 - ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;
- f) were subjected to ante- and post-mortem inspections in accordance with Chapter 6.23., with favourable results have been subjected, with favourable results, to ante-mortem inspection within 24 hours of slaughter and to post-mortem inspections within 24 hours before and after slaughter with no evidence of FMD;
- 2) comes from deboned carcasses:
 - a) from which the major lymphatic nodes have been removed;
 - b) which, prior to deboning, have been submitted to maturation at a temperature greater than + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was less than 6.0 when tested in the middle of both the longissimus dorsi muscle.

Article 8.8.22bis.

<u>Recommendations for importation of fresh meat of domestic pigs from countries or zones infected with FMDV, where</u> <u>an official control programme exists</u>

For fresh meat of domestic pigs

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

- 1) the meat comes from animals complying with points 1 to 6 of Article 8.8.12.;
- 2) the animals were transported, in a vehicle which was cleaned and disinfected before the pigs were loaded, directly from the establishment of origin or quarantine station to the approved slaughterhouse/abattoir without coming into contact with other FMD susceptible animals that do not fulfil the conditions required for export, either during transport or at the slaughterhouse/abattoir;
- 3) the animals were slaughtered in an approved slaughterhouse/abattoir:
 - a) which is officially designated for export;
 - b) in which no FMD has been detected during the period between the last disinfection carried out before slaughter and the shipment for export has been dispatched;
- <u>4)</u> <u>the animals were subjected to ante- and post-mortem inspections in accordance with Chapter 6.-23., with favourable results:</u>
- 5) <u>the carcasses were not released earlier than 24 hours after slaughter and not before Veterinary Authorities have</u> <u>confirmed that FMD has not occurred in the establishment of origin.</u>

Article 8.8.22ter.

<u>Recommendations for importation of fresh meat of domestic sheep and goats small ruminants (excluding feet, head and viscera) from FMD infected countries or zones where an official control programme exists</u>

<u>Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the meat</u> <u>comes from:</u>

- animals that were transported, in a vehicle which was cleaned and disinfected before the domestic sheep and goats were loaded, directly from the establishment of origin or quarantine station to the approved slaughterhouse/abattoir without coming into contact with other FMD susceptible animals that do not fulfil the conditions required for export, either during transport or at the slaughterhouse/abattoir;
- 2) animals that were slaughtered in an approved slaughterhouse/abattoir:
 - a) which is officially designated for export;
 - b) in which no FMD has been detected during the period between the last disinfection carried out before slaughter and the shipment for export has been dispatched;
- 3) <u>animals that were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., with favourable</u> results; and

EITHER,

4) <u>animals that comply with Article 8.8.12.; and the carcasses were not released earlier than 24 hours after slaughter and</u> not before Veterinary Authorities have confirmed that FMD has not occurred in the establishment of origin:

- 5) <u>animals that:</u>
 - <u>a)</u> <u>have remained, for at least three months prior to slaughter, in a zone of the exporting country where bovines</u> and water buffaloes are regularly vaccinated against FMD and where an official control programme is in <u>operation</u>:
 - b) were kept for the past 30 days in:
 - <u>a quarantine station; or</u>
 - an establishment, within a ten-kilometre radius of which FMD has not occurred during that period, and no susceptible animals were introduced into the establishment during that period;
 - c) had their carcasses deboned:
 - i) from which the major lymphatic nodes have been removed;
 - ii) which, prior to deboning, have been submitted to maturation at a temperature greater than + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was less than 6.0 when tested in the middle of both the longissimus dorsi muscle.

Article 8.8.23.

Recommendations for importation of <u>meat products of susceptible animals</u> from FMD infected countries or zones infected with FMDV

For meat products of FMD susceptible animals

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

- the entire consignment of meat products come from animals which have been slaughtered in an approved slaughterhouse/abattoir and have been subjected to ante- and post-mortem inspections for FMD with favourable results;
- 2) the *meat products* have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.31.;
- 3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMDV.

Article 8.8.24.

Recommendations for importation <u>of</u> milk and milkproducts of animal origin (other than those covered by other articles listed in Article 8.8.1bis.)-intended for human consumption and for products of animal origin (from susceptible animals) intended for use in animal feeding or for agricultural or industrial use free from FMD where whether vaccination either is <u>practised</u> or is not practised or FMD free compartments <u>free from</u> <u>FMD</u>

For milk and milk products (other than those defined in Article 8.8.1bis.) intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a FMD free country, zone or compartment free from FMD, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.

Article 8.8.25.

Recommendations for importation <u>of milk and milk products (other than those listed in Article 8.8.1bis.)</u> from FMD infected countries or zones infected with FMDV, where an official control programme exists

For milk and milk products (other than those defined in Article 8.8.1bis.)

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

- 1) these products:
 - a) originate from establishments which <u>at the time of milk collection</u> were not infected or suspected of being infected with FMDat the time of milk collection;
 - b) have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.35. and in Article 8.8.36.;
- 2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

Article 8.8.26.

Recommendations for importation from FMD infected countries or zones infected with FMDY

For blood meal and meat meals from FMD susceptible animals

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

the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes. 2) <u>the necessary precautions were taken after processing to avoid contact of the products with any potential source of</u> <u>FMDV.</u>

Article 8.8.27.

Recommendations for importation <u>of wool, hair, bristles, raw hides and skins from domestic susceptible animals</u> from FMD infected countries <u>or zones infected with FMDV</u>

For wool, hair, bristles, raw hides and skins from FMD susceptible animals

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

- 1) these products have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Articles 8.8.32., 8.8.33. and 8.8.34.;
- the necessary precautions were taken after collection <u>or and</u> processing to avoid contact of the products with any potential source of FMDV.

Veterinary Authorities should authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather such as wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 8.8.28.

Recommendations for importation of straw and forage from FMD infected countries or zones infected with FMDV

For straw and forage

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

- 1) are free of grossly identified contamination with material of animal origin;
- 2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:
 - a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ten <u>10</u> 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 <u>of skins and trophies derived from susceptible</u> wildlife animals (other than those <u>listed in Article 8.8.1bis.)</u>from FMD free countriesor,zones <u>or *compartments* free from FMD,</u> where <u>whether</u> vaccination either is <u>practised</u> or is not practised

For skins and trophics derived from FMD susceptible wildlife

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products are derived from animals that have been killed in such a country or zone <u>free from FMD</u> or which have been imported from a country, zone or compartment free from FMD.

Article 8.8.30.

Recommendations for importation <u>of skins and trophies derived from susceptible</u> wildlife-animals (other than those <u>listed in Article 8.8.1bis.)</u>from FMD infected countries or zones <u>infected with FMDV</u>

For skins and trophies derived from FMD susceptible wildlife

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

Article 8.8.31.

Procedures for the inactivation of FMDV in meat and meat products

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

1. Canning

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

2. Thorough cooking

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

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

3. Drying after salting

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

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

Article 8.8.31bis.

Procedures for the inactivation of FMDV in swill

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

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

Article 8.8.32.

Procedures for the inactivation of FMDV in wool and hair

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

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

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

Article 8.8.33.

Procedures for the inactivation of FMDV in bristles

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

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

Article 8.8.34.

Procedures for the inactivation of FMDV in raw hides and skins

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

Article 8.8.35.

Procedures for the inactivation of FMDV in milk <u>and milk products</u> and cream for human consumption

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

- 1) a process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]); or
- 21) if the *milk* has a pH less than 7.0, a process applying a minimum temperature of 72°C for at least 15 seconds (high temperature short time pasteurisation [HTST]);; or
- 32) if the milk has a pH of 7.0 or greater, the HTST process applied twice: or
- 3) any equivalent treatment that has been demonstrated to inactivate FMDV-

Article 8.8.36.

Procedures for the inactivation of FMDV in milk for animal consumption

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

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

Article 8.8.37.

Procedures for the inactivation of FMDV in skins and trophies from <u>susceptible</u> wildlife <u>animals</u> susceptible to the disease

For the inactivation of FMDV present in skins and trophies from <u>susceptible wildlife</u> <u>animals</u> <u>wild animals</u> <u>susceptible to</u> FMD, one of the following procedures should be used prior to complete taxidermal treatment

- 1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed; or
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher); or
- 3) soaking, with agitation, in a 4% (weight/volume) solution of sodium carbonate (Na₂CO₃) maintained at pH 11.5 or greater for at least 48 hours; or
- 4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at pH less than 3.0 for at least 48 hours; wetting and dressing agents may be added; or
- 5) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na₂CO₃).

Article 8.8.38.

Procedures for the inactivation of FMDV in casings of ruminants and pigs

For the inactivation of FMDV present in casings of ruminants and pigs, the following procedures should be used: treating for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl, $a_w < 0.80$), or with phosphate supplemented salt containing 86.5% NaCl, 10.7% Na₂HPO₄ and 2.8% Na₃PO₄ (weight/weight/weight), either dry or as a saturated brine ($a_w < 0.80$), and kept at a temperature of greater than 12°C during this entire period.

Article 8.8.39.

WOAH endorsed official control programme for FMD

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

<u>A</u> Member <u>Countries</u> <u>Country</u> may, on a voluntary basis, apply for endorsement of <u>their its</u> official control programme for FMD in accordance with Chapter 1.6., when they have it has implemented measures in accordance with this article.

For a Member Country's official control programme for FMD to be endorsed by WOAH, the Member Country <u>should provide</u> <u>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:</u>

- 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) <u>surveillance and diagnostic capabilities:</u>
 - a) FMD surveillance in place, in accordance with Chapter 1.4. and Articles 8.8.40. to 8.8.42.;
 - b) <u>diagnostic capability and procedures, including regular submission of samples to a laboratory that performs</u> <u>diagnostic testing and further characterisation of strains;</u>

- 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;
 - <u>vi)</u> <u>technical specification of the vaccines used including matching with the circulating FMDV strains and</u> <u>description of the vaccine licensing procedures in place;</u>
 - <u>vii)</u> 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;
- <u>4)</u> <u>the measures implemented to prevent the introduction of the pathogenic agent and to ensure the rapid detection of all FMD outbreaks;</u>
- 5) an emergency preparedness plan and an emergency response plan to be implemented in case of FMD outbreaks;
- 6) work plan and timelines of the official control programme;
- 7) performance indicators for assessing the effectiveness of the control measures to be implemented;
- 8) monitoring, evaluation and review of the official control programme to demonstrate the effectiveness of the strategies.
- 1) have a record of regular and prompt animal disease reporting in accordance with the requirements in Chapter 1.1.;
- submit documented evidence of the capacity of the Veterinary Services to control FMD; one way of providing this evidence is through the OIE PVS Pathway;
- 3) submit a detailed plan of the programme to control and eventually eradicate FMD in the country or zone including:
 - a) the timeline;
 - b) the performance indicators for assessing the efficacy of the control measures to be implemented;
 - e) documentation indicating that the official control programme for FMD is applicable to the entire country;
- submit a dossier on the epidemiology of FMD in the country describing the following:
 - a) the general epidemiology in the country highlighting the current knowledge and gaps and the progress that has been made in controlling FMD;

- the measures implemented to prevent introduction of infection, the rapid detection of, and response to, all FMD outbreaks in order to reduce the incidence of FMD outbreaks and to eliminate FMDV transmission of FMDV in at least one zone in the country;
- c) the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;
- 5) submit evidence that FMD surveillance is in place:
 - a) <u>FMD surveillance is in place</u>, taking into account provisions in <u>accordance with</u> Chapter 1.4. and the provisions on surveillance of this chapter;
 - b) <u>it has</u> have diagnostic capability and procedures, including regular submission of samples to a laboratory that carries out diagnosis and further characterisation of strains;
- 6) where vaccination is practised as a part of the official control programme for FMD, provide:
 - a) evidence (such as copies of legislation) that vaccination of selected populations is compulsory;
 - b) detailed information on vaccination campaigns, in particular on:
 - i) target populations for vaccination;
 - ii) monitoring of vaccination coverage, including serological monitoring of population immunity;
 - iii) technical specification of the vaccines used, including matching with the circulating FMDV strains, and description of the licensing procedures in place;
 - iv) the proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the Terrestrial Manual;
- 7) provide an emergency preparedness and response plan to be implemented in case of outbreaks.

The Member Country's official control programme for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence, based on the provisions of Article 1.6.11., has been accepted by the OIE.

<u>The country will be included in the list of countries having a WOAH endorsed official control programme for FMD in accordance with Chapter 1.6.</u>

Retention on the list requires an annual update on the progress of the official control programme and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

The OIE may withdraw the endorsement of the official control programme if there is evidence of:

- non-compliance with the timelines or performance indicators of the programme; or
- significant problems with the performance of the Veterinary Services; or
- an increase in the incidence or an extension of the distribution of FMD that cannot be addressed by the programme.

Article 8.8.40.

General principles of surveillance

Articles 8.8.40. to 8.8.42. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Member Countries seeking establishment, maintenance or recovery of freedom from FMD at the country,

zone or compartment level or seeking endorsement by WOAH of their official control programme for FMD, in accordance with Article 8.8.39. Surveillance aimed at identifying disease and FMDV infection with, or transmission of, FMDV should cover domestic and, where appropriate, wildlife species as indicated in point 2 of Article 8.8.1.

1. Early detection

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

2. Demonstration of freedom

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

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

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

A Member Country wishing to substantiate FMD freedom where *vaccination* is not practised should demonstrate no evidence of *infection* with FMDV in <u>unvaccinated animals</u>. Previously or newly introduced vaccinated animals should be considered in the strategy and design of the *surveillance* programme.

A Member Country wishing to substantiate FMD freedom where *vaccination* is practised should demonstrate that FMDV has not been transmitted in any susceptible *populations*. Within vaccinated *populations*, serological surveys to demonstrate no evidence of FMDV transmission <u>of FMDV</u> should target animals that are less likely to show vaccine-derived antibodies to non structural proteins <u>NSP</u>, such as young animals vaccinated a limited number of times, or unvaccinated animals. In any unvaccinated *subpopulation*, *surveillance* should demonstrate no evidence of *infection* with FMDV.

Surveillance strategies employed for establishing and maintaining a *compartment* should identify the prevalence, distribution and characteristics of FMD outside the *compartment*.

3. WOAH endorsed official control programme

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

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

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

4. <u>Surveillance strategies</u>

The strategy employed to establish the prevalence of *infection* with FMDV or to substantiate freedom from FMDV *infection* with, or transmission <u>of</u>, 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., <u>bovines cattlecattle bovines</u> and pigs). The Member Country should justify the *surveillance* strategy chosen and the frequency of sampling as adequate to detect the presence of FMDV infection with, or transmission <u>of</u>, 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. <u>Selection of diagnostic</u> <u>tests and interpretation of results should take into account</u> The sensitivity and specificity of the tests used should be validated for the vaccination or infection history and production class of animals in the target population.

The surveillance design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following-up positives results to determine with a high level of confidence, whether or not they are indicative of *infection* or transmission. This should involve supplementary tests and follow-up investigation to collect diagnostic material from the original *epidemiological unit* and *herds* which may be epidemiologically linked to it.

Laboratory results should be examined in the context of the epidemiological situation. Corollary il nformation needed to complement the serological survey and assess the possibility of viral transmission includes but is not limited to:

- characterisation of the existing production systems;
- results of clinical surveillance of the suspects and their cohorts;
- description of number of, and protocol for, vaccinations performed in the area under assessment;
- biosecurity and history of the establishments with reactors;
- identification and traceability of animals and control of their movements;
- other parameters of regional significance in historic FMDV transmission of FMDV.
- 6. Demonstration of population immunity

Following routine vaccination, evidence should be provided to demonstrate the effectiveness of the vaccination programme such as adequate vaccination coverage and population immunity. This can <u>support the interpretation of help to reduce reliance on post-vaccination surveys for residual infection and transmission.</u>

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.

<u>7.</u> Additional measures for early recovery of free status free from FMD where without vaccination is not practised or early recovery of free status free from FMD where with vaccination is practised in the area(s) where emergency vaccination has been applied but not followed by the slaughtering of all vaccinated animals

In addition to the general conditions described in this chapter, a Member Country seeking either recovery of status of a country or zone previously free from FMD where vaccination is not practised, including a containment zone, or recovery of status of a country or zone previously free from FMD where vaccination is practiced, earlier than the six months as specified respectively under point 1 c) of Article 8.8.7. or under point 3 a) of Article 8.8.7. should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved when answering the relevant questionnaire in Chapter 1.11. by demonstrating compliance with either a) or b) and c) below, in the area(s) where emergency vaccination has been applied. It is advisable that the Veterinary Authority countries should consider the different options for the recovery of a free status when control measures are first implemented at the onset of the outbreak in order to plan for the applicable requirements to be met.

- a) <u>The following serological surveys have been conducted in the area where emergency vaccination has been</u> <u>applied and have demonstrated the absence of infection in unvaccinated animals and the absence of</u> <u>transmission in emergency vaccinated animals</u>:
 - <u>for vaccinated ruminants, serological surveys using nonstructural protein NSP tests to detect antibodies</u> <u>in all vaccinated ruminants and their non-vaccinated offspring in all epidemiological units (census</u> <u>serosurveillance);</u>
 - ii) for vaccinated pigs and their non-vaccinated offspring, serological surveys using nonstructural protein NSP tests to detect antibodies in all vaccinated epidemiological units with maximum 5% within herd design prevalence (95% confidence level);
 - iii) for non-vaccinated susceptible species that do not show reliable clinical signs or husbandry systems that do not allow sufficient observation, serological surveys with maximum design prevalence of 1% at herd level and 5% within herds (95% confidence level).
- b) <u>The following surveillance components have been implemented in the area where emergency vaccination has</u> 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.
- <u>c)</u> <u>Vaccine efficacy and vaccination effectiveness of the emergency vaccination deployed have been</u> <u>demonstrated by documenting the following:</u>
 - i) Vaccine efficacy
 - <u>vaccine that provides high potency of at least 6PD50 or equivalent probability of protection which</u> <u>may be achieved by a vaccine with high potency of at least 6PD50 or equivalent and evidence of a</u> <u>good match between the vaccine strain and the field virus; or</u>
 - 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
 - <u>objective and strategy of the emergency vaccination deployed;</u>
 - <u>evidence of the timeliness of the emergency vaccination (start and completion dates);</u>
 - <u>evidence of vaccination delivery including preservation of vaccine (e.g., cold chain) and at least 95%</u> <u>vaccination coverage achieved in the targeted and eligible population;</u>
 - evidence of high population immunity at herd and individual level through serological surveillance.
- 8. Additional measures for early recovery of free status free from FMD where with vaccination is practised in the area outside of the area(s) where emergency vaccination has been applied.

In addition to the general conditions described in this chapter, a Member Country seeking recovery of status of a country or zone previously free from FMD where vaccination is practised in the area outside of the area(s) where emergency vaccination has been applied, earlier than six months as specified under point 3 a) of Article 8.8.7. should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved either by meeting the requirements listed in a) below or by demonstrating compliance with the requirements listed in b) and c) below, when answering the questionnaire in Article 1.11.2. or Article 1.11.4.

With regard to the surveillance requirements listed in b), it should be noted that clinical signs may not be apparent in the routinely vaccinated population. The expression of clinical signs would depend on the relationship between the virus strain used in the routine vaccination to the virus that caused the outbreak. For example, following an incursion of a new serotype it would be expected that the routinely vaccinated animals would show clinical signs if infected. In contrast, following an incursion of a serotype or strain covered by the vaccine it would be expected that most of the routinely vaccinated animals would be protected and therefore less likely to be infected and to show clinical signs if infected. Other factors such as vaccination coverage and timing of vaccination could influence the likelihood of infection and expression of clinical signs.

It is advisable that countries should the Veterinary Authority consider the different options for the recovery of a free status when control measures are first implemented at the onset of the *outbreak* in order to plan for the applicable requirements to be met.

a) Establishment of a containment zone

<u>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).</u>

- b) <u>The following surveillance components have been implemented in the area outside of the area(s) where</u> <u>emergency vaccination has been applied and have demonstrated the absence of infection in unvaccinated</u> <u>animals and the absence of transmission in vaccinated animals</u>:
 - 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;
 - <u>v)</u> <u>virological surveillance to investigate the status of vaccinated herds may also be conducted to contribute</u> 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. <u>Clinical surveillance</u>

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 <u>Services</u> Authority should implement programmes to raise awareness among them.

Clinical *surveillance* requires the physical examination of susceptible *animals*. Although significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection may provide a high level of confidence of detection of disease if a sufficient number of clinically susceptible *animals* is examined at an appropriate frequency and investigations are recorded and quantified.

Clinical examination and diagnostic testing should be applied to clarify the status of suspected cases. Diagnostic testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive laboratory test results. Clinical *surveillance* may be insufficient in *wildlife* and domestic species that usually do not show clinical signs or husbandry systems that do not permit sufficient observations. In such situations, serological *surveillance* should be used. <u>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 <u>also</u> be used to obtain information and diagnostic samples from *wildlife* species.</u>

2. Virological surveillance

Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is mostly dependent upon clinical *surveillance* to provide samples. FMDV isolates should be sent regularly to a WOAH Reference Laboratory.

Virological surveillance aims to:

- a) confirm clinically suspected cases;
- b) follow up positive serological results;
- c) characterise isolates for epidemiological studies and vaccine matching;
- d) monitor populations at risk for the presence and transmission of the virus.

3. <u>Serological surveillance</u>

Serological *surveillance* aims to detect antibodies resulting from *infection* or *vaccination* using nonstructural protein <u>NSP</u>tests or structural protein <u>SP</u> tests.

Serological surveillance may be used to:

- a) estimate the prevalence or substantiate freedom from FMDV infection with, or transmission of, FMDV;
- b) monitor population immunity.

Serum collected for other purposes can be used for FMD *surveillance*, provided the principles of survey design described in this chapter are met.

The results of random or targeted serological surveys are important in providing reliable evidence of the FMD situation in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

Article 8.8.42.

The use and interpretation of serological tests (see Figure 3)

The selection and interpretation of serological tests should be considered in the context of the epidemiological situation. Test protocols, reagents, performance characteristics and validation of all tests used should be known. Where combinations of tests are used, the overall test system performance characteristics should also be known.

Animals infected with FMDV produce antibodies to both the structural proteins <u>SP</u> and the nonstructural proteins <u>NSP</u> of the virus. Vaccinated animals produce antibodies mainly or entirely to the structural proteins <u>SP</u> of the virus depending upon vaccine purity. The structural protein <u>SP</u> tests are serotype specific and for optimal sensitivity one should select an antigen or virus closely related to the field strain expected. In unvaccinated populations, structural protein <u>SP</u> tests may be used to screen sera for evidence of FMDV infection with, or transmission <u>of</u>, FMDV or to detect the introduction of vaccinated populations, structural protein sensitivity and populations of the sensitivity one should select an antigen or virus closely related to the field strain expected.

to the vaccination. The SP tests are serotype specific. and fF or optimal sensitivity one should select an antigen or virus closely related to the field strain expected should be selected.

Nonstructural protein <u>NSP</u> tests may be used to screen sera for evidence of *infection* or transmission of all serotypes of FMDV regardless of the *vaccination* status of the *animals* provided the vaccines comply with the standards of the *Terrestrial Manual* with respect to purity. However, although *animals* vaccinated and subsequently infected with FMDV develop antibodies to nonstructural proteins <u>NSP</u>, the levels may be lower than those found in infected *animals* that have not been vaccinated. To ensure that all *animals* that had contact with FMDV have seroconverted, it is recommended that for each *vaccination* area samples for nonstructural proteins <u>NSP</u> antibody testing are taken 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 <u>bovines cattlecattle bovines</u> are usually found only up to six months of age but in some individuals and in some other species, maternal antibodies can be detected for longer periods);
- non-specific reactivity of the serum in the tests used.

1. Procedure in case of positive test results

The proportion and strength of seropositive reactors should be taken into account when deciding if they are *laboratory* confirmed reactors or further investigation and testing are required.

When false positive results are suspected, seropositive reactors should be retested in the *laboratory* using repeat and confirmatory tests. Tests used for confirmation should be of high diagnostic specificity to minimise false positive test results. The diagnostic sensitivity of the confirmatory test should approach that of the screening test.

All *herds* with at least one *laboratory* confirmed reactor <u>that has been confirmed in a *laboratory*</u> should be investigated. The investigation should examine all evidence, which may include the results of virological tests and of any further serological tests that might <u>used to</u> confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to FMDV transmission <u>of FMDV</u>, 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 <u>factors or</u> events, including the demographics of the *population* sampled, vaccinal exposure or the presence of *infection* or transmission. As clustering may signal *infection* or transmission, the investigation of all instances should be incorporated in the survey design.

Paired serology can be used to identify **FMDV** transmission <u>of FMDV</u> 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 <u>be identified as such and</u> remain in the *establishment* pending test results, should be clearly identified, accessible and should not be vaccinated during the investigations, so that they can be retested after an appropriate period of time. Following clinical examination, a second sample should be taken, after an appropriate time has elapsed, from the *animals* tested in the initial survey with emphasis on *animals* in direct contact with the reactors. If the *animals* are not individually identified, a new serological survey should be carried out in the establishments after an appropriate time, repeating the application of the primary survey design. If FMDV is not circulating, the magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample.

In some circumstances, unvaccinated sentinel *animals* may also be used. These can be young *animals* from unvaccinated dams or *animals* in which maternally conferred immunity has lapsed and preferably of the same species as in the positive sampling units. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the *animals* of the

epidemiological unit under investigation for at least two incubation periods<u>and lf there is no transmission of FMDV</u>, <u>they should will</u> remain serologically negative if FMDV is not circulating.

2. Follow-up of field and laboratory findings

If transmission is demonstrated, an outbreak is declared.

<u>It is difficult to determine</u> The significance of small numbers of seropositive *animals* in the absence of current FMDV transmission is difficult to determine. Such findings may be an indication of past *infection* followed by recovery or by the development of a carrier state, in ruminants, or due to non-specific serological reactions. Antibodies to nonstructural proteins <u>NSP</u> may be induced by repeated *vaccination* with vaccines that do not comply with the requirements for purity. However, the use of such vaccines is not permissible in countries or *zones* applying for an official status. In the absence of evidence of FMDV *infection* <u>with</u>, and transmission <u>of</u>, <u>FMDV</u>, such findings do not warrant the declaration of a new *outbreak* and the follow-up investigations may be considered complete.

However, if the number of seropositive *animals* is greater than the number of false positive results expected from the specificity of the diagnostic tests used, susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animals* should be investigated further.

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

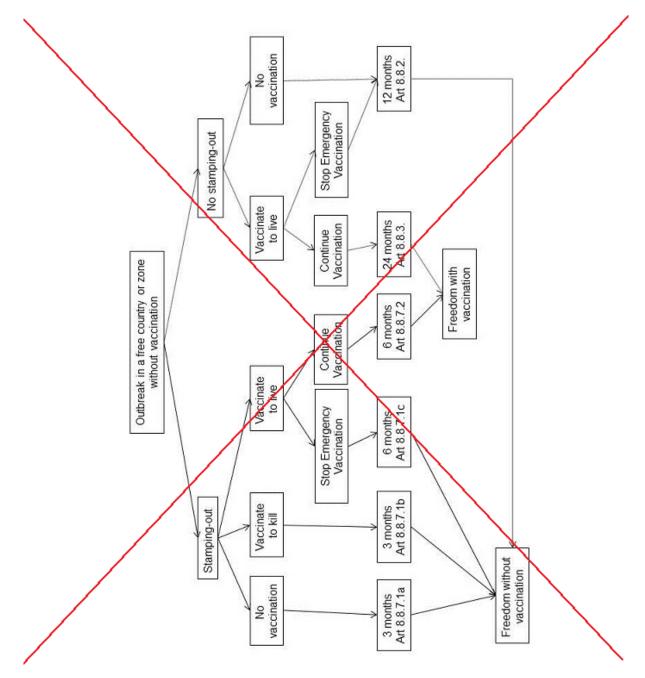
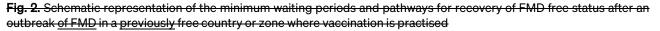
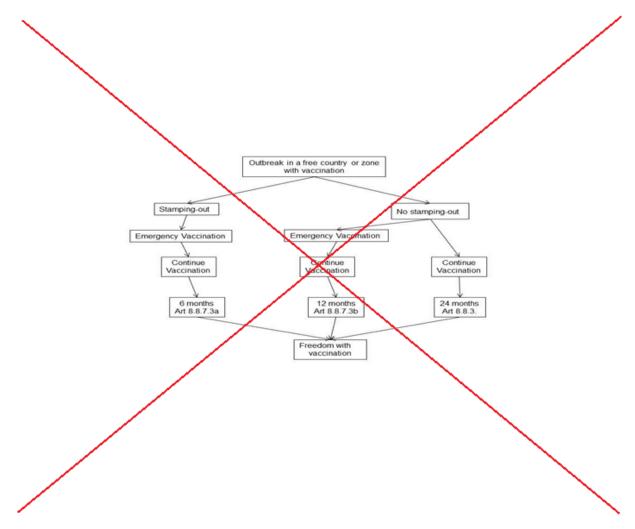


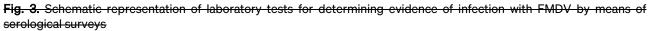
Fig. 1. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak <u>of FMD</u> in a <u>previously</u> free country or zone where vaccination is not practised

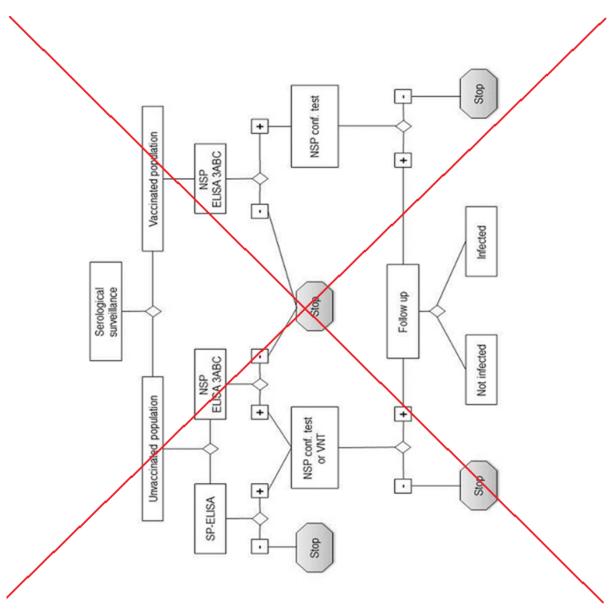
Waiting periods are minima depending upon outcome of *surveillance* specified in respective articles. If there are multiple waiting periods because of different control measures, the longest applies.





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





Annex 9

CHAPTER 8.14.

INFECTION WITH RABIES VIRUS

[...]

<u>Article 8.14.6bis.</u>

Recommendations for importation of dogs from countries or zones infected with rabies virus

<u>Veterinary Authorities should require the presentation of an international veterinary certificate complying with the model</u> of Chapter 5.11. attesting that the dogs:

1) <u>showed no clinical signs of rabies the day prior to or on the day of shipment:</u>

- 2) were permanently identified and their identification numbercode stated in the certificate;
- 3) and either:
 - a) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the Terrestrial Manual and were subjected, not less than 30 days and not more than 12 months prior to shipment, to an antibody titration test as prescribed in the Terrestrial Manual with a positive result of at least 0.5 IU/ml;
 - or
 - b) were kept in a quarantine station for six months prior to shipment.

Article 8.14.7.

Recommendations for importation of dogs, cats and ferrets from countries or zones infected with rabies virus

Veterinary Authorities should require the presentation of an international veterinary certificate complying with the model of Chapter 5.11. attesting that the animals:

- 1) showed no clinical signs of rabies the day prior to or on the day of shipment;
- 2) were permanently identified and their identification <u>numbercode</u> stated in the certificate;
- 3) and either:
 - a) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the *Terrestrial Manual* and were subjected not less than 3 months and not more than 12 months prior to shipment to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5 IU/ml;

or

b) were kept in a quarantine station for six months prior to shipment.

Article 8.14.11bis.

Recommendations for dog-mediated rabies vaccination programmes

When developing and implementing vaccination programmes for dog-mediated rabies, in addition to provisions in Chapter 4.18., Member Countries should:

- <u>1.</u> <u>Prepare for the vaccination programme:</u>
 - a) <u>consult with all relevant stakeholders, including target communities to define the most appropriate time to</u> increase community participation and reduce the time required to complete vaccination;
 - b) <u>ensure safety of vaccination teams including training in humane dog capture and handling, and a strategy to</u> <u>manage exposure to suspect rabid animals.</u>
- 2. <u>Choose a vaccine and the vaccination strategy:</u>
 - <u>a)</u> <u>Priority should be given to vaccinating free-roaming dogs, including puppies, to <u>immediately quickly interrupt</u> <u>the rabies virus transmission cycle.</u></u>
 - b) <u>Vaccination campaigns should be conducted recurrently (usually annually). More regular-frequent vaccination</u> campaigns may be considered in especially high-risk areas, or to quickly interrupt the cycle of virus transmission.
 - <u>c)</u> <u>The vaccination strategy should take into account simultaneous dog population management programmes as</u> <u>described in Chapter 7.7.</u>
- 3. Monitor the vaccination programme:
 - <u>a)</u> <u>To monitor the vaccination coverage, vaccinated dogs should be identified and registered in a database an</u> <u>animal identification system.</u>
 - b) <u>Vaccination certificates which state identification of the dog</u>, date of vaccination and product should be provided to dog owners as proof of vaccination.
 - <u>c)</u> <u>Vaccination coverage should be monitored at the smallest administrative level possible.</u>

Annex 10

CHAPTER 8.15.

INFECTION WITH RIFT VALLEY FEVER VIRUS

Article 8.15.1.

General provisions

- 1) The aim of this chapter is to mitigate the animal and public health risks posed by Rift Valley fever (RVF) and to prevent its international spread.
- 2) For the purposes of this chapter:
 - a) <u>'epizooticepidemic area' means a part of a country or zone in which an epizooticepidemic of RVF is occurrings</u>, and which does not correspond to the definition of zone;
 - b) <u>'epizooticepidemic of RVF' means a sudden and unexpected change in the distribution or increase in incidence</u> of, or morbidity or mortality of RVF;
 - <u>c)</u> <u>'inter-epizooticepidemic period' means a period-with low levels of vector activity and low rates of RVF virus</u> (RVFV) transmission between two epidemics;
 - d) <u>'susceptible animals' means ruminants and dromedary camels.</u>
- <u>32</u>) Humans and many animal species are susceptible to infection can be affected by RVF. For the purposes of the Terrestrial Code, RVF is defined as an infection of ruminants <u>susceptible animals</u> with <u>Rift Valley fever virus Rift Valley fever virus (RVFV)</u>.
- <u>43</u>) The following defines the occurrence of *infection* with RVFV:
 - a) RVFV, excluding vaccine strains, has been isolated and identified as such from a sample from a ruminant susceptible animal; or
 - b) antigen or ribonucleic acid specific to RVFV, excluding vaccine strains, has been identified detected in a sample from a ruminant susceptible animal showing clinical signs or pathological lesions consistent with RVF, or epidemiologically linked with epidemiological links either to a confirmed or suspected case of RVF. including in or to a human infected with RVFV, or giving cause for suspicion of association or contact with RVFV; or
 - c) antibodies <u>specific</u> to RVFV antigens which that are not the consequence of vaccination, have been identified detected in a sample from a ruminant susceptible animal showing clinical signs or pathological lesions consistent with RVF, or with either epidemiological links <u>either</u> to a confirmed or suspected case of RVF, including in or to a human infected with RVFV, or giving cause for suspicion of association or contact with RVFV.
- 54) For the purposes of the Terrestrial Code, the infective period for RVF shall be 14 days and the incubation period shall be 7 days.
- 6) For the purposes of the Terrestrial Code, the incubation period for RVF shall be 7 days.
- <u>76</u>5) In areas where RVFV is present, <u>epizooticepidemics</u> of RVF may occur following favourable climatic, <u>and other</u> environmental conditions and availability of susceptible <u>host animal</u> and competent vector populations. <u>EpizooticEpidemics</u> are separated by inter-<u>epizooticepidemic</u> periods. <u>The transition from an inter-</u><u>epizooticepidemic period to an epizooticepidemic complies with point 1)(-de) of Article 1.1.3. in terms of notification.</u>

- 6) For the purposes of this chapter:
 - area' means a part of a country that experiences epizootics and inter-epizootic periods, but which does not correspond to the definition of zone;
 - b) 'epizootic of RVF' means the occurrence of outbreaks at an incidence substantially exceeding that during an inter-epizootic period or the occurrence of indigenous human cases;
 - c) 'inter epizootic period' means the period of variable duration, often long, with intermittent low level of vector activity and low rate of virus transmission, which is often not detected;
 - d) ruminants include dromedary camels.
- 7) The historical distribution of RVF has been parts of the African continent, Madagasear, some other Indian Ocean Islands and the south western Arabian Peninsula. However, vectors, environmental and climatic factors, land-use dynamics, and animal movements may modify the temporal and spatial distribution of the infection.
- <u>78</u>) When authorising import<u>ation</u> or transit of the commodities covered in the chapter, with the exception of those listed in Article 8.15.2., Veterinary Authorities should require the conditions prescribed in this chapter relevant to the RVF status of the ruminant susceptible animal population of the exporting country.
- <u>89</u>) Standards for diagnostic tests and vaccines are described in the Terrestrial Manual.

Article 8.15.2.

Safe commodities

When authorising <u>the</u> import<u>ation</u> or transit of the following *commodities* and any products made from them, Veterinary Authorities should not require any RVF-related conditions, regardless of the <u>RVF animal health</u> status of the ruminant susceptible animal population of the exporting country or zone:

- 1) hides and skins;
- 2) wool and fibre .:
- 3) extruded dry pet food;
- 4) heat-treated meat products in a hermetically sealed container with an FO value of 3 or above.

Article 8.15.3.

Country or zone free from RVF

A country or a zone may be considered free from RVF when infection with RVFV is notifiable in the entire country and either:

- 1) it meets the requirements for historical freedom in point 1 a) of Article 1.4.6.; or
- 2) <u>it meets</u> the following conditions:
 - an on-going pathogen-specific surveillance programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with RVFV in ruminants <u>susceptible animals</u> in the country or *zone* for a minimum of ten years; and
 - b) during that period no indigenous human cases infections in humans have occurred has have been reported by the public health authorities in the country or zone.

A country or zone free from RVF will not lose its free status through the importation of ruminants <u>susceptible animals</u> that are seropositive, so long as they are either permanently identified as such or destined for immediate *slaughter*.

Article 8.15.4.

Country or zone infected with RVFV during the inter-epizootic period

A country or *zone* infected with RVFV, during the inter-epizootic period, is one <u>that does not comply with meet the</u> <u>requirements of Article 8.15.3.</u> in which virus activity is present at a low level but the factors predisposing to an epizootic are absent.

Article 8.15.5.

Country or zone infected with RVFV during an epizootic

A country or zone infected with RVFV, during an epizootic, is one in which outbreaks of RVF are occurring at an incidence substantially exceeding that of the inter epizootic period; or one in which indigenous human cases of RVF are occurring even in the absence of detection of animal cases.

Article 8.15.65.

Strategies to protect from vector attacks during transport

Strategies to protect <u>susceptible</u> animals from vector attacks during transport should take into account the local ecology <u>and potential insecticide resistance</u> of the vectors.<u>and potential r</u><u>Risk management</u><u>Protection</u> measures include:

- 1) treating animals <u>and vehicles/vessels</u> with insect repellents <u>and insecticides</u> prior to and during transportation;
- 2) loading, transporting and unloading animals at times of low vector activity;
- ensuring vehicles <u>/vessels</u> do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect-proof netting protected from vector attacks;
- 4) using historical and current information to identify low<u>er</u> risk ports and transport routes.

Article 8.15.7<u>6</u>.

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

For ruminants susceptible animals

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

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

AND

2) either:

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

Article 8.15.87.

Recommendations for importation <u>of susceptible animals</u> from countries or zones infected with RVFV-during the interepizoetic period

For ruminants susceptible animals

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

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

AND

- 3) either:
 - a) did not <u>originate in or</u> transit through an area experiencing an <u>epizooticepidemic area</u> during transportation to the place of shipment; or
 - b) were protected from vector attacks when transiting through an area experiencing an epizoetic area.

Article 8.15.98.

Recommendations for importation <u>of susceptible animals</u> from countries or zones infected with RVFV during an epizootic

For ruminants susceptible animals

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the susceptible animals: 1

- 1) showed no <u>clinical</u> signs of RVF on the day of shipment;
- 2) did not originate from an in the epizootic area of the epizootic;
- 3) were vaccinated against RVF at least 14 days prior to shipment;
- 4) were held for at least 14 days prior to shipment in a vector protected quarantine station, which is located in an area of demonstrated low vector activity outside the <u>of an epizoetic</u> area of the epizoetic. During this period the animals showed no <u>clinical signs</u> of RVF;

AND

- 5) either:
 - a) did not transit through an <u>epizootic</u>area experiencing an epizootic during transportation to the place of shipment; or

b) were protected from vector attacks when transiting through an <u>opizootic</u>area experiencing an opizootic.

Article 8.15.1098.

Recommendations for importation <u>of semen and *in vivo* derived embryos of susceptible animals</u> from countries or zones not free from <u>infected with</u> RVF<u>V</u>

For semen and in vivo derived embryos of ruminants susceptible animals

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

1) showed no <u>clinical signs</u> 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 <u>subjected to a serological test</u> demonstrated to be seropositive on the day of collection, <u>with positive</u> <u>result</u>; or
 - c) were subjected to a serological test on two occasions with negative results on the day of collection and at least <u>14 days after collection</u> testing of paired samples has demonstrated that seroconversion did not occur within <u>14</u> <u>days of</u> between semen or embryo collection and <u>14 days after</u>.

Article 8.15.11<u>10</u>9.

Recommendations for importation of fresh meat <u>and meat products</u> and <u>meat products</u> from ruminants <u>susceptible</u> <u>animals</u> from countries or zones not free from <u>infected</u> with RVF<u>V</u>

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

- 1) the entire consignment of *meat* <u>or *meat* products</u> comes from:
 - 1a) ruminants which susceptible animals that showed no clinical signs of RVF within 24 hours before slaughter;
 - 2<u>b</u>) <u>ruminants which</u> <u>susceptible animals that</u> 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;
 - <u>3c)</u> carcasses which <u>that</u> were submitted to maturation at a temperature above 2°C for a minimum period of 24 hours following *slaughter*;
- 2) <u>the necessary precautions were taken to avoid contact of the products meat or meat products with any potential</u> <u>source of RVFV.</u>

Article 8.15.10bis.

Recommendations for importation of meat products from susceptible animals from countries or zones infected with RVFV

<u>Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the entire</u> <u>consignment of meat products comes from meat that complies with Article 8.15.10.</u>

Article 8.15.12<u>1110</u>.

Recommendations for importation <u>of milk and milk products of from susceptible animals</u> from countries or zones not free from infected with RVF<u>V</u>

For milk and milk products

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

- 1) was subjected to pasteurisation; or
- was subjected to a combination of control measures treatments with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Article 8.15.13<u>12</u>11.

Surveillance

Surveillance for RVF should be carried out in accordance with Chapter 1.4.

Surveillance for arthropod vectors should be carried out in accordance with Chapter 1.5., especially to determine areas of low vector activity.

Detection of RVFV in vectors has low sensitivity and therefore is not a recommended surveillance method.

An epidemic should be suspected in countries or zones infected with RVFV, or countries or zones adjacent to a country or zone in which epidemics have been reported notified, when ecological conditions favour the breeding of large numbers of mosquitoes and other vectors with concurrent or consequent occurrence of an increased number of abortions, and mortality particularly in new-born susceptible animals showing clinical signs or pathological lesions consistent with RVF, or reports of indigenous infection in humans.

Ecological conditions can be assessed through the sharing and analysis of meteorological data, and data on precipitation and water levels data, as well as the monitoring of vector activity. Clinical surveillance targeted at abortions and the use of sentinel herds can support detection of epidemics. Serological surveillance can also be used to assess the increase of in the number of seroconversions.

- 1) During an <u>epizeoticepidemic</u>, surveillance should be conducted to define the extent of the <u>affected area</u> <u>epidemic</u> <u>area for the purpose of disease prevention and control as well of as the extent of movements and trade of susceptible animals.</u>
- 2) During the inter-<u>epizooticepidemic</u> periods:, surveillance and monitoring of climatic factors predisposing to an epizootic should be carried out in countries or zones infected with RVFV.
 - <u>1)</u> <u>the level of virus transmission should be assessed and determined by surveillance in sentinel herds of susceptible animals;</u>
 - 2) monitoring of ecological and meteorological factors should be carried out.
- 3) Countries or zones adjacent to a country or zone in which <u>epizoeticepidemic</u>s have been <u>reported notified</u> should determine their RVF status through an on-going <u>specific surveillance</u> programme.

To determine areas of low vector activity (see Articles 8.15.87. and 8.15.98.) surveillance for arthropod vectors should be carried out in accordance with Chapter 1.5.

Examination of vectors for the presence of RVFV is an insensitive surveillance method and is therefore not recommended.

<u>The Veterinary Authority should coordinate in a timely manner with public health and other relevant authorities and share information to support the surveillance outcomes</u>, the use of public health messages to prevent human exposure and the decision-making process for the prevention and control of RVF.

<u>Annex 11</u>

CHAPTER 10.9.

INFECTION WITH NEWCASTLE DISEASE VIRUS

Article 10.9.1.

General provisions!

- 1) For the purposes of the *Terrestrial Code*, Newcastle disease (ND) is defined as an *infection* of *poultry* caused by Newcastle disease virus (NDV), which is an avian paramyxovirus serotype 1 (APMV-1) that meets one of the following criteria for virulence:
 - a) the virus has an intracerebral pathogenicity index (ICPI) in day-old chicks (Gallus gallus) of 0.7 or greater; or
 - b) multiple basic amino acids have been demonstrated in the virus (either directly or by deduction) at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term 'multiple basic amino acids' refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test.

In this definition, amino acid residues are numbered from the N-terminus of the amino acid sequence deduced from the nucleotide sequence of the FO gene, 113–116 corresponds to residues –4 to –1 from the cleavage site.'

2) *Poultry* is defined as 'all domesticated birds, including backyard *poultry*, used for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions, or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.

- 3) For the purposes of the Terrestrial Code, the incubation period for ND shall be 21 days.
- 43) This chapter deals with NDV *infection* of *poultry-as defined in point 2 above* in the presence or absence of clinical signs.
- 54) The occurrence of *infection* with NDV is defined as the isolation and identification of NDV as such or the detection of viral ribonucleic acid specific for NDV.
- 65) A Member Country should not impose bans on the trade in *poultry commodities* in response to information on the presence of any APMV-1 in birds other than *poultry*, including *wild* birds.
- 76) Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. When the use of ND vaccines is appropriate, those vaccines should comply with the standards described in the *Terrestrial Manual*.

[...]

CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 11.4.1.

General provisions

- 1) Bovine spongiform encephalopathy (BSE) is an invariably fatal neurological prion disease of bovines caused by a misfolded form of the prion protein (PrP^{Sc}), which includes both classical (C-type (classical BSE) and atypical strains (H- and L-type (atypical BSE) agents. The recommendations in this chapter are intended to mitigate the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agents in cattle only. BSE manifests in two main forms: classical BSE and atypical BSE. Oral exposure to contaminated feed is the main route of transmission of classical BSE. Atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle-bovine population. Oral exposure to contaminated feed is the main route of transmission of classical BSE. [L-type BSE;]. Therefore and the potential for recycling of atypical BSE cannot be ruled out, is also potentially considered capable of being recycled in a cattle population if cattle are orally exposed to contaminated feed but although there is no evidence that it plays a significant role in the epidemiology of BSE.
- 2) BSE primarily affects-cattle bovines. Other animal species may be naturally and experimentally susceptible to BSE, but they are not regarded as being epidemiologically significant, particularly when feeding ruminants with ruminant-derived protein mealprotein meal is not practiced practised. The recommendations in this chapter are intended to mitigate the human and animal health risks associated with BSE in bovines only.
- 3) For the purposes of the Terrestrial Code,:
 - <u>1a</u>) BSE is an invariably fatal neurological prion disease of cattle caused by <u>a misfolded form of the prion protein</u> (PrP^{BSE}<u>PrP^{SE}</u>), including <u>which includes</u> both classical (C-type BSE) and atypical strains (H- and L-type BSE). <u>for</u> respectively having, respectively, a protease resistant PrP^{BSE}<u>PrP^{SE}</u> fragment of higher and lower molecular mass <u>than classical BSE</u>). The term 'BSE' includes both classical and atypical forms, unless otherwise specified.
 - 2b) Tthe occurrence of a BSE-case of BSE is defined by the immunohistochemical (IHC) or immunochemical detection of the <u>C-typeclassical BSE</u> PrP^{Bec} agent in brain tissue of a bovid bovine of the species Bos taurus or Bos indicus., with dDiscrimination between atypical and classical BSE strains is based on the Western immunoblot banding pattern, as described in the Terrestrial Manual.
- 4) For the purposes of this chapter:
 - 3a) --, 'Ceattlebovine' means a bovids an animal of the species Bos taurus or Bos indicus.
 - 4b) 'Protein meal' means any final or intermediate solid protein containing product, obtained when animal tissues are rendered, excluding blood and blood products, peptides of a molecular weight less than 10,000 daltons and amino_acids.
- 5) When commodities are imported in accordance with this chapter, the BSE risk of the importing country or zone of destination is not affected by the BSE risk of the exporting country, zone or compartment of origin.
- 6) Standards for diagnostic tests are described in the Terrestrial Manual.

Article 11.4.1bis.

Safe commodities

When authorising the importation or transit of the following *commodities<u>derived from-cattle bovines</u>*. Veterinary Authorities should not require any conditions related to BSE, regardless of the BSE risk posed by the <u>cattle bovine</u> population of the exporting country, zone or compartment:

- 1) milk and milk products;
- 2) semen and *in vivo* derived-<u>cattle_bovine</u> embryos collected and handled in accordance with the relevant chapters of the *Terrestrial Code*;
- 3) hides and skins;
- 4) gelatine and collagen;
- 5) tallow with maximum level of insoluble impurities of 0.15% in weight and derivatives made from this tallow;
- 6) tallow derivatives;
- 76) dicalcium phosphate (with no trace of protein or fat).):
- 7) foetal-fetal blood.

Other commodities of cattle bovines can be traded safely if in accordance with the relevant articles of this chapter.

Article 11.4.2.

The General criteria for the determination of the BSE risk of the cattle population of a country, zone or compartment

The <u>Due-Owing to its specific etiological and epidemiological features, the</u> BSE risk of the cattle population of a country, *zone* or *compartment* is determined on the basis of the following criteria:

 a<u>A</u> <u>BSE</u> *risk* assessment, in accordance with the provisions of <u>Chapter 1.8.the "Application for official recognition by</u> <u>WOAH of risk status for bovine spongiform encephalopathy"</u> that evaluates the <u>likelihood-risk</u> of <u>the classical</u> BSE <u>agents</u> being recycled within the <u>cattle bovine</u> population by identifying all potential factors associated with the occurrence of BSE and their historic perspective. Member Countries should review the *risk* assessment annually to determine whether the situation has changed.

AThe risk assessment for the purpose of BSE, based on the framework provided by Article 2.1.4., consists of:

a) Entry assessment

An<u>The</u> entry assessment evaluates the likelihood that the classical BSE agent has been introduced into the country, zone or compartment via imported through the importation of the following commodities- in the preceding eight years:

- i) <u>Ccattlebovines;</u>
- ii) <u>Rruminant-derived protein mealprotein meal;</u>
- iii) <u>Ffeed (except packaged and labelled pet food-not intended for pets) that contains ruminant-derived</u> protein meal<u>protein meal</u>;
- iv) <u>Ffertilizsers that contain ruminant-derived protein meal</u>protein meal;
- v) Any other commodity that either is or could be contaminated by commodities listed in Article 11.4.14.

b) Exposure assessment

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

The first step in the exposure assessment involves an evaluation of livestock industry practices through a consideration of the impact of:

- i) <u>Livestock industry practices on preventing cattle-bovines from being fed ruminant-derived protein</u> <u>mealprotein meal, taking account of:</u>
 - <u>demographics of the cattle bovine population and production and farming systems;</u>
 - <u>feeding practices, including the use of fertilisers containing ruminant proteins on land for grazing or harvesting forage;</u>
 - <u>slaughtering and waste management practices;</u>
 - rendering practices;
 - <u>feed production, labelling, distribution and storage.</u>

Depending on the outcome from this step, an evaluation of risk mitigation measures specifically targeting BSE may also need to be included through a consideration of the impact of:

- ii) <u>Specific risk mitigation measures on preventing cattle bovines from being fed ruminant-derived protein</u> <u>mealprotein meal, taking account of:</u>
 - <u>the nature and scope of a feed ban on feeding ruminants with protein meal protein meal derived from</u> ruminants;
 - the fate of commodities with the greatest BSE infectivity (those commodities as listed in point 1 of Article 11.4.14.);
 - _ parameters of the rendering process;
 - <u>prevention of cross-contamination during rendering, feed production, transport, storage and feeding;</u>
 - an awareness programme under the scope of the feed ban;
 - <u>monitoring and enforcement of the feed ban.</u>

Depending on the outcome of the exposure assessment, a consequence assessment (in point c) below) may not be required.

c) Consequence assessment

A<u>The</u> consequence assessment evaluates the likelihood of <u>cattle_bovines</u> becoming infected <u>with_following</u> <u>exposure to the classical</u> BSE <u>agents</u> together with the likely extent <u>and duration</u> of any subsequent recycling and amplification<u>within the cattle_bovine population during the preceding eight years. The factors to be considered in the consequence assessment are:</u>

- i) age at exposure;
- ii) production type;

- iii) the impact of cattle-bovine industry practices or the implementation of BSE-BSE-specific mitigation measures under a feed ban.
- d) Risk estimation

<u>The</u>risk estimation combines the results and conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk that of the classical BSE agents have been being recycled in within the cattle bovine population through the feeding of ruminant derived protein meal, with indigenous cases arising as a consequence and to determine the date from which the risk of BSE agents being recycled within the cattle bovine population has been negligible.

- the <u>The</u> ongoing implementation of a surveillance programme for <u>classical</u>-BSE in the <u>cattle bovine</u> population <u>in</u> <u>accordance with Article 11.4.18.</u>
- 3) the The history of occurrence and management of BSE cases of BSE and bovines affected by atypical BSE.

<u>Determination of the date from which the risk of BSE agents being recycled within the bovine population has been</u> negligible is based on the points 1 to 3 above.

Article 11.4.3.

Negligible BSE risk

The BSE risk of the cattle population of a country, or zone or compartment can be considered to be negligible if <u>all</u> the following conditions for the cattle bovine population are met for at least the preceding eight years:

 A risk assessment as described in <u>point 1 of</u> Article 11.4.2. <u>that has identified all potential risk factors associated with</u> <u>the occurrence of classical BSE, including feeding ruminants with ruminant-derived protein meal</u>, has been conducted, and the Member Country has demonstrated through documented evidence that <u>any identified risk</u> <u>factors have been adequately managed and that</u> the likelihoodrisk of <u>the classical</u> BSE agents being recycled in within the <u>cattle bovine</u> population has been negligible as a result of as the result of:.

EITHER:

a) livestock industry practices ensuring that protein meal derived from ruminants has not been fed to ruminants;

OR

b) effective and continuous mitigation of each identified risk ensuring that protein meal derived from ruminants has not been fed to ruminants.

EITHER:

a) livestock industry practices ensuring that protein meal derived from ruminants has not been fed to ruminants;

- b) <u>effective and continuous mitigation of each identified risk ensuring that protein meal derived from ruminants</u> <u>has not been fed to ruminants.</u>
- 2) The surveillance provisions as described in Article 11.4.2018. have been implemented.
- 3) EITHER:
 - a) there has been no case of BSE or, if there has been a case, every <u>each</u> case of BSE has been demonstrated to have been imported or has been diagnosed as atypical BSE as defined in this chapter;

OR

b) if there has been an indigenous case of classical-BSE:

EITHEReither:

i) all cases were born at least eight years ago before the date from which the risk of BSE agents being recycled within the cattle bovine population has been negligible;

OR<u>or</u>

- ii) where a case was born within the preceding eight years <u>after that date</u>, subsequent investigations have confirmed that <u>any identified source of *infection* has been mitigated</u>controlled and the <u>likelihoodrisk</u> of BSE <u>agents</u> being recycled within the <u>cattle bovine</u> population has continued to be negligible.
- 4) Any cases of BSE <u>or any bovines affected by atypical BSE</u> that have been detected have been completely destroyed or disposed of to ensure that they do not enter the animal feed chain.

The country or the *zone* will be included in the list of countries or *zones* posing a negligible risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1 to 4 above. Documented evidence should be resubmitted annually for points 1 to 4 above.

Any changes in the epidemiological situation or other significant events should be notified to WOAH in accordance with Chapter 1.1.

Article 11.4.3bis.

Recovery of negligible BSE risk status

When<u>Should</u> an indigenous case of classical BSE is reported in an animal born within the preceding eight years <u>occur</u> in a country or zone recognised as having<u>posing</u> a negligible BSE risk <u>for BSE, the</u>status, <u>of</u> the negligible BSE risk status<u>country or zone</u> is suspended and the recommendations for controlled BSE risk status apply, pending. <u>The status</u> <u>may be recovered when</u> the outcome of subsequent investigations confirming<u>confirms</u> that <u>any identified source of</u> <u>infection has been mitigated and</u> the likelihood<u>risk</u> of BSE <u>agents</u> being recycled within the cattle population continues to be negligible. The<u>In the interim, the provisions for a</u> country or zone will regain<u>with a controlled BSE risk status apply</u>.

<u>The negligible BSE risk status of the country or zone will be reinstated</u> only after the submitted evidence has been accepted by the OIE.

Article 11.4.4.

Controlled BSE risk

The BSE risk of the cattle population of a country \underline{or} , zone or compartment can be considered to be controlled provided <u>all</u> \underline{of} the conditions of Article 11.4.3. are met, but at least one $\underline{or more}$ of these conditions has not been met for at least the <u>preceding</u> eight years.

The country or the *zone* will be included in the list of countries or *zones* posing a controlled risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1 to 4 of Article 11.4.3. Documented evidence should be resubmitted annually for points 1 to 4 of Article 11.4.3.

Any changes in the epidemiological situation or other significant events should be notified to WOAH in accordance with Chapter 1.1.

Article 11.4.4bis.

Compartment with negligible or controlled BSE risk

<u>The establishment and bilateral recognition of a *compartment* posing negligible or controlled BSE risk should follow the relevant requirements of this chapter and the principles laid down in Chapters 4.4. and 4.5.</u>

Article 11.4.5.

Undetermined BSE risk

The BSE risk of the cattle population of a country <u>or</u>, zone or compartment is considered to be undetermined if it cannot be demonstrated that it meets the requirements for negligible or controlled <u>BSE</u>risk.

Article 11.4.5bis.

Maintenance of BSE risk status

The BSE risk status of a country or zone is not affected by imported cases of BSE or cases of BSE born before the date from which the risk of BSE agents being recycled within the bovine population has been negligible, or by any bovine affected by atypical BSE, as long as managed in accordance with Articles 11.4.3. or 11.4.4.

Should an indigenous case of classical BSE in an animal bovine born after the date from which the risk of BSE agents being recycled within the cattle-bovine population has been negligible occur in a country or zone recognised as posing a negligible or controlled risk for BSE, the status of the country or zone is maintained, provided that documented evidence regarding the outcome of subsequent investigations is submitted to WOAH within 90 days demonstrating that any identified source of *infection* has been controlled and the risk of BSE agents being recycled within the cattle-bovine population has continued to be negligible.

If no documented evidence is provided or if it is not accepted by WOAH, the provisions of Article 11.4.3. or Article 11.4.4. apply.

Article 11.4.6.

Recommendations for importation of cattle from a country, zone or compartment posing a negligible BSE risk

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that cattle selected for export came from a country, zone or compartment posing a negligible BSE risk.

Article 11.4.7.

Recommendations for importation of <u>cattle bovines</u> from a country, zone or compartment posing a <u>negligible or</u> controlled BSE risk

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

- 1) theThe cattle bovines selected for export:
- came from a country, zone or compartment posing a <u>negligible or controlled BSE risk</u> and are identified through an <u>animal identification system enabling each animal</u> them to be traced throughout its their lifetime;

AND EITHER:

2) <u>theThe cattle bovines selected for export</u> were born <u>and kept</u> in the <u>a</u> country, zone or compartment <u>posing a</u> <u>negligible or controlled BSE risk after the date from which</u> during the period when the likelihood<u>risk</u> of the BSE agents being recycled in <u>within</u> the <u>cattle bovine</u> population has been demonstrated to be negligible;

OR

3)

- a) are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime; and
- b) are <u>it-It is</u> demonstrated as havingthat the cattle bovines selected for export have not never been fed protein meal protein meal derived from ruminants.

Article 11.4.8.

Recommendations for importation of cattle bovines from a country or; zone or compartment posing an undetermined BSE risk

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that-cattle selected for export:

- the <u>the Che cattle bovines selected for export</u> are identified by a permanent individual <u>through an animal</u> identification system from birth enabling <u>cach animal</u> them to be traced throughout <u>its their</u> lifetime;
- areit_It is demonstrated as having-that the cattle bovines selected for export have not-never been fed protein mealprotein meal derived from ruminants.

Article 11.4.9.

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

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the cattle from which the fresh meat and meat products were derived:

- 1) came from a country, zone or compartment posing a negligible BSE risk;
- 2) have been subjected to an ante-mortem inspection with favourable results.

Article 11.4.10.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a <u>negligible or</u> controlled BSE risk

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

- the <u>cattle bovine</u> from which the fresh meat and meat products were derived <u>came from a country, zone or</u> <u>compartment posing a controlled BSE risknegligible or controlled BSE risk and are identified through an animal</u> <u>identification system;</u>
- 2) they have been subjected to an ante-mortem inspection with favourable results;

AND EITHER:

- 3) they were born and kept in the:
 - <u>a) a country, zone or compartment posing a negligible BSE risk; or</u>
 - b) a country, zone or compartment posing a controlled BSE risk after the date from which the risk of the BSE agents being recycled within the bovine population has been demonstrated to be negligible; or or controlled BSE risk after the date from which during the period when the likelihood <u>risk</u> of the BSE agents being recycled in <u>within</u> the cattle population has been demonstrated to be negligible;

- c) a country, zone or compartment posing a controlled BSE risk before the date from which the risk of the BSE agents being recycled within the bovine population has been demonstrated to be negligible, and the fresh meat and meat products:
 - i) derived from bovines not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to slaughter; and
 - ii) were produced and handled in a manner which ensures that such products do not contain and are not contaminated with the commodities listed in point 1 of Article 11.4.14. or mechanically separated meat from the skull or from the vertebral column of bovines over 30 months of age.

OR

- 4) the fresh meat and meat products:
 - a) derived from cattle not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, <u>or to any other procedure that can contaminate blood with nervous tissue</u>, prior to *slaughter*; and
 - b) were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
 - i) the commodities listed in points 1) a) and 1) b) of Article 11.4.14.;
 - ii) mechanically separated meat from the skull and <u>nor or</u> from the vertebral column from <u>of</u> cattle over 30 months of age.

Article 11.4.11.

Recommendations for importation of fresh meat and meat products from a country<mark>; <u>or</u>zone or compartment posing an undetermined BSE risk</mark>

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

- 1) the cattle bovines from which the fresh meat and meat products were derived:
- a) are identified through an animal identification system;
- <u>it is demonstrated as having that the cattle bovines from which the fresh meat and meat products were derived have</u> <u>not never</u> been fed <u>protein meal protein meal</u> derived from ruminants;
- b3) the cattle bovines from which the fresh meat and meat products were derived:
 - a) were subjected to an ante-mortem inspection with favourable results;
 - ebb) were not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to slaughter;
- 24) the fresh meat and meat products were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
 - a) the commodities listed in points 1) a) and 1) b) of Article 11.4.14.;
 - b) mechanically separated *meat* from the skull and<u>nor-or</u> from the vertebral column from <u>of</u> cattle <u>bovines</u> over 30 months of age.

Article 11.4.12.

Recommendations for importation of <u>bovine</u> cattle-derived protein meal from a country, zone or compartment posing a negligible BSE risk

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the cattle bovines from which the protein meal protein meal was derived-came from a country, zone or compartment posing a negligible BSE risk. 1) came from a country, zone or compartment posing a negligible BSE risk:

<u>were are-identified through an animal identification system and were born and kept in the a country, zone or compartment posing a negligible BSE risk, and</u>

<u>EITHER</u>

1) they were born after the date from which during the period when the risk of the BSE agents being recycled in within the cattle bovine population has been demonstrated to be negligible

OR

2) the protein meal was processed in accordance with Article 11.4.17.

Article 11.4.13.

Recommendations for importation of blood and blood products derived from bovinecattle (except foctal fetal blood)

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

EITHER:

 the blood and blood products came from a country, zone or compartment posing a negligible <u>or controlled</u> BSE risk; and

OR

12) <u>the blood and blood products came from a country, zone or compartment posing a controlled BSE risk and the cattle <u>bovines_from which</u> the blood and blood products were derived <u>from bovines that are-were identified through an</u> <u>animal identification system and</u> were born <u>and kept</u> in the <u>a</u> country, zone or compartment <u>posing a negligible</u> risk, or <u>a</u> <u>country, zone or compartment posing a</u> controlled BSE risk <u>after the date from which the risk of BSE agents being recycled</u> <u>within the bovine population has been demonstrated to be negligible</u> <u>after the date from which during the period when</u> the likelihood <u>risk of the BSE agents being recycled in within</u> the cattle population has been demonstrated to be negligible</u>

OR

- 23) the blood and blood products were:
 - a) collected from <u>cattle bovines</u> not subjected to a stunning process, <u>or to any other procedure that can</u> <u>contaminate the blood with nervous tissue</u>, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, <u>or to any other procedure that can contaminate the blood with nervous tissue</u>, prior to slaughter; <u>and</u>
 - b) collected and processed in a manner that ensures they are not contaminated with nervous tissue.

Article 11.4.14.

Recommendations in relation to the trade of the commodities with the greatest BSE infectivity

- 1) Unless covered by other articles in this chapter, the following commodities originating from a country, zone or compartment posing a controlled or undetermined BSE risk, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices:
 - a]) distal Distal ileum from cattle bovines of any age; b) skull, brain, eyes, vertebral column and spinal cord from cattle bovines that were at the time of slaughter over 30 months of age., or any commodity contaminated by them, for the preparation of protein products, food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices, which originate from a country, zone or compartment posing:
 - a) an undetermined BSE risk;
 - b) <u>a controlled BSE risk or a negligible BSE risk if the commodities they are derived from cattle bovines born</u> before the period when date from which the risk of the BSE agents being recycled in within the cattle bovine population has been demonstrated to be negligible.
- 2) Protein products, f<u>F</u>ood, feed, fertilisers, cosmetics, pharmaceuticals <u>including biologicals</u>, or medical devices <u>or any</u> <u>other product containing proteins</u> prepared using commodities listed in points 1) a) or 1) b) above of this article, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk, should not be traded.
- 3) Cattle<u>Bovine</u>-derived protein meal<u>protein meal</u>, or any commodities containing such products, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk, should not be traded.

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

Article 11.4.15.

Recommendations for importation of tallow (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

- 1) the tallow-came from a country, zone or compartment posing a negligible BSE risk; or
- 2) the tallow is derived from cattle <u>bovines</u> which have been subjected to an ante-mortem inspection with favourable results, and has not been prepared using the *commodities* listed in pointspoint 1) a) and 1) b) of Article 11.4.14.

Article 11.4.15bis.

Recommendations for importation of tallow derivatives (other than as defined in Article 11.4.1bis.)-intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

<u>Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the tallow</u> <u>derivatives either:</u>

- 1) <u>originate from a country, zone or compartment posing a negligible BSE risk; or</u>
- 2) are derived from tallow that meets the conditions referred to in Article 11.4.15.; or
- 3) have been produced by hydrolysis, saponification, or transesterification that uses high temperature and pressure.

Article 11.4.16.

Recommendations for importation of dicalcium phosphate (other than as defined in Article 11.4.1bis.)intended for food, food, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices Veterinary Authorities should require the presentation of an international veterinary certificate attesting that <u>the dicalcium</u> <u>phosphate</u>:

- 1) the dicalcium phosphate came from a country, zone or compartment posing a negligible BSE risk; or
- 2) the dicalcium phosphate is a co-product of bone gelatine.

Article 11.4.16bis.

Recommendations for importation of tallow derivatives (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

<u>Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the tallow</u> <u>derivatives either:</u>

- +> originate from a country, zone or compartment posing that poses a negligible BSE risk; or
- 2) are derived from tallow that meets the conditions referred to in Article 11.4.15.; or
- 3) have been produced by hydrolysis, saponification or transesterification that uses high temperature and pressure.

Article 11.4.17.

Procedures for reduction of BSE infectivity in bovine protein meal

The following procedure should be used to reduce the infectivity of any transmissible spongiform encephalopathy<u>BSE</u> agents which that may be present during the production of protein meal protein meal containing ruminant bovine proteins:

- 1) **F**<u>the</u> raw material should be reduced to a maximum particle size of 50 mm before heating:
- 2) ∓<u>and the</u> raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar; or
- 2) <u>an alternative procedure that has been demonstrated to achieve at least an equivalent level of reduction in BSE infectivity.</u>

Article 11.4.18.

Surveillance

The objective of BSE surveillance is to detect occurrence of BSE within the cattle bovine population.

- 1) Surveillance for BSE consists of the regular reporting of animals with clinical signs suggestive of BSE to the Veterinary Authority for subsequent investigation and diagnosis. The credibility of the surveillance programme is supported by:
 - a) compulsory notification of BSE throughout the whole territory by all those stakeholders involved in the rearing and production of livestock including farmers, herdsmen, veterinarians, transporters and slaughterhouse/abattoir workers;
 - b) an ongoing awareness programme to ensure that all stakeholders are familiar with the clinical signs suggestive of BSE as well as the reporting requirements;
 - c) appropriate laboratory investigations in accordance with the Terrestrial Manual and follow-up field investigation as necessary of all clinical suspects.

- 21) BSE is a progressive, fatal disease of the nervous system of cattle <u>bovines</u> that usually has an insidious onset <u>and</u> that is refractory to treatment. A range of clinical signs that vary in severity and between animals have been described for classical BSE:
 - a) progressive behavioural changes that are refractory to treatment such as increased excitability, depression, nervousness, excessive and asymmetrical ear and eye movements, apparent increased salivation, increased licking of the muzzle, teeth grinding, hypersensitivity to touch and/or sound (hyperaesthesia), tremors, excessive vocalizationvocalisation, panic-stricken response and excessive alertness;
 - b) postural and locomotory changes such as abnormal posture (dog sitting), abnormal gait (particularly pelvic limb ataxia), low carriage of the head, (head shyness), difficulty avoiding obstacles, inability to stand and recumbency;
 - c) <u>generalizedgeneralised</u> non-specific signs such as reduced *milk* yield, loss of body condition, weight loss, bradycardia and other disturbances of cardiac rhythm.

Some of these signs are also likely to be relevant for atypical BSE, particularly those associated with difficulty in rising and recumbency. A nervous form <u>of atypical BSE</u> resembling classical BSE may be observed with over-reactivity to external stimuli, unexpected startle responses and ataxia. In contrast, a dull form <u>of atypical BSE</u> may be observed. with dullness combined with a low head carriage and compulsive behaviour (licking, chewing, pacing in circles).

The clinical signs of BSE usually progress <u>on a spectrum</u> over a few weeks to several months, but <u>inon</u> rare occasions cases can develop acutely and progress rapidly. <u>In the continuum of the disease spectrum, tThe</u> final stages <u>of</u> <u>the disease</u> are characterised by recumbency, coma and death.

Cattle displaying some of the above mentioned progressive neurological signs without signs of infectious illness, and that are refractory to treatment, are candidates for examination.

Since these signs are not pathognomonic for either classical or atypical BSE, all Member Countries with <u>eattle bovine</u> populations <u>may are likely to</u> observe individual animals displaying clinical signs suggestive of BSE. The rate at which they are likely to occurr<u>General statements about the likely frequency of occurrence of such animals</u> cannot be reliably predicted made as they will vary depending on the epidemiological situation in a particular country. In addition, in

<u>2)</u> <u>Surveillance for BSE consists of the reporting of includes all animals bovines</u> that lie on the continuum of the show symptoms signs of the clinical spectrum of BSE-spectrum to the Veterinary AuthorityVeterinary Services for subsequent investigation and follow-up.

In those countries where cattle are intensively reared and production and farming systems that allow cattle-bovines to be subjected to regular observation, it is likely that such animals that display clinical signs suggestive of BSE will be more readily seen. Behavioural changes, that which may be very subtle in the early clinical phase, are best identified by those who handle animals on a daily basis and who can monitor them closely for a progression of the signs. In more extensive production and farming systems, however, where cattle bovines are not monitored as closely, situations may inevitably arise where an animal might be considered as a clinical suspect, yet if it was has not been observed for a period of time, it may only be initially seen as a downer (non-ambulatory) or found dead (fallen stock). Under such circumstances, if there is an appropriate supporting clinical history, these animals that lie on the continuum of a progressive disease from clinical suspect to downer to fallen stock may still be suitable candidates for surveillance.

The investigation of potential surveillance programmecandidates should take into account that the vast majority of <u>BSE-cases of BSE arise as single, isolated events. The concurrent occurrence concurrence of multiple animals with</u> behavioural or neurological signs, or non-ambulatory or fallen stock is most likely associated with other causes.

The following animals that lie on the continuum of the disease clinical spectrum of BSE should be targeted for BSE surveillance and the following animals should be reported and followed up with appropriate laboratory testing in accordance with the *Terrestrial Manual* to accurately confirm or rule out the presence of BSE agents, including discrimination between atypical and classical BSE strains:

- a) <u>those displaying some of the progressive clinical signs suggestive of BSE mentioned in point 1 of Article 11.4.18.</u> <u>suggestive of BSE-that are refractory to treatment, and where the presentation cannot be attributed to other</u> <u>common causes of behavioural or neurological signs (e.g. infectious, metabolic, traumatic, neoplastic or toxic</u> <u>causes)</u>-have been ruled out:
- b) <u>those showing behavioural or neurological signs at that have been subjected to an ante-mortem inspection with</u> <u>unfavourable results at slaughterhouses/abattoirs;</u>
- c) <u>those presented as downers (non-ambulatory), with an appropriate supporting clinical history (i.e. the</u> <u>presentation cannot be attributed to</u> other common causes of recumbency has have been ruled out);
- d) <u>those found dead (fallen stock), with an appropriate supporting clinical history (i.e. the presentation cannot be</u> <u>attributed to other common causes of death has have been ruled out</u>).

<u>All these animals should be followed up with appropriate laboratory testing in accordance with the Terrestrial Manual</u> to accurately confirm or rule out the presence of BSE agents.

- 3) <u>The credibility of the surveillance programme is supported by:</u>
 - a) <u>ongoing awareness and training programmes to ensure that all those stakeholders involved in the rearing and</u> <u>production of livestock, including farmers, herdsmen, cattle</u><u>bovine</u><u>breeders, owners</u><u>and</u><u>keepers</u>, <u>veterinarians</u>, transporters and <u>slaughterhouse/abattoir</u> workers are familiar with the clinical signs suggestive <u>of BSE as well as the statutory reporting requirements</u>;
 - b) the fact that BSE is a compulsorily notifiable disease throughout the whole territory;
 - c) <u>appropriate laboratory testing in accordance with the Terrestrial Manual;</u>
 - d) <u>robust, documented, evaluation procedures and protocols for:</u>
 - the definition of the target population for BSE surveillance,
 - <u>the identification and the reporting of potential candidates animals bovines described in points 2 a) to 2 d)targeted for BSE surveillance.</u>
 - <u>for the determination of animals to be subjected to laboratory testing.</u>
 - <u>for the collection and submission of samples for laboratory testing.</u>
 - and forthe follow-up epidemiological investigations for BSE positive findings.

Annex 13

DRAFT CHAPTER 1.8.

APPLICATION FOR OFFICIAL RECOGNITION BY WOAH OF RISK STATUS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 1.8.1.

GuidelinesGeneral principles

In accordance with Article 11.4.2., the bovine spongiform encephalopathy (BSE) risk of the cattle (Bos indicus and Bos taurus) population of a country or zone is determined on the basis of a risk assessment that evaluates the risk of the classical BSE agents (classical and atypical) being recycled within the cattle bovine (Bos indicus and Bos taurus) population by identifying all potential factors associated with the occurrence of BSE, the ongoing implementation of a surveillance programme, and the history of occurrence and management of BSE-cases.

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

<mark>For the purposes of this chapter, '</mark>A case of <mark>BSE <mark>case' means the occurrence of classical BSE, as</mark> is defined in point 3 of Article 11.4.1.</mark>

The information specified in Articles 1.8.2. to 1.8.6. should be provided by WOAH Member Countries in support of their application for official recognition of BSE risk status in accordance with Chapter 11.4. of the *Terrestrial Code*. The structure of the dossier should follow guidelines provided in the "Standard Operating Procedure for official recognition of disease status and for the endorsement of national official control programmes of Member Countries" (available on the WOAH website).

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

- T<u>the history of occurrence and management of BSE cases in the country or zone (Article 1.8.2.)</u>
- <u>L</u>egislation (Article 1.8.3.)
- Vveterinary system (Article 1.8.4.)
- BSE risk assessment (Article 1.8.5.)
- BSE surveillance (Article 1.8.6.).
- <u>the history of occurrence and management of BSE in the country or zone.</u>

<u>The dossier should indicate the date from which it can be considered that the risk of BSE agents being recycled within the bovine population has been negligible.</u>

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

Article 1.8.2.

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

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

- 1) If a case of BSE case has ever been diagnosed in the country or zone, indicate the total number of BSE cases, and:
 - a) Provide a table of aggregated data on all cases of BSE <u>cases</u> encountered in the country or zone, by type (classical or atypical), origin (indigenous or, if imported, the country of origin), and the year of birth;
 - b) For the past eight years, provide a table to indicate, for each case, the year of occurrence, the origin (indigenous or, if imported, the country of origin), the type (classical or atypical), and the year of birth of each indigenous case of classical BSE.
- 2) If there have been cases of BSE cases or bovines affected by atypical BSE, confirm that they were excluded from the feed chain and describe how this was achieved. In the table under Article 1.8.3. provide details of the national legislation, regulations and Veterinary Authority directives that describe these procedures.

Article 1.8.3.

Legislation

Provide a table listing all relevant legislation, regulations, Veterinary Authority directives, legal instruments, rules, orders, acts, decrees, etc., related to BSE. For each, provide the date of promulgation and implementation as well as a brief description of the relevance to mitigating against the risks associated with BSE. The table should include the legislation, regulations and directives referred to in the core document of the dossier. These instruments may be provided as annexes or as weblinks to supporting documents.

Article 1.8.4.

Veterinary system

The quality of the Veterinary Services of a Member is important to the establishment and maintenance of confidence in its *international veterinary certificates* by the Veterinary Services of other Members (Article 3.2.1.). It also supports an evaluation of the BSE risk status of the cattle population of a country or zone.

- 1) Describe how the Veterinary Services of the country comply with the provisions of Chapters 1.1., 3.2. and 3.3.
- 2) The applicant Member may provide information on any recent (not older than five years) WOAH PVS evaluation conducted in the country and follow-up steps within the PVS Pathway, and highlight the results relevant to BSE.
- 3) Describe how the Veterinary Services supervise, control, enforce and monitor all BSE-related activities.
- 4) Provide a description of the involvement and the participation of industry; producers; farmers; herdsmen; <u>cattle</u> <u>bovine breeders</u>, <u>owners and keepers</u>; private veterinarians; veterinary paraprofessionals; transporters; workers at livestock markets, auctions and slaughterhouses/abattoirs; and other relevant non-governmental stakeholders in the control of BSE.
- 5) Describe the official <u>cattle_bovine_identification</u>, registration, traceability and movement control system. Provide evidence of its effectiveness. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic. Indicate <u>if-whether_there</u> are any industry associations or organisations involved in <u>cattle_bovine</u> identification, registration, traceability and movement control systems that provide guidance, set standards or provide third party audits; include a description of their role, membership and interaction with the Veterinary Services or other_relevant Competent Authorityies.

Article 1.8.5.

BSE risk assessment (point 1 of Article 11.4.3.)

1.) Entry assessment (point 1 a) of Article 11.4.2.)

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

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

The commodities to be considered in the entry assessment are:

- Ccattlebovines.;
- Rruminant-derived protein mealprotein meal-;
- <u>Ffeed</u> (not intended for petsexcept packaged and labelled pet food) that contains ruminant-derived protein mealprotein meal;
- <u>F</u>fertilizers that contain ruminant-derived protein mealprotein meal-;
- Aany other commodity that either is or could be contaminated by commodities listed in Article 11.4.14., e.g. over 30 months old cattle carcass or half carcass from which the spinal cord and vertebral column were not removed, originating from a country, zone or compartment posing a controlled or undetermined BSE risk.
- a) For each *commodity* listed above indicate if <u>whether</u> they were imported in the preceding eight years, and, if so, from which countries.

For each commodity listed above describe the import requirements applied by the applicant country or zone and how they are related to the BSE risk status of the exporting country or zone and whether or not they are consistent with, or provide an equivalent level of assurance with to the recommendations laid out in Chapter 11.4. for the importation of such a commodity. Where the import requirements are not consistent with the recommendations in Chapter 11.4. but are considered to provide an equivalent level of assurance, provide an explanation outlining the rationale and supporting evidence. In situations where an import requirement does not provide an equivalent level of assurance to the relevant measure in Chapter 11.4., provide an explanation of how this is likely to impact the entry assessment.

Describe the importation process for these commodities and how are they controlled, regulated and monitored by the Competent Authority with references as appropriate to the relevant legislation in the table under Article 1.8.3. Provide supporting evidence of the importation process including, where relevant, import permits or their equivalent, and examples of international veterinary certificates issued by exporting countries.

Describe the intended end use of the imported *commodities*, for example: <u>cattle bovines</u> may be imported for breeding or immediate *slaughter*; rendered products may be imported for incorporation into feed for non-ruminant species such as pigs or *poultry*. Provide information on any systems in place and their results to monitor or track imported *commodities* and their results to ensure they are used as intended.

Describe the actions available under national legislation to prevent illegal introduction of the *commodities* considered above and provide information on any illegal introductions detected and the actions taken.

b) Conclusions for the entry assessment.

Given the sanitary measures applied (if any), what was the likelihood that, during the preceding eight years, any of the *commodities*, in the form that they were imported, harboured or were contaminated by the classical BSE agent?

Clearly and concisely describe the rationale leading to the conclusions reached.

2:) Exposure assessment (point 1 b) of Article 11.4.2.)

As emphasised in Article 11.4.1., atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population. Although uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated feed, this is the main route of transmission of classical BSE. Considering that atypical BSE may potentially be capable of being recycled in a cattle population if cattle were to be exposed to contaminated feed, it is necessary to undertake an exposure assessment regardless of the outcome of the entry assessment.

As described in Article 11.4.2., an exposure assessment evaluates the likelihood of cattle bovines being exposed to the <u>classical</u> BSE agents either through imported commodities (classical BSE) or as a result of the presence of <u>classical</u> BSE agents (classical or atypical BSE) in within the indigenous cattle bovine population of the country or zone.

For the purposes of undertaking an exposure assessment for the evaluation of BSE status, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.). At its discretion, the applicant Member may provide the information requested for a different period (i.e. longer than eight years for those applying for a negligible risk status, or for the time period for which they have the information if applying for a controlled risk status) to establish the period when indicate the date from which the likelihood risk of the BSE agents being recycled in within the eattle bovine population has been demonstrated to be negligible (i.e. to determine the period of time date to be attested in point 2 of accordance with Articles 11.4.6., 11.4.7., 11.4.910., 11.4.12. and 11.4.13. and 11.4.14.).

As indicated in point $1_{\underline{b}}$) of Article 11.4.2., the first step in the exposure assessment involves an evaluation of the impact of livestock industry practices on preventing <u>cattle_bovines_from</u> being fed ruminant-derived <u>protein</u> <u>mealprotein meal}</u> and, depending on the outcome of this step, an evaluation of the impact of specific mitigation measures on preventing <u>cattle_bovines_from</u> being fed ruminant-derived <u>protein mealprotein meal}</u>.

a) Livestock industry practices (point 1 b) i) of Article 11.4.2.)

Because oral exposure to contaminated *feed* is the principal route of transmission of the BSE agents, the exposure assessment begins with a detailed description of the <u>cattle bovine</u> population and associated industry practices, with a particular emphasis on: feeding practices; disposal of dead <u>stock animals</u> and waste from slaughtered animals; rendering; and production, <u>labelling</u>, distribution and storage of *feed* that may lead to <u>cattle bovines</u> being exposed to potentially contaminated *feed*.

The intent of this section is not to describe the implementation and enforcement of measures specifically targeting the exposure of the <u>cattle bovine population</u> to BSE agents (such as a legislated feed ban) as they will be considered where relevant in <u>Section point</u> b) An evaluation of BSE specific mitigation measures. The intention here is to evaluate the likelihood and extent of exposure of the <u>cattle bovine population</u> to the <u>classical</u> BSE agents, given the ongoing livestock industry practices in a country or zone.

i) Demographics of the cattle bovine population and production and farming systems.

Describe the composition of the <u>cattle bovine population</u> and how the <u>cattle bovine</u> industry is structured in the country or <u>zone</u> considering the types of production<u></u> systems, including all that apply, such as dairy, beef <u>rearing</u>, feedlot, fattening and <u>beef</u> finishing, and the farming systems, such as intensive, extensive, <u>semi semi-</u>intensive, transhumant, pastoral, agropastoral, and mixed-species farming. <u>The description</u> <u>should include the number and size of herds farms</u> in each type of production and farming system.

ii) Feeding practices.

For each type of production system, describe the rearing and production practices related to feeding ruminants of various ages, including the types of feed and feed ingredients (animal or plant based). Where animal-based ingredients are used, describe whether or not they are derived from rendered products of ruminant or non-ruminant origin as well as the respective proportions used.

Provide an indication of the proportion of the national *feed* production prepared commercially (including local mills) or mixed on farm using either imported or domestically produced ingredients.

Describe whether or not fertilizsers containing ruminant-derived protein mealprotein meal, composted materials derived from fallen stock (i.e. <u>cattle bovines</u> of any age which were found dead or were killed on a farm, during transportation, <u>at livestock markets or auctions</u>, or at a *slaughterhouse/abattoir*), *slaughterhouse/abattoir* waste or animals condemned at <u>ante-ante-</u>mortem inspections or any other materials derived from or that incorporate ruminant proteins are applied to land where cattle bovines graze or where forage is harvested for feeding to <u>cattle bovines</u>. Where such fertilizsers or <u>composted materials</u> are used, provide information on the extent and frequency of use <u>and any risk mitigation</u> measures to prevent accidental ingestion.

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

iii) Slaughtering and waste management practices-

Describe the practices for fallen stock, including eattle-bovines euthanised as part of a BSE surveillance programme under Article 11.4.18, that occur on farm, during transport, at livestock markets or auctions or prior to slaughter, with particular reference to their transportation, disposal or destruction, including composting, burial, rendering or incineration. In the table under Article 1.8.3, provide any legislation, regulation or directives relevant to this topic.

Describe the places where <u>cattle bovines</u> are slaughtered (for example, on farm, at a *slaughterhouse/abattoir* or *market*) together with the respective proportions and associated ages.

Describe whether or not places where animals are slaughtered are required to be registered or approved by the *Veterinary Services* or other <u>relevant</u> Competent Authority and if they are subject to official veterinary supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Describe how animals condemned at <u>ante ante-</u>mortem inspection and waste declared as unfit for human consumption from slaughtered animals are processed, disposed of or destroyed, including composting, burial, rendering, incineration or other industrial uses such as salvaging and crushing bones for use in animal *feed*. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

iv) Rendering practices.

Rendering is a process by which animal material is transformed into products such as <u>protein meal</u> <u>protein</u> <u>meal</u> that may be used in animal feed. It provides <u>the a</u> pathway for the introduction of <u>the <u>classical</u> BSE agents (classical or atypical) into the animal feed chain.</u>

Describe whether or not there are any rendering facilities in the country or *zone*, if they are required to be registered or approved by the *Veterinary Services* or other relevant Competent Authority and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Using tables as appropriate, for each of the preceding eight years, provide a breakdown of the number of rendering facilities operating, indicating for each facility:

- the source and types of raw materials handled;
- whether or not they receive and process material from a particular species or process mixed materials including those derived from ruminants;

- whether or not ruminant waste is segregated from non-ruminant waste and if so how segregation is maintained to avoid potential cross-contamination of non-ruminant rendered materials during processing, storage and transport of rendered products, for example through dedicated lines, storage bins or silos, transport vehicles or establishments;
- the parameters of the rendering process (time, temperature, pressure, etc.);
- the type and intended end use of <u>the</u> rendered products-produced. If available, provide the amount
 of rendered products produced annually by type and intended end use;
- if materials derived from imported cattle bovines are managed differently, describe the process.

Indicate if there are any industry associations or organisations involved in the rendering industry that provide guidance, set standards or provide third party audits in relation to Hazard Analysis and Critical Control Points (HACCP) programmes, good manufacturing practices, etc. Include a description of their role, membership and interaction with the Veterinary Services or other relevant Competent Authorityies.

v) Feed production, labelling, distribution and storage-

Where rendered products are used as ingredients in the production of animal *feed* the exposure of <u>cattle</u> <u>bovines</u> to the <u>classical</u> BSE agents (classical or atypical) may arise as a result of the use of rendered products containing materials of ruminant origin as ingredients in <u>cattle</u> <u>bovine</u> feed or as a result of <u>cattle</u> <u>bovine</u> feed being cross-contaminated when such products are used in the production of feed for other species.

Describe whether or not facilities producing feed for ruminant or non-ruminant livestock as well as <u>for</u> pets are required to be registered or approved by the Veterinary Services or <u>other-relevant</u> Competent Authority and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

For each of the preceding eight years, provide a breakdown using tables as appropriate of the number and types of facilities producing *feed*, indicating for each facility:

- excluding those listed in Article 11.4.1bis., whether or not rendered ruminant products, excluding those listed in Article 11.4.1bis., were used as ingredients in feed for ruminants, non-ruminants and pets;
- whether or not each facility was dedicated to manufacturing feed for a particular species or manufactured feed for multiple species including ruminants.

Where facilities manufactured feed for multiple species including ruminants, indicate whether or not there were any practices in place to avoid ruminant *feeds* from being contaminated with rendered ruminant products during feed manufacture, storage and transport.

Indicate if there are any industry associations or organisations involved in *feed* production, distribution and storage that provide guidance, set standards or provide third party audits in relation to HACCP program<u>mes</u>, *good manufacturing practices*, etc. Include a description of their role, membership and interaction with the Veterinary Services or other relevant Competent Authority set.

- vi) Conclusions for livestock industry practices-
 - Given the livestock industry practices described above, is the likelihood that the <u>cattle bovine</u> population has been exposed to <u>either the</u> classical <u>or atypical BSE</u> <u>agents</u> during the preceding eight years negligible or non-negligible?
 - Clearly and concisely describe the rationale leading to the conclusion reached.

- Where the likelihood estimate is negligible, proceed to Section 4) Risk estimation.
- Where the likelihood estimate is non-negligible, proceed to Section b) An evaluation of BSE specific mitigation measures.
- b) An evaluation of BSE-BSE-specific risk mitigation measures- (point 1 b) ii) of Article 11.4.2.)

For those countries that have reported <u>classical cases of</u> BSE <u>cases</u> in indigenous <u>cattle bovines</u>, it is apparent that their historic livestock industry practices did not prevent the recycling of the <u>classical</u> BSE agent in <u>within</u> their <u>cattle bovine</u> populations. These countries, together with others whose livestock industry practices would have been conducive to recycling, may have implemented specific measures, <u>such asnotably</u> through a legislated *feed* ban, to ensure that the likelihood of recycling would be negligible. To qualify for official recognition of a BSE risk status, these countries need to demonstrate that <u>thethese</u> measures specifically targeting BSE have been and continue to be effectively implemented and enforced.

i) The nature and scope of a feed ban-

Indicate if whether there is a ban on feeding ruminants with protein meal protein meal derived from ruminants.

Where a *feed* ban has been implemented, clearly and concisely describe the date it was introduced, its nature and scope and how it has evolved over time.

In addition, if the *feed* ban has been implemented through national legislation, provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

ii) Commodities with the greatest BSE infectivity-

Indicate whether or not any of those commodities listed in point 1 of Article 11.4.14. are removed from the carcass at the time of *slaughter* or subsequent fabrication or processing.

If so, also:

- Describe how they are disposed <u>of</u> or destroyed through burial, composting, rendering, alkaline hydrolysis, thermal hydrolysis, gasification, incineration, etc.
- Describe any measures in place that ensure slaughter waste declared as unfit for human consumption that is rendered is not cross-contaminated with these commodities.
- Describe whether these commodities from fallen stock and animals condemned at <u>ante ante-</u>mortem inspection are excluded from rendering and how this is done.
- Where these commodities are not excluded removed from fallen stock, animals condemned at antemortem inspection, or slaughter waste declared as unfit for human consumption, describe their final disposal of this waste, and how it is handled and processed.
- Describe whether or not all these processes and methods are subject to approval and oversight by the Veterinary Services or other relevant Competent Authority.

In addition, if there is specific national legislation concerning the definition, identification, removal and disposal or destruction of those *commodities* listed in point 1 of Article 11.4.14., provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with <u>references as appropriate</u>.

iii) Parameters of the rendering process.

Describe whether or not the parameters of the rendering process are prescribed in legislation and if they are consistent with, or provide an equivalent level of assurance to, the procedures for the reduction of BSE infectivity in ruminantbovine derived protein mealprotein meal as described in Article 11.4.17. Provide details of the legislation, if applicable, in the table under Article 1.8.3.

iv) Cross-contamination-

Describe the measures in place to prevent cross-contamination during rendering, *feed* production, transport, storage and feeding such as dedicated facilities, lines and equipment, as well as measures to prevent misfeeding, such as the use of warning labels. Provide information as to whether any of these measures are prescribed in legislation and if facilities involved in rendering and *feed* production are required to be registered or approved under the *feed* ban by the *Veterinary Services* or other <u>relevant</u> *Competent Authority*.

v) Awareness programme under the scope of the feed ban-

Provide information on the existence of any ongoing awareness programmes or other forms of guidance given to all those stakeholders involved in rendering, *feed* production, transport, storage, distribution, sale and feeding under the scope of the *feed* ban. Provide examples of communication materials including publications, brochures and pamphlets.

vi) Monitoring and enforcement of the feed ban-

Describe how the feed ban, if implemented, has been and continues to be monitored and enforced. Provide information on:

- official oversight from the Veterinary Authority, other Competent Authority or a<u>n approved</u> third party;
- training and accreditation programmes for inspectors;
- the planned frequency of inspections; and the procedures involved including manuals and inspection forms;
- sampling programmes and *laboratory* testing methods used to check the level of compliance with the feed ban and cross-contamination;
- options available to deal with infractions (non-compliances) such as recalls, destruction and monetary penalties.

Provide information on the ongoing results of the official inspection programme for each of the preceding eight years, using tables as appropriate:

- planned versus actual delivery inspections at rendering facilities, feed mills, farms, etc., with an
 explanation of any significant variance variation and how they it may have impacted the programme;
- number and type of samples taken during inspections to verify that ruminant feed does not contain
 or is not <u>cross_cross-</u>contaminated with rendered products containing ruminant material (excluding
 those listed in Article 11.4.1bis.). Provide information by year, by source (rendering facility, feed mill or
 farm), indicating the *laboratory* test(s) used and the results obtained;
- the types of infractions (non-compliance) that occurred and corrective actions undertaken;
- any infractions (non-compliances) that were likely to have led to <u>cattle bovines</u> being exposed to feed contaminated with ruminant material (excluding those listed in Article 11.4.1.bis) and how they were resolved.

- vii) Conclusions for the evaluation of BSE-BSE-specific risk mitigation measures-
 - In evaluating the effectiveness of a feed ban, if implemented, for each of the preceding eight years, consideration needs to be given to:
 - the management of *commodities* listed in point 1 of Article 11.4.14., and the associated likelihood that these materials, or other materials <u>cross cross-</u>contaminated by them, may have entered the animal feed chain;
 - the rendering industry and the associated likelihood that rendered products containing ruminant material may retain BSE infectivity;
 - the feed industry and the associated likelihood that feed for <u>cattle bovines</u> may contain or has been cross-contaminated with ruminant-derived protein mealprotein meal.
 - Given the evaluation of <u>BSE_BSE_specific</u> risk mitigation measures and their enforcement as described above, is the likelihood that, during the preceding eight years, the <u>cattle bovine</u> population has been exposed to <u>cither the</u> classical or atypical BSE <u>agent</u> negligible or non-negligible?
 - Clearly and concisely describe the rationale leading to the conclusion reached.
 - Where the likelihood estimate is negligible, proceed to Section 4) Risk estimation.
 - Where the likelihood estimate is non-negligible, proceed to Section 3) Consequence assessment.

3.) <u>Consequence assessment (point 1 c) of Article 11.4.2.)</u>

While uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated feed, it is reasonable to assume for the purposes of a consequence assessment, that the likelihood of cattle becoming infected would be similar to that for classical BSE.

As described in Article 11.4.2., a consequence assessment evaluates the likelihood of <u>cattle_bovines_becoming</u> infected following exposure to the <u>classical_BSE</u> agent<mark>s</mark> (classical or atypical) together with the likely extent and duration of any subsequent recycling and amplification.

For the purposes of undertaking a consequence assessment for the evaluation of BSE risk status, the period of interest is the preceding eight years.

Considering that, for all practical purposes, oral exposure to contaminated *feed* is the principal, if not the only, route of transmission of the the classical BSE agents, to initiate a cycle of BSE infectivity within a cattle bovine population the following series of events would need to unfold:

- commodities listed in point 1 of Article 11.4.14. from an infected animal are included in raw materials that are rendered into ruminant-derived protein mealprotein meal;
- the rendering process does not destroy <u>BSE</u>infectivity of the BSE agent(s);
- the ruminant-derived protein mealprotein meal is incorporated as an ingredient in cattle bovine feed, or cattle bovine feed is cross-contaminated during feed production, distribution and storage, or cattle bovines are incorrectly fed with feed intended for non-ruminant species that includes the ruminant-derived protein mealprotein meal as an ingredient;
- one or more animals that ingest contaminated feed become infected;
- the infected animal survives long enough to reach the later stages of a protracted incubation period when the levels of the <u>classical</u>BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically;

 commodities listed in point 1 of Article 11.4.14. are then included in raw materials that are rendered into ruminantderived protein meal<u>protein meal</u>, completing one cycle.

Recycling arises when this cycle is repeated one or more times. Any level of recycling within a given period is sufficient to conclude that the consequences of exposure to contaminated *feed* for that period within the <u>cattle bovine</u> population are non-negligible.

- a) Factors to consider when evaluating the likely extent of recycling of the <u>classical_BSE</u> agents within a cattle <u>bovine</u> population:
 - i) Age at exposure.

Animals less than 12 months of age are considered to be much more susceptible to *infection* than older animals, which are likely to be increasingly refractory to *infection* as they mature.

- ii) Production type.
 - Calves reared as replacement animals for the breeding herd-

Cattle-Bovines exposed to the classical BSE agents at less than 12 months of age and destined to enter the breeding *herd* are much more likely to become infected and survive long enough to reach the later stages of a protracted incubation period when the levels of the classical BSE agent in those commodities listed in point 1 of Article 11.4.14. would begin to rise dramatically. If these materials were rendered and subsequently contaminated cattle bovine feed, it is highly likely that some level of recycling would occur.

Feedlot-cattle bovines.

Even if <u>cattle_bovines</u> reared in a feedlot that were destined to be slaughtered within the next two to six months were to become infected after consuming contaminated *feed*, the likelihood that they would have reached the later stages of a protracted incubation period (when the levels of the <u>classical_BSE</u> agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically) would essentially be negligible.

Considering that mature <u>cattle bovines</u> are likely to be much more refractory to *infection* than animals within their first year of life, even if they were to consume contaminated *feed*, it is highly unlikely that those *commodities* listed in point 1 of Article 11.4.14. would pose a threat if they were rendered and subsequently contaminated <u>cattle bovine</u> feed.

iii) The impact of livestock industry practices or the implementation of measures under a feed ban-

When evaluating the potential for the recycling of the <u>classical_BSE</u> agent<mark>s</mark> in <u>within</u> the <u>cattle_bovine</u> population where an infraction (non-compliance) has occurred that may have led to feed being crosscontaminated, it is important to consider the impact of both the livestock industry practices and the ongoing measures under a feed ban. Even if an infraction that arose several years ago led to susceptible young animals becoming infected, in evaluating the likelihood of recycling in future years, consideration would need to be given to the effectiveness of the feed ban in subsequent years or whether or not any changes to livestock industry practices may have influenced the exposure risk.

b) Conclusions for the consequence assessment-

Where the outcome of the evaluation of livestock industry practices or the evaluation of <u>BSE_BSE_specific</u> mitigation measures, that include the nature and scope of the *feed* ban and its enforcement, has concluded that there was a non-negligible likelihood that the <u>cattle bovine</u> population has been exposed to the <u>classical</u> BSE agents, what is the likelihood that they have been recycled within the <u>cattle bovine</u> population during the preceding eight years?

Clearly describe the rationale leading to the conclusions reached.

4.) Risk estimation (point 1 d) of Article 11.4.2.)

As described in Article 11.4.2., risk estimation combines the results and the conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk that of the classical BSE agents have been being recycled in within the cattle bovine population through the feeding of ruminant-derived protein meal.

- a) Provide a summary of the entry and exposure assessments and the conclusions reached.
- b) If applicable, provide a summary of the consequence assessment, and the conclusions reached.
- e) When the condition of point 1 of Article 11.4.3. has not been met, that is, it cannot be demonstrated that for at least eight years the risk that the BSE agents have been recycled in the cattle population has been negligible, provide an explanation for the period of time within the preceding eight years for which it can be considered that the risk has been negligible. Clearly Indicate the period of time fordate from which it can be considered that the risk of classical BSE agents being recycled in within the cattle bovine population has been negligible. Provide explanations and clearly describe the rationale leading to the conclusions reached.

Article 1.8.6.

BSE sSurveillance (point 2 of Article 11.4.3.)

Article 11.4.18. describes the criteria that underpin a credible *surveillance* programme, together with an overview of the range and progression of clinical signs that <u>cattle bovines</u> affected by BSE are likely to exhibit.

Requirements under point 2 of Article 11.4.18. are focused on subsets of the cattle bovine population where disease <u>BSE</u> is more likely to be detected, if it is actually present.

The Member applying for recognition of a negligible or a controlled BSE risk status should submit documentary evidence that the provisions of point 3 of Article 11.4.18. have been effectively implemented.

For the purposes of surveillance, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.).

Animals that lie on the continuum <u>show symptoms signs</u> of the <u>clinical</u> disease spectrum <u>of BSE</u> (i.e. from clinically ill to non-ambulatory to fallen stock) should be targeted for BSE surveillance and <u>should</u> include those animals described in points 2(a) to 2(d) of Article 11.4.18.

1.) Awareness and training programmes (point 3 a) of Article 11.4.18.)

Ongoing awareness and training programmes are essential to ensure that all stakeholders are familiar with clinical signs suggestive of BSE (those described in point 1 of Article 11.4.8.) as well as their statutory reporting requirements.

- a) Describe the stakeholder groups targeted for BSE awareness and training programmes. Describe the methods used to identify stakeholder groups within the jurisdiction and methods used to identify how, for example, the size and characteristics of the stakeholder group changes over time.
- b) Describe the type(s) of awareness and training programmes implemented for specific stakeholder groups. Describe how these programmes are adapted to meet the specific obligations and activities of each stakeholder group by those involved in caring for livestock, as well as the protocols for sample collection and submission by veterinarians and animal health technicians).
- c) Provide information on the number of awareness and training activities, the stakeholder groups targeted, the number of individuals reached per activity (if available), and the geographic<u>al</u> coverage for of these activities.
- d) Provide a description including examples of materials used in the awareness programme including such as training manuals, supporting documents such as publications in local newspapers and farming magazines,

pamphlets and videos (weblinks to supporting documents in one of the WOAH official languages may also be provided, where they exist).

- e) Provide details on how the effectiveness of the awareness and training programmes is evaluated.
- f) Provide details of any contingency or preparedness plan for BSE.

2.) <u>Compulsory notification BSE reporting system (point 3 b) of Article 11.4.18.)</u>

To ensure the reporting and further investigations of any animals that lie on the continuum <u>show symptoms signs</u> of the <u>clinical BSE</u> spectrum <u>of BSE</u>, appropriate legislation, policies and incentives to support compulsory notification, investigation and verification should be in place.

- a) Indicate <u>whether Describe the BSE reporting system, including</u> the date of implementation of any supporting legislation and associated policies making <u>BSE a notifiable disease</u> notification of <u>BSE compulsory</u>. Indicate if a definition for a <u>"suspicion of BSE suspect"</u> exists. If appropriate, outline relevant legislation in the table under Article 1.8.3.
- b) Describe the supportive measures in place for notification of <u>targeting</u> animals that <u>lie on the continuum show</u> <u>symptoms</u> signs of the <u>clinical BSE</u> spectrum <u>of BSE and for reporting of animals described in points 2 a) to 2 d)</u> <u>of Article 11.4.18.</u>, such as incentives, compensations or penalties.
- c) Describe the guidance given to all stakeholders involved in the rearing and production of livestock including farmers, herdsmen, <u>cattle-bovine breeders</u>, owners and keepers, veterinarians, transporters, <u>and</u> workers at livestock markets, auctions and slaughterhouses/abattoirs in terms of the criteria for reporting animals that lie on the continuum <u>show symptoms signs</u> of the <u>clinical</u> BSE spectrum <u>of BSE</u>. What mechanisms are in place to ensure that these guidelines reach those stakeholders?
- d) Describe the <u>evaluation of the</u> reporting <u>system</u> framework for animals that lie on the continuum <u>show</u> <u>symptoms</u> <u>signs</u> of the <u>clinical</u> BSE spectrum <u>of BSE</u> for evaluation. Has this framework-reporting system</u> evolved over time and, if so, how?

3.) Laboratory testing (point 3 c) of Article 11.4.18.)

Provide documentary evidence that the relevant provisions of Chapter 3.4.5. of the *Terrestrial Manual* are applied, including the following:

- a) If BSE samples are submitted to <u>a laboratory laboratories</u> in the country or zone for testing, provide an overview of how many are involved in testing BSE samples, how they are approved or certified, their number, location and diagnostic procedures and the time frame for reporting results.
- b) If the BSE samples are not submitted to <u>a-laboratoryies</u> in the country or <u>zone</u> for testing, or <u>if</u> suspicious or positive samples are referred to <u>a laboratory laboratories</u> outside the country, provide the names of the laboratories <u>in other countries</u> providing the service, as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.
- c) Describe the diagnostic protocol and tests used for processing samples for elassical and atypical BSE and how they may have evolved over time, indicating: what is the primary test used?; what would be the series of secondary tests performed, if any, depending on the results of the primary test (i.e. negative, positive and inconclusive)?; and what test would be undertaken if discordant results arise between primary and secondary tests arise (e.g. primary positive result followed by a secondary negative result)?; and tests undertaken to discriminate classical BSE from atypical BSE.
- 4-<u>)</u> Evaluation procedures and protocols to identify and report potential candidates animals targeted for BSE surveillance, to determine animals to be subjected to laboratory testing, to collect and submit samples for laboratory testing, and to follow up BSE positive findings with epidemiological investigation BSE positive findings (point 3 d) of Article 11.4.18.)

Because <u>Given that</u> the incidence of BSE is likely to be very low in Member Countries it is important that *surveillance* efforts focus on subsets of the <u>cattle bovine</u> population where disease is more likely to be detected, if it is actually present. Hence, those animals described in points 2(a) to 2(d) of Article 11.4.18. must be targeted for BSE surveillance.

Considering that BSE is a progressive disease and that animals to be included in the *surveillance* programme may arise at the farm, the *slaughterhouse/abattoir*, or during transportation, procedures and protocols should be in place covering all points in the livestock production chain for: (1) the identification and reporting of animals potentially lying on the continuum showing symptoms signs of the clinical BSE-spectrum of BSE (e.g. by the farmer breeder, owner or keeper, animal handler, veterinarian, etc.); (2) the criteria to determine which of these reported animals need to be reported and tested for BSE (e.g. the criteria used by the veterinarian that allows the discrimination of reported animals subject to laboratory testing); (3) the collection and submission of samples for testing in a laboratory; and (4) a follow-up epidemiological investigation for BSE positive findings.

It is important that appropriate procedures and protocols are in place to ensure that BSE can be definitively ruled out on the list of differential diagnoses.

- List the common <u>cattle bovine</u> disorders with clinical signs compatible with BSE in the country or *zone*. If available, provide the incidence/prevalence of these disorders, ideally by production system (e.g. dairy, beef) and by age group.
- b) Describe the procedures and protocols in place for reporting animals potentially lying on the continuum showing symptoms signs of the clinical_BSE spectrum of BSE (those described in points 2 a) to 2 d) of Article 11.4.18.) to the Competent Authority. For example, these procedures and protocols may include the steps that a farmer breeder, owner or keeper may follow once an animal with clinical signs suggestive of BSE is identified. These procedures and protocols should cover the clinical continuum of the disease spectrum ranging from clinical suspects to non-ambulatory to fallen stock.
- c) Describe the procedures and protocols in place for the investigation of reported animals potentially lying on the continuum showing symptoms signs of the clinical BSE spectrum of BSE (those described in points 2(a) to 2(d) of Article 11.4.18.) that allow the discrimination of reported animals to be subjected to laboratory testing. For example, these procedures and protocols may include the range of clinical signs to be considered, and how the age, the clinical history of the animal and epidemiological data of the herd are taken into account. An evaluation procedure may, for example, be in the form of a protocol, a checklist or a decision tree, and should cover the clinical continuum of the disease spectrum ranging from clinical suspects to non-ambulatory to fallen stock.
- d) Describe the methods applied to assess the age of animals investigated, such as individual identification or dentition.
- e) Describe the procedures and protocols for the transport of live or dead animals for sampling, and transfer of samples to laboratories for testing, including details of the <u>cattle bovine</u> identification system, the maintenance of the chain of custody of the carcass and the samples, and the reconciliation of samples with the animals they were collected from.
- f) Provide the procedures and protocols for a follow-up epidemiological investigation of BSE positive results.
- g) Provide a summary table for each <u>of the preceding eight</u> years (Table 1) of the number of animals reported and the number of animals subjected to BSE testing for each clinical presentation (those in points 2 a) to 2 d) of Article 11.4.18.).

Table 1.
Year:
Table 1 - Summary of all animals that were reported and evaluated for testing by the Veterinary Authority

Clinical presentation (see point 2 of Article 11.4.18.)	Number of reported animals	Number of animals subjected to BSE testing
(A) <u>Cattle-Bovines</u> displaying progressive behavioural or neurological signs suggestive of BSE that are refractory to treatment		
(B) <u>Cattle Bovines</u> showing behavioural or neurological signs that did not pass the ante- mortem inspection at slaughterhouses/abattoirs		
(C) <u>Cattle Bovines presented as downers (non-ambulatory) with an appropriate supporting clinical history</u>		
(D) <u>Cattle-Bovines</u> found dead (fallen stock) with an appropriate supporting clinical history		

5.) Animals subjected to laboratory testing

a) Provide in Table 2<u>, for each of the preceding eight years</u>, details of all animals <u>counted in Table 1</u> that were subjected to laboratory testing (see point 2 of Article 11.4.18.).

Table 2. Details of the animals that were subjected to laboratory testing-									
Year notified	Laboratory identification number or individual identification number	Age (in months) at <u>the</u> <u>time of</u> <u>reporting</u> first detection	Type of productio n system (dairy, beef, mixed, etc.)	Description of observed clinical signs	Clinical presentation (A, B, C or D)	Final diagnosis (if BSE, specify the strain if C, L <u>or H type</u>)	For a <u>case</u> of BSE case, indicate the origin (indigenous or imported; if imported, indicate the country of birth)		

<u>Article 1.8.6bis.</u>

History of occurrence and management of BSE in the country or zone (points 3 and 4 of Article 11.4.3.)

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

- 1) If a case of BSE has ever been diagnosed in the country or zone, indicate the total number of cases of BSE, and:
 - a) <u>Provide a table of aggregated data on all cases of BSE encountered in the country or zone, origin (indigenous</u> or, if imported, the country of origin), and the year of birth;
 - b) For the past eight years, provide a table to indicate, for each case, the year of occurrence, the origin (indigenous or, if imported, the country of origin), and the year of birth of each indigenous case.

2) If there have been cases of BSE or bovines affected by atypical BSE, confirm that they were completely destroyed or disposed of to ensure they are excluded from the feed chain and describe how this was achieved. In the table under Article 1.8.2. provide details of the national legislation, regulations and Veterinary Authority directives that describe these procedures.

Article 1.8.7.

Recovery Maintenance of BSE risk status

Following the occurrence of an indigenous case of classical BSE in an animal <u>bovine</u> born within the preceding eight years <u>after the date from which the risk of BSE agents being recycled within the <u>cattle</u> bovine population has been negligible <u>occur</u> in a <u>country or zone with a</u> negligible <u>or controlled</u> BSE risk status of a <u>country or zone</u>, the outcome of the investigation together with any additional measures implemented that confirm or ensure that the risk of BSE <u>agents</u> being recycled within the <u>cattle bovine</u> population continues to be negligible should be provided with reference to the provisions in Article 1.8.5. as appropriate. Information in relation to other sections need to only be supplied if relevant.</u>

Annex 14

CHAPTER 12.2.

INFECTION WITH TAYLORELLA EQUIGENITALIS (CONTAGIOUS EQUINE METRITIS)

Article 12.2.1.

General provisions

This chapter addresses the occurrence of clinical or asymptomatic infection of a mare caused by Taylorella equigenitalis as well as the presence of *T. equigenitalis* on the genital mucous membrane surface in the male horse.

For the purposes of the Terrestrial Code, the following defines infection with T. equigenitalis:

- 1) T. equigenitalis has been isolated and identified as such from a genital swab sample from a horse; or
- 2) <u>nucleic acid specific to T. equigenitalis has been identified detected</u> in a sample from a horse; or
- 3) antigen or genetic materialantigen specific to *T. equigenitalis* has been identified detected in a sample from a mare horse showing clinical or pathological signs consistent with infection with *T. equigenitalis*, or epidemiologically linked to a confirmed or suspected case of infection with *T. equigenitalis*;
- 3) genetic material specific to T. equigenitalis has been identified in a sample from a male horse.

For the purposes of the Terrestrial Code:

- due to long-term persistence of *T. equigenitalis* in horses, in the absence of effective treatment, the infective period shall be lifelong;
- the incubation period in mares shall be 14 days.

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

For the purposes of this chapter, a temporary importation refers to the introduction of horses into a country or *zone*, for competition or cultural events excluding breeding, for a defined period of time, not exceeding 90 days, during which the *risk* of transmission of the *infection* is mitigated through specific measures under the supervision of the *Veterinary Authority*. Temporary imported horses are re-exported at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or *zone*, should be defined in advance.

When authorising <u>the</u> importation or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 12.2.2., Veterinary Authorities should require the conditions prescribed in this chapter relevant to the *T.* equigenitalis status of the exporting country, zone or establishmentherd.

Article 12.2.2.

Safe commodities

When authorising import<u>ation</u> or transit of the following commodities, Veterinary Authorities should not require any *T*. equigenitalis-related conditions, regardless of the \overline{T} . equigenitalis infection animal health status of the animal population of the exporting country, zone or establishmentherd:

- 1) geldings;
- 2) milk and milk products;
- 3) meat and meat products;
- 4) hides and skins;
- 5) hooves;
- 6) gelatine and collagen.

Article 12.2.3.

EstablishmentHerd free from infection with T. equigenitalis

1) <u>Prerequisite</u>

Infection with T. equigenitalis has been a notifiable disease in the entire country for at least the past two years.

2) Qualification

To qualify as free from infection with T. equigenitalis, an establishment <u>herd</u> should satisfy the following conditions:

- a) it is under the control of the Veterinary Authority;
- b) no case has occurred for at least two years;
- c) all horses from the <u>establishmentherd</u> have been subjected to *T*. equigenitalis tests, with negative results, <u>on</u> <u>samples collected</u> <u>These tests should have been carried out</u> on three occasions; within a 12-day period, with an interval of no less than three days apart-between each <u>tests</u> sample collections</u>. Horses must have not been treated with antibiotics <u>for at least 7 days prior to the first sampling</u>, <u>nor subjected to antiseptic washing of genital mucous membrane</u> for at least 21 days before prior to the <u>first sampling</u>;
- d) <u>any</u> stored semen was subjected to a test <u>for detection of genetic materialnucleic acid of to detect</u>-*T*. equigenitalis with negative results, carried out on an aliquot of the stored semen.
- 3) Maintenance of freedom
 - a) <u>the</u> requirements in points 1-and, 2(a) and 2(b) of Article 12.2.3. are met;
 - b) appropriate *surveillance*, capable of detecting *infection* with *T. equigenitalis* even in the absence of clinical signs, is in place; this may be achieved through a *surveillance* programme in accordance with Chapter 1.4. and this chapter;
 - c) the introduction of horses and their germplasm germinal products into the establishment<u>herd</u> is carried out in accordance with the importation conditions for these commodities listed in this chapter.

4. Recovery of freedom

When a case is detected in a previously free establishment<u>herd</u> the free status of the establishment should be suspended until the following conditions are metin the affected establishment:

- a) the disinfection of the establishment has been applied;
- b) <u>not before</u>21 days after the last removal or the last treatment of an infected horse, all horses have been subjected to a T. equigenitalis test <u>for the detection of the agent</u>, with negative results, on <u>samples collected on</u>

three occasions, within a 12-day period with an interval of no less than three days apart-between cach testssample collections;

- c) any fresh semen from all infected horses in the herd has been destroyed; aliquots of each collection of stored semen from all infected horses in the herd was were subjected to a test to detect for detection of genetic materialnucleic acid of *T*. equigenitalis with negative results in accordance with Article 12.2.8., carried out on an aliquot of the stored semen; and all positive stored semen has been destroyed;
- d) the introduction of horses and their germplasm germinal products into the establishment<u>herd</u> is carried out in accordance with the importation conditions for these commodities listed in this chapter.

Article 12.2.4.

Recommendations for importation of stallions or mares

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

1) mares showed no clinical sign of *infection* with *T. equigenitalis* on the day of shipment;

AND

- 2) horses have been kept in an establishment:
 - a) <u>kept since birth or for at least two years prior to shipment in an establishmentherd</u> that has been free from infection with *T. equigenitalis* since birth or for at least two years prior to shipment;

OR

- b)
- i) <u>kept for at least the last 60 days in an establishmentherd</u> in which no case has been reported during <u>that</u> <u>period the 60 days prior to shipment;</u>

AND

ii) were-subjected to tests for the detection of the agent *T*. equigenitalis tests, with negative results, carried out on samples collected on three occasions, within a 12-day period, with an interval of no less than three days apart-between each testssample collections, being the last testone being carried out within the 30 days prior to shipment. Horses must not have not been treated with antibiotics for at least 21-17 days nor subjected to antiseptic washing of genital mucous membranes for at least 21 days prior to the first sample collection, ing and have not been mated or inseminated after the first sampling.

Article 12.2.5.

Recommendations for temporary importation of stallions and maresorses

When importing on a temporary basis <u>stallions or mares</u> horses that do not comply with recommendations in Article 12.2.4. for purposes <u>different other</u> than breeding and rearing, *Veterinary Authorities* should:

- 1) require:
 - a) the <u>animalshorses</u> <u>to</u> be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status *subpopulation* as defined in Chapter 4.17.;
 - b) the presentation of an international veterinary certificate attesting that the mares showed no clinical sign of infection with *T. equigenitalis* on the day of shipment;

- c) the duration of the temporary importation period and, the destination after this period, and the conditions required to leave the country or zone $\frac{1}{100}$ be defined;
- 2) ensure that during their stay in the country or *zone*, the animalshorses:
 - a) are not used for breeding (including artificial insemination, semen collection, used as teaser<u>s</u>-stallions) and do not have any sexual contact with other horses;
 - b) do not undergo any genital examinationsare not subjected to any practice that may represent a risk of transmission of infection with *T. equigenitalis*;
 - c) are kept and transported individually in stalls and *vehicles/vessels* which are subsequently cleaned and disinfected before re-use.

Article 12.2.6.

Recommendations for importation of semen of from horsesstallions

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

1) semen was collected in an *approved* centre and collection, processing and storing <u>was were</u> done in accordance with Chapter 4.6; and

EITHER

2) the donor stallion was kept in an establishment<u>herd</u> free from infection with T. equigenitalis;

OR

3)

- a) the donor stallion was kept <u>for at least 60 days prior to semen collection</u> in an <u>establishmentherd</u> in which no case has been reported during <u>that period</u> the 60 days prior to semen collection; and
- b) the donor stallion was subjected to <u>tests for the detection of the agent T. equigenitalis tests</u>, with negative results, <u>carried out</u> on <u>samples collected on</u> three occasions, within a 12-day period with an interval of no less than three days apart between cach <u>tests</u> ample collections</u>, being the last <u>testone</u> <u>being</u> carried out within the 30 days prior to shipment. The donor stallion must not have been treated with antibiotics for at least 21 days prior to sampling Horses have not been treated with antibiotics for at least <u>21-7</u> days <u>nor subjected to antiseptic</u> washing of genital mucous membranes for at least 21 days prior to the first sample collection, and have not been mated <u>or inseminated</u> after the first sampling;

OR

aliquots of fresh semen were subjected to culture and a test for detection of genetic material<u>nucleic acid</u> for of *T*. equigenitalis with negative results, carried out immediately prior to processing and on an aliquot of semen collected within 15-to_30 days after the first collection of the semen to be exported;

OR

5) aliquots of frozen stored semen corresponding to the carliest oldest and the most recent collection were subjected to culture and a test for detection of genetic materialnucleic acid for *T. equigenitalis* with negative results.

Article 12.2.7.

Recommendations for importation of oocytes or embryos of horses

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- 1) the oocytes and embryos were collected, processed and stored in *approved* centres following the general provisions in accordance with Chapters <u>4.8</u>, 4.9. and 4.10.;
- 2) the donor mare showed no clinical signs of infection with T. equigenitalis on the day of collection;

AND

for the importation of embryos:

3) the semen used for embryo production complied with <u>Article 12.2.6. and</u> Chapters 4.6. and 4.7.

Article 12.2.8.

Surveillance

1) <u>General principles of surveillance</u>

Surveillance for infection with *T.* equigenitalis is relevant for establishments seeking to achieve and demonstrate freedom from infection, as well as <u>being</u> part of an official control programme in countries where the disease is endemic.

The surveillance strategy chosen should be adequate to detect the infection with *T. equigenitalis* even in the absence of clinical signs.

The Veterinary Services should implement programmes to raise awareness among farmers owners, breeders and workers who have day-to-day contact with horses, as well as veterinarians, veterinary paraprofessionals and diagnosticians, who should report promptly any suspicion of infection with *T. equigenitalis* to the Veterinary Authority.

Under the responsibility of the Veterinary Authority, Member Countries should have in place <u>an early warning system</u> in accordance with Article 1.4.5. and <u>+</u>

- a) a formal and ongoing system for detecting and investigating cases;
- b) a procedure for the rapid collection and transport of samples from suspected cases to a laboratory for diagnosis;
- e) a system for recording, managing and analysing diagnostic and surveillance data.
- 2) <u>Clinical surveillance</u>

Clinical surveillance aims at detecting clinical signs by close physical examination of horses and based on reproduction reproductive performance. However, clinical surveillance should be complemented by <u>culture for T.</u> <u>equigenitalis</u> <u>bacteriological</u> and molecular <u>teststesting</u>, as asymptomatic carriers play an important role in the maintenance and transmission of the *infection*.

3) Agent surveillance

An active programme of *surveillance* of horses to detect cases should be implemented to establish the status of a country, *zone* or *establishment<u>herd</u>*. Culture for *T. equigenitalis* and molecular testing are the most effective methods of detection of <u>the a</u> case.

Stored semen should be included in *surveillance* programmes. It represents a valuable source of material and may be very helpful in contributing to retrospective studies, including providing support for claims of freedom from *infection* and may allow certain studies to be conducted more quickly and at lower cost than other approaches. Samples can be gathered through representative sampling or following a *risk*-based approach.

4) <u>Serological surveillance</u>

Serological *surveillance* is not the preferred strategy for detecting *T. equigenitalis.* If used, serology should be <u>used</u> <u>done</u> in conjunction with <u>agent identification culture</u> in assessing the status of a mare that may have been infected with *T. equigenitalis.* The usefulness of serological tests is further described in the *Terrestrial Manual*.

CHAPTER 12.6.

INFECTION WITH EQUINE INFLUENZA VIRUS

Article 12.6.1.

General provisions

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an *infection* of domestic <u>and captive wild</u> equids <u>with equine influenza virus (EIV), i.e. subtypes H3N8 and H7N7 of influenza A viruses (H7N7 and H3N8).</u>

This chapter deals not only with the occurrence of clinical signs caused by <u>infection with</u> equine influenza virus (EIV), but also with the presence of infection with EIV in the absence of clinical signs.

The following defines the occurrence of infection with EIV:

- 1) <u>EIV, excluding modified-live virus vaccine strains following recent vaccination, has been isolated and identified as</u> such from in a sample from a domestic or captive wild equid; or
- <u>antigen or ribenucleic acid or antigen specific to EIV has been detected in a sample from a domestic or captive wild equid showing clinical signs or pathological lesions suggestive of consistent with equine influenza, or epidemiologically linked to a confirmed or suspected or confirmed case of equine influenza; or</u>
- 3) seroconversion due to recent exposure to EIV virus, demonstrated by a significant increase in antibody titres which arewhich is not the consequence of vaccination, have has been detected in paired samples from a domestic or captive wild equid showing clinical signs or pathological lesions consistent with suggestive of consistent with equine influenza, or epidemiologically linked to a confirmed or suspected or confirmed case of infection with EIV.

For the purposes of this chapter, isolation is defined as 'the separation of domestic equids from domestic equids of a different EI health status, utilising appropriate *biosecurity* measures, with the purposes of preventing the transmission of infection'.

For the purposes of the Terrestrial Code, the infective period for El shall be 21 10 days.

For the purposes of this chapter, a temporary importation refers to the introduction of horses into a country or zone, for a defined period of time, not exceeding 90 days, during which the *risk* of transmission of the *infection* is mitigated through specific measures under the supervision of the Veterinary Authority. Temporarily imported horses are re-exported at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or zone, should be defined in advance.

When authorising <u>the</u> importation or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 12.6.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the El status of the equine population of the exporting country, zone or compartment.

Standards for diagnostic tests and vaccines are described in the Terrestrial Manual.

Article 12.6.2.

Safe commodities

When authorising <u>the</u> import<u>ation</u> or transit of the following commodities, Veterinary Authorities should not require any EIV-related conditions, regardless of the $El \frac{animal health}{b}$ status of the equine <u>animal population of</u> the exporting country, zone or compartment:

- 1) equine semen;
- 2) *in vivo* derived equine embryos collected, processed and stored in accordance with Chapters 4.8. and 4.10., as relevant; (under study).
- 3) <u>meat and meat products from equids that have been slaughtered in a slaughterhouse/abattoir and have been</u> subjected to ante- and post-mortem inspections with favourable results.

Article 12.6.3.

Determination of the El status of a country, a zone or a compartment

The El status of a country, a zone or a compartment can be determined on the basis of the following criteria:

- 1) the outcome of a *risk* assessment identifying all risk factors and their historic relevance;
- 2) whether El is notifiable in the whole country, an ongoing El awareness programme is in place, and all notified suspect occurrences of El are subjected to field and, where applicable, *laboratory* investigations;
- 3) appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in domestic <u>and captive wild</u> equids.

Article 12.6.4.

El free eCountry, zone or compartment free from El

A country, zone or compartment may be considered free from El provided the disease that infection with EIV is notifiable in the whole country and it shows evidence, through an effective surveillance programme, planned and implemented in accordance with the general principles in Chapter 1.4., that no case of El infection with EIV occurred in the past two years. The surveillance may need to be adapted to parts of the country, zone or compartment depending on historical or geographical factors, industry structure, population data, movements of equids within and into the country, zone or compartment, wild equine populations or proximity to recent outbreaks.

A country, *zone* or *compartment* seeking freedom from EI, in which *vaccination* is practised, should also demonstrate that EIV has not been circulating in the population of domestic, <u>captive wild</u>, feral, and wild equids during the past 12 months, through *surveillance*, in accordance with Chapter 1.4.

In a country in which vaccination is not practised, surveillance may be conducted using serological testing alone. In countries where vaccination is practised, the surveillance should include agent identification methods described in the *Terrestrial Manual* for evidence of infection.

A country, *zone* or *compartment* seeking freedom from El should apply appropriate movement controls to minimise the risk of introduction of EIV in accordance with this chapter <u>and should be in accordance with relevant requirements and principles described in Chapter 4.4. and Chapter 4.5.</u>

If an outbreak of clinical El occurs in a previously free country, zone or compartment, free status can be regained 12 months after the last clinical case, providing that surveillance for evidence of infection has been carried out during that twelvemonth period in accordance with Chapter 1.4.

Article 12.6.4bis.

Recovery of free status

If a case of infection with EIV occurs in a previously free country, zone or compartment, free status can be regained 12 months after the last case, provideding that outbreaks were managed in accordance with Chapter 4.19. and that surveillance, in accordance with Chapter 1.4. Article 12.6.4., has been carried out during that 12-month period, with negative results.

Article 12.6.5.

Recommendations for the importation of domestic and captive wild equids for immediate slaughter

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the domestic and or captive wild equids showed no clinical sign of El on the day of shipment.

Article 12.6.6.

Recommendations for the importation of domestic and captive wild equids for unrestricted movement

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the domestic <u>or captive wild</u> equids :

came from an El free country, zone or compartment in which they had been resident for at least 21 10-14 days; in the case of vaccinated domestic equids, information on their vaccination status should be included in the veterinary certificate;

OR

2) <u>a) came from a country, zone or compartment not known to be free from El</u>, were subjected to pre-export isolation for 21 <u>10 14</u> days and showed no clinical sign of El during isolation nor on the day of shipment; <u>and</u>

<u>AND</u>

- 3b) were immunisedvaccinated in accordance with the recommendations of the manufacturer with a vaccine complying with the standards described in the *Terrestrial Manual* and considered effective against the epidemiologically relevant virus strains, between 21 and 90 days before shipment either with a primary course or a booster; information on their vaccination status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12 in accordance with one of the following procedures:
 - ai) between 14 and 90 days before shipment either with either a primary course or a booster; or
 - bii) between 14 and 180 days before shipment, if they are older than four years of age, previously having received up to the date of this pre-shipment vaccination, at least four doses of the same vaccine at intervals not greater than 180 days.

Information on the vaccination status should be included in the international veterinary certificate or the passport in accordance with Chapter 5.12. as relevant.

For additional security, c<u>C</u>ountries that are free of <u>from</u> El or undertaking an eradication programme may also request that the equids were tested negative for EIV bysubjected to an agent identification test for El described in the *Terrestrial Manual* with negative results, conducted on samples collected on two occasions, at 7 to 14 days<u>four to six days after</u> <u>commencement of pre-export isolation</u> and less than 5 prior to within four days before of prior to shipment.

Article 12.6.7.

Recommendations for the <u>temporary</u> importation of <u>domestic</u> equid which will be kept in isolation (see Article 12.6.1.) <u>horses</u>

<u>If the importation of horses on a temporary basis does not comply with the recommendations in Article 12.6.6.</u>, Veterinary Authorities <u>of importing countries</u> should require the presentation of an *international veterinary certificate* attesting that the domestic equids:

- 1) require that:
 - a) that the horses be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status *subpopulation* as defined in Chapter 4.17.;
 - b) the presentation of an international veterinary certificate attesting that the horses:
 - time from an El free-country, zone or compartment free from El, in which they had been resident for at least 24 14 days; in the case of a vaccinated domestic equid horses, information on its their vaccination status should be included in the veterinary certificate;

OR

- 2<u>ii</u>) showed no clinical sign of El in any premises in which the domestic equids <u>horses</u> had been resident for the 21 14 days prior to shipment nor on the day of shipment; and
- 3<u>iii</u>) were immunised in accordance <u>vaccinated</u> with the recommendations of the manufacturer with a vaccine complying with the standards described in the *Terrestrial Manual*; information on their vaccination status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12.;
- 2) <u>ensure that during their stay in the country or zone domestic equids horses are kept separated from domestic and captive wild equids of a different El health status through appropriate *biosecurity*.</u>

Article 12.6.8.

Recommendations for the importation of fresh meat of equids

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the fresh meat came from equids which had been subjected to ante- and post-mortem inspections as described in Chapter 6.3.

CHAPTER 12.7.

EQUINE PIROPLASMOSIS <u>INFECTION WITH *THEILERIA</u> <u>EQUI AND BABESIA CABALLI</u> (EQUINE PIROPLASMOSIS)</u>*

Article 12.7.1.

General provisions

The infection with use of the term equine piroplasmosis indicates clinical diseases caused by the transmission of Theileria equi (T. equi) or Babesia caballi (B. caballi) established after transmission of these pathogenic agents through competent ticks or iatrogenic practices may be asymptomatic or may cause a clinical disease known as equine piroplasmosis. Vertical transmission from mares to foals has also been reported. This chapter deals not only with the occurrence of clinical disease signs caused by infection with T. equi or B. caballi, but also with asymptomatic infections the presence of infection with T. equi or B. caballi, but also with asymptomatic infections.

<u>Susceptible aAnimals for susceptible to infection with T. equi or B. caballi are primarily domestic and wild equids. Although old-world camelids are susceptible to infection and are potential reservoirs, they are not found to play a significant role in the epidemiology of the disease.</u>

Equids infected with *T.* equi or *B.* caballi may remain carriers of these blood parasites for long periods, sometimes lifelong and act as sources of infection for competent tick vectors, including species of the genera Dermacentor, Rhipicephalus, Hyalomma and Amblyomma.

For the purposes of the Terrestrial Code, the following defines infection with T. equi or B. caballi:

- 1) <u>T. equi or B. caballi has been observed and identified as such identification of the parasite by microscopic examination</u> of in a sample from an equid which may be showing clinical or pathological signs consistent with infection with <u>T. equi</u> or <u>B. caballi or epidemiologically linked to a confirmed or suspected case of infection with T. equi or B. caballi; or</u>
- 2) <u>antigen or genetic material nucleic acid specific for to</u> *T. equi or B. caballi* has been identified detected in a sample from an equid which may be showing clinical or pathological signs consistent with infection with *T. equi or B. caballi*, or epidemiologically linked to a confirmed or suspected case of infection with *T. equi or B. caballi*; or
- 3) <u>antibodies specific to T. equi or B. caballi have been identified</u> <u>detected</u> in a sample from an equid <u>which may be</u> <u>showing clinical or pathological signs consistent with infection with T. equi or B. caballi, or epidemiologically linked to</u> a confirmed or suspected case of infection with T. equi or B. caballi.

For the purposes of the Terrestrial Code, the incubation period of infection with T. equi or B. caballi in equids shall be 30 days and the infective period shall be lifelong.

For the purposes of this chapter, a temporary importation refers to the introduction of equidshorses 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 reexported or slaughtered at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or zone, should be defined in advance.

When authorising the importation or transit of the commodities listed in this chapter, with the exception of those listed in Article 12.7.2., Veterinary Authorities should require the conditions prescribed in this chapter relevant to the status of infection with *T. equi* and *B. caballi* of the exporting country or zone.

Standards for diagnostic tests and vaccines are described in the Terrestrial Manual.

Article 12.7.2.

Safe commodities

When authorising importation or transit of the following commodities, Veterinary Authorities should not require any conditions related to conditions related with infection with *T. equi* or *B. caballi*-related conditions, regardless of the infection animal health status of the animal population of the exporting country or zone:

- 1) milk and milk products;
- 2) meat and meat products;
- 3) hides and skins;
- 4) hooves;
- 5) gelatine and collagen;
- 6) <u>semen collected in accordance with the relevant chapters of the Terrestrial Code;</u>
- 7) sterile filtered horse serum;
- 8) embryos collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10.

Article 12.7.3.

Country or zone free from infection with T. equi and B. caballi

- 1) Historical freedom as described in Chapter 1.4. does not apply to infection with T. equi and B. caballi.
- 2) A country or a zone may be considered free from infection with T. equi and B. caballi when:
 - <u>a)</u> <u>infection with T. equi and infection with B. caballi have been notifiable diseases in the entire country for at least the past 10 years and, in the country or zone:</u>

EITHER:

- i) there has been no case of infection with T. equi and no case of infection with B. caballi during the past six years; and
- ii) <u>a surveillance programme performed in accordance with Article 12.7.9. has demonstrated no evidence of infection with T. equi and no evidence of infection with B. caballi infor the past six years and has considered the presence or absence of competent vectors in the epidemiological situation:</u>

OR

- iii) <u>an ongoing surveillance programme performed in accordance with Article 12.7.9. has found no competent</u> <u>tick vectors for at least six years:</u>
- b) importations of equids into the country or zone are is carried out in accordance with this chapter. A country or zone free from infection with T. equi and B. caballi in which an epidemiological investigation has been conducted with favourable results ongoing vector surveillance, performed in accordance with Article 12.7.9., has found no competent tick vector will not lose its free status through the introduction of seropositive or infective

equidshorses were imported temporarily in accordance with Article 12.7.6. will not lose its free status provided an epidemiological investigation demonstrates that there has been no transmission of infection;

<u>c)</u> <u>a country or zone free from infection with T. equi and B. caballi adjacent to an infected country or zone should include a high-risk area in which continuous scrological, agent and vector surveillance is conducted in accordance with Article 12.7.9.</u>

Article 12.7.4.

Recovery of a free status

When infection with T. equi or B. caballi is detected in a previously free country or zone, Article 12.7.3. applies.

Article 12.7.25.

Recommendations for the importation of equines equids

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the animals:

- 1) <u>the animals</u> showed no clinical signs equine piroplasmosis of infection with T. equi or B. caballi on the day of shipment. and
- 2) EITHER:
 - a) the animals were kept in a country or zone free from infection with T. equi and B. caballi since birth;
 - <u>OR</u>
- 2) were subjected to diagnostic tests for equine piroplasmosis (Theileriaequi and Babesia caballi) with negative results during the 30 days prior to shipment;
 - b) i) were subjected to a-serological or-and agent identification tests with molecular techniques for the detection of *T. equi* and *B. caballi* with negative results carried out on a blood sample taken within the 14 days prior to shipment; and
- 3) were maintained free from ticks, by preventive treatment when necessary, during the 30 days prior to shipment.
 - ii) were maintained free from competent ticks in accordance with Article 12.7.7. and not subjected to any practice that may present a risk of iatrogenic transmission of *infection* with *T. equi* or *B. caballi* during the 30 days prior to sampling and after sampling until shipment and throughout the transport to the destination country or zone.; and
 - iii) <u>have not been treated with antiparasitic drugs capable of masking an infection with T. equi and B. caballi,</u> for at least six months prior to sampling.

Article 12.7.36.

Recommendations for the temporary importation of equids horses of competition horses on a temporary basis

Veterinary Authorities of importing countries should consider the possibility of importing competition horses on a temporary basis and which are positive to the testing procedure referred to in point 2) of Article 12.7.2. under the following safeguards:

If the importation of equidshorses on a temporary basis does not comply with the recommendations in Article 12.7.5., *Veterinary Authorities of importing countries should:*

1.1) require that:

- a) the horses are that the animalshorses be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status subpopulation as defined in Chapter 4.17.;
- 2.<u>b)</u> the Veterinary Authorities of importing countries require the presentation of an international veterinary certificate attesting that the <u>animalshorses</u>:
 - a.i) showed no clinical sign of equine piroplasmosis infection with T. equi or B. caballi on the day of shipment;
 - b) were treated against ticks within the seven days prior to shipment;
 - ii) were maintained free from ticks in accordance with Article 12.7.7. during the 30 days prior to shipment and during transport:
- <u>c)</u> <u>that</u> the duration of the temporary importation period and the destination after this period, as well as the <u>conditions required to leave the country or zone, be defined;</u>
- the horses are kept in an area where necessary precautions are taken to control ticks and that is under the direct supervision of the Veterinary Authority;
- 4) the horses are regularly examined for the presence of ticks under the direct supervision of the Veterinary Authority.
- 2) ensure that during their stay in the country or zone:
 - a) the animalshorses are protected from ticks in accordance with Article 12.7.7.;
 - b) <u>equidshorses are examined daily for the presence of ticks of the genera Dermacentor, Rhipicephalus,</u> <u>Hyalomma and Amblyomma with particular attention to the ears, false nostrils, inter-mandibular space, mane,</u> lower body areas, including the axillae, and inguinal region, and the perineum and tail, with negative results;
 - <u>c)</u> <u>the animalshorses are not subjected to any practice that may represent a risk of iatrogenic transmission of infection with *T. equi or B. caballi*.</u>

Article 12.7.7.

Protecting equids from ticks

- 1) <u>Under the direct supervision of the Veterinary Authority:</u>
 - af) equids are kept in tick-protected facilities and transported in protected vehicles-vehicles/vessels according to Article 12.7.8-point 3:
 - <u>b2</u>) <u>equids have been preventively treated according to received preventive treatment in accordance with the</u> <u>manufacturer's recommendations with an acaricide effective against the competent ticks.</u>

Article 12.7.8.

Protecting facilitics and transports from ticks

- 2) The establishment or facility should be approved by the Veterinary Authority and the means of protection should at least comprise the following:
 - <u>a-1)</u> measures to limit or eliminate habitats for competent tick vectors should be implemented for an appropriate time and over an appropriate distance in the vicinity of the area where equids are kept;

- b2) the facility and immediate surroundings of the stables and exercise or competition areas should be treated with an effective acaricide before the arrival of equids.
- 3) <u>Wwhen transporting animals equids through infected countries or zones:</u>
 - a) the vehicle/vessel should be treated with an effective acaricide before transporting the animals;
 - b) preventive treatment of the equids with an acaricide with an extended residual effect that lasts at least for the duration of any stopover during the trip should be conducted.

Article 12.7.9.

Surveillance strategies

1. General principles of surveillance

<u>A Member Country should justify the surveillance strategy chosen as being adequate to detect the presence of infection with T. equi and the presence of infection with B. caballi, even in the absence of clinical signs, given the prevailing epidemiological situation in accordance with Chapter 1.4. and Chapter 1.5. and under the responsibility of the Veterinary Authority.</u>

An active programme of *surveillance* of equids to detect evidence of *infection* with *T*. equi and evidence of *infection* with *B*. *caballi* by serological or agent identification molecular testing is required to establish the status of a country or *zone*, considering that asymptomatic carriers play an important role in the maintenance and transmission of the *infection*.

<u>The Veterinary Services should implement programmes to raise awareness among veterinarians, horse breeders,</u> <u>owners, keepers, and riders</u> <u>and workers</u> 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.

<u>Under the responsibility of the Veterinary Authority, Member Countries should have in place <mark>an early warning system</mark> <u>in accordance with Article 1.4.5. and :</u></u>

- <u>a formal and ongoing system for detecting and investigating cases;</u>
- <u>a procedure for the rapid collection and transport of samples from suspected cases of infection with T. equi or</u> <u>B. caballi to a laboratory for diagnosis</u>;
- <u>a system for recording, managing and analysing diagnostic and surveillance data.</u>
- 2. <u>Clinical surveillance</u>

Clinical surveillance aims at detecting clinical signs by close physical examination of equids.

3. Serological and agent surveillance

An active programme of *surveillance* of equids to detect evidence of *infection* with *T*. equi and evidence of *infection* with *B*. *caballi* by serological or agent identification testing with molecular techniques is required to establish the status of a country or *zone* considering that asymptomatic carriers play an important role in the maintenance and transmission of the *infection*.

The study population used for a serological survey should be representative of the population at risk in the country or zone.

4. Surveillance in high-risk areas

Disease-specific enhanced surveillance in a free country or zone should be carried out over an appropriate distance from the border with an infected country or zone, based upon geography, climate, history of infection and other relevant factors. The surveillance should be carried out particularly over the border with that country or zone unless there are relevant ecological or geographical features likely to limit the spatial distribution and thereby prevent the infestation of equids from competent ticks and interrupt the transmission of infection with *T. equi* or *B. caballi*.

5. Vector surveillance

Infection with T. equi or B. caballi is transmitted between equine hosts by species of competent lxodid ticks including species of the genera Dermacentor, Rhipicephalus, Hyalomma, and Amblyomma.

<u>Vector surveillance is aimed at demonstrating the absence of tick vectors or defining high, medium and low-risk areas</u> and local details of seasonality by determining the various species present in an area, their respective seasonal occurrence, and abundance. Vector surveillance has particular relevance to potential areas of spread. Long term surveillance can also be used to assess vector abatement measures or to confirm the continued absence of vectors.

Vector surveillance sampling should be scientifically based. The choice of the number and types of traps collection methods to be used in vector surveillance and the frequency of their use should consider the size and ecological characteristics of the area to be surveyed as well as the biology and behavioural characteristics of the local vector species of competent body ticks.

<u>The use of a vector surveillance system to detect the presence of circulating T. equi or B. caballi is not recommended</u> as a routine procedure. Rather, Aanimal-based surveillance strategies are preferred to detect T. equi or B. caballi transmission than entomological surveillance.

Report of the Meeting of the WOAH Terrestrial Animal Health Standards Commission/February 2023

CHAPTER 14.X.

INFECTION WITH THEILERIA LESTOQUARDI, T. LUWENSHUNI AND T. UILENBERGI

Article 14.X.1.

General provisions

Animal<u>s</u> susceptible to infection with Theileria are <u>Theileriosis is a disease of</u> bovines (Bos indicus, B. taurus<mark>, and-</mark>B. grunniens), water buffaloes (Bubalus bubalis), <u>and African buffaloes (</u>Syncerus caffer), sheep (Ovis aries), goats (Capra hircus), camels (Camel<u>lus</u> dromedarius and C. bactrianus) and some wild ruminants.

Infection with Theileria <u>Theileriosis</u> can give rise to disease of variable severity and to <u>Theileria</u> transmission. <u>Theileria</u> <u>the</u> <u>pathogenic agent</u> may persist in ruminants for their lifetime. Such animals are considered carriers.

Only sheep and goats play a significant epidemiological role in the infection with Theileria lestoquardi, T. luwenshuni and T. uilenbergi.

For the purposes of the Terrestrial Code, infection with Theileria lestoquardi, T. luwenshuni and T. uilenbergi are defined as a tickborne infection of sheep and goats with T. lestoquardi, T. luwenshuni and T. uilenbergi.

For the purposes of this chapter, Theileria means T. lestoquardi, T. luwenshuni and T. uilenbergi.

The following defines the occurrence of infection with Theileria:

- 1) Theileria has been identified observed and identified as such in a sample from a sheep or goat; or
- 2) antigen or nucleic acid specific to Theileria has been identified detected in a sample from a sheep or goat showing clinical signs consistent with infection with Theileria, or epidemiologically linked to a <u>confirmed or</u> suspected or <u>confirmed</u> case, or giving cause for suspicion of previous association with Theileria; or
- antibodies specific to Theileria have been detected in a sample from a sheep or goat that either showsshowing clinical signs consistent with Theileria, or is epidemiologically linked to a <u>confirmed or</u> suspected or confirmed case, or giving cause for suspicion of previous association with Theileria.

For the purposes of the Terrestrial Code, the incubation period for infection with Theileria shall be 35 days.

Standards for diagnostic tests-and vaccines are described in the Terrestrial Manual.

Article 14.X.2.

Safe commodities

When authorising <u>the</u> import<u>ation</u> or transit of the following commodities, Veterinary Authorities should not require any *Theileria*-related conditions regardless of the *Theileria infection* <u>animal health</u> status of <u>the animal population of</u> the exporting country <u>or zone</u>:

- 1) meat and meat products;
- 2) casings;

- 3) milk and milk products;
- 4) gelatine and collagen;
- 5) tallow;
- 6) semen and embryos collected in accordance with the relevant chapters of the Terrestrial Code;
- 7) hooves and horns;
- 8) bones.

Article 14.X.3.

Country or zone free from infection with Theileria in sheep and goats

- 1) A country or a *zone* may be considered free from *infection* with *Theileria* when the disease is notifiable in the entire country, importation of sheep and goats and their *commodities* is carried out in accordance with this chapter, and:
 - a) the country or zone is historically free as described in Article 1.4.6.; or
 - b) a *surveillance* programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with *Theileria* in the country or *zone* for at least two years; or
 - c) an ongoing *surveillance* programme in accordance with Chapter 1.5. has found no <u>competent</u> tick *vectors* for at least two years in the country or *zone*.
- 2) A country or zone free from infection with Theileria in which ongoing vector surveillance, performed in accordance with Chapter 1.5., has found no <u>competent</u> tick vectors will not lose its free status through the introduction of vaccinated, test-positive or infected sheep and goats from infected countries or zones.
- 32) A country or *zone* free from *infection* with *Theileria* will not lose its status as a result of introduction of seropositive or vaccinated sheep and goats or their *commodities*, provided they were introduced in accordance with this chapter.

Article 14.X.4.

Recommendations for importation of sheep and goats from countries or zones free from infection with Theileria

For sheep and goats

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals:

- 1) showed no clinical sign of *infection* with *Theileria* on the day of shipment;
- 2) come from a country or zone free from infection with Theileria.

Article 14.X.5.

Recommendations for importation of sheep and goats from countries or zones not free from infection with Theileria

For sheep and goats

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals:

- 1) showed no clinical sign of infection with Theileria and no infestation with tick vectors on the day of shipment;
- 2) were kept isolated for at least 35 days prior to shipment in an establishment where no case of infection with Theileria

has occurred during the preceding two years;

- 3) were treated with a registered acaricide, the efficacy of which has been confirmed in relation to the area of origin of the animals, at the time of entry into the isolation establishment and then at regular intervals, according to manufacturer's instructions, allowing continuous protection against ticks until their shipment 48 hours prior to entry to the establishment, no more than two days after entering the establishment and three days prior to shipment;
- 4) were subjected to serological and agent detection tests with negative results on samples taken <u>immediately prior to</u> on entry and at least 25 days after entry into to the <u>isolation</u> establishment and five days before shipment.

Article 14.X.6.

Recommendations for importation of hides and skins from countries or zones not free from infection with Theileria

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the products have been:

- 1) dry-salted or wet-salted for a period of at least 14 days prior to dispatch; or
- 2) treated for a period of at least seven days in salt (NaCl) with the addition of 2% sodium carbonate (Na₂CO₃); or
- 3) dried for a period of at least 42 days at a temperature of at least 20°C; or
- 4) frozen to at least -20°C for at least 48 hours.

Article 14.X.7.

Recommendations for importation of wool and fibre of sheep and goats from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the products were subjected to:

- 1) industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide or potassium hydroxide; or
- 2) industrial scouring, which consists of the immersion of wool in a water-soluble detergent held at 60–70°C.

Article 14.X.8.

Recommendations for importation of trophies derived from susceptible wild ruminants from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the products have been processed to ensure the destruction of tick vectors.

CHAPTER <mark>X<u>16</u>.X<u>1</u>.</mark>

INFECTION WITH MIDDLE EAST RESPIRATORY SYNDROME CORONAVIRUS

Article X.X<u>16.1</u>.1.

General provisions

Middle East respiratory syndrome (MERS) is a viral respiratory infection of humans and dromedary camels <u>(*Camelus*</u>) which is caused by a coronavirus called Middle East Respiratory Syndrome Coronavirus (MERS-CoV).

Dromedary camels (*Camelus dromedarius*) have been confirmed by several studies to be <u>are</u> the natural host and zoonotic source of the MERS-CoV infection in humans. Other species may be susceptible to *infection* with MERS-CoV. However, their epidemiological significance has not been demonstrated.

MERS-CoV has been associated with mild upper respiratory signs in some dromedary camels. While the impact of MERS-CoV on animal health is very low, human infections have a significant public health impactic can causes severe and sometimes fatal disease in humans.

For the purposes of the Terrestrial Code, MERS is defined as an infection of dromedary camels with MERS-CoV.

The following defines the occurrence of infection with MERS-CoV:

- 1) MERS-CoV has been isolated and identified as such in a sample from a dromedary camel; or
- <u>ribo</u>nucleic acid specific to MERS-CoV has been <u>identified detected</u> in <u>a</u> samples from a dromedary camel showing clinical signs or pathological lesions <u>suggestive of consistent with</u> MERS-CoV, or <u>epidemiologically linked with</u> <u>epidemiological links either</u> to a <u>suspected or</u> confirmed <u>or suspected</u> case <u>of MERS-CoV</u> or <u>to a human infected with</u> <u>MERS-CoV</u>, or <u>from a dromedary camel</u> giving cause for suspicion of previous association or contact with MERS-CoV.

Standards for diagnostic tests are described in the Terrestrial Manual.

CHAPTER <mark>X<u>8</u>.Y.</mark>

INFECTION WITH LEISHMANIA SPP. (LEISHMANIOSIS)

Article <mark>X8</mark>.Y.1.

General provisions

For the purposes of the Terrestrial Code, infection with Leishmania spp. <u>leishmaniosis</u> is defined as an infection of dogs and cats (hereafter 'susceptible animal') by protozoan parasites of the genus Leishmania, family Trypanosomatidae, order Kinetoplastida.

The *infection* is usually transmitted by the bite of an infected *Phlebotomus* sandflyphlebotomine sand fly belonging to the genera *Phlebotomus* (Old World) or *Lutzomyia* (New World).

The following defines the occurrence of infection with Leishmania spp.:

- Leishmania spp. amastigotes have been observed <u>and identified as such in a samples</u> from a dog or a cat <u>susceptible</u> animal; or
- nucleic acid specific to Leishmania spp. has been detected in a sample from a dog or a cat susceptible animal showing clinical signs or pathological lesions consistent with infection with Leishmania spp., or epidemiologically linked to a confirmed or suspected case, or giving cause for suspicion of previous association or contact with Leishmania spp.; or
- 3) antibodies specific to Leishmania spp. that are not the consequence of vaccination have been detected in a sample from a dog or a cat_susceptible animal showing clinical signs or pathological lesions consistent with infection with Leishmania spp., or epidemiologically linked to a <u>confirmed or suspected</u> case, or giving cause for suspicion of previous association or contact with Leishmania spp.

Standards for diagnostic tests and vaccines are described in the Terrestrial Manual.

TERMINOLOGY: USE OF THE TERMS 'FETAL', 'FOETAL', 'FETUS' AND 'FOETUS'

Article 4.10.3.

Procedures for micromanipulation

The term "micromanipulated" covers several different procedures and a variety of specialised microsurgical instruments and other equipment may be used. However, from the standpoint of animal health, any cutting, penetrating or breaching of the integrity of the zona pellucida is an action that can alter the health status of an embryo. To maintain health status during and after micromanipulation, the following conditions should apply:

1. Media

Any product of animal origin, including co-culture cells and media constituents, used in the collection or production of oocytes, embryos or other cells, and in their micromanipulation, culture, washing and storage should be free from pathogenic agents (including transmissible spongiform encephalopathy agents, sometimes called prions). All media and solutions should be sterilised by approved methods in accordance with the Manual of the IETS and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the Manual of the IETS.

2. Equipment

Equipment (e.g. microsurgical instruments which have direct contact with embryos) should either be of the single-use type (disposed of after each oocytes or embryos batch) or should be effectively sterilised between oocytes or embryos batch in accordance with recommendations in the Manual of the IETS.

3. Nuclei for transplantation ("nuclear transfer")

- a) Where it is intended to transplant nuclei derived from pre-hatching stage (i.e. zona pellucida intact) embryos, the parent embryos from which those nuclei are derived should fulfil the conditions of this chapter. Where nuclei derived from other types of donor cell (e.g. post-hatching stage embryos, embryonic, <u>foetal fetal</u> and adult cells, including spermatozoa or spermatids for ICSI) are to be transplanted, the parent embryo, <u>foetus fetus</u> or animal from which those donor cells originate, and the methods whereby they are derived, including cell culture, should comply with the relevant animal health standards recommended elsewhere in this *Terrestrial Code* and in the *Terrestrial Manual*.
- b) Where it is intended to transplant a nucleus into an intact oocyte (e.g. for ICSI), or into an enucleated oocyte (for nuclear transfer), those oocytes should be collected, cultured and manipulated in accordance with the recommendations in this chapter.

TERMINOLOGY

[...]

SECTION 9. APIDAE APINAE

SECTION 11. BOVIDAE BOVINAE

SECTION 16. CAMELIDAE

Chapter 16.1. Infection with Middle East respiratory syndrome coronavirus

TERMINOLOGY: USE OF THE TERMS 'ENZOOTIC', 'ENDEMIC', 'EPIZOOTIC' AND 'EPIDEMIC'

Article 4.19.1.

Introduction

The purpose of this chapter is to provide recommendations for the preparation, development and implementation of *official control programmes* for *listed* and *emerging diseases*. It is not aimed at providing ready-made fit-for-all solutions, but rather at outlining principles to follow when combating transmissible animal diseases, including zoonoses. Although this chapter focuses primarily on *listed* and *emerging diseases*, the recommendations may also be used by the *Veterinary Authorities* for any *notifiable diseases* or diseases against which they have established *official control programmes*.

The Veterinary Authority should determine the diseases against which official control programmes are to be prepared, developed and implemented, according to an evaluation of the actual or likely impact of the disease. Official control programmes should be prepared by the Veterinary Authority and Veterinary Services in close collaboration with the relevant stakeholders and other authorities, as appropriate.

When a *listed disease* or *emerging disease* occurs in a Member Country, the *Veterinary Authority* should implement control measures proportionate to the likely impact of the disease in order to minimise its spread and consequences and, if possible, eradicate it. These measures can vary from a rapid response (e.g. to the first occurrence of a disease) to long-term control (e.g. of an endemic disease).

Official control programmes should be justified by rationales developed on the basis of *risk analyses* and taking into account animal health, public health, socio-economic, *animal welfare* and environmental aspects. They should preferably be supported by relevant cost-benefit analysis and should include the necessary regulatory, technical and financial tools.

Official control programmes should be developed with the aim of achieving defined measurable objectives, in response to a situation in which private action is not sufficient. Depending on the prevailing epidemiological, environmental and socioeconomic situations, the goal may vary from the reduction of impact to the *eradication* of a given *infection* or *infestation*.

The general components of an *official control programme* should include:

- 1) a plan of the programme to control or eradicate the relevant *infection* or *infestation* in the country or *zone*;
- 2) appropriate veterinary legislation;
- 3) emergency preparedness plans and emergency response plans;
- 4) surveillance of the relevant infection or infestation in accordance with Chapter 1.4.;
- 5) regular and prompt animal disease reporting;
- 6) detection and management of *cases* of the relevant *infection* or *infestation*, to reduce the *incidence* and the *prevalence* by minimising transmission;

- 7) measures implemented to prevent introduction or spread of the relevant *infection* or *infestation*, including *biosecurity* and *sanitary measures* such as movement control;
- 8) a *vaccination* programme, if appropriate;
- 9) measures to protect public health, if appropriate;
- 10) communication and collaboration among all relevant Competent Authorities;
- 11) awareness programme for relevant stakeholders including the general public if appropriate.

The critical components of *official control programmes* for diseases that are not present in the country or *zone* are measures to prevent their introduction, an *early warning system*, and a plan for rapid response and effective action, possibly followed by long-term measures. Such programmes should include options for revising or ending them.

Official control programmes and the application of their components should be regularly evaluated. Learning from past *outbreaks*, from both <u>epizoetic epidemic</u> or <u>enzoetic endemic</u> situations, reviewing the response sequence and revising the methods are critical for adaptation to evolving circumstances and for better future performance. Experiences of the *Veterinary Services* of other Member Countries may also provide useful lessons. Plans should be tested regularly to ensure that they are fit-for-purpose, practical, feasible and well understood, and that staff are proficient and other stakeholders are fully aware of their respective roles and responsibilities.

Article 9.3.1.

General provisions

For the purposes of the *Terrestrial Code*, European foulbrood is a disease of the larval and pupal stages of honey bees (species of the genus *Apis*), caused by *Melissococcus plutonius* (*M.plutonius*), a non-sporulating bacterium, which is widely distributed. Subclinical *infections* are common and require *laboratory* diagnosis. *Infection* remains—<u>enzootic</u>_<u>endemic</u> because of mechanical contamination of the honeycombs. Recurrences of disease can therefore be expected in subsequent years.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the European foulbrood status of the honey bee population of the *exporting country* or *zone*.

Standards for diagnostic tests are described in the Terrestrial Manual.

GLOSSARY

ANIMAL PRODUCT

<u>means any part of an animal, and raw or manufactured products containing any material derived from animals,</u> excluding germinal products, biological products and pathological material.

COMMODITY

means live animals, <u>animal products</u> of animal origin, animal genetic material germinal products, biological products and pathological material.

<u>GERMINAL PRODUCTS</u>

means animal semen, oocytes, embryos and hatching eggs.

CHAPTER 4.6.

<mark>GENERAL HYGIENE IN</mark>SEMEN COLLECTION, PROCESSING AND STORAGE

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 various species of donor animals with potentially pathogenic agents in a semen collection centre.

- 1) This chapter provides recommendations on:
 - <u>fa</u>) procedures for the collection, processing, and storage of semen of bovine, ovine, caprine, porcine, equine, and cervid donor animals;
 - <mark>2b</mark>) biosecurity <mark>measures</mark>for the <mark>operation of</mark>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, t<u>T</u>he recommendations in this chapter may also be appropriately applyied when to semen is collected, processed, and stored for <u>international trade or for</u>domestic distribution.

Recommendations on animal welfare <u>in accordance with the principles in Chapter 7.1. of the Terrestrial Code are applicable</u> <u>should be applied</u> to the animals kept within the semen collection centre<mark>, in accordance with relevant articles in Chapter</mark> 7.1. of the Terrestrial Code.

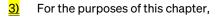
Recommendations regarding specific animal health requirements for donor animals to provide assurance of the absence of selected *listed diseases*, infections and infestations are found in Chapter 4.7. and other-relevant disease-specific chapters.

2) For the purposes of the Terrestrial Code, the semen collection centre is comprised of:

- 1a) animal accommodation facilities;
- 2b) semen collection facilities;
- <mark>3c</mark>) semen processing facilities, including mobile<mark>-laboratories_processing units</mark>;
- 4<u>d</u>) semen storage facilities;

5e) administration offices.

The listed facilities may be on one location or consist of single or multiple facility entities on several locations.



- ¹a) 'biosecure' refers to the state of a place or facility, in which biosecurity is effectively implemented;
- 2b) 'resident facility' means a biosecure <u>animal</u> accommodation facility where donor and teaser animals are kept for the purpose of semen collection;
- 3c) 'pre-entry isolation facility' means a biosecure <u>animal</u> accommodation facility where donor and teaser animals are subjected to testing prior to entering the resident facility;
- 4<u>d</u>) 'germplasm <u>cryogenic storage</u>tank' means a sealable <u>canister tank</u> for storage and transport of semen, embryos or oocytes.

Article 4.6.2.

General conditions applicable to semen collection centres

For the approval of <mark>Ft</mark>he semen collection centre<mark>-should be approved</mark> by the Veterinary Authority<mark>-</mark>

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 supervision, the health, and welfare of animals are monitored, and the biosecurity <u>plan in the facilities under his/her supervision are is</u> implemented, and all documentation including records of procedures is kept current and accessible.

Animal identification, animal traceability, and movement registration should be in accordance with Chapter 4.2. and Chapter 4.3.

The semen collection centre should implement and document processes that ensure identification and traceability of semen from collection to processing and storage and final dispatch from the semen storage facility. Fresh, chilled, or frozen semen products stored and/or dispatched from the semen storage facility should be identified in accordance with the national regulation to allow accurate and transparent identification of the donor animal, where the semen was collected and/or processed, and when it was collected.

Donor and teaser animals should be maintained kept in animal accommodation facilities separate y 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:

- Personnel on the semen collection centre should be technically competent and apply high standards of personal hygiene, to prevent the introduction of pathogenic agents. Personnel should receive regular training and demonstrate competency of skills applicable to the semen collection centre and covering his/her-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 the semen collection centre. All donor and teaser animals should meet the animal health status as determined by the semen collection centre and comply with the regulations set out by the Veterinary Authority. If other animals are needed on the semen collection centre, such as dogs for herding purposes, these should be kept on the semen collection centre and not transferred

from one establishment to another and measures to prevent their contacts with *wildlife* should be implemented. If Ogther species are needed may be resident on 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 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.

- Natural mating should be avoided at least four weeks <u>30 days</u> 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 (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,

- <u>1</u> <u>**Ft**</u>he entry of visitors to any part of the semen collection centre where biosecurity is required should only be allowed if authorised and controlled.
- ii) A<u>a</u>ppropriate protective clothing and footwear only for use within the semen collection centre facilities should be provided:
- iii) F<u>f</u>ootbaths should be provided, where necessary, and regularly cleaned and the disinfectant renewed.;
- iv) any additional measures such as complete change or shower may be required depending on the risks; and
- v) **R**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.
- 87) Vehicles for the transport of animals, feed, and waste and manure removal should be used in a manner which minimises health risks to animals in the semen collection centre.
- 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.

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 <u>can be</u> 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 preentry isolation facility is not required such as for the collection of equine semen, pre-entry conditions to enter the resident facility or semen collection facility should be included in the *biosecurity plan* of the semen collection centre. The decision to house animals indoors or outdoors will be determined by the semen collection centre in accordance with the biosecurity plan. Donor animals and teasers that are housed outdoors or allowed access outdoors, should be accommodated to minimise vector attacks and adequately protected from adverse weather conditions. Donor animals and teasers that are housed indoors, should be accommodated to allow for adequate ventilation and proper footing and bedding.

All donor and teaser animal accommodations should be adapted to the needs of the species of donor being collected. Watering and feeding systems should be constructed so that <u>it-they</u> provides minimum contact between donor animals and can be easily cleaned.

Bedding should be clean and dry, soft, easy to spread and remove. Bedding should be removed regularly and replaced, following thorough cleaning and *disinfection* of relevant surfaces.

Feed and bedding material should be kept in a dry place and stored in a manner to prevent access by *wildlife* or pests and stored in conditions that are well monitored.

Manure, litter, and bedding material should be disposed of in such a way as to prevent the transmission of diseases <mark>and be</mark> 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 the resident facility. If the semen collection facility is co-located with a resident facility, the semen collection facility should not be used to collect other donor animals not housed in the resident facility. If the semen collection facility is a separate facility, *biosecurity* should be in place to allow only animals of the same *animal health status* to be permitted entry into that facility.

Donors and teaser animals should be kept and prepared in a way to facilitate the hygienic collection of semen. Donor animals should be dry and clean when arriving in the semen collection area.

Donor animals <u>Semen</u>should be collected <u>from donor animals</u>in the semen collection facility and not <mark>collected</mark>in the resident facility. <u>Any exception should be justified and adequately managed by the *biosecurity plan.*</u>

In addition to point 5 of Article 4.6.2...Ppersonnel and visitors should <u>may</u> be provided with <u>specific</u> protective clothing and footwear for use only at the semen collection facilities and worn at all times. and waiting periods before re-entering the <u>centre can be required</u>.

Equipment used for the animals should be dedicated to the semen collection facility 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 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 reassembly 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 <u>labelled</u> 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 arca 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 <u>the other</u>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 <u>and processed</u> 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.

<u>If not immediately processed, t</u>he receptacle containing freshly collected semen should be stoppered or covered in a way to prevent contamination as soon as possible after collection, until processing. During processing, containers containing the semen should be stoppered or covered during times when diluent or other components are not being added.

Equipment used for gender-sorting of sperm should be clean and disinfected between ejaculates in accordance with the recommendations of the manufacturer. Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from animals of the same *animal health status*.

Recommendations regarding the use of diluents for processing semen:

- 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.
- If the constituents of a diluent are supplied in commercially available powder form, the water used <u>for preparing the</u> <u>semen diluent</u> 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 <u>an</u>egg yolk <u>only</u> is used <u>as the extender</u>, it should be separated from the egg white using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination. Commercial <u>UHT milk or</u> powdered skim milk for human consumption may be used. Other additives should be sterilised before use.
- 5) Diluent should be stored according to manufacturer's instructions. Storage vessels should be stored according to manufacturer's instructions.
- 6) Antibiotics may be added to the diluent to minimise the growth of bacterial contaminants or control specific venereal pathogens that may be present in semen.

Article 4.6.6.

General principles applicable to semen storage and storage facilities

Semen storage facilities and germplasm storage tanks should allow for easy cleaning and disinfection.

The manufacturer's instructions for the safe disinfection of germplasm storage tanks should be complied with.

Movement of germplasm storage tanks from one semen storage facility to another should be completed under controlled conditions subject to the *biosecurity plan* of the semen collection centre.

Access to the semen storage facility should be restricted to authorised personnel<u>and the storage room should be locked</u> when not in use

Accurate records should be maintained that identify semen being transferred in, stored, and transferred out of the semen storage facility.

Only new liquid nitrogen should be used to fill or top up germplasm storage tanks.

DRAFT CHAPTER 7.5.

ANIMAL WELFARE DURING SLAUGHTER

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 is essential for <u>(including food safety)</u> and consequently to the improvement of economical returns [Blokhuis *et al.*, 2008; Lara and Rostagno, 2018].

Article 7.5.2.

Scope

This chapter identifies potential <u>hazards to</u> animal welfare <u>hazards</u> during slaughter and provides recommendations for arrival and *unloading*, *lairage*, handling, *restraint*, *stunning* and bleeding of animals in <u>slaughterhouses/abattoirs</u>. It provides animal-based measures to assess the level of welfare and recommends remedial actions to be applied, when necessary.

This chapter applies to the *slaughter* in *slaughterhouses/abattoirs* of <u>free-moving animals</u> the following domestic animals, <u>e.g.</u> cattle, buffalo, bison, sheep, goats, horses, <u>donkeys, mules, ruminants</u>, equids and pigs, <u>and animals in containers</u> (e.g. rabbits and <u>most poultry species</u>). 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 <u>in conjunction</u> with the guiding principles for *animal welfare* provided in Chapter 7.1., <u>Chapter 7.14</u>. <u>killing of reptiles for their skins, meat and other products</u> and <u>with</u> 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.

Definition<mark>s</mark> for the purpose of this chapter

For the purposes of this chapter:

Bleeding means the act of severing major blood vessels that supply the brain, to ensure death.

Article 7.5.4.

<u>Hazards to a</u>Animal welfare <mark>hazards</mark>

Hazards to animal welfare during each of the pre-slaughter stages have an additive <u>cumulative</u> 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), 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 aAnimal 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.

<mark>Criteria (or</mark> m <u>M</u>easures<mark>)</mark>

The welfare of animals at *slaughter* should be assessed using outcome <u>animal</u>-based measures. Although consideration should be given to the resources provided as well as the design and management of the system, animal-based <u>criteria</u> <u>measures</u> are preferential. <u>However, key stunning parameters need to be considered alongside animal-based measures</u>.

The routine use of these <u>outcome_animal</u>-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 <u>welfare measurables</u> be based on current scientific <u>knowledge</u> <u>evidence</u> and appropriate national, sectorial or regional standards.

Article 7.5.6.

Management

The *slaughterhouse/abattoir* operator is responsible for the development and <u>enforcement implementation</u> of a dedicated operating plan that should consider the following:

- <u>=</u> <u>training and competency of personnel;</u>
- design of premises and choice of equipment;
- <u>standard</u> operating procedure and corrective actions;
- <u>recording, reporting adverse incidents and taking corrective actions;</u>
- 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 <u>species-specific</u> behavioural patterns of <u>the</u> animals<u>they are working with</u> and their underlying principles to <u>for</u> carry<u>ing</u> out the required tasks whilst ensuring good animal welfare. They should be experienced and competent in handling and moving the animals <u>with knowledge about animal behaviour and physiology</u> and able <u>that allows them</u> to identify signs of <u>distress</u>, fear, pain and suffering <u>and take preventive and corrective actions</u>. Personnel in charge of *restraint* <u>(including pre-stun shackling)</u> and of *stunning* and bleeding operations should be familiar with the relevant equipment, their its key working parameters and procedures. Personnel *stunning*, <u>post-stun</u> shackling 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;
- <u>c)</u> <u>animal is still alive signs of life prior to dressing or scalding.</u>

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 these these areas in order to prevent unnecessary noise, should not 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 on the welfare of animals. The y should consider the animals' needs should be considered, in terms of their physical comfort including:

- thermal <u>comfort</u>-conditions,;
- <u>ease of movement</u>;
- protection from injury, protection from sudden or excessive noise;
- protection from visual, auditory and olfactory overstimulation;
- minimising fear;
- <u>and</u> ability to perform natural and social behaviours; as well as
- watering and feeding needs, including the need of sick or injured animals;
- <u>needs arising from illness or injury;</u>
- 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.

<u>Flooring should be non-slip to prevent injury and stress due to slipping <mark>or falling</mark>. <u>There should be Aa</u>dequate quality and <u>quantity of lighting to allow allowing adequate appropriate</u> ante-mortem inspection of animals and <u>to enable assist the</u> <u>moving of animals utilising low-stress handling techniques.</u></u>

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 <u>primary</u> stunning equipment initially used.

Article 7.5.9.

<mark>The tT</mark>hroughput <mark>is (number of animals slaughtered per hour)</mark>

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. It 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 clean and well maintained, 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 <u>handling</u>, *unloading*, *lairage* and moving facilities <u>and equipment</u> contribute to ensuring that animals are handled smoothly, preventing pain and fear.

Maintenance and cleaning of <u>handling</u>, restraining, stunning and bleeding equipment are essential to ensure reliable and efficient <u>effective</u> stunning and slaughter, thereby minimising pain, fear and suffering.

Article 7.5.11.

Contingency Emergency plans

Contingency <u>Emergency</u> 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.

<u>Each p</u>Personnel who hashave a role to play in implementing <mark>contingency</mark> 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 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.) <u>Animal welfare concerns:</u>

Delay in unloading of animals is <u>a major</u> the main animal welfare concern at arrival [NAMI, <mark>2017<u>2021</u>].</mark>

Animals in *vehicles* have smaller space allowances than on farm, undergo water and feed deprivation, <u>may have</u> 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 <u>may</u> not be identified <u>or dealt with</u> <u>appropriately</u> and therefore the duration of their suffering will be increased.

2<mark>-) Animal-based and other measurables</mark> measures include:

It can be difficult to assess animal-based measures while animals are in the *vehicle*. Some measurables that may be assessed include animals with injuries, <u>lameness and / or poor body condition</u> 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 <u>or emergency killed (see Article 7.5.19.)</u> 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.) <u>Recommendations:</u>

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 <u>unloading or</u> 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.

<u>Animals should be provided with drinking water as soon as possible after unloading.</u>

Special consideration should be given to aAnimals that have undergone long or arduous journey 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 female having given birth. Mortalities and injuries should be reported to the competent authority.

4.) <u>Species-specific recommendations:</u>

<u>Some species such as Ppigs and shorn sheep</u> 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 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.

<u>Unweaned animals are especially sensitive to extreme temperatures and can find it difficult to regulate their body</u> temperature. They are verymore susceptible to dehydration, illness and stress after transportation and handling. These animals must be given special attention and be given priority when unloading and processing.

Article 7.5.13.

Displacements Handling of free-moving animals

This article addresses the handling of animals during unloading and lairage, and in the killing area.

1.) <u>Animal welfare concerns:</u>

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, <u>slippery surfaces</u> or an absence of foot battens, may result in animals slipping, falling or being trampled, causing injuries. <u>The absence of ramps</u>, <u>er lifts or an unloading bay or dock could ean-result in animals being pushed or thrown off the vehicle</u>. 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, <u>smell</u>) will cause fear and reluctance to move, or turning back. <u>Poorly designed facilities will increase the risk of such fear and injuries</u>.

2<mark>-)</mark> Animal-based and other measurables measures include</mark>:

- a) animals running slipping and falling;
- b) animals with broken or otherwise injured limbs;
- c) animals turning-back, <u>attempting to escape</u> <u>and or</u> reluctant to move;
- <u>d) animal vocalisation and frequency of (e.g. high-pitched vocalisation for in pigs) especially for pigs and cattle:</u>
- <u>de</u>) animals that are unable to move by themselves <u>due to reasons other than</u> the the terminate the terminate the terminate the terminate terminate the terminate terminate terminates the terminates t
- e<u>f</u>) animals that strike against the facilities;
- f<u>g</u>) frequency of use of excessive force by personnel;
- gh) frequency of use of electrical prods.

Animals are safely handled when these measures are below an acceptable threshold.

3<mark>.)</mark> <u>Recommendations:</u>

Ramps or lifts should be provided and used except when the vehicle and the unloading dock are at the same hight. 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.Tthe gradient should not be too steep preventing animals from moving voluntarily meving. and solid side barriers should be in place.

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 *unloading* 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, <u>loud or sudden noises</u>). 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, <u>emergency</u> killing should be <u>performed</u> cuthanised without moving them and without delay. Refer to Articles 7.5.19. and 7.5.201. <u>Such animals should never be dragged</u>, nor should they be lifted or handled in a way that might cause further pain and <u>suffering or exacerbate injuries</u>.

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 fear or pain to the animals. Under no circumstances should *animal handlers* resort to violent acts to move animals (see Article 7.5.20.).

<u>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.</u>

Animals should be moved in small groups as this decreases fear and makes use of their natural tendency to follow other animals.

Mechanical <u>handling</u> aids and electric goads should be used in a manner to encourage and direct movement of the animals without causing distress, <u>fear</u> and 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 enly 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, or on calves or piglets. Shocks shall should not be used repeatedly if the animal fails to respond and should not last longer than one second [Ritter et al., 2008].

Mechanical <u>Other Hhandling</u> 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. <u>Species-specific recommendations</u>:

None identified.

Article 7.5.14.

Lairage of free-moving animals

1<mark>.) Animal welfare concerns:</mark>

Animals during lairage may be exposed to several hazards to animal welfare hazards during lairage including:

- a) food feed and water deprivation leading to prolonged hunger and thirst
- b) absence of protection against extremes adverse in weather or climate conditions, leading to thermal stress;
- c) sudden or excessive noises, including from personnel, $\frac{\text{machinery, metal yards and gates}}{\text{machinery, metal yards and gates}} \frac{\text{facilities, and}}{\text{facilities, and}}$
- d) insufficient space to lie down and move freely leading to fatigue and aggressive behaviour;
- e) poor design and maintenance leading to distress and injuries;
- f) mixing of unfamiliar animals leading to aggressive behaviour, or social stress;
- g) limited access to resources (e.g. drinkers, bedding) leading to aggressive behaviour
- h) exposure to hard, sharp or abrasive surfaces leading to injury or lameness (e.g. sharp, abrasive).
- 2<mark>.) Animal-based and other measurables</mark> measures include:
 - a) thermal stress (e.g. panting, sweating, shivering, huddling behaviour);
 - b) space allowance;
 - c) excessive soiling with faeces (e.g. coat cleanliness, dag score for sheep);
 - d) injuries (e.g. lameness, open wounds, fractures);
 - e) illness (e.g. limping, diarrhoea, coughing);;
 - f) aggressive behaviours (e.g. mounting, fighting);
 - g) <u>frequency of</u> 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<mark>.)</mark> <u>Recommendations:</u>

Animals should have constant access to clean water. Water supply points should be designed according to the species and age of the animal, with environmental conditions that allow for effective consumption. The number and location of the water supply points should minimise competition.

Animals should be provided with feed in lairage if the duration between loading and expected time for slaughter exceeds 24 hours. Animals should be provided with feed in lairage if the duration between loading their last meal and expected time for slaughter exceeds a period appropriate for the species and age of animals. In the absence of information on the transport duration in any case, Aanimals which that are not expected to be slaughtered afterwithin 12 hours of arrival should be fed as appropriate for the age and 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 <u>and sudden</u> 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 <u>categories (e.g. sexes, sizes, horned or not, species)</u> groups (or different species) should not be mixed <u>except if they are already familiar to each other</u>.

Animals that <mark>can move freely but</mark> are injured, sick, <mark>very young</mark> neonate or pregnant should be <mark>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 injuries should be euthanized (see Article 7.5.19.).</mark>

4.2 <u>Species-specific recommendations:</u>

None identified. <u>Pigs should be <mark>kept</mark> moved</u> in small groups (up to 15) [Barton-Gade and Christensen ,1998] <mark>when</mark> resting in lairage, when moving to the stunner and when stunned.

<u>Bison and cervids need specific design and construction standards for the unloading and holding prior to slaughter.</u>

Article 7.5.15.

Restraint for stunning or bleeding (free-moving animals)

1.) <u>Animal welfare concerns:</u>

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 <u>distress, fear and</u> pain and <u>distress</u>.

Other hazards include:

- a) slipp<u>ery</u> 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) <u>a restraint box that is not appropriate to the size of the animal;</u>

de) fear caused by prolonged restraint, which may exacerbate insecure or excessive restraint.

In addition, s<u>S</u>laughter 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<mark>-) Animal-based and other measurables</mark> measures include:
 - a) animal slipping or falling;
 - b) struggling;
 - c) escape attempts;

- d) <u>animal vocalisation (cattle and pigs)(e.g. high-pitched vocalisation in pigs);</u>
- e) reluctance to enter the restrainer;
- f) frequency of use of electric goads.
- 3<mark>.) <u>Recommendations:</u></mark>

<u>Where individual restraint is used</u>, \mp the restrainer should be narrow enough that the animals cannot move either backwards 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 restrainting should be maintained until the animal is unconscious.

When restrainers are used that hold an animal with its feet off the floor <u>are used</u>, the animal must <u>should</u> 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.

<u>Flooring design</u> 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, <u>loose chains or objects, shadows, shiny surfaces or floors</u>) should be minimised to prevent <u>baulking balking</u> 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.

<u>Animals should not be left in conveyor style restrainers during work breaks, and in the event of a breakdown animals</u> should be removed from the conveyor 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<u>-)</u> <u>Species-specific recommendations:</u>

Gondolas for gas stunning of pigs should not be overloaded and pigs should 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.

<mark>General principles for <mark>Ss</mark>tunning of free-moving animals <mark>and animals in containers</mark></mark>

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.

<u>Stunning prior to slaughter decreases or avoidprevents pain and suffering to animals and also improves workers'</u> <u>safety.</u>

Mechanical stunning is divided into penetrativeng stunning and non-penetrating non-penetrative percussive <u>stunning applications. Both applications <u>use different types of devices</u> aim<u>ed</u> to induce immediate loss of</u> 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 <u>eranium damaging the brain. Non penetrative percussive stunning devices propel a blunt bolt which does not</u> 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 i<mark>neffective stunning and pain or short-lasting unconsciousness. <u>Poor maintenance of the equipment or inadequate</u></mark> <u>cartridge power or air line pressure (in pneumatic stunners) can result in low bolt velocity., Llow bolt velocity.</u> <u>misuseInappropriate use of cartridge</u> Low bolt velocity, narrow bolt diameter or short length of bolt leading to <mark>shallow penetration, may also affect the effectiveness of stunning. <u>In older animals with a thicker skull, low bolt</u></mark> <u>velocity may result inthere is an increase risk of an ineffective stun., especially with</u> In non penetrating <u>non-</u> 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 <u>high concentrations</u>), low gas temperature and humidity. The main *hazards* causing increasing increased distress during induction of unconsciousness are irritant or aversive gas mixtures (e.g. CO₂ in <u>high concentrations</u>), low gas temperature and humidity. The main *hazards* causing ineffective controlled atmosphere stunning are incorrect gas concentration and <u>too</u> 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.

Animal based and other measurables include.:

Effectiveness of stunning should be monitored at different stages: immediately after stunning, just before <u>and during</u> <u>bleeding until death occursis confirmed</u> neck cutting, and during bleed-out [EFSA, 2013a; EFSA, 2013b; AVMA, 2016]. <mark>No single indicator should be relied upon alone. <u>Multiple indicators should be used to determine whether a stun is</u> <u>effective and the animal is unconscious.</u></mark>

Mechanical stunning:

<mark>An effective stun is characterised by the presence of all the following signs: immediate collapse; apnoca; tonic seizure;</mark> absence of corneal reflex; absence of eye movements.

The presence of any of the following signs may indicates an <u>a high risk of</u> ineffective stun or recovery of consciousness: <u>rapid eye movement or nystagmus,</u> 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; apnoca; and absence of corneal reflex.

The presence of any of the following signs may indicate<u>s</u> an <u>high risk of</u> 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<u>s</u> an <u>high risk of</u> ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

3. <u>Recommendations:</u>

Animals should <u>always</u> be stunned as soon as they are restrained.

When a two-step electrical stun-kill method is used, the electrical current must reachbe applied to the brain before it reaches the heart otherwise the animal will experience cardiac arrest while still conscious.

In the case of ineffective stunning or recovery, animals should be re stunned immediately using a backup system <u>method</u>. Ineffective stunning or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be <u>used, cleaned, maintained and stored following manufacturer's recommendations</u>.

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 <u>and</u> follow the manufacturer's recommendations for st*unning*, 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 <u>et al.,</u> 2<u>015</u>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 <u>contact</u> between electrode and head;

<u>wetting point of contact;</u>

<u>— minimum exposure time;</u>

-----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 <u>such as a device that</u> monitors and displays duration of exposure, voltage and applied current.

c) Controlled atmosphere:

<u>gas concentrations and exposure time;</u>

temperature and humidity;

<u>rate of decompression (law atmospheric pressure system for stunning);</u>

- <u>animal based measure should be monitored during the induction phase, if possible, because this can be a point of highest welfare risk for animals.</u>
- <u>visual or auditory warning system to alert the operator to proper or improper function such as a device that</u> <u>monitors gas concentration and temperature.</u>

4. <u>Species-specific recommendations:</u>

<mark>Non-penetrati<u>ve</u>ng captive bolt should not be used in <u>animals with thick skull (e.g. bison, water buffalo)</u>mature cattle and pigs [Finnie, 1993 and Finnie et al., 2003].</mark>

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.) <u>Animal welfare concerns:</u>

The main *animal welfare* concern associated with *stunning* is 'ineffective *stunning*' which results in <u>distress, fear and</u> 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. <u>Animals should only be stunned using stunning methods that have been scientifically</u> validated as effective for stunning that species.

<u>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.</u>

2<mark>.) Animal-based and other measurables</mark> measures include.

Effectiveness of stunning should be monitored at different stages: immediately after stunning, just before <u>and during</u> <u>bleeding until death occursis confirmed</u> neck cutting, and during bleed-out [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

No single indicator should be relied upon alone. <u>Multiple indicators should be used to determine whether a stun is effective and the animal is unconscious.</u>

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.) <u>Recommendations:</u>

Animals should <u>always</u> 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 <u>method</u>. 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 <u>using multiple animal-based measures</u> at different stages: immediately after *stunning*, just before <u>and during bleeding until death occurs is confirmed</u> 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. <mark>Effectiveness</mark> of the stunning should be monitored regularly.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters or <u>and</u> follow the manufacturer's recommendations for stunning <u>the species and age group concerned., such as:</u>

4.) Species-specific recommendations:

Article 7.5.17

Mechanical stunning of free-moving animals

1.) <u>Animal welfare concerns:</u>

Mechanical stunning is divided into penetrative generative generative percussive stunning applications. Both applications use different types of devices aimed to induce immediate loss of consciousness as the impact of the bolt on the skull results in concussion and disruption of normal brain function [Daly et al., 1987; EFSA, 2004]. In addition to the concussive effect, Ppenetrative stunning devices propel a bolt which penetrates the skull and enters the cranium causing additional damaginge 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., How 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 nonpenetrative 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.

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 animal welfare concern is a shot that kills the animal immediately.

2<mark>-) Animal-based and other measurables</mark> measures include:

<mark>Mechanical stunning:</mark>

<u>Animal-based_measures_of_a</u>An_effective_stun_<u>are</u>_is_characterised_by_the_presence_of_all_the_following_signs: immediate collapse; apnoea; tonic<mark>-clonic</mark> seizure; absence of corneal reflex; absence of eye movements.

<u>Animal-based measures</u> The presence of any of the following signs may indicates an <u>a high risk</u> of ineffective stun or recovery of consciousness <u>are</u>: <u>absence of collapse or attempts to regain posture</u> rapid eye movement or nystagmus, vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

3<mark>.)</mark> <u>Recommendations:</u>

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters <mark>or <u>and</u> follow the manufacturer's recommendations for stunning <u>the species and age group concerned</u>, such as:</mark>

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 <u>et al.</u>, <u>2015</u>2014];
- <u>calibre and type of gun and ammunition (free bullet);</u>
- length and diameter of the penetrating bolt (captive bolt);
- <u>shape and diameter of the non-penetrating bolt;</u>
- position and direction of the shot [AVMA, 2016];
- calibre and type of gun and ammunition (free bullet).

4.) <u>Species-specific recommendations:</u>

Non-penetrativeng captive bolt should not be used in <u>animals with thick skull (e.g. bison, water buffalo)</u>mature cattle and pigs [Finnie, 1993 and Finnie et al., 2003].

<u>Water buffaloes should be stunned with penetrative captive bolt in the occipital position using a heavy-duty contactfired captive bolt gun directed at the nose or using large-calibre firearms and deformation ammunition (e.g. 0.357 Magnum).</u>

<u> Article 7.5.18</u>

Electrical stunning in free moving animals

<u>1-)</u> <u>Animal welfare concerns:</u>

Electrical stunning involves application of an electric current <u>across</u> 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, <u>electrical arcing, high contact resistance caused by wool or dirt on</u> the animal surface, dirty or corroded electrode, low voltage/current or high <u>electrical</u> frequency [EFSA, 2004]. Excessively wet hides or fleeces may result in ineffective stunning due to electrical current taking the path of least

<u>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.</u>

2:) Animal-based and other measures:

Electrical stunning:

<u>Animal-based measures of an effective stun are: An effective stun is characterised by the presence of all the following <mark>signs:</mark>tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex; <mark>or palpebral reflex.</mark></u>

Animal-based measures of ineffective stun or recovery of consciousness are: <mark>The presence of any of the following</mark> signs may indicate<u>s</u> an <u>high risk of</u> ineffective stun or recovery of consciousness: <u>absence of tonic-clonic seizures;</u> vocalisation; spontaneous blinking; righting reflex; presence of corneal <u>reflex; palpebral</u> reflex; rhythmic breathing.

3<mark>-)</mark> <u>Recommendations:</u>

When a two-step electrical stun-kill method is used, the electrical current should reach be applied <mark>to the brain before</mark> it reaches the heart otherwise the animal will experience cardiac arrest while still conscious.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters and follow the manufacturer's recommendations for stunning the species and age group concerned, such as:

When a two-step electrical stun-kill method is used, the electrical current must reachbe applied to the brain before it reaches the heart otherwise the animal will experience cardiae arrest while still conscious.

Electrical:

- shape, size and placement of the electrodes [AVMA, 2016];
- pressure contact between electrode and head;
- wetting point of contact;
- <u>minimum exposure time;</u>
- electrical parameters (current intensity(A), waveform type (AC and DC), voltage(V) and frequency(Hz));
- <u>maximum stun to stick interval;</u>
- 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.) <u>Species-specific recommendations:</u>

The Competent Authority should determine effective electrical parameters, based on scientific evidence for different types of animals.

For head-only stunning, minimum parameters are recommended for the following species:

- <u>1.15 [AVMA] to 1.28 A for bovines [EFSA 2020b]</u>,
- <u>1.25 A for slaughter (finished) pigs [AVMA]</u>,
- <u>1.8 A for sows and boars [AVMA]</u>,
- <u>1 A for small ruminants [EFSA 2013c, and EFSA 2015, AVMA].</u>

<u>The minimum parameters above are recommended to be used with an electrical frequency of 50Hz</u>. Where high<mark>er</mark> electrical frequencies <mark>is</mark> are used, the amperage should also be increased.

<u> Article 7.5.19</u>

Controlled atmosphere stunning in free moving animals

1.) <u>Animal welfare concerns:</u>

Controlled atmosphere stunning methods involve the exposure to high concentrations of carbon dioxide (hypercapnia), low concentration of oxygen (hypoxia) or a combination of the two (hypercapnic hypoxia). Loss of consciousness is not immediate following exposure of animals to controlled atmosphere stunning. The main hazards causing increased distress during induction of unconsciousness are irritant or aversive gas mixtures (e.g. CO_2 in <u>high concentrations</u>), low gas temperature and humidity. The main hazards causing ineffective controlled atmosphere stunning are incorrect gas concentration and <u>too</u> 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<mark>-) Animal-based and other measurables</mark> measures include.

Gas stunning:

Animal-based measures of an effective stun are<mark>:</mark>An effective stun is characterised by the presence of all the following <mark>signs:</mark> loss of posture; apnoea; absence of corneal reflex; absence of muscle tone.

Animal-based measures of an ineffective stun or recovery of consciousness are: The presence of any of the following signs may indicate<u>s</u> an <u>high risk of</u> ineffective stun or recovery of consciousness; vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

3<mark>-)</mark> <u>Recommendations:</u>

c) Controlled atmosphere:

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters and follow the manufacturer's recommendations for stunning the species and age group concerned, such as:

- <u>gas</u> concentrations and exposure time;
- temperature and humidity;
- <u>rate of decompression (law atmospheric pressure system for stunning);</u>
- 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
- 4.) <u>Species-specific recommendations:</u>

<u>Gases or gas mixtures that are painful to inhale should <mark>preferably</mark> not be used to stun or kill pigs. <u>However, if such</u> methods allow animals 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.</u>

Article 7.5.2017

Bleeding of free-moving animals

1.) <u>Animal welfare concerns:</u>

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 *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 <u>bled and or</u> further processed while they are still conscious or have the potential to recover consciousness.

2<mark>.) Animal-based and other measurables measures include</mark>:

The main animal-based measurable is the blood flow (rate and duration). For animal-based and other <u>measurables</u> <u>measures</u> of return of consciousness after *stunning*, see Article 7.5.16.

In cases of bleeding without *stunning* the animal-based and other <u>measurables</u> <u>measures</u> that indicate loss of consciousness include all the following: absence of muscle tone; absence of corneal reflex; absence of rhythmic breathing. <u>Unconsciousness should be reassessed until death is confirmed</u>. In addition, cessation of bleeding <u>after a</u> <u>continuous and rapid blood flow</u> can be used as an indicator of death.

3<mark>.)</mark> <u>Recommendations:</u>

- 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;
- bc) cessation of blood flow death should be assured before further processing;
- e <u>d</u>) bleeding knives should be sharpened for each animal <u>as necessary to fulfil recommendation a) and b)</u>.

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 <u>die beforenot</u> recovering consciousness <u>before it dies</u>;
- b) unconsciousness should be confirmed before 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) <u>Further processing may only be carried out when the death of the animal has been ascertained and no</u> 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, tThe 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.<u>21</u>18.

Slaughter of pregnant free-moving animals

1<mark>-) Animal welfare concerns:</mark>

Foetuses in the uterus <u>are considered not to</u> cannot achieve consciousness [EFSA, 2017; <u>Mellor, D. J. et al.</u>, <u>2005</u>Diesch *et al.*, 2005]. However, if removed from the uterus the foetus may perceive pain or other negative impacts.

2.) Animal-based and other measurables measures include:

None identified. Signs of consciousness in the foctus neonate after removal from the uterus, such as breathing [Mellor, 2003; Mellor, 2010; EFSA, 2017].

3<mark>.)</mark> <u>Recommendations:</u>

Under normal circumstances <u>WOAH recommendations (Chapter 7.3. Animal transport by land)</u>, 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 <u>pregnant</u> females are handled separately.

The foetus should be left undisturbed in utero for at least 30 minutes after the *death* of the dam [EFSA, 2017; Anon, 2017]. <u>The uterus could be removed as a whole, clamped and kept intact such that there is no possibility for the foetus to breathe.</u>

In cases where the foetus is removed before 30 minutes has elapsed <u>euthanasia (captive bolt followed by bleeding)</u> should be carried out immediately.

4.<u>) Species-specific recommendations:</u>

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 <u>below</u> <u>should be described in the emergency plan and</u> may also apply to animals that are not suitable for *slaughter* for commercial reasons, even if they do not present signs of <u>distress</u>, pain or suffering.

1<mark>.) Animal welfare concerns:</mark>

Some animals can arrive at *slaughterhouses/abattoirs* with injuries or severe illnesses that can cause <mark>undue</mark> <u>distress</u> <u>and pain</u> and suffering. <mark>This is more likely in animals of low economic value.</mark>

2.) Animal-based and other measurables measures include:

Animals requiring emergency *killing* are unable to walk independently or present severe injuries such as fractures, large open wounds, or prolapses. They may also present clinical signs of serious illness or being in a state of extreme weakness. New-born animals or animals that gave birth within the last 48 hours may also belong to this category.

3.) <u>Recommendations:</u>

Animals should not be moved unless it can be done without causing further 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.) <u>Species-specific recommendations:</u>

None identified.

Article 7.5.2320.

Methods, procedures or practices <u>that should not be used</u> unacceptable on animal welfare grounds for free-moving animals

- None of t<u>T</u>he following practices for handling animals are <u>unacceptable and</u> should not be used <u>under any</u> <u>circumstances</u>:
 - a) crushing, <u>twisting</u> or breaking tails of animals;
 - b) applying pressure using an injurious object or applying an irritant substance <u>to any part of an animal</u> to sensitive areas such as eyes, mouth, cars, 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;
 - <u>1</u> <u>dragging animals by any body part, by any means, including with chains, or ropes or by hand;</u>
 - g) forcing animals to walk over other animals;
 - h) interfering with any sensitive area (e.g. eyes, mouth, ears, anogenital region, udder or belly).
- None of t<u>T</u>he following practices for restraining <u>conscious</u> animals are <u>un</u>acceptable and should not be used <u>under</u> <u>any circumstances</u>:
 - a) mechanical clamping of the legs or feet of the animals as the sole method of *restraint*. <u>including tying limbs</u> 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 <u>for example</u> a puntilla or dagger;
- d) applying electrical current that does not span the brain;
- e) suspending or hoisting conscious animalsthem by the feet or legs;
- f) severing brain stem by piercing through the eye socket or skull bone;
- g) forcing animals to the groundsit 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 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.) <u>Animal welfare concerns:</u>

Animals in *containers* have smaller space allowances than on farm, undergo water and *feed* deprivation, <u>may have</u> <u>suffered from injury</u> and may be exposed to thermal stress due to adverse weather conditions <u>and stress from social</u> <u>disturbance</u>, <u>noise</u>, <u>vehicle vibration</u> and <u>motion</u>. In addition, stationary <u>vehicles</u> may have insufficient ventilation. Delays in <u>unloading containers</u> 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<mark>-) Animal-based and other measurables</mark> 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 <u>or when many containers are stacked on top of each other</u>. Some <u>measurables measures</u> that may be assessed include animals with injuries, or those that are sick or have died. Panting, <u>reddening of the ears</u> (<u>heat stress in rabbits</u>), 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 <u>(e.g. ambient, inside the</u> <u>vehicle)</u> can be used to establish relevant thresholds for corrective action.

3.) <u>Recommendations:</u>

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 <u>compromised</u> 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, <u>cooling or heating systems</u> or additional ventilation during waiting periods, or animals should be transported to an alternative nearby location where such provisions <u>are</u> is available. <u>Mortalities</u> and injuries should be reported to the competent authority.

4.) <u>Species-specific recommendations:</u>

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 during unloading and lairage, and into the killing area.

1<mark>-) Animal welfare concerns:</mark>

During *unloading* and moving *containers*, animals can be exposed to pain<u>, stress</u> and fear due to tilting, dropping or shaking of the *containers*.

<u>During unloading and moving containers, animals can be exposed to adverse weather or climate conditions and face</u> <u>heat stress, frost bite, or death.[EFSA, 2019]</u>.

2<mark>-) Animal-based and other measurables</mark> measures include:

- a) animals with broken limbs;
- b) animals that strike against the facilities;
- c) animals vocalizing;
- d) body parts (i.e. wings, limbs, feet, paws or heads) stuck between containers;
- e) animals injured by sharp projections inside containers.

3-) <u>Recommendations:</u>

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 <u>and prevent animals piling on one another</u>. 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 7.5.8, 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.) <u>Animal welfare concerns:</u>

Animals <mark>during lairage</mark> may be exposed to several <u>hazards to</u> animal welfare <mark>hazards</mark> during lairage</mark> including:

- a) food feed and water deprivation leading to prolonged hunger and thirst;
- b) poor ventilation;
- <u>c</u>b) absence of protection against <u>adverse weather or climate conditions</u> extremes in climate leading to thermal stress;
- de) sudden or excessive noises, including from personnel, leading to fear;
- ed) insufficient space to lie down and move freely leading to fatigue and aggressive behaviour:
- fe) not being inspected or accessible for emergency killing when necessary.
- 2<mark>.) Animal-based and other measurables</mark> measures include:
 - a) thermal stress (e.g. panting, shivering, huddling behaviour);
 - b) space allowance;
 - c) excessive soiling with faeces;
 - d) injuries (e.g. splay leg, open wounds, fractures);
 - e) dead animals.
- 3-) <u>Recommendations:</u>

Animals should be slaughtered upon arrival at the slaughterhouse/abattoir.

<u>Staff should routinely inspect and monitor containers while in the lairage to observe animals for signs of distress, fear</u> 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 <u>sudden and</u> excessive noise (e.g. ventilation fans, alarms, or other indoor or outdoor equipment).

4.) <u>Species specific recommendations:</u>

None identified.

Article 7.5.2724.

Unloading animals from containers

1.) <u>Animal welfare concerns:</u>

Animals are removed manually or automatically by tilting (poultry) from the transport containers.

When the *containers* with <u>birds animals</u> are <u>manually or</u> mechanically emptied by tipping, animals fall on to conveyors. Dumping, piling up and shock <u>might happen may occur</u>, especially for the last <u>birdsanimals</u>, which are often removed by <u>manual or</u> 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;
- ed) 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) <u>conveyor belts that are running too fast or too slowly</u> resulting in piling or injury.
- 2<mark>.) Animal-based and other measurables</mark> measures include:
 - a) animal<mark>s</mark> falling;
 - b) struggling, including wing flapping;
 - c) escape attempts;
 - d) vocalisation;
 - e) injuries, dislocation<u>s</u>, fractures;
 - f) pilling-off<u>up</u> of animals.
- 3.) <u>Recommendations:</u>

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, swiung or dropped.

<u>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).</u>

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<u>-)</u> <u>Species-specific recommendations:</u>

<u>Any animal</u> Birds with broken bones and/or dislocated joints should be humanely emergency killed before being hung on shackles for processing.

Article 7.5.<u>2825.</u>

Restraint for stunning animals from containers

1.) <u>Animal welfare concerns:</u>

The purpose of *restraint* is to facilitate the correct application of the stunning <u>and or</u> bleeding <u>procedures</u> equipment. Incorrect *restraint* <u>and handling</u> cause <u>distress, fear and</u> pain <u>fear and distress</u> and may lead to ineffective stunning <u>and</u> or bleeding.

Other hazards include:

- a) Inversion can provoke compression of the heart and lungs <u>or air sacs</u> by the viscera and might compromise breathing and cardiac activity. This might will cause <u>distress</u>, 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 pain and fear.
- c) Inappropriate shackling <u>(e.g. shackles are too narrow or too wide, birds are hung by one leg, or when one bird is shackled on two different adjacent shackles</u> leads to 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, when one bird is shackled on two different adjacent shackles. <u>Line speed</u>, without a concomitant increase in workforce, can contribute to poor shackling outcomes.
- d) Drops, curves and inclination of the shackle line or high speed of the shackle line create fear and possible pain due to the sudden changes in position as well as increase<u>d</u> effects of inversion.
- 2<mark>-) Animal-based and other measurables</mark> measures include:
 - a) struggling (wing flapping for birds;
 - b) escape attempts;
 - c) <u>high frequency</u> vocalisations (distress calls) of high frequency (poultry);
 - d) injuries and pain caused by excessive force of restraint or shackling.
 - e) fear caused by prolonged restraint, which may exacerbate insecure or excessive restraint.

3.) <u>Recommendations:</u>

Stunning methods that avoid handling, shackling and inversion of conscious animals should always be preferred.

<u>Where, this is not possible</u>, <u>Aa</u>nimals should be handled and restrained <u>to minimise</u> without provoking <u>strugg</u>leing 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<u>animals</u> as <u>because</u> this is likely to stimulate flapping (poultry) or struggleing</u>. Shackle line speeds must should be optimised so that they do not cause the birdsanimals to struggle. Shackling duration prior to stunning should be kept to a minimum.

To minimise wing flapping (poultry) or struggleing, breast support should be provided to the birds from the shackling point up to the stunner.

Inappropriate shackling, such as <u>shackles that are</u> too narrow or too wide shackles, <u>birdsanimals</u> being pushed into the shackles with force, <u>birdsanimals</u> shackled by one leg, or shackled on two different adjacent shackles, should be avoided.

Inappropriate shackling can be prevented by training staff to handle <u>birdsanimals</u> with care and compassion, <u>by and competent professional</u> shackleing <u>birdsanimals</u> gently by both legs and killing injured <u>birdsanimals</u> before shackling, by rotating staff at regular intervals to avoid boredom and fatigue and by using shackles that are appropriate <u>and adjustable for to</u> the species and size of the <u>birdsanimals</u>.

4.) <u>Species-specific recommendations:</u>

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<u>, head or, one leg</u> 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, wings or one leg.

Article 7.5.2926.

Head-only electrical stunning

1<mark>-) Animal welfare concerns:</mark>

Electrical stunning involves application of an electric current teacross the brain of sufficient magnitude magnitude <u>current and intensity</u> 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, <u>electrical arcing, high contact resistance caused by wool or dirt on the animal surface, and</u> inappropriate electrical parameters (low voltage/current or high frequency [EFSA, 2004]).

2<mark>-) Animal-based and other measurables</mark> measures include:

<mark>Effectiveness of st*unning* should be monitored at different stages: immediately after stunning, <u>and</u> just before and during bleeding until death occurs <u>is confirmed</u> [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].</mark>

<mark>No indicator should be relied upon alone.</mark> <u>Multiple indicators should be used to determine whether a stun is effective</u> and the animal is unconscious.

<u>Animal based measures of an effective stun are:</u> <mark>An effective stun is characterised by the presence of all the following</mark> <mark>signs:</mark> tonic-clonic seizures; <mark>loss of posture</mark>; apnoea; <mark>and</mark> absence of corneal reflex <u>and palpebral reflex</u>.

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 <u>reflex</u>; and pebral reflex; rhythmic breathing: spontaneous swallowing and head shaking.

3<mark>.)</mark> <u>Recommendations:</u>

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 <u>or</u> 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 <u>used</u>, cleaned, maintained and stored following <u>the</u> manufacturer's recommendations.

Constant current stunners 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 <u>and</u>or follow the manufacturer's recommendations for *stunning*, such as:

- shape, size and placement of the electrodes [AVMA, 2016];
- contact between electrode and head;
- electrical parameters (current intensity[<u>A], waveform type [AC and DC]</u>, voltage [<u>V]</u> and frequency [<u>Hz]</u>);
- 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<u>-)</u> <u>Species-specific recommendations:</u>

The Competent Authority should determine effective electrical parameters, based on scientific evidence for different types of animals.

For head-only stunning, minimum parameters are recommended for the following species:

- <u>240 mA for hens and broiler chicken [EFSA, 2019]</u>,
- <u>400 mA for turkeys [EFSA, 2019]</u>,
- 600 mA for geese and ducks [EFSA, 2019],
- <u>140 mA for rabbits (100V of a 50 Hz sine wave AC) [EFSA, 2020a]</u>].

Article 7.5.3027.

Electrical water-bath stunning for poultry

1.) <u>Animal welfare concerns:</u>

In electrical water-bath *stunning* poultry are inverted and hung 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, <u>differences in</u> <u>individual bird resistance</u> 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]).

<u>Hazards that increase the likelihood of animals experiencing pre-stun shocks are: poor handling at shackling, line speed, physical contact between birds, incorrect angle of entry ramp, wet entry ramp, incorrect water-bath height, and shallow immersion.</u>

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 electrical stunning parameters (e.g. high frequency) are used, conscious animals are at risk of being electro-immobilized or paralysed causing pain and suffering.

2<mark>.) Animal-based and other measurables</mark> measures include:

Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, <u>and</u> just before and during bleeding until death occurs [EFSA, 2019; EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

No indicator should be relied upon alone. <u>Multiple indicators should be used to determine whether a stun is effective</u> and the animal is unconscious.

<u>Animal-based measures of an effective stun are <mark>An effective stun is characterised by the presence of all the following</mark> <mark>signs</mark>: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex <u>or palpebral reflex</u>.</u>

Animal-based measures of ineffective stun or recovery of consciousne<u>ss are</u> <mark>The presence of any of the following</mark> 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<mark>-)</mark> <u>Recommendations:</u>

The height of the water-bath stunner <mark>must <u>should</u> be adjusted so that the birds cannot pull themselves up and avoid the stunner. Avoid distractions such as people walking under the birds <u>as because this</u> can cause birds to pull up.</mark>

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. <u>These birds should be stunned in the slaughter line (e.g. penetrative captive bolt) or removed and euthanised.</u>

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 can be reduced by having a smooth shackle line <u>and entry in to</u> 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 <u>and</u> <u>be killed immediately</u>. Ineffective stunning or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be <u>used</u>, cleaned, maintained and stored following <u>the</u> manufacturer's recommendations.

<u>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 animal independently from individual impedance.</u>

Regular calibration of the equipment according to the manufacturer's procedure are <u>is</u> 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;
- <u>number of birds in the water-bath</u>;
- 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.

<u>Hazards to</u> animal welfare <mark>hazards</mark> such as inversion of conscious inversion of</mark> 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 <mark>animal</mark> welfare hazards.

4.) <u>Species-specific recommendations:</u>

The Competent Authority should determine effective electrical parameters, 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]:

- Frequency below 200 Hz:
 - <u>100 mA for chicken,</u>
 - <u>250 mA for turkeys,</u>
 - <u>130 mA for Ducks and geese</u>,
 - <u>45 mA for quails.</u>
- For frequency from 200 to 400 Hz:
 - <u>150 mA for chicken,</u>
 - <u>400 mA for turkeys.</u>
- For frequency from 400-600 Hz:
 - 200 mA for chicken,
 - 400 mA for turkeys.

<u>Ducks, geese and quails should not be stunned at frequencies higher than 200 Hz.</u>

<u>Chicken and turkeys should not be stunned at frequencies higher than 600 Hz.</u>

Article 7.5.<u>3128.</u>

Mechanical stunning

The mechanical methods described here are <u>penetrative and non-penetrative</u> captive bolt <u>systems</u>, <u>percussive blow to the</u> head, cervical dislocation and decapitation. Effective mechanical *stunning* requires a severe and immediate damage to the brain <u>caused</u> by the application of mechanical force. For that reason, cervical dislocation and decapitation cannot be considered as *stunning* methods.

1.) <u>Animal welfare concerns:</u>

Mechanical methods require<mark>d</mark> precision and often physical strength to restrain and stun the animals. A eCommon cause<u>s for of the</u> misapplication of these methods is are the a lack of proper skill and the operator fatigue.

Penetrative and non-penetrative ceaptive bolt

An incorrect shooting position or incorrect captive bolt parameters <u>(not hitting the skull with sufficient force)</u> will misstunned the animal, <u>leaving it conscious and</u> leading to serious wounds and consequently distress, fear and pain, suffering, and fear.

Improper captive bolt parameters may be linked to<mark>:</mark> the use of <u>an inappropriateimproper gun (<u>bolt</u> diameter); <u>inappropriateimproper</u> cartridges; <u>or an</u> overheated or badly maintained gun.</u>

Percussive blow to the head

An incorrect application of the blow, by not hitting the brain with sufficient force will also mis stunned the animals leading to serious wounds and consequently pain and fear.

In addition, the blow might not be consistently effective when delivered to an animal held upside down by its legs (part of the energy is dissipated by the movement of the body instead of damaging the brain).

Cervical dislocation and decapitation

Because neither method apply<u>ies</u> to the brain, t<u>T</u>he loss of consciousness <u>may be delayed.</u> is not immediate and, in some cases,W <mark>w</mark>hen the method is not properly applied <u>there is a</u> risk of neck crushing and</u> the <mark>distress fear and</mark> pain and fear</mark> of the animal might be prolonged.

Decapitation

<mark>In addition, d</mark>Decapitation is associated with an open wound <mark>leading to intense pain</mark> <u>and delayed loss of</u> consciousness, leading to intense distress, fear and pain [EFSA, 2019].

2<mark>.) Animal-based and other measurables measures include</mark>:

Penetrative and non-penetrative Ccaptive bolt and percussive blow to the head

With birds, s<u>S</u>evere convulsions (wing flapping [poultry] and leg kicking <u>i.e. uncontrolled muscular movements</u>) occur immediately after shooting <u>or percussive blow</u>. 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 <mark>reflex;or palpebral reflex, apnoea,; the absence of rhythmic breathing and the presence of immediate collapse loss of posture; presence of tonic-clonic seizure.</mark>

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 <mark>reflex; or palpebral reflex; rhythmic breathing.</mark>

Cervical dislocation and decapitation

Death can be confirmed from several indicators: <u>complete severance between the brain and the spinal cord (i.e. gap</u> <u>between neck vertebrae and base of skull)</u>, permanent absence of breathing, absence of corneal or palpebral reflex, dilated pupil, or relaxed carcass [EFSA, 2013a].

Decapitation

<mark>ABM for death by decapitation: dD</mark>eath can be confirmed by complete severance between the head and the body

3.) <u>Recommendations:</u>

<u>Penetrative and non-penetrative</u> <u>C</u> aptive bolt and percussive blow to the head should only be used as backup or for small-scale slaughtering as in small slaughterhouses/abattoirs or on-farm slaughter <u>or for emergency killing</u>.

Penetrative and non-penetrative Gcaptive bolt

The captive bolt gun should be <u>used</u>, cleaned, maintained and stored following <u>the</u> manufacturer's recommendations.

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

<u>As far as captive bolt i</u>th chickens (and <u>other</u> poultry with comb development) is concerned, the placement <u>of the</u> <u>device</u> 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.

<u>This method should be dealt with a single sufficiently strong hit the frontoparietal region of the head and should</u> 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. <u>It should not be used as a routine method and should be limited as a back-up method limited to small-animals (e.g.</u> <mark>up to 3kg liveweight manually and up to 5 kg mechanical).</mark>

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 <u>animal</u> 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 <u>number of guns</u> 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 <u>The blow</u> 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 <u>to use</u> as a back-up method limited to <u>for</u> 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 <u>because</u> the efficiency of the <u>firstformer</u> is less dependent on the operator's strength than the latter.

Cervical dislocation should not be <mark>undertakenperformed</mark> 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 <u>in conscious rabbits because it does not render the animal unconscious immediately.</u>

4.) <u>Species-specific recommendations:</u>

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 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]

Article 7.5.<u>32</u>29.

Controlled atmosphere stunning for animals in containers poultry

Animals may be exposed to controlled atmosphere *stunning* methods either directly in crates or after being unloaded on a conveyor belt. Animals are not subject to restraint. Controlled atmosphere *stunning* includes exposure to carbon dioxide, inert gases, <u>mixtures of carbon dioxide with inert gases</u> or low atmosphere pressure (LAPS). <u>The effectiveness and animal</u> 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-.) <u>Animal welfare concerns:</u>

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 <u>recovering</u> returning to consciousness before bleeding<u> and</u> <u>causecausing respiratory</u> <u>distress</u> respiratory, fear and pain <u>and fear</u></u>. The insufficient exposure to <u>the</u> modified atmosphere may be due to either a too short exposure time, a too low concentration of gas or a combination of these variables.

These variables are critical because animals being stunned in large groups need special attention to ensure unconsciousness prior to neck cutting. For this reason, the duration of unconsciousness induced needs to be longer than required by other *stunning* methods to ensure <u>that</u> animals do not recover prior to being killed.

Furthermore, <u>hazards causing increased distress during induction of unconsciousness are irritant or aversive gas</u> <u>mixtures, low gas temperature and humidity</u>. In the case of exposure to carbon dioxide, there is a risk that animals are exposed to $\frac{1}{8}$ too high $\frac{1}{8}$ concentration of this gas, leading to pain. 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<mark>.)</mark> Animal-based and other <u>measurables measures</u> include:

It may be difficult to monitor the effectiveness of controlled atmosphere stunning due to because of limited access to observation 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 death of animals is confirmed at the end of the exposure to the controlled atmosphere.

Death can be confirmed <u>from by</u> permanent absence of breathing, absence of corneal or palpebral reflex, dilated pupils and relaxed carcass.

Since animal-based measures are difficult to monitor, resource-based measures should <u>also</u> be used such as <u>monitoring of gas concentration(s)</u>, exposure time, <u>gas displacement rate</u>, and decompression rate <u>of air removal</u> (for <u>LAPS</u> low atmosphere pressure).

3<mark>.)</mark> Recommendations:

Conscious animals should not be exposed to carbon dioxide <u>concentrations</u> exceeding 40%. <u>Any compressed gas</u> <u>should also be vaporised prior to administration and humidified at room temperature to prevent the risk of animals</u> <u>experiencing thermal shock.</u>

The duration of exposure and the gas concentration should be designed and implemented in such a way that all animals are <u>rendered unconscious until death</u> dead before being shackled.

Gas concentrations and exposure time, temperature and humidity must <u>should</u> 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 <u>the</u> 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 <u>the</u> second phase, a minimum atmospheric pressure of 160 Torr shall 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:

Low atmosphere pressure *stunning* has only been scientifically studied on commercial broilers <u>chickens [Gurung et</u> <u>al., 2018, Jongman and Fisher, 2021]</u> and therefore should not be used for other animals until further information is available.

The recommended CO_2 displacement rate for rabbits is 50-60% of the chamber or cage volume/min as this results in a significantly shorter time to insensibility and death [Walsh *et al.*, 2016, AVMA 2020]. Exposure to CO_2 at high concentrations can reduce pre-stun handling and produce irreversible *stunning* in rabbits. With a stun_tto_sstick interval of up to 2 min, 200 s of exposure at 80%, 150 s at 90% and 110 s at 98% are recommended [Dalmau *et al.*, 2016]. While there are advantages to high CO_2 exposure in rabbits, it is not without welfare concerns (aversion, vocalisation).

Article 7.5.3330.

Bleeding in of animals arriving in containers

1-.) Animal welfare concerns

In poultry, to most common animal welfare concern at the time of bleeding is recovery of consciousness due to ineffective electric water bath stunning practices. 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 animal<mark>s 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 <u>to</u> bones (coracoid and scapula), wings and joints due to <mark>flapping</mark> struggling if <mark>birds</mark> animals regain consciousness.</mark>

Bleeding without prior *stunning* increases the 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 distress, fear, and pain and distress [Gregory, 2004; Johnson et al., 2015].

In case of bleeding without *stunning*, higher_more cases of injury, bruisesing, haemorrhage and broken body parts are expected to occur due to wing flapping and violent muscular contractions [McNeal *et al.*, 2003).

Bleeding duration also plays an integral part in processing, where animals that have not undergone a sufficient bleeding period (<u>a minimum 40 sec</u>), 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 <u>and death by drowning</u>.

2<mark>.) <u>Animal-based and other</u> measurables measures include</mark>:

The main animal-based measurables measure is the blood flow (rate and duration). For animal-based and other measurables measures of return of consciousness after stunning, (see Article 7.5.16Article 7.5.26. to Article 7.5.29).

One of the most common parameters in determining bleeding efficiency is the percentage of blood loss, where the amount of blood loss is estimated-through from the difference between pre-slaughter weight and post-slaughter weight [Velarde et al., 2003; Sabow et al., 2015].

For poultry, 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 apnoca. Presence of one or more signs during bleeding may be the result of ineffective stunning procedure.

3.) <u>Recommendations:</u>

The slaughterhouse/abattoir operators should ensure that:

- $\underline{=}$ <u>both carotid arteries should be severed</u>;
- 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;
- <u>immediately after bleeding,</u> 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 <u>90</u> seconds (for chickens) so that there is minimum blood loss of 60 <u>%</u> percent 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 <u>euthanised immediately</u> removed from shackle.

Decapitation should not be <u>applied only</u> in to unconscious birds animals used as a bleeding technique because it does not allow monitoring possible return of consciousness.

4-) Species-specific recommendations

- <u>for chicken, the slaughter line speed should allow a minimum bleeding period of 90 seconds (for chickens) so</u> that there is minimum blood loss of 60 % before reaching the scalding tank or other potentially painful operation;
- <u>qualified personnel should check that at the bleeding line, especially before scalding, birds are completely dead.</u> <u>Birds that are still alive need to be euthanised immediately and removed from shackle.</u>

None identified.

Article 7.5.<u>34</u>31

Emergency killing ofn animals arriving in containers

This article addresses animals that show signs of severe <u>distress or</u> 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-<u>)</u> <u>Animal welfare concerns:</u>

Some animals can arrive at *slaughterhouses/abattoirs* with injuries or severe illnesses that can cause undue pain <mark>and</mark> <mark>suffering</mark>.

2<mark>.) Animal-based and other measurables measures include</mark>:

Animals requiring emergency *killing* are those, among others that present 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<mark>.) <u>Recommendations</u>:</mark>

Animal handlers should euthanise the animal<u>s</u> 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.) <u>Species specific recommendations:</u>

None identified yet.

Article 7.5.<u>35</u>32.

Methods, procedures or practices <u>that should not be used</u> unacceptable on animal welfare grounds for animals arriving in containers

- None of the following practices for handling animals are <u>unacceptable and they</u> should not be used <u>under any</u> <u>circumstances</u>:
 - applying pressure using an injurious object or applying an irritant substance to any part of the body of the animal;
 - b) hitting animals with instruments such as large sticks, sticks with sharp ends, metal-piping, stones, fencing wire or leather belts;
 - c) <u>kicking,</u> throwing or dropping animals;

- d) <u>stepping on or crushing animals</u>:
- de grasping, lifting or dragging animals only by some body parts such as their tail, head, ears, limbs, hair or feathers.
- e) dragging animals by any body parts.
- 2) None of $t_{\underline{T}}$ he following practices for restraining animals $\frac{1}{2} \frac{1}{2} \frac{1}{2}$
 - 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 <u>the</u> brain stem by piercing through the eye socket or skull bone;
 - e) <u>crushing the neck crushing</u>.

In poultry, electro-immobilisation for neck-cutting or preventing wing flapping during bleeding, or the method of brain piercing through the skull without prior stunning <u>should not be used under any circumstances</u> 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 cx 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: <u>https://www.avma.org/KB/Resources/Reference/AnimalWelfare/Documents/Humane-Slaughter-Guidelines.pdf</u>

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 Serratosa, J. (2008). Animal welfare's impact on the food chain. Trends in Food Science & Technology, 19 (2008), 79-88.

Dalmau, A., Pallisera, 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: <u>http://www.efsa.europa.eu/de/scdocs/doc/45.pdf</u>.

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: <u>http://dx.doi.org/10.2903/j.efsa.2013.3460</u>.

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: <u>http://dx.doi.org/10.2903/j.efsa.2013.3522</u>.

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 : <u>https://doi.org/10.2903/j.efsa.2017.4782</u>.

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. Patholo. 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.

<u>Gibson, Troy J., Emma King, Jade Spence, and Georgina Limon. (2019). Pathophysiology of Concussive Non-Penetrative</u> 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.

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 foetuses 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.

<u>Mellor D. (2010). Galloping colts, fetal feelings, and reassuring regulations: putting animal-welfare science into practice.</u> JVME 37(1):94-100.

<u>Micera, Elisabetta, Albrizio, Maria, Surdo, Nicoletta C., Moramarco, Angela M. and Zarrilli, Antonia. (2010). Stress-related</u> hormones in horses before and after stunning by captive bolt gun, Meat Science, 84(4), 634-637.

Nielsen, S. S., Alvarez, J., Bicout, 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). (20172021). Recommended Animal Handling Guidelines & Audit Guide: A Systematic Approach to Animal Welfare. Rev. 1.

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.

<u>Stiewert AM, Archer GS. (2021). Comparing two captive bolt devices on market age Pekin ducks. Journal of Applied Poultry</u> Research 30(2), 100162.

<u>Visser, E. Kathalijne, Ellis, Andrea D. and Van Reenen, Cornelis G. (2008). The effect of two different housing conditions</u> 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. <u>http://www.dialrel.eu/images/veterinary-concerns.pdf.</u>

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/.

Annex 26

GLOSSARY

[...]

DEATH

means the irreversible permanent loss of all vital functions brain activity demonstrable by the loss of brain stem reflexes. This may be confirmed through a combination of criteria such as dilated pupil and absence of corneal reflex, cardiac activity and breathing.

EUTHANASIA

means the killing of an animal act of inducing death using a method that causes a rapid and irreversible loss of consciousness with minimum pain and distress to animal.

SLAUGHTER

means <u>the</u> any <u>killing</u> procedure that causes the death of an animal by bleeding of <u>an</u> animal<mark>s</mark> <u>primarily intended for</u> <u>human consumption</u>.

STUNNING

means any mechanical, electrical, chemical or other procedure that causes <u>rapid</u> immediate loss of consciousness for the purpose of killing without minimal avoidable distress, fear and pain and other types of and suffering for the purpose of killing: when used before slaughter, the loss of consciousness lasts until death from the slaughter process. in the absence of slaughter, the procedure would allow the animal to recover consciousness.

г			٦	
L	•	•	J	

Annex 27

CHAPTER 8.X.

INFECTION WITH COXIELLA BURNETII (Q FEVER)

Article 8.X.1.

General provisions

Various animal species and humans can be affected by Q fever<u>, 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*.</u>

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
- nucleic acid specific to C. burnetii has been detected in a sample from a susceptible animal <u>showing clinical signs or</u> <u>pathological lesions consistent with infection with C. burnetii, or</u> that is epidemiologically linked to a confirmed or suspected case; or
- antibodies specific to C. burnetii, that are not the consequence of vaccination, have been detected in a sample from a susceptible animal <u>showing clinical signs or pathological lesions consistent with infection with C. burnetii, or</u> that is epidemiologically linked to a confirmed or suspected case.

Standards for diagnostic tests and vaccines are described in the Terrestrial Manual.

CHAPTER 8.Z.

INFECTION WITH TRYPANOSOMA EVANSI (SURRA)

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; 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. tabanids, *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.

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 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; or
- 3) nucleic acid specific to *Trypanozoon* has 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; 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 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 surrarelated 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 Article 1.4.6.; or
- b) for at least the past two years, *surveillance* in accordance with Articles 8.Z.16. to 8.Z.19. 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* 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 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 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* on the day of shipment;
- 2) were kept since birth or at least six months 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 during isolation and on the day of shipment;
- 2) were isolated in a quarantine station for at least 90 days prior to shipment, and all animals from the same flock or herd were subjected to serological and agent identification (microscope and molecular) on two occasions, 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 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* on the day of the shipment;
- were negative in an agent identification (microscope and molecular) and a serological test within 15 days prior to shipment;
- 3) were kept for the six months prior to shipment in an *establishment* in which *surveillance* in accordance with Articles 8.Z.12., 8.Z.13. and 8.Z.14. demonstrates that no case had occurred during that period;
- 4) were permanently identified and transported under the supervision of the Veterinary Services in a vectorprotected 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) were negative in an antibody detection test within 15 days prior to departure from the country of origin;
 - ii) showed no clinical sign of infection with T. evansi on the days of shipments;
 - c) the duration of the temporary importation period and the destination after this period, and the conditions required to leave the country or *zone* be defined;
- 2) ensure that during their stay in the country or zone:
 - a) measures are taken to protect 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*;
 - c) the equids are kept and transported individually in stalls and *vehicles/vessels* which are subsequently cleaned and disinsected before re-use.

Article 8.Z.10.

Recommendations for importation of semen of susceptible animals from countries, zones or compartments free from surra

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that:

- 1) the donor males:
 - a) showed no clinical sign of infection with T. evansi on the day of semen collection;
 - b) have been kept for at least six months prior to semen collection in a free country, zone or compartment; and
- 2) the semen was collected, processed and stored 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 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* on the day of semen collection;
- c) were negative in an agent identification (microscopic) and a serological test on a blood sample collected on the day of collection of the semen;
- 2) molecular examination of semen for *T. evansi* was negative;
- 3) the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.

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*, 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* 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 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 *Trypanosom* a 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 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* should be in accordance with Chapter 1.4. and be under the responsibility of the Veterinary Authority.

- 1) It should include:
 - a) formal and ongoing system for detecting and investigating outbreaks of disease;
 - b) each country should establish a *surveillance* system or integrate activities into already established animal health *surveillance* programmes for purposes of sustainablity;

- c) the collection and transport of samples from suspected cases to a *laboratory* for diagnosis or a procedure for the rapid diagnosis in the field;
- d) 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* to the Veterinary Authority;
 - 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* is essential to establish the animal health status of a country, zone or compartment.

1. <u>Clinical surveillance</u>

Clinical surveillance aims to detect clinical signs of *infection* with *T. evansi* in susceptible animals, particularly during a newly introduced *infection*. However, neither clinical nor post-mortem signs of *infection* with *T. evansi* 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. <u>Molecular techniques</u>

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. <u>Serological surveillance</u>

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 to:
 - i) demonstrate individual or population freedom;
 - ii) detect subclinical or latent infection by T. evansi;
 - iii) determine by seroprevalence the magnitude of *infection* by *T. evansi* in the host population.
- d) Positive test results can have different possible causes:
 - i) current infection;
 - ii) antibodies from previous infection (after effective treatment or self-cure);
 - iii) maternal antibodies;
 - iv) cross reactions with other Kinetoplastid species.
- 5. Sentinel animals

Sentinel surveillance may provide evidence of freedom from infection or provide data on prevalence and incidence as well as the distribution of the infection. Sentinel surveillance may consist of:

- a) the identification and regular testing of one or more of sentinel animal units of known health or immune status in a specified geographical location to detect the occurrence of *infection* with *T. evansi*;
- b) the investigation of clinical suspect cases targeting highly susceptible animals such as dogs (hunting dogs and dogs living around *slaughterhouses/abattoirs*), camels, donkeys or horses.
- 6. Vector surveillance

This point should be read in conjunction with Chapter 1.5.

For the purposes of this chapter, vector surveillance aims at determining different levels of risk by identifying the presence and abundance of various vector species (biting flies and vampire bats) in an area.

The most effective way of gathering vector surveillance data should consider the biology and behavioural characteristics of the local vector species and include traps, net, sticky targets or other collection tools. The choice of the number and type of collecting tools to be used and the frequency of their use should be made by considering the size and ecological characteristics of the area to be surveyed. In the surveillance of wildlife species, molecular techniques may be applied to vectors.

When sentinel animals are used, vector surveillance should be conducted at the same locations.

Article 8.Z.15.

Additional surveillance procedures for recovery of free status

In addition to the general conditions described in this chapter, a Member Country seeking recovery of country or *zone* free status, including a *containment zone* established in accordance with Article 4.4.7., should show evidence of an active *surveillance* programme to demonstrate absence of *infection* with *T. evansi*.

Populations under this *surveillance* programme should include:

- 1) establishments in the proximity of the outbreak;
- 2) establishments epidemiologically linked to the outbreak;
- 3) animals moved from previously affected establishments;
- 4) animals used to re-populate previously affected establishments.

Annex 29

CHAPTER 11.5.

INFECTION WITH *MYCOPLASMA MYCOIDES* SUBSP. *MYCOIDES*-SC (CONTAGIOUS BOVINE PLEUROPNEUMONIA)

Article 11.5.1.

General provisions

- <u>1) For the purposes of this chapter, susceptible animals means domestic bovines (Bos indicus, B. taurus, B. grunniens and Bubalus bubalis).</u>
- <u>121</u> 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 infectioned 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)

- 22) For the purposes of international tradet 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.
- <u>34</u>) The following defines the occurrence of <u>infection with MmmSC infection</u>:
 - 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
 - <u>2b</u>) <u>Mmm deoxyribo</u>nucleic acid <u>specific to Mmm</u> has been detected in a sample from a <u>susceptible animal bovine</u> showing pathological lesions consistent with an *infection* with MmmSC, and epidemiological <u>ly</u> linksed to a confirmed case.
 - <u>c)</u> antibodies <u>specific</u> to MmmSC antigens, which are not the consequence of vaccination, <u>have been detected in</u> <u>a sample from a susceptible animal bovine</u> showing pathological lesions consistent with an infection with Mmm, <u>and epidemiologically</u> linksed to a confirmed case or MmmSC deoxyribonucleic acid have been identified in one or more animals showing pathological lesions consistent with infection with OmmSC with or without clinical signs, and epidemiological links to a confirmed outbreak of CBPP in susceptible animals.
- 45) 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 diagnostic tests and vaccines are described in the Terrestrial Manual.

Article 11.5.2.

Safe commodities

When authorising <u>the</u> importation or transit of the following commodities, Veterinary Authorities should not require any CBPP-related conditions, regardless of the <u>CBPP-animal health</u> status of the domestic bovids <u>bovine-and water buffalo</u> 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

<u>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:</u>

- 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;
- <u>4)</u> 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 has 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 the OIE stating that:
 - a) there has been no outbreak of CBPP during the past 24 months;
 - b) no evidence of CBPP infection has been found during the past 24 months;
 - e) no vaccination against CBPP has been carried out during the past 24 months,

and supply documented evidence that surveillance for CBPP in accordance with this chapter is in operation and that regulatory measures for the prevention and control of CBPP have been implemented;

3) not have imported since the cessation of vaccination any animals vaccinated against CBPP.

The country or zone will be included in the list of countries or zones free from CBPP in accordance with Chapter 1.6. only after the submitted evidence has been accepted by the OIE.

Retention on the list requires <u>annual reconfirmation of compliance with all points above and relevant provisions under point <u>4 of Article 1.4.6.</u> that the information in points 2 a), 2 b), 2 c) and 3 above be re submitted annually and <u>Documented</u></u>

<u>evidence should be resubmitted annually for points 1 to 4 above. Any</u> changes in the epidemiological situation or other significant events should be <u>reported notified</u> to WOAH in accordance with <u>the requirements in Chapter 1.1</u>.

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.

<u>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.</u>

A Member Country wishing to establish a compartment free from CBPP should:

- 1) <u>have a record of regular and prompt animal disease reporting and, if not free, have an official control programme and</u> <u>a surveillance system for CBPP in place in accordance with Articles 11.5.13. and 11.5.14. that allows knowledge of the</u> <u>prevalence, distribution and characteristics of CBPP in the country or zone;</u>
- 2) declare for the free compartment that:
 - a) there has been no case of CBPP during the past 24 months;
 - b) <u>no infection with Mmm has been detected during the past 24 months;</u>
 - c) vaccination against CBPP is prohibited;
 - d) no animal vaccinated or treated against CBPP within the past 24 months is in the compartment;
 - <u>e)</u> <u>animals, semen and embryos may only enter the compartment in accordance with relevant articles in this chapter;</u>
 - <u>f)</u> <u>documented evidence shows that surveillance in accordance with Articles 11.5.13. and 11.5.14. is in operation;</u>
 - g) an animal identification and traceability system in accordance with Chapters 4.1. and 4.2. is in place;
- 3) describe in detail:
 - a) the animal subpopulation in the compartment;
 - b) the biosecurity plan to mitigate the risks identified by the surveillance carried out in accordance with point 1 notably to prevent the aerosol transmission of CBPP.

The compartment should be approved by the Veterinary Authority.

Article 11.5.5.

Country of zone infected with Mmm CBPP infected country or zone

<u>A country or zone shall be considered as infected with Mmm</u> Wwhen the requirements for acceptance as a CBPP free country or zone free from CBPP are not fulfilled, a country or zone shall be considered as infected.

Article 11.5.5bis.

Establishment of a containment zone within a country or zone previously free from CBPP

In the event of outbreaks of CBPP within a country or zone previously free from CBPP, including within a protection zone, a containment zone, which includes all epidemiologically linked outbreaks, can-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 WOAH, in addition to the requirements of Article 4.4.7., in support of the application, documented evidence that:

- 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.;
- 32) 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;
- 43) epidemiological investigations into the likely source of the outbreaks have been carried out:
- 54) <u>a slaughter policy, with or without the use of emergency vaccination, has been applied;</u>
- <u>65</u>) <u>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:</u>
- 76) 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 the se 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 WOAH as complying with Article 4.4.7. and points 1 to $\frac{67}{above.}$

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 11.5.4. are fulfilled.

In the event of occurrence of infection with Mmm in the outer zone of a containment zone established in accordance with point 4(b) of Article 4.4.7., the approval of the containment zone is withdrawn and the free status of the whole country or zone is suspended until the relevant requirements of Article 11.5.4. are fulfilled.

The recovery of the CBPP free status of the containment zone should follow the provisions of Article 11.5.46.

Article 11.5.<u>6</u>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:

- <u>1)</u> <u>the disinfection of the last affected establishment, provided that a slaughter policy without vaccination has been</u> <u>implemented; or</u>
- 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 <mark>status of CBPP free country or zone:</mark>

- 12 months after the last case where a stamping out policy-and scrological 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) <u>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</u>
- 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 WOAH.

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 <u>of susceptible animals bovines f</u>rom CBPP free countries<u></u>, or zones, or <u>compartments</u> <u>free</u> 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 <u>of susceptible animals bovines f</u>rom CBPP infected countries or zones <u>infected with</u> <u>Mmm for immediate slaughter</u>

For domestic bovids and water buffaloes for slaughter

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals:

- 1) showed no clinical sign of CBPP on the day of shipment;
- 2) originate from an establishment in which surveillance in accordance with Articles 11.5.13. and 11.5.14. demonstrates that where no case of CBPP had occurred was officially reported for during the past six months; and
- 3) are transported directly under the supervision of the Veterinary Authority in a vehicle/vessel, which was subjected to disinfection before loading, directly from the establishment of origin to the slaughterhouse/abattoir_place of shipment in sealed vehicles without coming into contact with other succeptible animals bovines.

Article 11.5.9.

Recommendations for importation <u>of bovine semen</u> from CBPP free countries<u></u>, or zones, or <u>compartments free</u> from CBPP free compartments

For bovine semen

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- 1) the donor animals:
 - a) showed no clinical sign of CBPP on the day of collection of the semen;
 - b) were kept in a CBPP free country, zone or compartment since birth or for at least the past six months;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.

Article 11.5.10.

Recommendations for importation of bovine semen from CBPP infected countries or zones infected with Mmm

For bovine semen

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- 1) the donor animals:
 - a) showed no clinical sign of CBPP on the day of collection of the semen;
 - b) were subjected to the complement fixation <u>a serological</u> test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;
 - c) were isolated from other domestic bovids and water buffaloes <u>susceptible animals bovines</u> from the day of the first the complement fixation <u>serological</u> test until collection;
 - were kept since birth, or for the past six months, in an establishment <u>in which surveillance in accordance with</u> <u>Articles 11.5.13. and 11.5.14. demonstrates that</u> where no case of CBPP was reported <u>had occurred</u> during that period<u></u>, and that the establishment was not situated in a CBPP infected zone;
 - e) AND EITHER:
 - i) have not been vaccinated against CBPP;

OR

- were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than four months prior to collection; in this case, the condition laid down in point b) above is not required;
- 2) the semen:
 - a) was collected, processed and stored in accordance with Chapters 4.56. and 4.67.;
 - b) was subjected to a test for the identification detection of the agent.

Article 11.5.11.

Recommendations for importation <u>of *in vivo* derived or *in vitro* produced oocytes or embryos of susceptible animals bovines from CBPP free countries, or zones, or <u>compartments free</u> from CBPP free compartments</u>

For in vivo derived or in vitro produced oocytes or embryos of domestic bovids and water buffaloes

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- 1) the donor animals:
 - a) showed no clinical sign of CBPP on the day of collection of the oocytes or embryos;
 - b) were kept in a CBPP free country, zone or compartment since birth or for at least the past six months;
- 2) the oocytes were fertilised with semen meeting the conditions of Articles 11.5.9. or 11.5.10.;
- 3) the oocytes or embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.

Article 11.5.12.

Recommendations for importation <u>of *in vivo* derived or *in vitro* produced oocytes or embryos of susceptible animals bovines from CBPP infected countries <u>or zones infected with *Mmm*</u></u>

For in vivo derived or in vitro produced oocytes or embryos of domestic bovids and water buffaloes

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- 1) the donor animals:
 - a) showed no clinical sign of CBPP on the day of collection of the embryos or oocytes;
 - b) were subjected to the complement fixation <u>a serological</u> test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;
 - c) were isolated from other domestic bovids and water buffaloes bovines from the day of the first the complement fixation serological test until collection;
 - were kept since birth, or for the past six months, in an establishment <u>in which surveillance in accordance with</u> <u>Articles 11.5.13. and 11.5.14. demonstrates that</u> where no case of CBPP was reported <u>had occurred</u> 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

- were vaccinated using a vaccine complying with the standards described in the Terrestrial Manual not more than four months prior to collection; in this case, the condition laid down in point b) above is not required;
- 2) the oocytes were fertilised with semen meeting the conditions of Articles <u>11.5.9</u>. and <u>or</u> 11.5.10.;
- 3) the oocytes or embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.

Article 11.5.13.

Introduction to surveillance General principles of surveillance

Articles 11.5.13. to and 11.5.1714. define the principles and provide a guide for the *surveillance* of CBPP in accordance with Chapter 1.4. <u>notably point 2(h) of Article 1.4.3.</u> concerning <u>quality assurance</u> applicable to Member Countries seeking establishment of freedom from CBPP. Guidance is provided for Member Countries seeking reestablishment, maintenance

<u>or recovery</u> of freedom from CBPP for <u>at</u> the entire country, or for a zone, following an outbreak <u>or compartment level or</u> <u>seeking endorsement by WOAH of their official control programme for CBPP, in accordance with Article 11.5.13.</u> Surveillance aims at identifying infection in <u>bovines susceptible species as indicated in Article 11.5.1</u>.

1. Early detection

<u>A surveillance system for early detection should be in place in accordance with Chapter 1.4. under the responsibility of the Veterinary Authority.</u>

2. Demonstration of freedom

The impact and epidemiology of CBPP differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from CBPP at an acceptable level of confidence should be adapted to the local situation. It is incumbent upon the applicant Member Country to submit a dossier to the OEWOAH in support of its application that not only explains the epidemiology of CBPP in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically-based supporting data. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that the absence of CBPP *infection* is assured at an acceptable level of confidence.

Surveillance for CBPP should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from CBPP *infection*.

<u>A Member Country wishing to substantiate freedom from CBPP should demonstrate absence of infection with Mmm</u> in susceptible populations.

Article 11.7.14.

General conditions and methods for surveillance

3. OIEWOAH endorsed official control programme

<u>Surveillance strategies employed in support of an OIEa WOAH endorsed official control programme should</u> <u>demonstrate evidence of the effectiveness of any control strategy used and of the ability to rapidly detect all</u> <u>outbreaks of CBPP outbreaks</u>.

<u>Considerable latitude exists for Member Countries to design and implement surveillance to establish that the whole</u> <u>country or a zone is free from CBPP and to understand the epidemiology of CBPP as part of the official control</u> <u>programme.</u>

The Member Country should submit a dossier to the OIEWOAH in support of its application that explains the epidemiology of CBPP in the region concerned and demonstrates how all the risk factors are identified and managed. This should include provision of scientifically based supporting data.

The entire investigative process should be documented within the *surveillance* programme. All the epidemiological information should be substantiated, and the results should be collated in the final report.

The entire investigative process should be documented within the *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the Veterinary Authority. A procedure should be in place for the rapid collection and transport of samples from suspect cases of CBPP to a laboratory for CBPP diagnoses.

- 2) The CBPP surveillance programme.should:
 - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers (such as community animal health workers) who have day-to-day contact with livestock, meat inspectors as well as laboratory diagnosticians, should report promptly any suspicion of CBPP. They should be integrated directly or indirectly (e.g. through private veterinarians or

veterinary para professionals) into the surveillance system. All suspect cases of CBPP should be investigated immediately. Where suspicion cannot be resolved by the epidemiological and clinical investigation, samples should be taken and submitted to a laboratory. This requires that sampling kits information should be substantiated, and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in CBPP diagnosis and control;

- b) implement, when relevant, regular and frequent clinical inspection and testing of high risk groups of animals, such as those adjacent to a CBPP infected country or zone (for example, areas of transhumant production systems);
- c) take into consideration additional factors such as animal movement, different production systems, geographical and socio-economic factors that may influence the risk of disease occurrence.

An effective surveillance system will periodically identify suspicious cases that require follow up and investigation to confirm or exclude that the cause of the condition is CBPP. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predieted reliably. Applications for freedom from CBPP infection should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand still orders, etc.). should be collated in the final report.

Article 11.7.15.

- 4. Surveillance strategies
- 1. Introduction

The target population for surveillance aimed at identifying disease and infection should cover all the susceptible species (Bos taurus, B. indicus, B. grunniens and Bubalusbubalis) within the country or zone.

Given the limitations of the diagnostic tools available, tT he interpretation of <u>serological</u> surveillance results should be at the herd level rather than at the individual animal level.

Randomised surveillance may not be the preferred approach given the epidemiology of the disease (usually uneven distribution and potential for occult foci of *infection* in small populations) and the limited sensitivity and specificity of currently available tests. Targeted-Risk-based surveillance (e.g. based on the increased likelihood of *infection* in particular localities or species, focusing on *slaughter* findings, and active clinical surveillance) may be the most appropriate strategy. The applicant Member Country should justify the surveillance strategy chosen as adequate to detect the presence of CBPP *infection* in accordance with Chapter 1.4. and the epidemiological situation.

Targeted <u>Risk-based</u> 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.

<u>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.</u>

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 $t_{\rm T}$ is surveillance system employed, the design should anticipate the occurrence of false positive <u>laboratory results</u>-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 <u>or not</u> they are indicative of *infection or not*. This should involve follow-up with supplementary tests, elinical and follow-up investigation and post-mortem examination in to collect diagnostic material from the original sampling <u>epidemiological</u> 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. <u>Clinical surveillance</u>

Clinical surveillance aims at detecting clinical signs of CBPP in a herd by close physical examination of susceptible animals bovines. Clinical inspection is an important component of CBPP surveillance contributing to reach the desired level of confidence of detection of disease if a sufficiently large number of clinically susceptible animals bovines is examined.

Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of CBPP suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing and post-mortem examination may contribute to confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced.

32. 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 <u>highly</u> recommended.

4. Serological <u>3.</u> <u>Laboratory testing</u>

Serological *surveillance* is not the preferred strategy for CBPP. However, in the framework of epidemiological investigations, serological testing may be used.

The limitations of available serological tests for CBPP make the interpretation of results difficult and useful only at the *herd* level. Positive findings should be followed up by clinical and pathological investigations and agent identification.

Clustering of seropositive reactions should be expected in CBPP *infections* and is usually accompanied by clinical signs. As clustering may signal field strain *infection*, the investigation of all instances should be incorporated in the *surveillance* strategy.

Following the identification of a CBPP infected *herd*, contact *herds* should be tested serologically. Repeated testing may be necessary to reach an acceptable level of confidence in *herd* classification.

5. Agent surveillance

Agent surveillance should be conducted to follow up and confirm or exclude infection with Mmm. suspect cases. Isolates should be typed to confirm MmmSC.

Article 11.5.16.

Countries or zones applying for recognition of freedom from CBPP

In addition to the general conditions described in this chapter, a Member Country applying for recognition of CBPP freedom for the country or a zone should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme depend on the prevailing epidemiological circumstances and should be planned and implemented in accordance with general conditions and methods in this chapter, to demonstrate absence of CBPP infection, during the preceding 24 months in susceptible populations. This requires the support of a national or other laboratory able to undertake identification of CBPP infection.

Article 11.5.17.

Countries or zones re-applying for recognition of freedom from CBPP following an outbreak

In addition to the general conditions described in this chapter, a Member Country re applying for recognition of country or zone freedom from CBPP should show evidence of an active surveillance programme for CBPP, following the recommendations of this chapter.

Two strategies are recognised by the OIE in a programme to eradicate CBPP infection following an outbreak:

- 1) slaughter of all clinically affected and in-contact susceptible animals;
- 2) vaccination used without subsequent slaughter of vaccinated animals.

The time periods before which an application can be made for re-instatement of freedom from CBPP depends on which of these alternatives is followed. The time periods are prescribed in Article 11.5.4.

Article 11.5.<u>15</u>18.

OIEWOAH endorsed official control programme for CBPP

The overall objective of an OIE endorsed official control programme for CBPP is for Member Countries to progressively improve their situation and eventually attain CBPP free status. The official control programme should be applicable to the entire country even if certain measures are directed towards defined subpopulations.

<u>A</u> Member Countr<u>y</u>ies may, on a voluntary basis, apply for endorsement of their <u>its</u> official control programme for CBPP <u>in</u> <u>accordance with Chapter 1.6.</u>, when they have <u>it has</u> implemented measures in accordance with this article.

For an official control programme for CBPP to be endorsed by the OIEWOAH, the Member Country should <u>provide a</u> <u>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:</u>

- <u>1)</u> <u>epidemiology:</u>
 - 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) <u>surveillance and diagnostic capabilities:</u>
 - a) <u>CBPP surveillance in place, in accordance with Chapter 1.4. and Articles 11.5.13. and 11.5.14.</u>
 - b) <u>diagnostic capability and procedures, including regular submission of samples to a laboratory that performs</u> <u>diagnostic testing and further characterisation of strains in accordance with the Terrestrial Manual including</u> <u>procedures to isolate and identify Mmm</u>;
- 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;
- <u>4)</u> <u>the measures implemented to prevent the introduction of the pathogenic agent and to ensure the rapid detection of all CBPP outbreaks:</u>
- 5) an emergency preparedness plan and an emergency response plan to be implemented in case of CBPP outbreaks;
- 6) work plan and timelines of the official control programme;
- 7) performance indicators for assessing the effectiveness of the control measures to be implemented;
- 8) monitoring, evaluation and review of the official control programme to demonstrate the effectiveness of the strategies.
- 1) have a record of regular and prompt animal disease reporting in accordance with the requirements in Chapter 1.1.;
- 2) submit documented evidence of the capacity of Veterinary Services to control CBPP; this evidence can be provided by countries following the OIE PVS Pathway;
- 3) submit a detailed plan of the programme to control and eventually eradicate CBPP in the country or zone including:
 - a) the timeline;
 - b) the performance indicators for assessing the efficacy of the control measures to be implemented;
 - 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 the OIE only after the submitted evidence has been accepted by the OIE.

The country will be included in the list of countries having an OIEa WOAH endorsed official control programme for CBPP in accordance with Chapter 1.6.

Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

The OIE may withdraw the endorsement of the official control programme if there is evidence of:

- non-compliance with the timelines or performance indicators of the programme; or
- significant problems with the performance of the Veterinary Services; or
- an increase in the incidence of CBPP that cannot be addressed by the programme.

Annex 30

CHAPTER 11.X.

INFECTION WITH BOVINE PESTIVIRUSES (BOVINE VIRAL DIARRHOEA)

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*) (herafter 'susceptible animals') with bovine viral diarrhoea virus type 1 (pestivirus A), type 2 (pestivirus B), and type 3 (pestivirus H) (herein after 'bovine pestiviruses').

The following defines the occurrence of infection with bovine pestiviruses:

- bovine pestivirus, excluding vaccine strains, has been isolated and identified as such in a sample from a succeptible animal bovine; or
- antigen or ribonucleic acid specific to bovine pestivirus, excluding vaccine strains, has been detected in a sample from a susceptible animal bovine.

Standards for diagnostic tests and vaccines are described in the Terrestrial Manual.

Annex 31

CHAPTER 12.1.

INFECTION WITH AFRICAN HORSE SICKNESS VIRUS

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 <u>as such in a sample</u> from an equid or a product derived from that equid; or
- 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 <u>due to recent exposure to with</u> production of antibodics against structural or nonstructural proteins of AHSV that are which is not a the consequence of vaccination, have has been identified <u>detected</u> in a paired samples from an equid that either showsing 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<u>. for domestic horses</u>. Although critical information is lacking for some species, this chapter applies to all Equidac..

All countries or *zones* adjacent to a country or *zone* not having free status should determine their AHSV status from an ongoing *surveillance* programme. Throughout the chapter, *surveillance* is in all cases understood as being conducted as described in Articles 12.1.11. to 12.1.13.

Standards for diagnostic tests and vaccines are described in the Terrestrial Manual.

Article 12.1.2.

AHS free eCountry or zone free from AHS

- +) A country or zone may be considered free from AHS when <u>the relevant provisions in point 2 of Article 1.4.6.-have been</u> <u>complied with, and when within the proposed free country or zone:</u> *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:
 - <u>a)</u> <u>the Veterinary Authority has current knowledge of, and authority over, all domestic and captive wild equids in</u> <u>the country or zone</u>;
 - b) <u>the Veterinary Authority has current knowledge of the distribution, habitat and indication of disease occurrence</u> <u>through passive surveillance of wild and feral equids in the country or zone;</u>

<u>c)</u> <u>either:</u>

- 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) <u>a surveillance programme has demonstrated no evidence of Culicoides in accordance with Chapter 1.5.</u>;
- d) appropriate surveillance has been implemented in accordance with:
 - i) Article 1.4.6. where historical freedom can be demonstrated; or
 - ii) Articles 12.1.11. to 12.1.13. where historical freedom cannot be demonstrated; or
 - iii) <u>Chapter 1.5. where a surveillance programme has demonstrated no evidence of Culicoides</u>.
- e) if adjacent to an infected country or zone, include an area in which surveillance is conducted in accordance with Articles 12.1.11. to 12.1.13.;
- <u>f)</u> <u>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;</u>
- 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 <u>annual reconfirmation of compliance with all points above and relevant provisions under point <u>4 of Article 1.4.6.</u> that the information in points 4 b) ii) and iii) and 4 c) above be annually re submitted and <u>Documented</u> <u>evidence should be resubmitted annually for point 1 above. Any</u> changes in the epidemiological situation or other significant events <u>should</u> be <u>reported</u> <u>notified</u> to WOAH in accordance with the requirements in Chapter 1.1., and in particular, formally state that:</u>

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 eCountry or zone infected with AHSV

<u>A country or zone shall be considered as infected with AHSV</u> 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 <u>limited</u> outbreaks <u>of AHS</u> within an AHS free country or zone <u>previously free from AHS</u>, <u>including within a</u> <u>protection zone</u>, a <u>single</u> containment zone, which includes all epidemiologically linked <u>outbreaks</u>, <u>can-may</u> be established, <u>in accordance with Article 4.4.7.</u>, for the purpose of <u>to</u> minimiseing the impact on the <u>entire</u> <u>rest of the</u> country or zone. Such a zone should include all cases and can be established within a protection zone.

For this to be achieved <u>and for the Member Country to take full advantage of this process</u>, the Veterinary Authority should provide <u>submit as soon as possible to WOAH</u>, in addition to the requirements of Article 4.4.7., in support of the application, documented evidence that:

- 1) the *outbreaks* <u>have been contained</u> are limited based on the following factors:
 - a) immediately on suspicion, a rapid response <u>has been implemented</u>, including notification reporting, standstill of movements of equids and effective controls of the movements of equine commodities has been madeon 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.;
 - <u>cb</u>) 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 placeon confirmation, the standstill and movement controls described in point 1 have been reinforced;
 - c) epidemiological investigation (trace-back, trace-forward) has been completed;

<u>cd) the infection has been confirmed and notified in accordance with Chapter 1.1;</u>

- 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.;
- 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*;
- 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 the sea of outside the containment zone may be reinstated irrespective of Article 12.1.5. once the containment zone has been approved is recognised by the WOAH 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 <u>4(a) of Article 4.4.7.</u> the approval of the containment zone is withdrawn and the <u>AHS-free</u> 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 <u>for the</u> <u>identification detection of the agent</u> 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;
- had not been immunised <u>vaccinated</u> 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:
 - 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
 - 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 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 <u>vaccinated</u> 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. <u>Vector-protected establishment or facility</u>

The establishment or facility should be approved by the Veterinary Authority and the means of protection should at least comprise the following:

- a) appropriate physical barriers at entry and exit points, for example double-door entry-exit system;
- b) openings of the building are *vector* screened with mesh of appropriate gauge impregnated regularly with an approved insecticide in accordance with the instructions of the manufacturer;
- c) vector surveillance and control within and around the building;
- d) measures to limit or eliminate breeding sites for vectors in vicinity of the establishment or facility;
- e) Standard Operating Procedure, including description of back-up and alarm systems, for operation of the establishment or facility and transport of equids to the place of *loading*.
- 2. During transportation

When <u>equids are</u>transportinged equids through AHS infected countries or zones, Veterinary Authorities should require <u>that they are strategies to</u>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 AHS, prior to the opening of any aircraft door and until all doors are closed, netting of appropriate gauge impregnated with an approved insecticide should be placed over all crates, *containers* or jet stalls.

Article 12.1.11.

Introduction to surveillance

Articles 12.1.11. to 12.1.13. define the principles and provide guidance on *surveillance* for AHS, complementary to Chapter 1.4. and, for *vectors*, complementary to Chapter 1.5.

AHS is a vector-borne infection transmitted by a limited number of 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 a country or *zone* is free from AHS. *Surveillance* deals not only with the occurrence of clinical signs caused by AHSV, but also with evidence of *infection* with AHSV in the absence of clinical signs.

Article 12.1.12.

General conditions and methods for surveillance

- 1) A surveillance system should be under the responsibility of the Veterinary Authority. In particular the following should be in place:
 - a) a formal and ongoing system for detecting and investigating *outbreaks* of disease;
 - b) a procedure for the rapid collection and transport of samples from suspected cases of AHS to a *laboratory* for diagnosis;
 - c) a system for recording, managing and analysing diagnostic, epidemiological and *surveillance* data.
- 2) In a free country or zone, the surveillance programme for AHS should include an early warning system for reporting suspected cases. Persons who have regular contact with equids, as well as diagnosticians, should report promptly any suspicion of AHS to the Veterinary Authority. An effective surveillance system will periodically identify suspected cases that require follow-up and investigation to confirm or exclude that the cause of the condition is AHS. The rate at which such suspected cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected cases of AHS should be investigated immediately and samples should be taken

and submitted to a *laboratory*. This requires that sampling kits and other equipment be available to those responsible for *surveillance*.

- 3) In a free country or zone bordering 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; lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of AHSV.
- <u>4)</u> In an AHS infected country or *zone*, random or targeted serological and virological *surveillance*, appropriate to the epidemiological situation, should be conducted in accordance with Chapter 1.4.

Article 12.1.13.

Surveillance strategies

The target population for *surveillance* aimed at identification of disease or *infection* should cover susceptible equids within the country or *zone*. Active and passive *surveillance* for *infection* with AHSV should be ongoing. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate to the epidemiological situation.

A Member Country should justify the *surveillance* strategy chosen as appropriate to detect the presence of *infection* with AHSV in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. horses). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. donkeys).

In vaccinated populations serological and virological *surveillance* is necessary to detect the AHSV types circulating to ensure that all circulating types are included in the *vaccination* programme.

Serological or virological surveillance is also needed to detect subclinical infections in free countries or zones adjacent to countries or zones in which live attenuated AHS vaccines are used.

For random surveys, the design of the sampling strategy should incorporate epidemiologically appropriate design prevalence. The sample size selected for testing should be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size, expected prevalence and diagnostic sensitivity of the tests determine the level of confidence in the results of the survey. The Member Country should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence, in particular, should be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination* or *infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles for surveillance for disease or infection are technically well defined. Surveillance programmes to prove the absence of AHSV infection or transmission, should be carefully designed to avoid producing results that are insufficiently reliable to be accepted by WOAH for official recognition of status. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

1. <u>Clinical surveillance</u>

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. <u>Serological surveillance</u>

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. <u>Surveillance plans should include consideration of species that display clinical signs less</u> <u>commonly, such as donkeys or zebra.</u> Management variables that may reduce the likelihood of *infection*, such as the use of insecticides and animal housing, should be taken into account when selecting equids to be included in the *surveillance* system.

Samples should be examined for antibodies against AHSV. Positive AHSV antibody tests results can have four possible causes:

- a) natural infection with AHSV;
- b) vaccination against AHS;
- c) maternal antibodies;
- d) lack of specificity of the test.

Sera collected for other purposes may be used for AHSV *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of *infection* with AHSV should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no *infection* with AHSV is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the animals being sampled.

Serological *surveillance* in a free *zone* should target those areas that are at highest risk of AHSV transmission, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of AHSV, either random or targeted sampling is suitable to select *herds* or animals for testing.

Serological surveillance in a free country or zone should be carried out over an appropriate distance from the border with an infected country or zone, based upon geography, climate, history of *infection* and other relevant factors. The surveillance should be carried out over a distance of at least 100 kilometres from the border with that country or zone, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of AHSV. An AHS free country or zone may be protected from an adjacent infected country or zone by a protection zone.

Serological *surveillance* in infected *zones* will identify changes in the boundary of the *zone*, and can also be used to identify the AHSV types circulating. In view of the epidemiology of *infection* with AHSV, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis of AHSV from a proportion of infected animals is beneficial in terms of providing information on serotype and genetic characteristics of the viruses concerned.

Virological surveillance can be conducted:

- a) to identify virus transmission in at risk populations;
- b) to confirm clinically suspected cases;
- c) to follow up positive serological results;
- d) to better characterise the genotype of circulating virus in a country or zone.

4. Sentinel animals

Sentinel animals are a form of targeted *surveillance* with a prospective study design. They comprise groups of unexposed equids that have not been vaccinated and are managed at fixed locations and observed and tested regularly to detect new *infections* with AHSV.

The primary purpose of a sentinel equid programme is to detect *infections* with AHSV occurring at a particular place, for instance sentinel groups may be located on the boundaries of infected *zones* to detect changes in distribution of AHSV. In addition, sentinel equid programmes allow the timing and dynamics of *infections* to be observed.

A sentinel equid programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of AHSV in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting AHSV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid confounding factors sentinel groups should comprise animals selected to be of similar age and susceptibility to *infection* with AHSV. The only feature distinguishing groups of sentinels should be their geographical location. Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling should reflect the equine species used and the reason for choosing the sampling site. In endemic areas virus isolation will allow monitoring of the serotypes and genotypes of AHSV circulating during each time period. The borders between infected and non-infected areas can be defined by serological detection of *infection*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that *infections* with AHSV are not occurring unobserved. Here sampling prior to and after the possible period of transmission is sufficient.

Definitive information on AHSV circulating in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required sentinels should be sampled at sufficiently frequent intervals to ensure that some samples are collected during the period of viraemia.

5. Vector surveillance

AHSV is transmitted between equine hosts by species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential *vector* species accurately although many such species are closely related and difficult to differentiate with certainty.

Vector surveillance is aimed at demonstrating the absence of vectors or defining high, medium and low-risk areas and local details of seasonality by determining the various species present in an area, their respective seasonal

occurrence, and abundance. Vector surveillance has particular relevance to potential areas of spread. Long term surveillance can also be used to assess vector abatement measures or to confirm continued absence of vectors.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local vector species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to equids.

Vector surveillance should be based on scientific sampling techniques. The choice of the number and types of traps to be used in vector surveillance and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of vector surveillance sites at the same locations as sentinel animals is advisable.

The use of a vector surveillance system to detect the presence of circulating viruses is not recommended as a routine procedure as the typically low vector infection rates mean that such detections can be rare. Animal-based surveillance strategies are preferred to detect virus transmission.

<u>Annex 32</u>

CHAPTER 13.2.

<u>INFECTION WITH PATHOGENIC RABBIT</u> LAGOVIRUSES (RABBIT HAEMORRHAGIC DISEASE)

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 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 and vaccines are described in the Terrestrial Manual.

Article 13.2.2.

<u>Country free from</u> RHD free country

A country may be considered free from RHD when it has been <u>demonstrated</u>shown that <u>no case has occurred</u> the disease has not been present for at least <u>the past 12 months one year</u>, that no vaccination has been carried out in the <u>past previous</u> 12 months, and that virological or serological <u>surveillance surveys</u> in both domestic and wild rabbits leporids have confirmed the absence of the <u>infection disease</u>.

This period may be reduced to six months after the last case has been <u>destroyed</u> <u>eliminated</u> and *disinfection* procedures <u>have been</u> completed in countries adopting a *stamping-out policy*, and where <u>the</u> serological <u>surveillance</u> <u>surveys</u> confirmed that <u>no case the disease had not</u> occurred in the *wild* <u>rabbits leporids</u>.

[...]

Annex 33

CHAPTER <mark>X<u>16</u>.Z.</mark>

INFECTION WITH CAMELPOX VIRUS

Article ¥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 ecamelpox virus of genus Orthopoxvirus, family Poxviridae.

The following defines the occurrence of *infection* with **<u>cC</u>***amelpox virus*:

- 1) eccamelpox virus has been isolated and identified as such in a sample from a susceptible animal; or
- characteristic orthopox virions have been observed in a sample from a susceptible animal showing clinical signs suggestive of consistent with infection with constraint and constraints or epidemiologically linked to a confirmed or suspected case; or
- antigen or nucleic acid specific to e<u>C</u>amelpox virus has been detected in a sample from a susceptible animal showing clinical signs suggestive of consistent with infection with e<u>C</u>amelpox virus, or epidemiologically linked to a confirmed or suspected case; or
- 4) antibodies specific to <u>eC</u>amelpox virus, that are not the consequence of vaccination, have been detected in a sample from a susceptible animal showing clinical signs <u>suggestive of consistent with</u> infection with <u>eC</u>amelpox virus, or epidemiologically linked to a confirmed or suspected case.

Standards for diagnostic tests and vaccines are described in the Terrestrial Manual.

<u>Annex 34</u>

TERMINOLOGY: USE OF THE TERMS 'COMPETENT AUTHORITY', 'VETERINARY AUTHORITY' AND 'VETERINARY SERVICES'

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 <u>central Veterinary Services</u> <u>Veterinary Authority</u>. Describe the communication systems between the <u>central authorities</u> <u>Veterinary Authority</u> and the <u>border posts</u>, and between <u>border posts</u>.

[...]

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 <u>central Veterinary Services Veterinary Authority</u>. Describe the communication systems between the <u>central authorities Veterinary Authority</u> and the <u>border posts</u>, and between <u>border posts</u>.

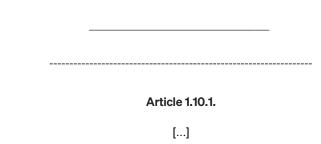
[...] Article 1.9.1.

[...]

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 <u>central Veterinary Services</u> <u>Veterinary Authority</u>. Describe the communication systems between the <u>central authorities</u> <u>Veterinary Authority</u> and the <u>border posts</u>, and between <u>border posts</u>.

[...]



6. <u>CBPP prevention</u>

- 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 <u>central Veterinary Services</u> <u>Veterinary Authority</u>. Describe the communication systems between the <u>central authorities</u> <u>Veterinary Authority</u> and the <u>border posts</u>, and between <u>border posts</u>.

[...]

Article 1.10.2.

[...]

6. <u>CBPP prevention</u>

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 <u>central Veterinary Services</u> <u>Veterinary Authority</u>. Describe the communication systems between the <u>central authorities</u> <u>Veterinary Authority</u> and the <u>border posts</u>, and between <u>border posts</u>.

[...]

Article 1.10.3.

[...]

3. Official control programme for CBPP submitted for WOAH endorsement

- e) CBPP prevention
 - iii) Import control procedures
 - Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the <u>central Veterinary Services</u> <u>Veterinary Authority</u>. Describe the communication systems between the <u>central authorities</u> <u>Veterinary Authority</u> 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 <u>Veterinary Authority</u>. Describe the communication systems between the central authorities <u>Veterinary Authority</u> 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 <u>Veterinary Authority</u>. Describe the communication systems between the central authorities <u>Veterinary Authority</u> 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 <u>central Veterinary Services</u> <u>Veterinary Authority</u>. Describe the communication systems between the <u>central authorities</u> <u>Veterinary Authority</u> and the <u>border posts</u>, and between <u>border posts</u>.

[...]

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 <u>Veterinary Authority</u>. Describe the communication systems between the central authorities <u>Veterinary Authority</u> and the border posts, and between border posts.

[...]

Article 1.11.5.

[...]

3. Official control programme for FMD submitted for WOAH endorsement

- e) FMD prevention
 - iv) Import control procedures
 - Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the <u>central Veterinary Services</u> <u>Veterinary Authority</u>. Describe the communication systems between the <u>central authorities</u> <u>Veterinary Authority</u> 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 <u>central Veterinary Services</u> <u>Veterinary Authority</u>. Describe the communication systems between the <u>central authorities</u> <u>Veterinary Authority</u> and the <u>border posts</u>, and between <u>border posts</u>.

[...]

Article 1.12.2.

[...]

6. <u>PPR prevention</u>

- 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 <u>central Veterinary Services</u> <u>Veterinary Authority</u>. Describe the communication systems between the <u>central authorities</u> <u>Veterinary Authority</u> and the <u>border posts</u>, and between <u>border posts</u>.

[...]

Article 1.12.3.

[...]

3. Official control programme for PPR submitted for WOAH endorsement

- e) PPR prevention
 - iii) Import control procedures
 - Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the <u>central Veterinary Services</u> <u>Veterinary Authority</u>. Describe the communication systems between the <u>central authorities</u> <u>Veterinary Authority</u> and the *border posts*, and between *border posts*.

[...]

Report of the Meeting of the WOAH Terrestrial Animal Health Standards Commission/February 2023

Article 3.2.3.

[...]

 formal external coordination mechanisms with clearly described procedures or agreements for activities (including preparedness and response mechanisms) between the *Veterinary Authority*, <u>other_Competent</u> *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 <u>Veterinary Services other Competent</u> <u>Authorities</u> 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 Authorityies 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.

[...]

 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 <u>national</u> competent <u>authorities</u>. The animal and public health *risks* associated with livestock populations vary across regions and animal husbandry systems, and ante- and post-mortem inspection needs to be tailored to the individual country situation and its animal and public health objectives.

The-national competent authority(ies) <u>Competent Authority(ies)</u> should provide an appropriate institutional environment to allow Veterinary Services to develop the necessary policies and standards.

[...]

[...]

Article 6.3.6.

[...]

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 <u>Authority Services</u>*.

	[]	
		_

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 <u>Authority Services</u>. All suspected cases of high pathogenicity avian influenza should be investigated immediately and samples should be taken 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 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 <i>cases</i> . Diagnosticians and those with regular with pigs should report promptly any suspicion of PRRS to the <i>Veterinary-Authority Services</i> ;

[...]

contact

Report of the Meeting of the WOAH Terrestrial Animal Health Standards Commission/February 2023