WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

ANNEX 1

Original: English

February 2022

REPORT OF THE MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION
Paris, 1–11 February 2022

PART A - Texts to be proposed for adoption in May 2022

EU position

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

A number of general comments on this part A of the February 2022 meeting report of the Code Commission as well as the intended positions of the EU on the draft Terrestrial Code chapters proposed for adoption at the 89th OIE General Session are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report (appended as Annexes 3 to 17 to this document).

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

The OIE Terrestrial Animal Health Standards Commission (the Code Commission) held its meeting electronically from 1 to 11 February 2022. The list of participants is attached as **Annex 1**.

Considering the ongoing COVID-19 pandemic the 89th Annual General Session of the World Assembly of Delegates will be held in a semi-hybrid format from Monday 23 to Friday 27 May 2022. During the 89th General Session new and revised chapters of the OIE International Standards (the *Aquatic Animal Health Code*, the *Terrestrial Animal Health Code*, the *Manual of Diagnostic Tests for Aquatic Animals* and the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*) will be proposed for adoption.

To facilitate this process, the **February 2022 meeting report of the Code Commission will be distributed in two parts**: **Part A** (herewith) provides information about the new and revised texts for the *Terrestrial Code* that will be proposed for adoption at the 89th General Session; and **Part B** (to be published in April 2022) will provide information about other topics discussed at the Commission's February 2022 meeting including texts circulated for comments and information.

In preparation for the 89th General Session, the OIE will once again organise information webinars to ensure that Members are aware of the background and key aspects of the standards being presented for adoption. Attendance to these webinars will be by invitation only. Please note that Delegates will soon receive detailed information about the 89th General Session, and in particular the process for the adoption of standards.

The Code Commission thanked the following Members for providing comments: Argentina, Australia, Brazil, Canada, China (People's Republic of), Chinese Taipei, Colombia, Japan, Mexico, New Caledonia, New Zealand, Norway, Saudi Arabia, South Africa, Switzerland, Thailand, the United Arab Emirates, the United Kingdom (UK), the United States of America (USA), Zimbabwe, the Member States of the European Union (EU), the African Union Inter-African Bureau for Animal Resources (AU-IBAR) on behalf of African Members of the OIE. The Commission also thanked the following organisations for providing comments: the Global Alliance of Pet Food

Associations (GAPFA), the International Meat Secretariat (IMS), the World Renderers Organization (WRO), as well as various experts of the OIE scientific network.

The Code Commission reviewed all comments that were submitted prior to the deadline and supported by a rationale. The Commission made amendments to draft texts, where relevant, in the usual manner by '<u>double underline</u>' and '~~strikethrough~~'. In relevant annexes, amendments proposed at this meeting are highlighted with a coloured background to distinguish them from those made previously. Due to the large number of comments, the Commission was not able to provide a detailed explanation on the reasons for accepting or not each of the comments considered, and focused its explanations on significant issues. Where amendments were of an editorial nature, no explanatory text has been provided. The Commission wished to note that not all texts proposed by Members to improve clarity were accepted; in these cases, it considered the text clear as currently written.

The Code Commission encourages Members to refer to previous reports considering longstanding issues. 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 (the Laboratories Commission), a Working Group or an *ad hoc* Group have addressed specific comments or questions and proposed answers or amendments. In such cases the rationale is described in the reports of the Scientific Commission, the Laboratories Commission, Working Group or *ad hoc* Groups, and Members are encouraged to review these reports together with the report of the Code Commission. These reports are readily available on the OIE website.

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1. Welcome from the Deputy Director General

The OIE Deputy Director General, International Standards and Science, Dr Montserrat Arroyo, welcomed members of the Code Commission. She thanked all members for their contributions, noting the efforts to maintain outputs of high quality despite the significant challenges posed by the COVID-19 pandemic. She also extended her appreciation to the members' employing institutions and national governments. Dr Arroyo briefed the members on the ongoing process to prepare the 89th OIE General Session, including the planning of pre-General Session webinars that will be conducted by the OIE Specialist Commissions to inform Members on the revised and new standards being proposed for adoption. She also informed the Commission that the Technical Item would be on OIE and Veterinary Services engagement in global, regional and national Emergency Management Systems. Dr Arroyo summarised ongoing work on the OIE standards development and review system, including the development and planning for digital tools. Finally, she informed the Commission of an 'after-action review' conducted by the OIE in response to the COVID-19 pandemic.

The members of the Code Commission thanked Dr Arroyo for the excellent support provided by the OIE Secretariat. They highlighted the work done to improve the information provided to Members on the management of the Code Commission's work programme, in particular, the better follow up on the progress of different topics. The Commission highlighted the importance of strengthening the process to identify needs for standards setting work and their prioritisation, prioritizing quality over quantity, involving Members and in good coordination with the other OIE Specialist Commissions to ensure efficient management of their workload and quality outputs.

Dr Arroyo and the members of the Code Commission discussed and agreed on the importance of promoting Member's involvement in the OIE standards setting process, and how to best support them. In this regard the Commission highlighted the value of providing clear, evidence-based information in its report. They also agreed on the importance of ensuring alignment of the texts produced in the three OIE official languages.

2. Meeting with the Director General

The OIE Director General, Dr Monique Eloit, met the Code Commission on 8 February 2022 and thanked its members for their support and commitment to achieving OIE objectives. She recognised the Commission's efforts and adaptability to develop new ways of working to sustain the OIE standards setting process despite the challenges imposed by the COVID-19 pandemic. Dr Eloit provided an update on the 89th OIE General Session preparation and informed the Commission of new initiatives to review the OIE science system.

Dr Eloit informed the Code Commission of the budgetary situation of the Organisation and noted that due to the continued increase of activities, the current regular budget would not be sufficient to ensure the sustainable delivery of some core OIE activities, which should not rely on voluntary donor funding through the OIE World Fund. Dr Eloit highlighted that this situation might impact how the Commission and its Secretariat undertake some of their work and acknowledged the work already being done by the Commission and the OIE Secretariat to strengthen the discussions and communication with Members regarding their work programme and the prioritisation of their work.

The Code Commission discussed with Dr Eloit some of the new work it had planned and prioritised for this term, notably on Sections 4 (Disease Prevention and Control) and 5 (Trade Measures, Import/Export Procedures and Veterinary Certification) of the *Terrestrial Code*. The Commission welcomed the initiative to review the OIE science system and noted that this work should also take into consideration how this system interacts with the OIE standard setting process, Dr Eloit and the Code Commission discussed and agreed on the importance to consider the roles and responsibilities of the Specialist Commissions and how they contribute to these systems, as well as the importance of achieving unified management of their standard setting role, which would avoid possible duplication or contradiction. The Commission also highlighted the importance of ensuring clarity on different outputs of the Organisation, and their alignment with OIE standards, which have a specific value in the context of the WTO Sanitary and Phytosanitary Agreement as well as for a robust practical guidance of the Members' Veterinary Authorities.

The Code Commission thanked Dr Eloit for making time to meet with its members and commended the excellent work of the Secretariat for meeting preparations and its work during the meeting especially given the challenges of virtual meetings.

3. Adoption of the agenda

The proposed agenda was discussed, taking into consideration the priorities of the work programme and time availability. The adopted agenda of the meeting is attached as **Annex 2**.

4. Texts proposed for adoption in May 2022

4.1. Glossary A ('Competent Authority', 'Protein meal', 'Stray dog', 'Veterinary Authority', and 'Veterinary Services')

a) 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'

Comments were received from Australia, Mexico, New Caledonia, New Zealand, Saudi Arabia, South Africa, the UK, the AU-IBAR and the EU.

Background

At its September 2018 meeting, the Code Commission agreed to revise the Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' in the *Terrestrial Code* following Member requests and feedback from the *ad hoc* Group on Veterinary Services. The revised definitions were circulated for comments in the Code Commission's September 2018 report. The *ad hoc* Group on Veterinary Services considered the comments submitted and proposed revised definitions.

At their respective September 2020 meetings, the Code Commission and the Aquatic Animals Commission discussed the importance of ensuring alignment of these definitions in the two Codes except where differences could be justified and agreed to circulate the revised Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' in the *Terrestrial Code* and 'Competent Authority', 'Veterinary Authority' and 'Aquatic Animal Health Services' in the *Aquatic Code* for comments in the September 2020 report of the Code Commission and the Aquatic Animals Commission, respectively. Neither Commission addressed comments received during their respective February 2021 meetings due to time constraints.

In preparation for the September 2021 meetings, the Presidents of the Terrestrial and the Aquatic Commissions met to review all comments previously received. They acknowledged that the comments received indicated some confusion amongst some Members as to the intended meaning and use of these terms and that their September 2020 Commission reports did not provide sufficient information about the rationale for the proposed amendments. The Presidents agreed that the proposed definitions did not need significant changes and they proposed to provide a more detailed explanation of the rationale for the proposed amendments in the respective September 2021 Commission reports, as well as some more detailed information on the use of these terms in each Code.

At its September 2021 meeting, the Code Commission considered the comments received on its September 2020 report, as well as the feedback from the Presidents discussions. The Aquatic Animals Commission made one additional amendment to the definition for 'Veterinary Authority' that was not included in the Code Commission proposal, as not relevant for the *Terrestrial Code*. The revised definitions were circulated for comments in the Code Commission September 2021 report.

Discussion

The Code Commission considered the comments received on its September 2021 report and the President's feedback regarding the coordination with the Aquatic Animals Commission. The Code Commission was informed that, after considering the comments received, the Aquatic Animals Commission would not propose any further amendments at its February 2022 meeting to the revised definitions to be proposed for adoption in the *Aquatic Code*.

General comments

The Code Commission acknowledged a comment to review the foreword to the *Terrestrial Code* and other published OIE documents to ensure the use of consistent language with regards to the standards to provide certainty to Members about the roles of Competent Authorities, Veterinary Authorities and Veterinary Services as described in the new definitions. The Commission requested that the OIE Secretariat review this request once the revised definitions are adopted.

The Code Commission did not agree with a comment to modify the wording of the definitions as this comment did not consider the explanations provided in its September 2021 report.

'Competent Authority'

The Code Commission did not agree with a comment to replace "a Governmental Authority" by "any Governmental Authority" as it considered that the term is defined in singular, and as written it does not refer to a specific authority but to any given one that complies with the definition.

'Veterinary Authority'

The Code Commission did not agree with a comment to include "and for communication with the OIE with this regard" at the end of the proposed text. The Commission explained that the definition is not intended to provide specific recommendations in this regard, which are specifically included in relevant chapters of the Code (e.g. in Chapter 1.1.).

b) 'Protein meal'

In response to a comment requesting further clarification on the scope of the Glossary definition for 'protein meal', the Code Commission explained that the definition included all products regardless of intended uses as long as they meet its definition. The Commission reminded Members that the objective of the Glossary is to provide definitions of key terms that require precise interpretation for the purpose of their use in the Code, and definitions are expected to be as concise as possible and should not contain unnecessary descriptive detail or further elaborations beyond what is necessary to define the term. Further descriptive detail or explanation that may be necessary for the implementation of a standard are normally provided within relevant chapters.

In response to a query on possible impacts that the adoption of this new definition may have throughout the Code, the Code Commission referred Members to its discussions on the use of terms 'meat-and-bone meal' and 'greaves' (see item 4.9. of this report).

c) 'Stray dog': Proposed replacement with 'Free-roaming dog'

During work to revise Chapter 7.7. Stray dog population control, it was agreed that the term 'free-roaming dog' was more appropriate than 'stray dog' because 'free-roaming' described the behaviour of a dog that is currently roaming freely regardless of its ownership status. Consequently, it was agreed to replace 'stray dog' with 'free-roaming dog' throughout the chapter.

Given that 'Stray dog' is a defined term in the Glossary, it was agreed to replace 'Stray dog' in the Glossary with 'Free-roaming dog' and amend the definition accordingly.

In response to comments received on the proposed Glossary definition for 'Free-roaming dog', the Code Commission did not agree with a proposal to add the word 'restriction', as it considered the concept was already addressed by the term 'control' when describing the relationship between dogs and humans. In addition, the Commission did not agree to add text that described other categories of dogs as it considered this could be confusing.

The Code Commission confirmed that if the proposed Glossary definition for 'Free-roaming dog' is adopted, the term 'Stray dog' will be replaced by 'Free-roaming dog' throughout the *Terrestrial Code* for the 2022 edition.

Revised Glossary definitions for 'Competent Authority', 'Protein meal', 'Stray dog' (replaced by new definition for 'Free-roaming dog'), 'Veterinary Authority', 'Veterinary Services' are presented in **Annex 3** and will be proposed for adoption at the 89th General Session in May 2022.

EU position

The EU thanks the OIE and supports the adoption of these revised Glossary definitions.

4.2. Diseases, Infections and Infestations listed by the OIE (Articles 1.3.2., 1.3.4., 1.3.6.)

Article 1.3.2.

Comments were received from the AU-IBAR and the EU.

Background

As part of the revision of Chapter 11.10., Theileriosis (refer to item 4.10. of this report), the Code Commission has agreed to replace 'Theileriosis' with 'Infection with *Theileria annulata*, *Theileria orientalis and Theileria parva'*, and had circulated a revised Article 1.3.2. in its September 2021 report.

Discussion

The Code Commission noted comments in support of the proposed change and that no other comments had been received.

Article 1.3.4. and Article 1.3.6.

The OIE Secretariat informed the Code Commission of some discrepancies observed between the names of some listed diseases in Chapter 1.3. and the corresponding disease-specific chapters (i.e. Chapter 12.6., Chapter 12.8. and Chapter 10.5.). The Commission discussed this issue and agreed to amend the disease names in the list to align with those in the disease-specific chapters as they had been adopted more recently. The Commission decided to propose the revised articles for adoption at the 89th General Session in May 2022, given that these amendments were of editorial nature.

In Article 1.3.4., the Code Commission agreed to replace 'equine influenza' with 'infection with equine influenza virus', and replace 'infection with equid herpesvirus-1 (EHV-1)' with 'infection with equid herpesvirus-1 (Equine rhinopneumonitis)'.

In Article 1.3.6., the Code Commission agreed to replace 'avian mycoplasmosis (*Mycoplasma gallisepticum*)' with 'infection with *Mycoplasma gallisepticum* (Avian mycoplasmosis)', and 'avian mycoplasmosis (*Mycoplasma synoviae)'* with 'infection with *Mycoplasma synoviae* (Avian mycoplasmosis)'.

The Code Commission also acknowledged the discrepancy between the listed disease 'haemorrhagic septicaemia' in Article 1.3.2. and Chapter 11.7. Haemorrhagic septicaemia (*Pasteurella multocida* serotypes 6:b and 6:e), but decided not to amend Article 1.3.2. for the time being, considering that the Scientific Commission was considering the possibility of expanding the scope of this disease to include other strains of *Pasteurella multocida*.

Revised Articles 1.3.2., 1.3.4. and 1.3.6. are presented as part of **Annex 4**, and will be proposed for adoption at the 89th General Session in May 2022.

EU position

The EU in general supports the adoption of these revised articles. Comments are included in Annex 4.

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

Comments were received from Australia, Chinese Taipei, Mexico, New Caledonia, Saudi Arabia, the USA, the AU-IBAR and the EU.

Background

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

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

At its meeting in September 2021, the Code Commission proposed to include some text in Article 3.1.1. to explain the meaning of the 'One Health approach' given that this was the first instance where this term was used in the *Terrestrial Code*, rather than including a specific definition of 'One Health'. The Commission noted that the explanatory text was aligned with the definition for 'One Health' used in the Tripartite Zoonoses Guide.

The Code Commission also proposed amendments to Article 3.2.3. in consideration of the 'One Health approach', and Article 3.2.9. in response to a comment to refer to the storage of veterinary medicinal products.

Discussion

The Code Commission considered the definition of 'One Health' recently developed by the One Health high level expert panel (OHHLEP) and agreed that its proposed amendments in Article 3.1.1. are aligned with this definition.

Article 3.1.1.

In the second sentence of paragraph 1, the Code Commission agreed with a comment to replace 'interaction' with 'collaboration', noting that this better describes the One Health approach.

In the same sentence, the Code Commission did not agree with a comment to replace 'all relevant sectors and disciplines' with 'governmental and non-governmental individuals and organisations' as this is already covered by the definition for 'Veterinary Services'.

The Code Commission did not agree with a comment to delete 'all' before 'relevant sectors and disciplines' as it considered it was important to clarify that this means 'all', not 'some', reflecting the comprehensive approach of One Health.

In the last paragraph, the Code Commission did not agree with a comment to delete 'terrestrial' before 'animal health' to align with paragraph 2, and explained that the last paragraph referred to Section 3 of the *Terrestrial Code* which concerned terrestrial animals specifically.

Article 3.2.3.

In the first sentence, the Code Commission agreed with a comment to replace 'epidemiological' with 'epidemiology', but not to move 'and' before 'economics'.

In paragraph 2, the Code Commission did not agree with a comment to replace 'other relevant governmental authorities' with 'all governmental and non-governmental individuals and organisations', as it considered that the involvement of non-governmental authorities was already covered by the term 'stakeholders' in point 8.

For the same reason, in point 8, the Code Commission did not agree with a comment to replace 'other relevant governmental authorities and stakeholders' with 'all governmental and non-governmental individuals and organisations'. It reiterated its explanation in its February 2021 report that these entities were addressed by the term 'stakeholders'.

Article 3.2.9.

In paragraph 1, the Code Commission did not agree with a comment to add 'as well as monitoring and observe the food that comes from farms', and noted that the term 'including' meant that the mentioned activities were not exhaustive.

In point 1(b), the Code Commission did not agree with a comment to replace 'and appropriate safe storage and disposal' with 'safe storage and appropriate disposal', noting that 'disposal' should be not only appropriate but also safe.

Revised Article 3.1.1. and Articles 3.2.3. and 3.2.9. are presented as **Annexes 5 and 6** and will be proposed for adoption at the 89th General Session in May 2022.

EU position

The EU supports the adoption of these revised chapters.

4.4. Veterinary legislation (Article 3.4.11.)

Comments were received from Australia, Chinese Taipei, New Caledonia, Saudi Arabia, the AU-IBAR and the EU.

Background

A revised Chapter 3.4. Veterinary Legislation was adopted at the 88th General Session in May 2021.

At its meeting in September 2021, the Code Commission proposed amendments to point 1(b) of Article 3.4.11. in response to comments received at the 88th General Session, and also introduced changes to Article 3.4.5. as a consequence of the revision of the term 'sanitary measures' across the *Terrestrial Code* (see item 4.11. of this report).

Discussion

Article 3.4.11.

In the first sentence of paragraph 1, the Code Commission agreed with a comment to add 'safety and effectiveness' after 'quality'. Although the Commission considered that safety and effectiveness were addressed by 'quality', it agreed that it was important to emphasise these attributes.

In the same paragraph, the Code Commission did not agree with a comment to add 'and determining the period of drug withdrawal from animal products such as meat and dairy, and when will be able to consume by humans' as it considered that this point was covered in points 3(b)(iv) and 3(b)(v).

Revised Articles 3.4.5. and 3.4.11. are presented as **Annex 7** and will be proposed for adoption at the 89th General Session in May 2022.

EU position

The EU supports the adoption of this revised chapter.

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

Comments were received from Mexico, Saudi Arabia, the UK, the USA, the AU-IBAR and the EU.

Background

At its February 2019 meeting, in response to a request from the European Association of Zoos and Aquaria (EAZA), the Scientific Commission requested the Working Group on Wildlife to conduct a review of whether hepatitis B is a zoonotic disease that can be transmitted from gibbons to humans. As reported in its March 2020 meeting report, the Working Group on Wildlife concluded that hepatitis B was a disease of humans, not a zoonotic disease, as the *Hepadnaviridae* strains affecting humans are different from those affecting non-human primates. Moreover, current diagnostic techniques have made it possible to differentiate the different hepatitis B virus strains circulating in humans and non-human primates.

At its February 2021 meeting, the Code Commission considered the Scientific Commission's proposal to amend Chapter 6.12. to reflect that hepatitis B is a disease of humans and agreed to revise Articles 6.12.4., 6.12.6. and 6.12.7. accordingly. The revised articles have been circulated twice for comments.

Discussion

The Code Commission noted comments suggesting the possible inclusion of SARS-CoV-2 in Chapter 6.12. and requested that the OIE Working Group on Wildlife and the *ad hoc* Group on Covid-19 and safe trade in animals and animal products be consulted on this matter. The Code Commission also noted comments requesting the inclusion of "*Macacine Herpesvirus 1*", and requested the OIE Secretariat to seek expert opinion.

As noted in its February 2021 and September 2021 reports, the Code Commission reiterated that the scope of the proposed amendments to Chapter 6.12. was to reflect that hepatitis B is a disease of

humans and not a zoonotic disease, and that only this point was under review, i.e. other texts in the chapter were not under review. However, the Commission noted that some comments received on the test schedule and animal species to be tested for tuberculosis in Articles 6.12.5. and 6.12.6. may need to be reviewed. Consequently, the Code Commission requested that the opinion of the Laboratories Commission be sought on these comments.

Article 6.12.4.

In point 2(b), in response to a comment to specify a laboratory that is 'official, regulated by the Competent Authority of each country', the Code Commission proposed to replace 'laboratory approved for this purpose' with 'approved laboratory', given that 'approved' is a defined term in the Glossary.

In paragraph 2, in response to a comment questioning the inclusion of measles, the Code Commission requested the OIE Secretariat to seek expert opinion.

Article 6.12.7.

In point 3, the Code Commission did not agree with a comment to add 'and have the necessary facilities according to the level of risk posed by possible zoonoses', after 'personal hygiene practices'. While the Commission agreed that this was important, it noted that this point referred to the management measures to be followed by staff and not the physical facility. Furthermore, elaboration on the necessary facilities according to the level of biological risk is described in Chapter 1.1.4. Biosafety and biosecurity: standard for managing biological risk in the veterinary laboratory and animal facilities of the *Terrestrial Manual*.

Revised Articles 6.12.4., 6.12.6. and 6.12.7. are presented as **Annex 8** and will be proposed for adoption at the 89th General Session in May 2022.

EU position

The EU supports the adoption of this revised chapter.

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

Comments were received from Australia, Canada, Mexico, Norway, New Caledonia, Saudi Arabia, Switzerland, the USA, the AU-IBAR, the EU and the GAPFA.

Background

In September 2018, the Code Commission agreed to revise Chapter 7.7. Stray dog population control to ensure it was aligned with the Global Strategic Framework for the elimination of dog mediated human rabies by 2030.

The *ad hoc* Group on the Revision of Chapter 7.7. Stray dog population control was reconvened for a third time in 2021 to address comments on the revised draft chapter circulated in the Code Commission's September 2020 report. The Commission considered the Group's proposal and agreed to circulate the report and draft chapter for Member comments after its September 2021 meeting.

Discussion

The Code Commission reviewed comments received on the draft chapter circulated in its September 2021 report.

General

The Code Commission considered comments that proposed to replace the concept of 'five freedoms' with 'five domains' and while it recognised the importance of 'five domains', it agreed not to make any changes until more consideration is given to the possible inclusion of this concept in Chapter 7.1. Introduction to the recommendations for animal welfare. The Commission recommended the OIE

Secretariat to work with the Animal Welfare Collaborating Centres to provide more information about this concept for further consideration at its September 2022 meeting.

Article 7.7.1.

In the first paragraph, the Code Commission did not agree with a comment to add a sentence to emphasise the percentage of dog-mediated rabies cases in humans, as this chapter is relevant not only for rabies but also for other dog-mediated diseases.

In the first paragraph, the Code Commission did not agree with a comment to add 'animal health and public health' to specify the problem that may be reduced by the Dog Population Management (DPM), as it considered that any concern or nuisance, and not only those related to animal or public health could be a problem.

In the first paragraph, the Code Commission did not agree with a comment to add 'group of' before 'dogs' because the chapter addresses all dogs whether in groups or alone. The Commission did not agree with a comment to add 'within a specific area' because it considered that it was unnecessary to limit the geographical scope of the DPM approach.

In the second paragraph, the Code Commission agreed with a comment to remove 'unwanted' when referring to the reduction of puppies as it was implicit. The Commission did not agree with comments to change the text of this paragraph to specify that mass culling is not an effective long-term method, as the Commission considered that this may imply that short-term mass culling is acceptable. In addition, the World Health Organization (WHO) states that mass culling (whether short-term or long-term) is ineffective (WHO Expert Consultation on Rabies, third report. Geneva: World Health Organization; 2018 (WHO Technical Report Series, No. 1012). The Commission did not agree with a comment to add 'integral part of' for sustainable rabies control as it does not provide any additional clarity.

The Code Commission did not agree with a comment to add a new paragraph regarding the use of routine vaccination as it considered it was not needed in this context.

Article 7.7.2.

The Code Commission agreed with a comment to remove the term 'DPM' as it agreed it was redundant to use the defined term within its definition.

Article 7.7.3.

The Code Commission agreed with a comment to amend the text to specify that the zoonotic diseases of concern are those transmitted by dogs and added 'dog-mediated' as this term is already used in the text.

The Code Commission did not agree with a comment to add 'and more specifically free-roaming dog population dynamics' to the description of the scope of this chapter and highlighted that the scope is to manage the whole population of dogs and not just free roaming population.

The Code Commission did not agree with a comment to replace 'human health' with 'animal health, public health' as it considered 'human health and safety' as clear as written and that 'animal health' is already included in the sentence.

Article 7.7.4.

The Code Commission did not agree with a comment to replace 'dependent on' with 'have a strong relationship with' as it considered that domesticated dogs are dependent on humans to some extent even when resources to which dogs have access are not provided to them intentionally.

Article 7.7.5.

In the first bullet point, the Code Commission agreed with the proposal to add ‘in accordance with Article 7.7.17’ to provide the link to the relevant article.

In the third bullet point, the Code Commission did not agree with a comment to replace ‘manageable’ with ‘minimum’. However, the Commission deleted ‘to a manageable level’ which did not add meaningful information.

In the fourth bullet point, the Code Commission did not agree with a comment to replace the whole point by ‘promote and support the sterilisation of stray dog’ because these points describe objectives and not specific measures.

In the fifth bullet point, the Code Commission agreed with a comment to add examples such as ‘leishmaniosis and echinococcosis’, as it considered them to be relevant examples.

In the seventh bullet point, the Code Commission agreed with a comment to remove all examples because it considered that they were unnecessary. The Commission rephrased the text to clarify that this point is about the nuisance that might be caused by dogs when roaming freely.

Article 7.7.6.

In the first paragraph, the Code Commission agreed with a comment to add ‘environment’ to the list of areas where the Competent Authorities have responsibilities.

Article 7.7.7.

In the first paragraph, the Code Commission agreed with a comment to add ‘relevant stakeholders’ to the list of entities between which a DPM should be coordinated to include non-governmental stakeholders.

In point 1, the Code Commission agreed with a comment to replace ‘should be identified as’ by ‘is’ to simplify the sentence and emphasise that a DPM is under the responsibility of the Competent Authority.

In point 5, the Code Commission did not agree with a comment to add ‘resources including’ when describing the access to appropriate veterinary medicinal products as it did not provide any additional clarity. The Commission did not agree with a comment to add ‘in collaboration with the multi-sectoral group’ to the last sentence because this group was already addressed in the first paragraph.

Article 7.7.8.

In point 2, the Code Commission did not agree with a comment to add ‘or education institutions’ as an entity with which Veterinary Services should coordinate because many others could potentially be involved.

In point 3(a), the Code Commission agreed with a comment to replace ‘would normally’ with ‘usually’ for clarity.

In point 5, the Code Commission did not agree with a comment to replace ‘dog behaviour’ with ‘ethology’ as it considered the text clear as currently written.

Article 7.7.9.

In the first paragraph, the Code Commission agreed with a comment to change ‘DPM Legislation’ by ‘Legislation that addresses DPM’ to include other legal instruments not primarily for DPM but could be important when implementing a DPM programme.

In the third bullet point, the Code Commission agreed with a comment to delete ‘in centralised or interoperable databases’, and to add ‘in an animal identification system’, a defined term in the Glossary that addresses options for registration and identification of dogs.

In the fourth and fifth bullet points, the Code Commission agreed with a comment to add '*Registration*,' but instead of replacing 'authorisation and licensing', it was added as an additional option to authorisation and licensing.

In the last paragraph, the Code Commission agreed with a comment to add 'and should be adapted to the national context' at the end of the sentence.

Article 7.7.10.

In the title, the Code Commission agreed with a comment to add 'DPM' for clarity and consistency.

In the third paragraph, the Code Commission agreed with a comment to add 'in collaboration with the multi-sectoral group' as it considered that it was important that additional groups with relevant experience collaborate with the Competent Authorities.

Article 7.7.11.

In point 5, the Code Commission agreed with a comment to add 'and greater local engagement' given the importance of ensuring adequate engagement when estimating the dog population size.

In the second paragraph of point 5, the Code Commission did not agree with a comment to modify the example for monitoring changes in population trends as it considered that it was appropriate as it is to target areas with a high density of free-roaming dogs to create a more efficient and sensitive way of measuring changes in free-roaming dog density.

Article 7.7.12.

In the first bullet point, the Code Commission did not agree with a comment to add the word 'information' after 'responsible dog ownership' but agreed to replace 'they are receiving' with 'there is' to avoid misinterpretation.

In the second bullet point, the Code Commission agreed with a comment to delete the text at the end of the sentence as it was considered too specific.

In the third bullet point, the Code Commission did not agree with a comment to reinstate the reference to the two disease-specific chapters as the reference to disease names (i.e. rabies and echinococcus) is sufficient.

Article 7.7.13.

The Code Commission did not agree with a comment to move the fourth bullet point up, as the list is not hierarchical and thus it would not change the understanding of this point.

In the sixth bullet point, the Code Commission agreed with a comment to change 'vaccination' to 'vaccinate' to accurately describe the acronym i.e. CNVR. This change was applied throughout the draft chapter.

Article 7.7.14.

In the penultimate paragraph, the Code Commission agreed with a comment to replace the sentence 'in centralised or interoperable databases', with 'an animal identification system', to be consistent with the modification made in Article 7.7.9. The Commission also agreed with a comment to add a sentence at the end of the paragraph to describe the potential partnerships that may be needed to develop and operate relevant databases.

In the last paragraph, the Code Commission agreed with a comment to make an amendment to clarify that the database remains under the authority of the *Competent Authority*.

The Code Commission noted a comment that resources are needed to implement databases and emphasised the importance of collaboration with other stakeholders.

Article 7.7.15.

The Code Commission did not agree with a comment to add a new outcome 'prevention of uncontrolled reproduction of the dog population' to the list as it considered that controlling commercial breeding and sale would not achieve the outcome of preventing uncontrolled reproduction of the dog population; non-commercial dogs have an important role to play.

In the second paragraph, the Code Commission did not agree with a comment to add 'professional' when referring to breeders and sellers because 'mandatory registration of all breeders' is needed to gain control of breeding where puppies are sold; whether the breeders are professional or not.

In the last paragraph, the Code Commission did not agree with a comment to specify 'sales from the street' because there are many other places where these unregulated sales can take place.

Article 7.7.17.

In point 1, the Code Commission did not agree with a comment to replace 'is a choice' with 'comes with responsibilities' as it considered dog ownership to be a 'choice' and if the choice is taken, it comes with responsibilities which is noted in the next sentence.

In point 2, in the first indent, the Code Commission did not agree with a comment to replace the concept of 'five freedoms' with 'five domains' (see explanation in the General comments above).

Article 7.7.18.

The Code Commission did not agree with a proposal to add text to address the concept of owner's consent as it considered this to be an unnecessary detail.

In point 1, the Code Commission did not agree with a comment to add a new outcome of controlling reproduction in dogs as it considered that there was no strong evidence that there is a reduced risk to the human population when male free-roaming dogs are castrated, and the impact on the population is lower than reproduction controls with a focus on females.

Article 7.7.19.

The Code Commission did not agree with a comment to add text about the level of immunity that free-roaming dogs have to have developed prior to adoption, as it did not consider that the measures were feasible.

Article 7.7.20.

The Code Commission did not agree with a comment to remove the text 'as an alternative to abandonment' because it would imply that relinquishment was a bad choice and might be seen as a disincentive. Relinquishment in an *ad hoc* place is not the same as abandonment on the street.

Article 7.7.25.

In the third paragraph, the Code Commission agreed with a comment to add 'where appropriate' to add flexibility.

Article 7.7.27.

In the first sentence of the first paragraph, the Code Commission deleted the terms 'humanly' and added 'in accordance with Article 7.6.1.', to improve clarity, as the defined term 'Euthanasia' clearly describes how the induction of death of an animal should be done and Article 7.6.1. describes the general principle to consider. Consequently, it also deleted the term 'humane' under point 1 and point 3 for consistency.

The Code Commission did not agree with a comment to elaborate the text on euthanasia because this paragraph is about the role of euthanasia as a specific activity within DPM.

In the last paragraph of point 2, the Code Commission agreed with a comment to add 'and any other methods that could compromise the welfare of the animal' to be more encompassing.

Revised Chapter 7.7. Stray Dog population control is presented as **Annex 9** and will be proposed for adoption at the 89th General Session in May 2022.

EU position

The EU thanks the OIE for having taken into consideration the majority of our comments submitted previously. We welcome and in general support the adoption of this revised chapter. Comments are inserted in the text of Annex 9.

4.7. Infection with rinderpest virus (Chapter 8.16.)

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

Background

At its September 2018 meeting, the Code Commission considered Member requests to clarify the definitions of 'case' and 'suspected case', the reporting obligations of Members, and the inclusion of measures that should be implemented if there is a re-emergence of rinderpest virus, and agreed that there should be a thorough review of Chapter 8.16.

The Code Commission also agreed with the Scientific Commission that in this post-eradication era, the priority should be the maintenance of global freedom from rinderpest and its prompt recovery in case of re-emergence, and consequently, the structure of the chapter and trade provisions should be revised to ensure they are aligned with this objective.

A thorough review of Chapter 8.16. Infection with rinderpest virus was undertaken by the *ad hoc* Group on Rinderpest (March 2020 report). A revised chapter was circulated for comments on three occasions, the last time as an annex in the Code Commission's September 2021 report.

Discussion

Article 8.16.1.

In response to a comment on the lack of clarity as to whether potential and suspected cases may be confirmed in a national laboratory, or whether this needs to be done at an OIE Reference Laboratory in order to meet the definitions for potential and suspected cases, the Code Commission explained that samples from potential cases of rinderpest virus (RPV) may be submitted to an approved laboratory for diagnosis, not necessarily an OIE Reference Laboratory for rinderpest. However, as elaborated in Article 8.16.5., if there is a positive reaction in a diagnostic test for RPV conducted outside of an OIE Reference Laboratory for rinderpest, samples should be sent to an OIE Reference Laboratory for confirmation. The Commission clarified that cases could only be confirmed by an OIE Reference Laboratory for rinderpest, because rinderpest is the only globally eradicated disease. To ensure that this important point was clear to Members, the Commission proposed to add the sentence 'a case of infection with RPV shall be confirmed in an OIE Reference Laboratory for rinderpest' to point 1. It also proposed similar amendments to Article 8.16.3.

In point 2(c)(iii), the Code Commission agreed with a comment to delete 'with or' before 'without clinical signs', noting that the detection of RPV-specific antibodies that are not a consequence of vaccination in a susceptible animal with clinical signs would constitute a case in accordance with point 2(b)(iii), or a suspected case in accordance with 2(c)(ii), depending on whether the diagnosis was performed at an OIE Reference Laboratory for rinderpest.

Article 8.16.2.

The Code Commission proposed to add the title 'safe commodities' for consistency with other disease-specific chapters.

In point 2(a), the Code Commission did not agree with a comment to reinstate the text 'which have been submitted to the usual chemical and mechanical processes in use in the tanning industry'. The Commission reiterated that for commodities to be assessed as safe, the processing or treatment of these commodities should use standardised protocols, as described in Chapter 2.2. Criteria applied by the OIE for assessing the safety of commodities, and as such this addition would not provide any added value. The Commission proposed to delete the example of 'wet blue and crust leather' in parenthesis as it did not consider that examples were necessary, and agreed to include this issue in its work on the development of a standard operating procedure for safe commodities. (See Part B of this report).

Article 8.16.2bis.

The Code Commission proposed amendments to the second sentence to clarify that point 2 of Article 8.16.5. would apply in the event of re-emergence of rinderpest.

Article 8.16.3.

In the title, the Code Commission agreed with a comment to replace 'post' with 'during' for clarity.

In the third sentence of paragraph 1, in line with proposed amendments made in Article 8.16.1., the Code Commission proposed amendments to clarify that countries may send samples from potential cases to an approved laboratory, which may not necessarily be an OIE Reference Laboratory. The Commission also proposed to delete 'for routine checking' as it considered this to be vague.

The Code Commission acknowledged a comment on the obligation for all countries to keep rinderpest a notifiable disease in their territory given the global freedom of rinderpest.

Article 8.16.5.

Similarly, the Code Commission acknowledged a comment that the obligation to notify a suspected case of infection with RPV to the OIE is an exceptional circumstance, justified because of the globally eradicated status of the disease.

In paragraph 3 of points 1 and 2, the Code Commission proposed to delete 'appointed' as it considered this to be unnecessary.

In paragraph 4 of point 2, the Code Commission proposed to replace 'may' with 'should' to emphasise the implementation of a containment zone for consistency with Article 8.16.8.

In the last paragraph of the same point, the Code Commission proposed to delete 'with the infected country or countries' as it was considered redundant.

Article 8.16.8.

In paragraph 1, the Code Commission did not agree with a comment to replace 'should' with 'may' and explained that the implementation of a containment zone should be clearly recommended for the purposes of disease control and eradication of rinderpest should it reoccur. This also ensured alignment with proposed changes in paragraph 4, point 2 of Article 8.16.5. In the same paragraph, the Commission agreed with a comment to delete 'safe' before 'commodities' as it was not considered necessary given there is a reference to Article 8.16.2. The Commission also agreed with a comment to add 'for the whole country in accordance with Article 8.16.9.' to clarify that this applies to the whole country.

Article 8.16.9.

In point 2(a), the Code Commission agreed to replace 'animal disease reporting' with 'disease notification' given this is a defined term in the Glossary and to ensure consistency with Chapter 1.1. Notification of diseases and provision of epidemiological information.

Article 8.16.11.

In point 4, the Code Commission proposed to delete 'appointed' before 'OIE Reference Laboratory' to align with its proposed changes in Article 8.16.5.

Revised Chapter 8.16. is presented as **Annex 10** and will be proposed for adoption at the 89th General Session in May 2022.

EU position

The EU thanks the OIE and in general supports the adoption of this revised chapter. Comments are inserted in the text of Annex 10.

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

Comments were received from Mexico, New Caledonia, New Zealand, the UK, the USA, the AU-IBAR and the EU.

Background

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

The Code Commission was informed that relevant amendments had been proposed by the Laboratories Commission for Chapter 3.10.3. Cysticercosis (including infection with *Taenia solium*) of the *Terrestrial Manual*, which was subsequently adopted in May 2021, and Chapter 3.1.6. Echinococcosis (infection with *Echinococcus granulosus* and with *E. multilocularis*) which would be proposed for adoption in 2022.

At its September 2021 meeting, the Code Commission proposed amendments to Chapters 8.5. and 15.4. to align with the latest modifications included in the corresponding chapters of the *Terrestrial Manual*. The Commission also proposed to include provisions on vaccination as a prevention or control tool.

Discussion

a) Infection with *Echinococcus granulosus* (Chapter 8.5.)

Article 8.5.1.

In the fifth paragraph, the Code Commission agreed with a comment concerning the sole Spanish version, to replace the word 'hombre' with 'ser humano', which is gender neutral.

Article 8.5.3.

In response to comments and for consistency with the amendments of some terms being proposed in the revised Chapter 7.7. Stray dog population control (Dog population management) and in the Glossary, the Code Commission proposed to replace 'stray' with 'free-roaming' throughout this article (see item 4.1. of this report). The Commission noted that these changes would only be made should the proposed amendments in Chapter 7.7. and the Glossary are adopted in May 2022.

In points 1 and 2, the Code Commission proposed to delete '(owned and stray)' as the scope of dogs is already covered in the chapter.

In point 2(b), the Code Commission noted a comment regarding the preference to use vaccination in view of antimicrobial resistance (AMR), and the impracticability of disposal of faeces by incineration or burial. The Commission explained that there was no vaccine against *Echinococcus* infection in dogs described in the corresponding revised *Terrestrial Manual* chapter. The Commission also wished to inform Members of the new publication: A key role of veterinary

authorities and animal health practitioners in preventing and controlling neglected parasitic zoonoses – A handbook with focus on *Taenia solium*, *Trichinella*, *Echinococcus* and *Fasciola*.

In point 3(c), the Code Commission agreed with a comment noting that vaccines registered for use in livestock are limited to a few countries and that its use should remain optional, and proposed to add 'where indicated' at the beginning of the sentence.

b) Infection with *Taenia solium* (Porcine cysticercosis) (Chapter 15.4.)

Article 15.4.1.

In the first sentence of paragraph 1, the Code Commission did not agree with a comment to replace 'parasite' with 'parasitic infection', noting that *Taenia solium* as used here refers to the pathogenic agent. In the second sentence, the Commission noted a comment to add 'Eastern Europe' to the geographical areas where *Taenia solium* may be found, and proposed to delete as a whole the information on spatial distribution as this is not normally included in other disease-specific chapters of the *Terrestrial Code* and is difficult to keep up to date. In the third sentence of the same paragraph, the Commission did not agree with a comment to add 'and cat' after 'dogs', but proposed to replace 'dogs' with 'other carnivores' for completeness, as mustelids are also susceptible.

If the first, second and fifth paragraphs, the Code Commission agreed with a comment concerning the sole Spanish version, to replace the word 'hombre' with 'ser humano', which is gender neutral. This change was also applied in Article 15.4.3.

Article 15.4.3.

In paragraph 2, in response to a comment querying whether the use of 'animal health management' is appropriate, the Code Commission explained that this was in line with the Glossary definition.

In point 1(f), the Code Commission agreed with a comment to add 'where indicated' to the beginning of the sentence, noting that the use of vaccines may be limited to a few countries and therefore vaccine use may not always be possible.

Regarding a comment querying whether point 1(f) is a control measure which should be in point 2, the Code Commission clarified that point 1(f) should remain under point 1 as point 2 pertains to veterinary public health measures and not to the individual treatment of pigs.

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

EU position

The EU thanks the OIE and supports the adoption of these revised chapters.

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

Background

In February 2018, following preliminary work and discussions, the Code Commission and the Scientific Commission agreed to an in-depth review of Chapter 11.4. Bovine spongiform encephalopathy (BSE). The OIE convened three different *ad hoc* Groups between July 2018 and March 2019: i) an *ad hoc* Group on BSE risk assessment, which met twice, ii) an *ad hoc* Group on

BSE surveillance, which met once, and iii) a joint *ad hoc* Group on BSE risk assessment and surveillance, which met once.

At its September 2019 meeting, the Code Commission reviewed the four *ad hoc* Group reports together with the opinion of the Scientific Commission and circulated a 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 the OIE of risk status for bovine spongiform encephalopathy to ensure alignment with the proposed changes in Chapter 11.4.

At its September 2020 meeting, the Code Commission reviewed the joint *ad hoc* Group report and the 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.

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

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

At its September 2021 meeting, the Code Commission considered comments received and amended the chapters, as appropriate, and circulated the revised chapters for a fourth round of comments.

Discussion

a) Chapter 11.4. Bovine spongiform encephalopathy

Comments were received from Argentina, Australia, Brazil, Canada, China (People's Rep. of), Chinese Taipei, Japan, New Zealand, the UK, the AU-IBAR, the EU and the WRO.

General comments

The Code Commission noted concerns raised by some Members on the determination and publication of the date from which the risk of BSE agents being recycled within the cattle population has been negligible. The Commission also noted that a Member questioned some of the details of suspension of negligible BSE risk status described in Article 11.4.3bis., and eligibility for countries and zones that are currently recognised as having a controlled BSE risk status and that could meet the conditions of the new Article 11.4.3. to apply for negligible risk status. The Code Commission explained that the specific procedures related to OIE official status recognition would be discussed by the Scientific Commission at its February 2022 meeting. The Code Commission encouraged Members to refer to the February 2022 report of the Scientific Commission for outcomes of this specific point of discussion.

The Code Commission noted that some Members expressed their interests in the "Guidelines for BSE surveillance" that the Scientific Commission had requested the OIE to develop to help Members revise their surveillance programmes in accordance with the new BSE chapter, especially for some countries posing currently a negligible risk. The Code Commission clarified that these guidelines would not create a need for any further modifications to the chapter. The Code Commission was informed that a proposal to develop the guidelines would be discussed by the Scientific Commission at its February 2022 meeting.

The Code Commission noted a comment that it is essential that any changes to the chapter do not increase the administrative burdens or trade barriers for countries that hold a negligible BSE risk status, given the global context and epidemiology with respect to diminishing overall BSE and vCJD risks. The Commission explained that the proposed text was based on the scientifically

justified concept that even negligible BSE risk countries may have two subpopulations (the cattle population born before the date from which the risk of BSE agents being recycled has been negligible and the cattle population born after that date). The Commission also highlighted that, although this might create some administrative burden, the outcome of the risk assessment described in Article 11.4.2. could often conclude that the date from which the risk of BSE agents being recycled has been negligible occurred at a time point dating back for longer than the maximum life span of cattle, and, in that specific case, it would not be necessary to differentiate the two subpopulations at all.

The Code Commission considered concerns raised that the proposed recommendations are not proportionate to the current BSE risks and that the OIE should re-evaluate the negative impact on the international trade of protein meal and other by-products. In response, the Commission agreed and proposed some amendments on the recommendation for importation of cattle-derived protein meal from a country, zone or compartment posing negligible BSE risk and the recommendation in relation to the trade of the commodities with the greatest BSE infectivity (see Article 11.4.12. and Article 11.4.14. below).

The Code Commission noted that some Members disagreed with the Code Commission's position that the risk of atypical BSE being recycled in cattle through oral exposure to contaminated feed is significant enough to warrant the new risk assessment and management measures proposed in the draft text. The Commission also noted that some Members requested the OIE to consider a broader scale of evidence and experience relating to BSE risk over time and to conduct an epidemiological field study to conclude if an amplification of an atypical case is a realistic probability, rather than putting weight on isolated experimental transmission study. In response to these comments, the Commission reiterated that the joint *ad hoc* Group on BSE risk assessment and surveillance had concluded that atypical BSE is considered to be capable of being recycled in a cattle population if cattle are exposed to contaminated feed, as atypical BSE arises as a spontaneous disease in any country. The Commission emphasised that the conclusion on possible recycling of atypical BSE in a cattle population had been based on the result of an experimental transmission study, which is highly relevant, and reiterated that both the Code Commission and the Scientific Commission had considered that the risk of atypical BSE being recycled in cattle needs to be addressed. The Code Commission encouraged Members to refer to the relevant information provided in the March 2019 report of the *ad hoc* Group on BSE risk assessment and surveillance, notably Annex IV of the report which provides the overview of relevant scientific findings on atypical BSE.

In response to a suggestion to include in the Glossary a description as to how to differentiate 'risk' from 'likelihood' in the *Terrestrial Code*, the Code Commission explained that the term 'risk' was defined in the Glossary as 'the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health', likelihood meaning probability while risk includes likelihood and consequences.

In response to a comment that the requirements in this chapter are nearly impossible to be met for some Members in some regions and that testing to prove absence of BSE is very expensive and that many Members in the region cannot afford, the Code Commission highlighted that the proposed Article 11.4.18. focuses on passive surveillance rather than active surveillance, which would facilitate the Members' application for the official recognition of the BSE risk status.

Lastly, the Code Commission was informed that the OIE Secretariat had considered implications on official status recognition and maintenance with regard to the potential adoption of the revised BSE standards and that the best way to address the transition from the current to the new standards would be discussed at the February 2022 Scientific Commission meeting. The Code Commission encouraged Members to refer to relevant part of the February 2022 Scientific Commission meeting report for the agreed way forward.

Article 11.4.1.

In point 3, the Code Commission did not agree with a comment to revert to 'PrP^{BSE}' or to change to 'PrP^{TSE}' and reiterated the need to ensure alignment with the corresponding *Terrestrial Manual* chapter. The Commission requested that this comment be forwarded to the Laboratories Commission for its advice on this point.

In point 4(b), the Code Commission agreed to delete the definition for protein meal given that the Glossary definition would be proposed for adoption in May 2022 (see item 4.9.(c) of this report).

Article 11.4.2.

In point 1(a)(i), the Code Commission did not agree with a comment to add 'sheep and goats' in the commodities that should be considered in the entry assessment, as it had agreed with the *ad hoc* Group's opinion that, 'although the evidence provided (on the emergence of classical BSE from atypical/Nor98 scrapie in small ruminants) represents a hazard of interest, the revised standards account for mitigation strategies to avoid the exposure of cattle to ruminant-derived protein irrespective of the source of that ruminant-derived protein'. The Commission encouraged Members to refer to the June 2021 *ad hoc* Group report on the revision of BSE standards and its impact on the official status recognition for relevant information.

In point 1(c)(iii), the Code Commission did not agree with a comment to add 'number of BSE cases reduced due to the' before 'impact of cattle industry practices'. The Commission considered that this point describes the impact of cattle industry practices or the implementation of BSE-specific mitigation measures under a feed ban, which were considered in the exposure assessment, and the degree of decrease in BSE cases is not necessarily considered relevant and not possible to estimate for countries with no cases.

In point 1(d), the Code Commission did not agree with a comment to replace ', and to' with '. When applicable, it may also' and explained that all Members that apply for an official BSE risk status have to estimate the date from which the risk of BSE agents being recycled within the cattle population has been negligible in the step of risk estimation.

In the same point, the Code Commission did not agree with a comment to add descriptions on possible dates for countries and zones with negligible BSE risk status or controlled BSE risk status, as it considered this article describes the process for the determination of the BSE risk.

In point 2, the Code Commission agreed with comments to delete 'classical' to align with the proposed addition of the first paragraph of Article 11.4.18.

Article 11.4.3.

In point 1, the Code Commission did not agree with a comment to add 'and routes' after 'all potential risk factors' as it was important to ensure alignment with the wordings in point 1 of Article 11.4.2.

In the same point, in response to a comment to reinstate the deleted point 1(a) and 1(b) to clearly describe what requirement Members must fulfil, the Code Commission reiterated that the reinstatement was not necessary as the two pathways, described in these deleted points, have already been well addressed in the new point 1 of Article 11.4.2. The Commission reiterated that in the dossier for the OIE the applicant Members should provide documented evidence that ruminant-derived protein meal has not been fed to ruminants, and the measures implemented to ensure that, including a feed ban, as explained in the June 2020 report of the *ad hoc* Group on BSE risk assessment and surveillance. Nevertheless, in order to make that clear in the text of the article, the Commission proposed an amendment to highlight the fact that the major risk factor is feeding cattle with ruminant-derived protein meal and this must be considered in the risk assessment and the related risk mitigation measures.

In point 3(b)(ii), the Code Commission did not agree with a comment that an indigenous case of classical BSE in animals born after the date from which the risk of BSE agents being recycled within the cattle population has been negligible indicates that there has either been a breakdown in control measures (specifically, in the feed ban) or in surveillance. The Commission reiterated that the cases do not necessarily reflect a breakdown of effective control measures, considering that the BSE agent can remain biologically active for many years and therefore isolated pockets of residual infectivity in a complex network of rendering, feed production, distribution and storage may account for rare, sporadic opportunities of exposure to contaminated protein meal. The Commission encouraged Members to refer to the July 2018 report of the *ad hoc* Group on

BSE risk assessment, in which the outcome of a detailed investigation of 60 classical BSE cases in the EU born after the "total" feed ban was discussed. The Commission also noted a recently published modelling study (*Epidemiol. Infect.* (2017), 145, 2280-2286) to which the Members could also refer.

In the same point, the Code Commission agreed with a comment that the word 'mitigated' did not reflect the importance of the control measures, and proposed to replace it with 'controlled'. The Commission proposed a similar amendment in Article 11.4.3bis.

In the same point, the Code Commission did not agree with a comment to replace 'a case was' with 'any cases were' and explained that if the applicant country has two or more cases born after the date, the information on subsequent investigations for all the cases should be included in the dossier that must be submitted to the OIE. In response to a comment to clarify what would happen if the source of a classical BSE case born after the date cannot be determined by the subsequent investigations, the Commission explained that such a situation is possible, given the uncertainties resulting from the timespan between the confirmation of any BSE cases and their potential exposure to the BSE agent within their first year of life; in that case, additional risk mitigation measures would not be needed as long as the country could demonstrate that the risk of BSE agent being recycled within the cattle population has continued to be negligible.

In point 4, in the first paragraph, the Code Commission did not agree with a comment to delete 'disposed of' as it considered that whilst destruction is not related to inactivation of the pathogenic agents, some disposal procedures such as the ones described in Article 11.4.17. could inactivate BSE agents, and inclusion of 'disposed of' was relevant here.

Article 11.4.3bis. (proposed to be renumbered Article 11.4.5bis.)

In the first paragraph, the Code Commission did not agree with a comment to add 'and atypical' after 'classical' and reiterated that the occurrence of atypical cases would not affect the BSE risk status.

In the same paragraph, the Code Commission agreed with a comment to replace 'within the preceding eight years' with 'after the date from which the risk of BSE agents being recycled within the cattle population has been negligible' as it considered it necessary to align with the approach taken throughout the chapter.

In response to a comment to develop a new article on maintenance of controlled BSE risk status aligned with Article 11.4.3bis., the Code Commission agreed to amend Article 11.4.3bis. based on the Scientific Commission's proposal to develop an article on maintenance of negligible or controlled BSE risk status after detection of an indigenous case of classical BSE born after the date (from which the risk of BSE agents being recycled within the cattle population has been negligible) in a country or zone recognised as posing a negligible or controlled risk for BSE. The Code Commission proposed some amendments to Article 11.4.3bis. to reflect this change and ensure alignment with text used throughout the chapter, and it also proposed that the article be renumbered 11.4.5bis.

Article 11.4.4.

In the first paragraph, in response to comments to clarify the meaning, the Code Commission proposed an amendment to improve clarity. The Commission also highlighted that 'all of the conditions of Article 11.4.3. are met' is written in present tense (i.e. at the time of application), but the part after 'but' is written in present perfect tense (duration).

Article 11.4.7.

In point 1, the Code Commission agreed with a comment to delete 'came from a country, zone or compartment posing a negligible or controlled BSE risk and', as this is covered by point 2 and

ensures alignment with the amendments which have been introduced in Articles 11.4.10., 11.4.12. and 11.4.13.

In the same point, in response to a comment that the requirement for an animal identification system is not mentioned as a requirement for negligible BSE risk countries under Article 11.4.2. and that an animal identification system is not necessary for the appropriate management of risk of BSE, the Code Commission reiterated that BSE concerns the lifespan of an animal and therefore an animal identification system is essential to enable the Veterinary Authority to trace the origin of animals for the purpose of effective control. The Commission highlighted that this point refers to an animal identification system, as defined in the Glossary, meaning that it could involve identification and registration by animals individually, or collectively by its epidemiological unit or group. It also highlighted that this requirement concerned live animals destined for exportation, for which common sanitary measures require such identification.

In point 2, the Code Commission did not agree with comments to replace 'a country, zone or compartment' with 'one or more countries, zones or compartments'. The Commission explained that this point does not mean that the cattle selected for export must be born and kept in only one country (or zone or compartment) posing a negligible or controlled BSE risk and that as long as the cattle selected for export were born and kept in such countries (or zones or compartments) after the date (from which the risk of BSE agents being recycled within the cattle population has been negligible), the number of countries/zones/compartments where the cattle were kept does not matter in terms of BSE risk mitigation. The Commission noted that this response also applies to similar comments submitted for Articles 11.4.10., 11.4.12. and 11.4.13.

Article 11.4.10.

In response to a query as to whether Articles 11.4.10. and 11.4.11. apply to meat and meat products only for human consumption, the Code Commission explained that they are not limited to human consumption as long as it meets the Glossary definitions. Additionally, the Code Commission reminded that the recommendations within the Code for trading commodities were to provide sufficient risk mitigations measures in relation to the relevant disease, and apart few exceptions, irrespectively of the final destination of those commodities.

Article 11.4.12.

In response to a query on the scope of protein meal to be defined in Glossary, the Code Commission clarified that the proposed definition could include protein meal for all uses as long as they meet the Glossary definition.

The Code Commission noted a number of concerns on the recommendations described in Article 11.4.12. These concerns included: some Members considered that the revised recommendations for the importation of cattle-derived protein meal from a country, zone or compartment posing a negligible BSE risk is disproportionate to the objective of reducing BSE and vCJD risks; some Members and the rendering industry pointed out that it would not be possible to implement the recommendations in many countries due to lack of a system to trace back the derived cattle; and queries that in the revised chapter the rendering procedures are not considered as a risk mitigation measure for safe trade of cattle-derived protein meal. In response to these, and in order to prevent unjustified trade barriers whilst ensuring effective risk mitigation measures, the Commission proposed to add a new point that allows for the possibility of protein meal being derived from cattle that cannot be certified as born after the date, as long as the protein meal was subjected to the procedures for reduction of BSE infectivity as described in Article 11.4.17.

Article 11.4.14.

In the title, the Code Commission did not agree with a comment to add 'potential' before 'greatest BSE infectivity' as it considered it was clear as written.

In point 1(b), regarding the recommendation not to trade the listed commodities from country, zone or compartment posing negligible BSE risk, the Code Commission agreed to remove the reference to this risk category in line with the amendment to Article 11.4.12., noting that the overall burden would significantly exceed the risk.

In the same point the Code Commission did not agree with a comment to delete ‘a controlled BSE risk or’. In this case, the risk represented by the cattle population born after the date from which the risk of BSE agents being recycled has been negligible warrants this measure.

In point 2, in response to a comment as to what is meant by ‘pharmaceuticals including biologicals’, the Code Commission explained that this term is used in the current Article 11.4.14., and was also included in the revised text at its September 2020 meeting, following a request from a Member to ensure completeness of potential commodities that pose a risk. The Commission noted that while the nomenclature for veterinary biological products varies from country to country, this term is used extensively in the *Terrestrial Manual*, e.g. in relation to veterinary medicinal products.

Article 11.4.15bis.

In point 3, in response to a comment as to how a minor amendment proposed by the *ad hoc* Group on the Revision of BSE standards and its impact on the official status recognition was reflected in the current draft, the Code Commission clarified that the Group’s proposal had been to revert to the text of point 3 of current Article 11.4.18. The Commission did not agree with the proposal as it considered the revised wording clearer. In the same point, in response to a comment to add ‘by’ before ‘transesterification’ to clarify that the expression ‘that uses high temperature and pressure’ only applies to the transesterification process, the Commission did not agree as it considered the current text clear as written, the verb ‘uses’ being at the third-person of singular. The Commission proposed to add a comma for clarity.

Article 11.4.17.

In the chapeau paragraph, the Code Commission did not agree with a comment to revert ‘BSE’ to ‘transmissible spongiform encephalopathy’. The Commission reiterated that this chapter pertains to BSE, not all TSEs, and that not all TSEs are listed diseases.

Article 11.4.18.

The Code Commission agreed with a comment to include the objective of BSE surveillance for clarity and proposed to add a sentence at the start of the article.

In point 2, the Code Commission agreed with comments to replace ‘Veterinary Authority’ with ‘Veterinary Services’ as it considered that more accurate from the perspective of the first step of field passive surveillance. The Commission did not agree to add ‘where appropriate’ before ‘follow-up’, as it considered that a follow-up is always necessary.

In point 2, in the second paragraph, the Code Commission agreed with a comment to replace the terms ‘intensively reared’ and ‘extensive systems’ with ‘production and farming systems’ as this wording is used previously in the text and improves clarity.

In point 2, in the fourth paragraph, the Code Commission did not agree with a comment to add ‘All’ before ‘The following animals’ as it did not add any clarity. However, the Code Commission made an amendment to highlight that while the animals that should be targeted for BSE surveillance were all those showing signs of the clinical spectrum of BSE, only the animals listed in points 2(a) to 2(d) should be followed up with appropriate laboratory testing to confirm or rule out the presence of BSE agents.

In points 2(c) and 2(d), the Code Commission did not agree with a comment to clarify the meaning, as it considered the text clear as written.

In point 3(d), in response to a comment to clarify the meaning of ‘candidates’, the Code Commission proposed an amendment to improve clarity. The Commission noted that this change was also made in Article 1.8.6. in response to a similar comment.

The Code Commission wished to inform Members that all of the reports of BSE *ad hoc* Groups are available on the OIE website.

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

Comments were received from Australia, Chinese Taipei, New Caledonia, New Zealand, the USA, the AU-IBAR and the EU.

General comments

In response to a comment that many of the requirements in the questionnaire are not included in Article 11.4.2. General criteria for the determination of the BSE risk of a country, zone or compartment, the Code Commission reminded Members that the *ad hoc* Groups had revised the text in Chapter 1.8. with the aim of providing guidance to Members who wish to apply for official recognition of BSE risk status.

In response to a comment that the proposed chapter includes the use of fertilisers and compost although previous Specialist Commission reports did not present evidence that grazing land exposed to such commodities represent a risk of exposure or infection of BSE to cattle, the Code Commission explained that fertilisers have already been taken into consideration in the BSE risk assessment based on current standards, and the risk of misuse of fertilisers containing rendered products of ruminant origin or the risk that cattle ingest the fertilisers applied to land is a potential hazard that should be properly assessed in the exposure assessment.

The Code Commission noted a comment from a Member stating that there are very few countries that could meet the conditions to apply for official recognition of BSE risk status in their region. The Commission reiterated that the proposed Article 11.4.18. focuses on passive surveillance rather than active surveillance, which would make the Members' application for the official recognition of the BSE risk status easier.

In response to a request to ensure that the terms 'likelihood' and 'probability' used in Articles 1.8.5. to 1.8.7. are consistent with Chapter 2.1. Import risk analysis, the Code Commission considered that the proposed usage of these terms is correct.

Article 1.8.2.

In point 1(a), the Code Commission did not agree with a comment to add 'of each indigenous case of classical BSE' at the end of the point, as it considered that the purpose of this point was to provide general information on BSE cases that applicants experienced irrespective of classical/atypical or indigenous/imported, whereas point (b) focuses on indigenous case of classical BSE.

In point 1(b), the Code Commission did not agree with a comment to add '(or, if imported, the year of import)' after 'the year of birth of each indigenous case', and clarified that this point was about information needed to assess the outcome of BSE risk mitigation measures taken in the country, rather than information required in the entry assessment. The Commission noted that an imported case by definition implies that exposure occurred before import.

Article 1.8.5.

In the third indent of point 1, the Code Commission did not agree with a comment that some countries use packaged and labelled pet food for livestock species and therefore they should be considered in the entry assessment, as it considered that this was not necessary given that packaged pet food is much more expensive than livestock feed and the practice of feeding livestock with packaged and labelled pet food is uncommon. The Commission encouraged Members to refer to relevant discussions noted in its September 2021 report for more details on this point.

In point 1(a), the Code Commission did not agree with a comment to add 'and the quantity imported' at the end of the point. The Commission encouraged Members to refer to the November 2018 report of the *ad hoc* Group on BSE risk assessment which considered that detailed quantitative information (e.g. volume, statistics, etc.) on imported commodities was not

informative for the entry assessment as long as they were imported under conditions consistent with the recommendations in Chapter 11.4. or where it can be demonstrated that an equivalent level of assurance was provided.

In the second paragraph of point 2, the Code Commission agreed with a comment to delete 'indigenous', as it considered that in the exposure assessment, the likelihood of cattle being exposed to the BSE agents as a result of the presence of BSE agents in the cattle population of the country or zone, which includes both populations born in the country or zone and populations imported from other countries, should be properly evaluated.

In point 2(a)(v), the Code Commission did not agree with a comment to delete 'labelling', as it considered it necessary to include given that correct labelling is essential to confirm that the prevention of cross-contamination of contaminated materials has been managed. In the first paragraph of point 2(a), the Commission proposed to add labelling so the text stated 'production, labelling, distribution and storage of feed' to ensure alignment with point 2(a)(v).

In point 2(a)(v), the Code Commission partially agreed with a comment to clarify which feed producing facilities are referred to, and proposed an amendment.

In point 2(b), as also noted above for Article 11.4.3., the Code Commission did not agree with a comment to add text stating that the implementation of a feed-ban should be a mandatory risk mitigation measure in countries where livestock industry practices do not prevent cattle from being fed with ruminant-derived protein meal, noting that Chapter 1.8. is a questionnaire for applications for official recognition by the OIE of risk status for BSE. Nevertheless, the Commission made some amendments to highlight the importance of a legislated feed ban to properly address the risk, as demonstrated by the list of measures from i) to vii), to be described in the dossier.

In the first paragraph of point 4, the Code Commission did not agree with a comment to add a sentence 'the risk estimation can be qualitative or quantitative' and reiterated that it is not a quantitative assessment.

Article 1.8.7.

The Code Commission proposed to amend the article to ensure alignment with the proposed new article on maintenance of BSE risk status in Chapter 11.4.

c) <u>The use of terms' meat-and-bone meal' and 'greaves' throughout the *Terrestrial Code*</u>

<u>Background</u>

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

<u>Discussion</u>

The OIE Secretariat informed the Code Commission that six disease-specific chapters (Chapter 8.1., Chapter 8.4., Chapter 8.11., Chapter 10.4., Chapter 14.8. and Chapter 15.3.) used the terms 'greaves' or 'meat-and-bone meal' and provided a summary as to where the terms were used.

The Code Commission agreed to propose the Glossary definition for protein meal for adoption in May 2022 and to propose the deletion of the definition described in point 4(b) of Article 11.4.1. However, due to time constraints, the Commission was not able to finalise the discussion regarding where in the other relevant chapters 'greaves' or 'meat-and-bone meal' should be replaced with 'protein meal' and agreed to discuss at its next meeting should the new definition for 'protein meal' be adopted.

The Code Commission acknowledged that many changes have been made to the revised Chapter 11.4. Bovine spongiform encephalopathy during the period of revision. For this meeting report, the

Commission agreed to provide as **Annex 13**, for Member information only, a version that shows the changes made at this meeting in the version circulated in its September 2021 report. The Commission noted that Annex 13 does not show in track changes all amendments being proposed.

EU position

The EU thanks the OIE for the latest version of the revised Chapter 11.4. on bovine spongiform encephalopathy and appreciates the amendments introduced in the draft to address some of the EU comments transmitted in December 2021. The EU can support the adoption of this revised chapter as it stands. Comments are included in Annex 13.

The revised Chapter 11.4. Bovine spongiform encephalopathy is presented as **Annex 14** and will be proposed for adoption at the 89th General Session in May 2022.

The revised Chapter 1.8. Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy and the Glossary definition for 'protein meal' are presented as **Annex 15** and as part of **Annex 3**, respectively, and will be proposed for adoption at the 89th General Session in May 2022.

EU position

The EU thanks the OIE for the latest version of the revised Chapter 1.8. on application for official recognition by the OIE of risk status for bovine spongiform encephalopathy and appreciates the amendments introduced in the draft to address some of the EU comments transmitted in December 2021. The EU can support the adoption of this revised chapter as it stands. Comments are included in Annex 15.

4.10. Theileriosis (Chapter 11.10.)

Comments were received from New Caledonia, New Zealand, South Africa, the USA, the AU-IBAR and the EU.

Background

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

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

At its September 2020 meeting, the Code Commission considered comments received previously on the revised Chapter 11.10. and circulated a revised chapter for comments. At its September 2021 meeting, the Commission considered comments received, together with advice from the Scientific Commission and the Laboratories Commission on selected comments, and circulated a revised chapter for comments.

Discussion

General comments

In response to a question as to why the recommendations in the revised chapter only address bovines and water buffalo, the Code Commission reminded Members that a revised Chapter 11.10. Infection with *Theileria annulata, T. orientalis* and *T. parva* and a new Chapter 14.X. Infection with *Theileria lestoquardi, T. luwenshuni* and *T. uilenbergi* were first circulated in September 2017, following the work of the *ad hoc* Group on Theileriosis that met in February 2017. The Commission encouraged

Members to refer to the relevant part of its September 2017 report for the background of the decision to have the two separate chapters.

Article 11.10.1.

In the first paragraph, the Code Commission noted a comment that water buffalos and African buffalos are also bovines. Acknowledging that there were some variations in the use of terms of 'bovines', 'bovids' and 'cattle' in the *Terrestrial Code*, the Code Commission agreed to further discuss this issue and requested that the OIE Secretariat review the use of the terms and report back to the Commission at its September 2022 meeting to ensure that it can assess and prioritise the work needed to ensure consistency throughout the *Terrestrial Code*.

In point 3, the Code Commission agreed with a comment to add 'that are not a consequence of vaccination' after 'antibodies specific to Theileria' to ensure alignment with other disease-specific chapters.

Article 11.10.5.

In point 4, the Code Commission did not agree with a comment that the second test should occur after at least one incubation period (35 days), as it considered it unjustified as the current time would allow to detect a positive animal, and also to be impractical given the justified isolation time (35 days) described in point 2. The Commission reminded Members that the modification of point 4 regarding the duration of 25 days between the two tests had been proposed in agreement with the Laboratories Commission, and that the other three risk mitigation measures in this article should also be met.

In the same point, regarding a comment to replace 'serological and agent identification tests' with 'serological or agent identification tests', the Code Commission noted that the Laboratories Commission had considered that even though the tests are rated as 'recommended' method for individual animal freedom from infection prior to movement in the Table 1 of Chapter 3.4.15. in the *Terrestrial Manual*, because of possible cross-reactions both tests complement each other and therefore are needed to ensure individual animal freedom from infection. The Code Commission agreed with the Laboratories Commission that no further amendment was needed in the point, and encouraged Members to refer to the February 2022 report of the Laboratories Commissions for more details regarding its rationale.

Revised Chapter 11.10. is presented as **Annex 16** and will be proposed for adoption at the 89th General Session in May 2022.

EU position

The EU thanks the OIE and supports the adoption of this revised chapter.

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

Background

Following the adoption of the Glossary definition of 'sanitary measure' in 2020, the Code Commission requested the OIE Secretariat to assess whether the terms 'sanitary measure' and 'biosecurity' have been used appropriately throughout the *Terrestrial Code.*

At its September 2021 meeting, the Code Commission noted that the term 'sanitary measure' has not been used appropriately in the following articles and consequently it had proposed amendments which were circulated for comment in its September 2021 report:

- Article 3.4.5. of Chapter 3.4. Veterinary legislation (see item 4.4. of this report),
- Article 4.15.6. of Chapter 4.15. Official health control of bee diseases,
- Article 6.3.3. of Chapter 6.3. Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection.

Discussion

The Code Commission noted that no comments were received on the circulated texts.

Revised Article 4.15.6. of Chapter 4.15. Official health control of bee diseases and Article 6.3.3. of Chapter 6.3. Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection, are presented as **Annex 17** and will be proposed for adoption at the 89th General Session in May 2022.

EU position

The EU supports the adoption of these revised articles.

_____

…/Annexes

G L O S S A R Y

EU position

The EU thanks the OIE and supports the adoption of these revised Glossary definitions.

COMPETENT AUTHORITY

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

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.

~~***STRAY DOG***~~ ***FREE-ROAMING DOG***

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

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

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

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

VETERINARY AUTHORITY

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

VETERINARY SERVICES

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

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY THE OIE

EU position

The EU in general supports the adoption of these revised articles.

We note however that Code Chapter 10.5. Infection with *Mycoplasma gallisepticum* (Avian mycoplasmosis) does not cover infection with *Mycoplasma synoviae*, while both pathogens are listed separately in Chapter 1.3.

What's more, Chapter 10.5. does not contain a case definition, and the articles refer to "avian mycoplasmosis" in general instead of to *Mycoplasma gallisepticum*.

We also note that the corresponding Manual chapter covers both pathogens (Chapter 3.3.5. Avian mycoplasmosis (*Mycoplasma gallisepticum*, *M. synoviae*), and in addition refers to *M. meleagridis* and *M. iowae*.

This is somewhat confusing, especially as regards the concept of freedom from avian mycoplasmosis, referred to in several articles in Chapter 10.5.

We therefore query whether these four pathogens should be assessed against the listing criteria, with a view to possible amendments of Code Chapters 1.3. and 10.5.

[…]

Article 1.3.2.

The following are included within the category of cattle diseases and *infections*:

– Bovine anaplasmosis

– Bovine babesiosis

– Bovine genital campylobacteriosis

– Bovine spongiform encephalopathy

– Bovine viral diarrhoea

– Enzootic bovine leukosis

– Haemorrhagic septicaemia

– Infection with lumpy skin disease virus

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

– Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

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

– Trichomonosis.

[…]

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 influenza~~

– Equine piroplasmosis

– Infection with *Burkholderia mallei* (Glanders)

– Infection with African horse sickness virus

– Infection with equid herpesvirus-1 (~~EHV-1~~Equine rhinopneumonitis)

– Infection with equine arteritis virus

– Infection with equine influenza virus

– Venezuelan equine encephalomyelitis.

[…]

Article 1.3.6.

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

– Avian chlamydiosis

– Avian infectious bronchitis

– Avian infectious laryngotracheitis

– ~~Avian mycoplasmosis *(Mycoplasma gallisepticum)*~~

– ~~Avian mycoplasmosis *(Mycoplasma synoviae)*~~

– 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.

[…]

CHAPTER 3.1.

INTRODUCTION TO RECOMMENDATIONS ON VETERINARY SERVICES

EU position

The EU supports the adoption of this revised chapter.

Article 3.1.1.

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

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

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

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

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

CHAPTER 3.2.

QUALITY OF VETERINARY SERVICES

EU position

The EU supports the adoption of this revised chapter.

[…]

Article 3.2.3.

Policy and management

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

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

This component should comprise the following specific elements:

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

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

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

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

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

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

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

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

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

[…]

Article 3.2.9.

Veterinary medicinal products

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

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

This component should comprise the following specific elements:

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

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

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

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

[…]

CHAPTER 3.4.

VETERINARY LEGISLATION

EU position

The EU supports the adoption of this revised chapter.

[…]

Article 3.4.5.

Competent Authorities

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

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

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

1. Necessary powers of the Competent Authority

The *veterinary legislation* should also ensure that:

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

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

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

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

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

ii) access to documents;

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

– taking samples;

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

– seizure of *commodities* and fomites;

– destruction of *commodities* and fomites;

– suspension of one or more activities of a facility;

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

iv) establishment of compensation mechanisms.

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

2. Delegation of powers by the Competent Authority

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

[…]

Article 3.4.11.

Veterinary medicinal products

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

1. General measures

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

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

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

2. Raw materials for use in veterinary medicinal products

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

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

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

3. Authorisation of veterinary medicinal products

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

b) Special provisions should be made for:

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

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

iii) emergencies and temporary situations;

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

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

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

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

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

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

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

4. Facilities producing, storing and wholesaling veterinary medicinal products

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

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

b) definition of the responsibilities of operators;

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

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

e) mechanisms for traceability and recall.

5. Retailing, use and traceability of veterinary medicinal products

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

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

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

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

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

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

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

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

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

[…]

CHAPTER 6.12.

ZOONOSES TRANSMISSIBLE FROM NON-HUMAN PRIMATES

EU position

The EU supports the adoption of this revised chapter.

[…]

Article 6.12.4.

Quarantine requirements for non-human primates from an uncontrolled environment

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

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

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

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

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

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

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

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

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

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

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

[…]

Article 6.12.6.

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

Veterinary Authorities of *importing countries* should require:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Article 6.12.7.

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

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

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

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

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

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

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

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

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

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

_____

CHAPTER 7.7.

DOG POPULATION MANAGEMENT

EU position

The EU thanks the OIE for having taken into consideration the majority of our comments submitted previously.

We welcome and in general support the adoption of this revised chapter.

We note that in several instances the wording "Catch, Neuter, Vaccination and Return" was amended to read "Catch, Neuter, Vaccinate and Return". We support this editorial change and suggest consistently changing that wording throughout the text, such as in Articles 7.7.19. (3 times, in 3rd paragraph (2) and 5th indent) and 7.7.20. (1 time, in last paragraph).

In addition, we have only one comment under Article 7.7.26.

Article 7.7.1.

Introduction

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

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

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

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

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

Article 7.7.~~4~~.2

Definitions

For the purpose of this chapter:

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

Rabies means dog-mediated rabies.

Article 7.7.~~2~~3.

Scope

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

Article 7.7.~~3~~4.

Guiding principles

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

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

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

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

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

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

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

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

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

~~Article 7.7.4.~~

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

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

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

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

Article 7.7.5.

Dog Population Management programme objectives

DPM programmes may include the following objectives:

– promote and establish *responsible dog ownership,* in accordance with Article 7.7.17.;

– improve health and welfare of dog populations;

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

– stabilise the dog population by reducing turnover;

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

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

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

– prevent harm to livestock and other animals;

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

Article 7.7.6.

Roles and responsibilities

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

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

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

Article 7.7.7.

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

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

1. Governance

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

2. Legislation

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

3. Enforcement

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

4. Funding

   To establish sustainable DPM with long-lasting impacts, the *Competent Authority* and multi-sectorial group should establish a policy and legislative basis for sufficient funding of national action plans and DPM

programmes. The One Health concept ~~provides~~strengthens ~~to~~ the argument for increasing the priority of DPM across the animal health, environmental and public health sectors.

5. Training and support

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

Article 7.7.8.

Other organisations and actors involved in ~~D~~dog ~~P~~population ~~M~~management

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

1. Veterinary Authority

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

2. Veterinary Services

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

3. Other governmental agencies

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

a) Public health

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

b) Environmental protection

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

c) Education

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

d) Local authorities

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

4. Civil Society

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

a) Dog owners

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

b) Dog breeders and sellers

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

5. Advisory group

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

Article 7.7.9.

Regulatory framework

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

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

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

– *animal welfare* obligations of authorities;

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

– *registration*, or authorisation and licensing of dog breeders and sellers;

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

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

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

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

– dog movements and trade at international and national levels;

– waste management.

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

Article 7.7.10.

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

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

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

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

Competent Authorities, in collaboration with the multi-sectoral group, should support evidence-based DPM programmes ~~assessment, monitoring and evaluation~~by:

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

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

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

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

Article 7.7.11.

DPM programme ~~development~~assessment and planning

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

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

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

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

   – *owned dogs* that roam freely;

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

   – unowned dogs that roam freely and reproduce.

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

5) Estimating dog population size and demography:

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

   For evaluation of DPM programme effectiveness, *monitoring* changes in population trends (e.g. changes in the density of free-roaming dogs along routes designed to traverse areas of high free-roaming dog density~~on public streets~~, proportion of lactating females and presence of puppies) may be sufficient, rather than investing in repeated estimates of population size [(Hiby and Hiby, 2017)]. Methods to estimate population size may

also measure demographic factors such as age, sex, sterilisation and reproductive status (lactation and pregnancy in females) to allow for refinement of estimates to sub-populations of relevance.

Available methods for population size estimates include the following:

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

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

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

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

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

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

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

Article 7.7.12.

DPM programme monitoring and evaluation

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

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

Indicators are the measurable signsresults of objectives. Indicators of DPM objectives may include:

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

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

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

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

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

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

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

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

– Compensation costs relating to dog-related damage~~s~~ to people, livestock~~,~~ or property.

Article 7.7.13.

Recommendations for DPM measures

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

– ~~*R*~~*registration* and identification of dogs;

– ~~R~~regulation of ~~C~~commercial dog breeding and sale;

– ~~C~~control of national and international (export and import) dog movements;

– ~~P~~promoting *responsible dog ownership*;

– ~~R~~reproductive control;

– ‘Catch, Neuter, Vaccinate~~ion~~ and Return’;

– ~~R~~reuniting and adoption;

– ~~A~~access to veterinary care;

– ~~E~~environmental controls;

– ~~E~~education on safe dog–human interaction.

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

Article 7.7.14.

Registration and identification of dogs

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

– support~~s~~ for the enforcement of legislation through proof of ownership;

– improve~~s~~ment of the success rate in reuniting lost dogs with their owners;

– ~~enables~~d enabling traceability in commercial breeding and sale;

– encourage~~s~~ment of responsible ownership behaviours;

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

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

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

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

Article 7.7.15.

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

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

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

– avoidance of abandonment~~,~~;

– transparency in dog breeding and sales.

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

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

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

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

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

Article 7.7.16.

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

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

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

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

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

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

– protecting dog *welfare*.

Article 7.7.17.

Promoting responsible dog ownership

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

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

   – support ing the human–animal bond;

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

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

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

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

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

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

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

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

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

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

3) Achieving sustained and widespread responsible ownership requires an understanding of barriers and motivations for responsible behaviour and taking action to address these. This ~~will~~ is likely to require a combination of legislation, public awareness and enforcement, behaviour change campaigns, formal education in schools and encouragement through the building of social expectations. It may also be necessary to improve availability and accessibility ~~to~~ of resources supporting responsible ownership, such as veterinary care, identification and *registration* services and measures for control of zoonotic diseases.

Article 7.7.18.

Reproductive control

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

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

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

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

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

3) Methods of controlling reproduction will require direct veterinary input to individual animals. Involvement of both private and public veterinary sectors may be required to meet demand for services. Subsidisation of sterilisation programmes by government or other organisations may be considered to encourage uptake. The

control of reproduction in *owned dogs* is essentially the responsibility of owners and should be incorporated into promotion of responsible ownership (see Article 7.7.17.).

4) Methods for controlling reproduction in dogs include:

   – surgical sterilisation;

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

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

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

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

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

Article 7.7.19.

'Catch, Neuter, Vaccinateion and Return'

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

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

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

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

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

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

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

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

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

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

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

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

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

Article 7.7.20.

Reuniting and adoption

Free-roaming dogs can be removed to housing facilities for reuniting with their owners, or adopted. This addresses only the current free-roaming population and not the source of these dogs, hence must be used in combination with other measures to prevent replacement of removed dogs. These facilities can also offer the option for owners to relinquish dogs they can no longer care for, as an alternative to abandonment. Evidence collected about dogs and dog owner practices during DPM programme development must confirm that reuniting and adoption is are probable and achievable before developing reuniting and adoption facilities. Without sufficient adoptive homes or systems for reuniting, facilities quickly fill to capacity, creating an ineffective and expensive measure. The *Competent Authority* should establish and enforce regulations for facilities providing reuniting and rehoming services to ensure capture, transport, and holding of dogs is are done humanely.

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

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

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

Article 7.7.21.

Access to veterinary care

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

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

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

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

Article 7.7.22.

Environmental controls

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

Article 7.7.23.

Education on safe dog–human interaction

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

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

Article 7.7.24.

Specific considerations for D~~d~~og P~~p~~opulation M~~m~~anagement activities

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

– Dog capture and handling;

– Dog housing;

– *Euthanasia.*

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

Article 7.7.25.

Dog capture and handling

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

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

Competent Authorities and *V~~v~~eterinary S~~s~~ervices* should ensure their staff and volunteers expected to handle dogs have received rabies pre-exposure *vaccination* where appropriate and are provided with clear protocols for treating injuries, including dog bites.

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

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

Article 7.7.26.

Dog housing

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

~~a~~1. Facilities

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

~~b~~2. Management

- provision of adequate fresh water and nutritious food;
- regular hygiene and cleaning;

EU comment:

We suggest adding:

"- Appropriate sanitary breaks before the entrance of new dogs in the cages;"

Justification:

The period of sanitary breaks might not be defined, because it could vary depending on the situation.

- routine inspection, handling and exercise of the dogs;

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

c3. Assessment

Dog housing performance may be assessed using the following measurables:

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

Article 7.7.27.

Euthanasia

Euthanasia of dogs, used alone, is not effective for DPM. If used, it should be done humanely in accordance with Article 7.6.1. and should be implemented in combination with other measures as part of a DPM programme to achieve effective long-term management. Reducing dog population size is not an effective means of reducing the number of rabies cases [(WHO, 2018)].

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

a1) Restraint

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

b2) Euthanasia methods

The following are recommended methods of canine *euthanasia*:

- intravenous barbiturates.;

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

– intravenous anaesthetic overdose~~,~~;

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

If anaesthetised:

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

If sedated:

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

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

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

~~c~~3. Confirmation of death

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

A combination of criteria is most reliable in confirming *death*, including lack of pulse, breathing~~,~~ and corneal reflex, and response to firm toe pinch; inability to hear respiratory sounds and heartbeat by use of a stethoscope; greying of the mucous membranes; and rigor mortis. None of these signs alone, except rigor mortis, confirms *death*. If an animal is not dead, another ~~humane~~ method of *euthanasia* should be performed.

~~d~~4. Carcass disposal

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

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

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CHAPTER 8.16.

INFECTION WITH RINDERPEST VIRUS

EU position

The EU thanks the OIE and in general supports the adoption of this revised chapter.

Comments are inserted in the text below.

Article 8.16.1.

General provisions

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

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

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

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

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

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

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

   A *case* of *infection* with RPV shall be confirmed in an OIE Reference Laboratory for rinderpest.

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

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

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

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

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

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

EU comment

For clarity and consistency with other chapters, the EU suggests rearranging point iii) above as follows:

"antibodies ~~that are not a consequence of vaccination~~ to RPV, that are not a consequence of vaccination, have been identified [...]".

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

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

ii~~i~~) a potential *case* which has given a positive reaction in a diagnostic test for RPV conducted outside of an OIE ~~r~~Reference ~~l~~Laboratory for rinderpest; or

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

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

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

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

3) For the purposes of this chapter:

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

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

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

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

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

Article 8.16.2.

Safe commodities

1. Safe commodities during global freedom

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

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

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

a) semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather~~, e.g. wet blue and crust leather~~) ~~which have been submitted to the usual chemical and mechanical processes in use in the tanning industry~~;

b) *meat products* in hermetically sealed containers with a F_0 value of 3 or above;

c) gelatine.

Article 8.16.2bis.

Article 8.16.3., Article 8.16.4. and point 1 of Article 8.16.5. apply during global freedom.

Point 2 of Article~~s~~ 8.16.5. and Articles 8.16.6. to 8.16.13. apply in the event of re-emergence of rinderpest.

~~First section: applicable during global freedom~~

Article 8.16.3.

Ongoing surveillance ~~post~~ during global freedom

All countries in the world, whether or not Member Countries of the OIE, have completed all the procedures necessary to be recognised as free from rinderpest ~~*infection*~~, and annual re-confirmation of ~~rinderpest absence~~ absence of *infection* with RPV is no longer required. However, rinderpest should still be notifiable in the whole territory and countries are still required to carry out general *surveillance* in accordance with Chapter 1.4. to detect rinderpest should it recur and to comply with OIE reporting obligations concerning the occurrence of unusual epidemiological events in accordance with Chapter 1.1. Countries should either maintain the capacity for local investigation of potential *cases* or have protocols in place to send samples from such potential *cases* to ~~an OIE Reference Laboratory~~an *approved laboratory*, which can be an OIE Reference Laboratory for rinderpest ~~for routine checking~~. Countries should also maintain national contingency plans for responding to events suggestive of rinderpest including the checking of potential *case*s and the prompt identification of suspected *case*s.

The Global Rinderpest Action Plan (GRAP) complements all national and regional contingency plans and lays out the roles and responsibilities of all relevant stakeholders to prepare for, prevent, detect, respond to and recover from a rinderpest *outbreak*. If needed, expertise from the region or continent, or international organisations may be requested to provide resources to help confirm or rule out ~~if~~ whether the potential *case* meets the definition for a suspected *case* or a *case* ~~of rinderpest~~.

Article 8.16.4.

Annual update on RPV-containing material

Annual reports on RPV-containing material should be submitted to the OIE each year by the *Veterinary Authority* of a Member Country hosting an institution or institutions holding RPV-containing material, using the online platform designated for such a purpose. A final report should be submitted to the OIE for each institution when all RPV-containing materials have been destroyed and no new related activities are foreseen.

~~Second section: applicable in the event of re-emergence of rinderpest~~

Article 8.16.5.

Response to a recurrence of rinderpest

1. Procedures to be followed in the event of the suspicion of rinderpest

Any suspected *case* of *infection* with RPV should be immediately ~~notified~~ reported to the *Veterinary Authority.*

Veterinary Authorities shall immediately notify any suspected *case* of *infection* with RPV to the OIE.

Upon detection of a suspected *case*, the national contingency plan should be implemented immediately. If the

presence of rinderpest cannot be ruled out or if there is a positive reaction in a diagnostic test for RPV conducted outside of an OIE Reference Laboratory for rinderpest, samples should be collected in accordance with the *Terrestrial Manual* and dispatched to one of the ~~appointed~~ OIE Reference Laboratories for rinderpest for confirmation and, if applicable, for molecular characterisation of the virus to facilitate identification of its source. A full epidemiological investigation should be conducted simultaneously to provide supporting information and to assist in identifying the possible source and spread of the virus.

2. Procedures to be followed after confirmation of rinderpest

Veterinary Authorities shall immediately notify any *case* of *infection* with RPV to the OIE.

A *case* of *infection* with RPV shall constitute a global emergency requiring immediate, concerted action for its investigation and elimination.

Immediately following the confirmation of the presence of RPV, viral RNA or antibody as described in Article 8.16.1., the ~~appointed~~ OIE Reference Laboratory for rinderpest should inform the country concerned, the OIE and the FAO, allowing the initiation of the response operations described in the GRAP.

When epidemiological investigation has indicated the extent of the infected area, zoning can be implemented for the purposes of disease control. In the event of a limited *outbreak*, a *containment zone* ~~may~~ should be established in accordance with Article 8.16.8.

EU comment

The EU can accept replacing "may" with "should" in the paragraph above, even if this deviates from the wording of Article 4.4.7. and the spirit of Chapter 4.4. that leaves the choice of disease control measures to Members, owing to the distinct feature of rinderpest being a globally eradicated animal disease.

Emergency *vaccination* is acceptable only with rinderpest vaccines produced in accordance with the *Terrestrial Manual*. Vaccinated animals should always be clearly and permanently identified at the individual level.

Global rinderpest freedom is suspended and the *sanitary measures* for trade ~~with the infected country or countries~~ shall be those in Articles 8.16.12. and 8.16.13.

Article 8.16.6.

Country free from rinderpest

In the event of re-emergence of rinderpest, all OIE Member Countries without a *case* will remain free from rinderpest. However, all OIE Member Countries will be asked to provide a *risk assessment* to the OIE and free status will be suspended if their *risk assessment* is not accepted by the OIE.

Some countries will be at heightened *risk*. In particular, countries meeting the conditions below would be regarded as being at heightened *risk* and should carry out appropriate *surveillance*, capable of detecting the presence of *infection* with RPV even in the absence of clinical signs; this may be achieved through a *surveillance* programme in accordance with Article 8.16.11. in addition to ongoing *surveillance* in accordance with Article 8.16.3.~~:~~

1) countries that are adjacent to a country infected with RPV; or

2) countries that have relevant epidemiological or ecological links through trade or animal movements to a country infected with RPV.

Article 8.16.7.

Country infected with RPV

A country infected with RPV is one in which a *case* of ~~rinderpest~~ *infection* with RPV has occurred.

Article 8.16.8.

Establishment of a containment zone within a country previously free from rinderpest

In the event of a limited *outbreak* within a country previously free ~~of~~ from rinderpest, a *containment zone* for the purposes of disease control and eradication ~~can~~ should be established in accordance with Article 4.4.7. Notwithstanding the establishment of a *containment zone* for disease control and eradication, *international trade* ~~in~~ of *commodities* of susceptible species from the entire country will be limited to the ~~*safe*~~ *commodities* listed in point 2 of Article 8.16.2. until free status is recovered for the whole country in accordance with Article 8.16.9.

Article 8.16.9.

Recovery of free status for a country

Should a *case* of ~~rinderpest~~ *infection* with RPV occur, a country is considered infected with RPV until shown to be free from rinderpest in accordance with the procedures below.

The time needed to recover ~~rinderpest~~ free status of a country depends on the methods employed to achieve the elimination of *infection*.

One of the following waiting periods is applicable:

1) when a *stamping-out policy* has been applied:

   a) three months after the *disinfection* of the last affected *establishment* where a *stamping-out policy* without *vaccination* and targeted *surveillance* in accordance with Article 8.16.11. have been applied; or

   b) three months after the *disinfection* of the last affected *establishment* and the *slaughter* of all vaccinated animals, where a *stamping-out policy*, emergency *vaccination* and targeted *surveillance* in accordance with Article 8.16.11. have been applied; or

   c) 18 months after the *disinfection* of the last affected *establishment* and the last *vaccination*, where a *stamping-out policy*, emergency *vaccination* not followed by the *slaughter* of all vaccinated animals, and targeted *surveillance* in accordance with Article 8.16.11. have been applied;

2) when a *stamping-out policy* is not practised, the above waiting periods do not apply. Instead, the country must be in compliance with the requirements below:

   a) have a record of regular and prompt ~~animal disease reporting~~ disease *notification* in accordance with Chapter 1.1.;

   b) send a declaration to the OIE stating that:

      i) there has been no *case* of ~~rinderpest~~ *infection* with RPV during the past 24 months;

      ii) no suspected *case* of *infection* with RPV ~~*infection*~~ has been found during the past 24 months;

      iii) no *vaccination* against rinderpest has been carried out during the past 24 months;

   c) supply documented evidence that targeted *surveillance* for *infection* with RPV in accordance with Chapter 1.4. and Article 8.16.11. is in operation and that regulatory measures for the prevention and control of rinderpest have been implemented;

   d) not have imported, since the cessation of *vaccination*, any animals vaccinated against rinderpest.

In ~~the scenarios mentioned in~~ point~~s~~ 1~~(a), (b) and (c)~~ and ~~in~~ point 2 above, the recovery of free status requires an international expert mission to verify the successful application of containment and eradication measures, as well as a review of documented evidence by the OIE. The country shall be considered free only after the outcome of the mission and submitted evidence ~~has~~ have been accepted by the OIE.

Article 8.16.10.

Recovery of global freedom

The suspension of global freedom will be lifted when all countries infected with RPV have recovered freedom in accordance with Article 8.16.9.

Unless it is verified through an OIE expert mission that the conditions below are met for all countries having experienced an *outbreak* within 12 months of suspension, then global rinderpest freedom is lost and recovery of freedom would require an assessment of free status of all countries by the OIE. If the conditions below are met within 12 months, then global freedom will remain suspended, subject to periodic review by the OIE.

1) The *outbreak* is limited to a country or *zone*, without any further *outbreaks* outside the ecosystem of the first *outbreak*.

2) The *outbreak* is handled in a prompt and efficient manner, with robust control measures including movement controls, which were rapidly implemented and were shown to be successful in mitigating the spread of rinderpest and reducing its ~~incidence~~*incidence*.

Article 8.16.11.

Surveillance for recovery of ~~rinderpest~~ free status

A country infected with RPV applying for recovery of ~~rinderpest~~ free status in accordance with Article 8.16.9. should provide evidence demonstrating effective *surveillance* in accordance with Chapter 1.4. and the points below.

1) The target for *surveillance* should be all populations of ~~rinderpest~~ susceptible ~~species~~ animals within the country. In certain areas some *wildlife* populations, such as African buffaloes, act as sentinels for ~~rinderpest~~ *infection* with RPV.

2) An awareness programme should be established for all animal health professionals including *veterinarians*, both official and private, and livestock owners to ensure that ~~rinderpest's~~ clinical and epidemiological characteristics of rinderpest and *risks* of its recurrence are understood. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any potential *case*.

3) Differing clinical presentations can result from variations in levels of innate host resistance (*Bos indicus* breeds being more resistant than *B. taurus*), and variations in the virulence of the attacking strain. In the case of sub-acute (mild) cases, clinical signs are irregularly displayed and difficult to detect. Experience has shown that syndromic *surveillance* strategies, i.e. *surveillance* based on a predefined set of clinical signs (~~i.e.~~ 'stomatitis–enteritis syndrome'), are useful to increase the sensitivity of the system.

4) Given these differing clinical presentations, virological *surveillance* should be conducted in addition to clinical surveillance. A procedure should be established for the rapid collection and transport of samples from suspected *cases* to an ~~appointed~~ OIE Reference Laboratory for rinderpest.

5) Since rinderpest is an acute *infection* with no known carriers, serological *surveillance* should be conducted to detect mild *infections* that are not detected clinically. There are no serological means to differentiate animals infected with field virus from vaccinated animals. Consequently, serological surveys should target unvaccinated animals and young animals devoid of maternal antibodies.

~~2~~Article 8.16.12.

Recommendations for importation of ~~rinderpest~~ susceptible animals and their products ~~except safe commodities in point 2 of Article 8.16.2~~ from countries free from rinderpest

1) For ~~rinderpest~~ susceptible animals, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the animals remained in a country free from rinderpest since birth or for at least 30 days prior to shipment. Animals must not transit through a country infected with RPV, in accordance with Chapter 5.7.

2) For *fresh meat* or *meat products* (except those listed in point 2 of Article 8.16.2.) of susceptible animals, for *milk or milk products* from susceptible animals, and for all products of animal origin intended for use in animal feeding, for agricultural use or for industrial use, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting the entire consignment of product is derived from animals that remained in a country free from rinderpest since birth or for at least 30 days prior to *slaughter* or harvesting of the product.

3) For semen and oocytes of susceptible animals, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

   a) the donor animals showed no clinical signs of ~~rinderpest~~ *infection* with RPV on the day of collection and had been kept in a country free from rinderpest for at least 30 days prior to collection;

   b) the semen and oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.6., 4.7. or 4.9., as relevant.

4) For *in vivo* derived embryos of susceptible animals, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

   a) the donor females showed no clinical signs of ~~rinderpest~~ *infection* with RPV on the day of collection and had been kept in a country free from rinderpest for at least 30 days prior to collection;

   b) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.8. and 4.10., as relevant.

Article 8.16.13.

Recommendations for importation from countries ~~infected with~~ not free from rinderpest

~~In the event of re-emergence of rinderpest,~~ From countries not free from rinderpest, only ~~*safe commodities*~~ listed in point 2 of Article 8.16.2. can be traded.

CHAPTER 8.5.

INFECTION WITH *ECHINOCOCCUS GRANULOSUS*

EU position

The EU thanks the OIE and supports the adoption of this revised chapter.

Article 8.5.1.

General provisions

Echinococcus granulosus (E. granulosus) is a widely distributed cestode (tapeworm). The adult worms occur in the small intestine of canids (definitive host). Larval stages (hydatid) occur in tissues of liver, lung and other organs of other mammals (intermediate host), including humans. *Infection* with the larval stage of the parasite in the intermediate host, referred to as 'cystic echinococcosis' or 'hydatidosis', is associated with significant economic losses in livestock production and causes a major disease burden in humans.

For the purposes of the *Terrestrial Code*, *infection* with *E. granulosus* is defined as a zoonotic parasitic *infection* of canids, ungulates and macropod marsupials with *E. granulosus* (ovine, bovine, cervid, camelid and porcine strains).

For the purposes of this chapter, offal is defined as internal organs of ungulates and macropod marsupials.

Transmission of *E. granulosus* to canids occurs through ingestion of hydatid-infected offal.

Infection in intermediate hosts, as well as in humans, occurs by ingestion of *E. granulosus* eggs from contaminated environments. In humans, *infection* may also occur following contact with infected canids or by consumption of food or water contaminated with *E. granulosus* eggs from canine faeces.

Infection in humans can be prevented by good food hygiene and personal hygiene, community health education and preventing *infection* of canids. Collaboration between the *Competent Authority* and the public health authority is an essential component in preventing and controlling *E. granulosus* transmission.

This chapter provides recommendations for prevention of, control of, and *surveillance* for *infection* with *E. granulosus* in dogs and livestock.

When authorising the import or transit of the *commodities* covered in this chapter, with the exception of those listed in Article 8.5.2., *Veterinary Authorities* should apply the recommendations in this chapter.

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

[…]

Article 8.5.3.

Programmes for the prevention and control of infection with *E. granulosus*

In order to prevent and control *infection* with *E. granulosus*, the *Veterinary Authority* or other *Competent Authority* should carry out community awareness programmes about the risk factors associated with transmission of *E. granulosus*, the role of dogs (including ~~*stray*~~ *free-roaming dogs*) and the importance of *responsible dog ownership*. The *Veterinary Authority* or other *Competent Authority* should also implement the following prevention and control measures.

1. Prevention of infection in dogs ~~(owned and stray)~~

   a) Dogs should not be fed offal unless it has been treated in accordance with Article 8.5.6.

   b) Dogs should be prevented from scavenging on dead ungulates and macropod marsupials. Dead animals should be disposed of in accordance with Article 4.13.6.

c) The *Veterinary Authority* or other *Competent Authority* should ensure that *slaughterhouses/abattoirs* have implemented measures that prevent access of dogs to the premises, and to animal carcasses and waste containing offal.

d) When livestock cannot be slaughtered in a *slaughterhouse/abattoir* and are slaughtered on-farm, dogs should be prevented from having access to raw offal, and not be fed offal unless it has been treated in accordance with Article 8.5.6.

2. Control of infection in dogs ~~(owned and stray)~~

a) For control of ~~*stray*~~ *free-roaming dog* populations, the *Veterinary Authority* or other *Competent Authority* should implement relevant aspects of Chapter 7.7.

b) Dogs known to be infected or suspected of having access to raw offal or in contact with livestock should be dewormed at least every 4-6 weeks with praziquantel (5 mg/kg) or another cestocidal product with comparable efficacy. Where possible, faeces excreted up to 72 hours post treatment should be disposed of by incineration or burial.

c) In areas of persistent transmission, the *Veterinary Authority* and other *Competent Authority* should collaborate to identify the possible origins of the *infection*, and review and amend the control programme, as appropriate.

3. Control of infection in livestock

a) The *Veterinary Authority* should ensure that all slaughtered livestock are subjected to post-mortem *meat* inspection in accordance with Chapter 6.3., including inspection of offal for hydatids.

b) When hydatids are detected during post-mortem *meat* inspection:

~~c)~~ i) offal containing hydatids should be disposed of in accordance with Article 4.13.6., or treated in accordance with Article 8.5.6.;

~~d)~~ ii) an investigation should be carried out by the *Veterinary Authority* and other *Competent Authority* to identify the possible origin of the *infection*, and review and amend, as appropriate, the control programme.~~;~~

c) Where indicated, ~~C~~control programmes should include the *vaccination* of livestock with the objective of decreasing the prevalence of *infection* in livestock.

[…]

CHAPTER 15.4.

INFECTION WITH *TAENIA SOLIUM* (PORCINE CYSTICERCOSIS)

EU position

The EU thanks the OIE and supports the adoption of this revised chapter.

Article 15.4.1.

General provisions

Taenia solium (T. solium) is a zoonotic cestode (tapeworm) parasite of pigs and occasionally of other animals. ~~*T. solium* is a cestode (tapeworm) that is endemic in large areas of Latin America, Asia and sub-Saharan Africa~~. The adult cestode occurs in the small intestine of humans (definitive host) causing taeniosis. The larval stage (cysticercus) occurs in striated muscles, subcutaneous tissues and central nervous system of pigs (intermediate hosts), causing cysticercosis. Other suids and ~~dogs~~ some carnivores can be infected but are not epidemiologically significant. Humans may also become infected with the larval stage through the ingestion of eggs shed in faeces of infected humans. The most severe form of human *infection* by the larval stage is neurocysticercosis which causes neurological disorders including seizures (epilepsy) and sometimes death. Cysticercosis, although normally clinically inapparent in pigs, is associated with significant economic losses due to carcass condemnation and decreased value of pigs, and causes a major disease burden in humans.

In humans, taeniosis occurs following ingestion of pig *meat* containing viable cysticerci and can be prevented by avoiding consumption of raw or undercooked contaminated pig *meat*. In humans, cysticercosis occurs following ingestion of *T. solium* eggs and can be prevented by avoiding exposure to *T. solium* eggs through detection and treatment of human tapeworm carriers, community health education, appropriate sanitation, personal hygiene, and good food hygiene. Collaboration between the *Veterinary Authority* and the public health authority is essential in preventing and controlling *T. solium* transmission.

In pigs, cysticercosis occurs by ingestion of *T. solium* eggs from faeces, or environments contaminated with faeces of humans harbouring adult *T. solium*.

For the purposes of the *Terrestrial Code*, *infection* with *T. solium* is defined as an *infection* of pigs.

The aim of this chapter is to reduce the risk of *infection* with *T. solium* of humans and pigs and to minimise the international spread of *T. solium*. The chapter provides recommendations for prevention, control and *surveillance* of *infection* with *T. solium* in pigs.This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005).

When authorising the import or transit of the *commodities* covered in this chapter, with the exception of those listed in Article 15.4.2., *Veterinary Authorities* should apply the recommendations in this chapter.

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

[…]

Article 15.4.3.

Measures to prevent and control infection with *T. solium*

The *Veterinary Authority* and other *Competent Authorities* should carry out community awareness and education programmes on the risk factors associated with transmission of *T. solium* emphasising the role of pigs and humans.

The *Veterinary Authority* or other *Competent Authorities* should promote the comprehensive *animal health management* of pigs, which should include the following measures:

1. Prevention of infection in pigs

Transmission of *T. solium* eggs from humans to pigs can be avoided by:

a) preventing the exposure of pigs to environments contaminated with human faeces;

b) preventing the deliberate use of human faeces as pig *feed* or the use of pigs as a means of human faeces disposal;

c) preventing the use of untreated sewage effluent to irrigate or fertilise land to be used by pigs for forage or for food crops;

d) ensuring that any treated sewage effluent used to irrigate or fertilise land to be used by pigs for forage or for food crops has been treated in a manner shown to inactivate *T. solium* eggs;

e) providing adequate toilet and sanitation facilities for people in areas and *establishments* where pigs are kept to prevent the exposure of pigs and their environment to human faeces~~.~~;

f) where indicated, vaccinating pigs in combination with an anthelmintic treatment in accordance with the *Terrestrial Manual*.

2. Control of infection in pigs

a) The *Veterinary Authority* should ensure that all slaughtered pigs are subjected to post-mortem *meat* inspection in accordance with Chapter 6.3., and with reference to Chapter 3.9.5. of the *Terrestrial Manual*.

b) When cysticerci are detected during post-mortem *meat* inspection:

i) if cysticerci are detected in a carcass of a pig in multiple locations (systemic infection), that carcass and its viscera, as well as all pigs from the same *establishment* of origin should be disposed of in accordance with Article 4.13.6.;

ii) if only localised cysticerci are detected in a carcass of a pig, the *meat* from that carcass and from all pigs from the same *establishment* of origin should be treated in accordance with Article 15.4.6. or may be disposed of in accordance with Article 4.13.6.;

iii) an investigation should be carried out by the *Veterinary Authority* and the public health authority to identify the possible source of the *infection* in order to target an intervention;

iv) post-mortem examination of pigs at *slaughter* from known infected *establishments* should be intensified until evidence has been obtained indicating that the *infection* has been eliminated from the *establishment*.

An optimal control programme should include detection and treatment of human tapeworm carriers and control of sewage used for agricultural production.

[…]

CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

EU position

The EU thanks the OIE for the latest version of the revised Chapter 11.4. on bovine spongiform encephalopathy and appreciates the amendments introduced in the draft to address some of the EU comments transmitted in December 2021.

The EU can support the adoption of this revised chapter as it stands.

However, the EU regrets the position of the OIE to not reinstate in Article 11.4.3. a ruminant-to-ruminant feed ban as a clear requirement for Member countries applying for obtaining an official BSE risk status. The EU considers notably that the implementation of a ruminant-to-ruminant feed-ban should have been a mandatory risk mitigation measure in countries where livestock industry practices do not prevent cattle from being fed with ruminant-derived protein meal as there is no alternative risk mitigation measures in this case to ensure that the risk of recycling the BSE agent is negligible.

Additionally, the EU considers that it would have been appropriate to keep the feed ban as an explicit requirement in Chapter 11.4. and a reminder for the future, as Members' knowledge and awareness of the aim and the value of such a measure to avoid contamination of cattle population is likely to progressively diminish over time.

Finally, the EU suggests, for added clarity, to consider the following amendment to Article 11.4.1. in a future revision of Chapter 11.4.: the sentence "*Oral exposure to contaminated feed is the main route of transmission of classical BSE*" should be replaced by "*Oral exposure to feed contaminated with prions from bovines is the main route of transmission of classical BSE.*"

Article 11.4.1.

General provisions

1) The recommendations in this chapter are intended to mitigate the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agents in cattle only. BSE manifests in two main forms: classical BSE and atypical BSE. Oral exposure to contaminated *feed* is the main route of transmission of classical BSE. Atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population. ~~Oral exposure to contaminated *feed* is the main route of transmission of classical BSE.~~ ~~Given that c~~Cattle have been experimentally infected by the oral route with a low molecular weight type of atypical BSE (L-type BSE~~,~~). Therefore atypical BSE is also ~~potentially~~ considered capable of being recycled in a cattle population if cattle are orally exposed to contaminated *feed*.

2) BSE primarily affects cattle. Other animal species may be naturally and experimentally susceptible to BSE, but they are not regarded as being epidemiologically significant, particularly when feeding ruminants with ruminant-derived ~~protein meal~~*protein meal* is not ~~practiced~~practised.

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

~~1~~a) BSE is an invariably fatal neurological prion disease of cattle caused by a misfolded form of the prion protein (~~PrP^{BSE}~~PrP^{Sc}~~, including~~ which includes both classical (C-type BSE) and atypical strains (H- and L-type BSE~~). for respectively~~ having, respectively, a ~~protease resistant~~ ~~PrP^{BSE}~~PrP^{Sc} fragment of higher and lower molecular mass than classical BSE). The term 'BSE' includes both classical and atypical forms~~, unless otherwise specified~~.

~~2~~b) The occurrence of a BSE *case* is defined by the immunohistochemical (IHC) or immunochemical detection of ~~PrP^{BSE}~~PrP^{Sc} in brain tissue of a bovid of the species *Bos taurus* or *Bos indicus*. ~~, with d~~Discrimination between atypical and classical BSE strains is based on the Western immunoblot banding pattern, as described in the *Terrestrial Manual*.

4) For the purposes of this chapter~~:~~

~~3a) ~~, '~~C~~cattle' means ~~a~~ bovids of the species *Bos taurus* or *Bos indicus.*

~~4b) 'Protein meal' means any final or intermediate solid protein-containing product, obtained when animal tissues are rendered, excluding blood and blood products, peptides of a molecular weight less than 10,000 daltons and amino acids.~~

5) When *commodities* are imported in accordance with this chapter, the BSE risk of the *importing country* or *zone* of destination is not affected by the BSE risk of the *exporting country*, *zone* or *compartment* of origin.

6) Standards for diagnostic tests are described in the *Terrestrial Manual.*

Article 11.4.1bis.

Safe commodities

When authorising the importation or transit of the following *commodities* derived from cattle, *Veterinary Authorities* should not require any conditions related to BSE, regardless of the BSE risk posed by the cattle population of the *exporting country*, *zone* or *compartment*:

1) *milk* and *milk products*;

2) semen and *in vivo* derived cattle embryos collected and handled in accordance with the relevant chapters of the *Terrestrial Code*;

3) hides and skins;

4) gelatine and collagen;

5) tallow with maximum level of insoluble impurities of 0.15% in weight and derivatives made from this tallow;

~~6) tallow derivatives;~~

~~7~~6) dicalcium phosphate (with no trace of protein or fat~~).~~);

7) ~~foetal~~ fetal blood.

Other *commodities* of cattle can be traded safely if in accordance with the relevant articles of this chapter.

Article 11.4.2.

~~The~~ General criteria for the determination of the BSE risk ~~of the cattle population~~ of a country, zone or compartment

~~The~~ ~~Due~~ Owing to its specific etiological and epidemiological features, the BSE risk of ~~the cattle population of~~ a country, *zone* or *compartment* is determined on the basis of the following criteria:

1) ~~a~~A BSE *risk assessment*, in accordance with the provisions of ~~Chapter 1.8.~~the "'Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy"' that evaluates the ~~likelihood~~ risk of BSE agents being recycled within the cattle population by identifying all potential factors associated with the occurrence of BSE and their historic perspective. Member Countries should review the *risk assessment* annually to determine whether the situation has changed.

~~A~~The *risk assessment* for the purpose of BSE, based on the framework provided by Article 2.1.4., consists of:

a) Entry assessment

~~An~~The entry assessment evaluates the likelihood that the classical BSE agent has been introduced into the country, *zone* or *compartment* ~~via imported~~through the importation of the following *commodities*~~.~~ in the preceding eight years:

i) ~~C~~cattle;

ii) ~~R~~ruminant-derived ~~protein meal~~*protein meal*;

iii) ~~F~~*feed* (except packaged and labelled pet food ~~not intended for pets~~) that contains ruminant-derived ~~protein meal~~*protein meal*;

iv) ~~F~~fertili~~z~~sers that contain ruminant-derived ~~protein meal~~*protein meal*;

v) ~~A~~any other *commodity* that either is or could be contaminated by *commodities* listed in Article 11.4.14.

b) Exposure assessment

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

The first step in the exposure assessment involves an evaluation of livestock industry practices through a consideration of the impact of:

i) Livestock industry practices ~~on~~ preventing cattle from being fed ruminant-derived ~~protein meal~~*protein meal*, taking account of:

- demographics of the cattle population and production and farming systems;
- feeding practices;
- slaughtering and waste management practices;
- rendering practices;
- *feed* production, labelling, distribution and storage.

Depending on the outcome from this step, an evaluation of mitigation measures specifically targeting BSE may also need to be included through ~~a~~ consideration of the impact of:

ii) Specific risk mitigation measures ~~on~~ preventing cattle from being fed ruminant-derived ~~protein meal~~*protein meal*, taking account of:

- the nature and scope of a *feed* ban on feeding ruminants with ~~protein meal~~*protein meal* derived from ruminants;
- the fate of *commodities* with the greatest BSE infectivity (those *commodities* listed in point 1 of Article 11.4.14.);
- parameters of the rendering process;
- prevention of cross-contamination during rendering, *feed* production, transport, storage and feeding;
- an awareness programme under the scope of the *feed* ban;
- monitoring and enforcement of the *feed* ban.

Depending on the outcome of the exposure assessment, a consequence assessment (in point (c) below) may not be required.

c) Consequence assessment

~~A~~The consequence assessment evaluates the likelihood of cattle becoming infected ~~with~~ following exposure to the BSE agents together with the likely extent and duration of any subsequent recycling and

amplification within the cattle population during the preceding eight years. The factors to be considered in the consequence assessment are:

i) age at exposure;

ii) production type;

iii) the impact of cattle industry practices or the implementation of ~~BSE~~ BSE-specific mitigation measures under a *feed* ban.

d) Risk estimation

The risk estimation combines the results and conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk ~~that~~ of BSE agents ~~have been~~ being recycled ~~in~~ within the cattle population ~~through the feeding of ruminant-derived protein meal, with indigenous *cases* arising as a consequence~~, and to determine the date from which the risk of BSE agents being recycled within the cattle population has been negligible.

2) ~~the~~ The ongoing implementation of a *surveillance* programme for ~~classical~~ BSE in the cattle population in accordance with Article 11.4.18.

3) ~~the~~ The history of occurrence and management of BSE *cases*.

Article 11.4.3.

Negligible BSE risk

The BSE risk of ~~the cattle population of~~ a country~~,~~ or *zone* ~~or *compartment*~~ can be considered to be negligible if all the following conditions for the cattle population are met for ~~at least~~ at least the preceding eight years:

1) A *risk assessment* as described in Article 11.4.2. that has identified all potential risk factors associated with the occurrence of BSE, including feeding ruminants with ruminant-derived *protein meal*, has been conducted, and the Member Country has demonstrated through documented evidence that any identified risk factors have been adequately managed and that the ~~likelihood~~risk of BSE agents being recycled ~~in~~ within the cattle population has been negligible ~~as the result of:~~.

~~EITHER:~~

~~a) livestock industry practices ensuring that protein meal derived from ruminants has not been fed to ruminants;~~

~~OR~~

~~b) effective and continuous mitigation of each identified risk ensuring that protein meal derived from ruminants has not been fed to ruminants.~~

2) The *surveillance* provisions as described in Article 11.4.~~20~~18. have been implemented.

3) EITHER:

a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported or has been diagnosed as atypical BSE as defined in this chapter;

OR

b) if there has been an indigenous *case* of classical BSE:

~~EITHER~~either:

i) all *cases* were born ~~at least eight years ago~~ before the date from which the risk of BSE agents being recycled within the cattle population has been negligible;

~~OR~~or

ii) where a *case* was born ~~within the preceding eight years~~ after that date, subsequent investigations have confirmed that any identified source of *infection* has been ~~mitigated~~controlled and the ~~likelihood~~risk of BSE agents being recycled within the cattle population has continued to be negligible.

4) Any *cases* of BSE that have been detected have been completely destroyed or disposed of to ensure that they do not enter the animal *feed* chain.

The country or the *zone* will be included in the list of countries or *zones* posing a negligible risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1 to 4 above. Documented evidence should be resubmitted annually for points 1 to 4 above.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

~~Article 11.4.3bis.~~

~~**Recovery of negligible BSE risk status**~~

~~When~~Should ~~an indigenous *case* of classical BSE is reported in an animal born within the preceding eight years occur in a country or *zone* recognised as having~~posing ~~a negligible BSE risk for BSE, the status, of the negligible BSE risk status~~country ~~or *zone* is suspended and the recommendations for controlled BSE risk status apply, pending. The status may be recovered when the outcome of subsequent investigations confirming~~confirms ~~that any identified source of *infection* has been mitigated and the likelihood~~risk ~~of BSE~~ agents ~~being recycled within the cattle population continues to be negligible. The~~In ~~the interim, the provisions for a country or *zone* will regain~~with a ~~controlled BSE risk status apply.~~

~~The negligible BSE risk status of the country or *zone* will be reinstated only after the submitted evidence has been accepted by the OIE.~~

Article 11.4.4.

Controlled BSE risk

The BSE risk ~~of the cattle population~~ of a country or~~,~~ *zone* ~~or *compartment*~~ can be considered to be controlled provided all of the conditions of Article 11.4.3. are met, but ~~at least~~ one or more of these conditions has not been met for ~~at least~~ the preceding eight years.

The country or the *zone* will be included in the list of countries or *zones* posing a controlled risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1 to 4 of Article 11.4.3. Documented evidence should be resubmitted annually for points 1 to 4 of Article 11.4.3.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

Article 11.4.4bis.

Compartment with negligible or controlled BSE risk

The establishment and bilateral recognition of a *compartment* posing negligible or controlled BSE risk should follow the relevant requirements of this chapter and the principles laid down in Chapters 4.4. and 4.5.

Article 11.4.5.

Undetermined BSE risk

The BSE risk ~~of the cattle population~~ of a country or~~,~~ *zone* ~~or *compartment*~~ is considered to be undetermined if it cannot be demonstrated that it meets the requirements for negligible or controlled BSE risk.

Article 11.4.5bis.

Maintenance of BSE risk status

Should an indigenous *case* of classical BSE in an animal born after the date from which the risk of BSE agents being recycled within the cattle population has been negligible occur in a country or *zone* recognised as posing a negligible or controlled risk for BSE, the status of the country or *zone* is maintained, provided that documented evidence regarding the outcome of subsequent investigations is submitted to the OIE within 90 days demonstrating that any identified source of *infection* has been controlled and the risk of BSE agents being recycled within the cattle population has continued to be negligible.

If no documented evidence is provided or if it is not accepted by the OIE, the provisions of Article 11.4.3. or Article 11.4.4. apply.

~~Article 11.4.6.~~

~~**Recommendations for importation of cattle from a country, zone or compartment posing a negligible BSE risk**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that cattle selected for export came from a country, *zone* or *compartment* posing a negligible BSE risk.~~

Article 11.4.7.

Recommendations for importation of cattle from a country, zone or compartment posing a negligible or controlled BSE risk

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

1) ~~the~~The cattle selected for export~~:~~

~~1)~~ ~~came from a country, *zone* or *compartment* posing a negligible or controlled BSE risk and~~ are identified through an *animal identification system* enabling ~~each *animal*~~ them to be traced throughout ~~its~~ their lifetime~~;~~.

AND EITHER:

2) ~~the~~The cattle selected for export were born and kept in ~~the~~ a country, *zone* or *compartment* posing a negligible or controlled BSE risk after the date from which ~~during the period when~~ the ~~likelihood~~risk of ~~the~~ BSE agents being recycled ~~in~~ within the cattle population has been demonstrated to be negligible~~;~~.

OR

3)

~~a) are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime; and~~

~~b)~~ ~~are it~~ It is demonstrated ~~as having~~that the cattle selected for export have not been fed ~~protein meal~~*protein meal* derived from ruminants.

Article 11.4.8.

Recommendations for importation of cattle from a country ~~or~~, zone ~~or compartment~~ posing an undetermined BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that ~~cattle selected for export~~:

1) ~~the~~The cattle selected for export are identified ~~by a permanent individual~~ through an *animal identification system* ~~from birth~~ enabling ~~each *animal*~~ them to be traced throughout ~~its~~ their lifetime~~;~~.

2) ~~areit~~ It is demonstrated ~~as having~~ that the cattle selected for export have not been fed ~~protein meal~~*protein meal* derived from ruminants.

~~Article 11.4.9.~~

~~**Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a negligible BSE risk**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the cattle from which the *fresh meat* and *meat products* were derived:~~

~~1) came from a country, *zone* or *compartment* posing a negligible BSE risk;~~

~~2) have been subjected to an ante-mortem inspection with favourable results.~~

Article 11.4.10.

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

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

1) the cattle from which the *fresh meat* and *meat products* were derived ~~came from a country, *zone* or *compartment* posing a controlled BSE risk~~negligible or controlled BSE risk and are identified through an *animal identification system*;

2) they have been subjected to an ante-mortem inspection with favourable results;

AND EITHER:

3) they were born and kept in ~~the~~ a country, *zone* or *compartment* posing a negligible or controlled BSE risk after the date from which~~during the period when~~ the ~~likelihood~~ risk of ~~the~~ BSE agents being recycled ~~in~~ within the cattle population has been demonstrated to be negligible;

OR

4) the *fresh meat* and *meat products*:

   a) derived from cattle not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to *slaughter*; and

   b) were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

      i) the *commodities* listed in point~~s~~ 1~~)~~ ~~a) and 1) *b)*~~ of Article 11.4.14.;

      ii) mechanically separated *meat* from the skull ~~and~~nor or from the vertebral column ~~from~~ of cattle over 30 months of age.

Article 11.4.11.

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

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

1) the cattle from which the *fresh meat* and *meat products* were derived~~:~~

~~a)~~ are identified through an *animal identification system*;

2) it is demonstrated ~~as having~~that the cattle from which the *fresh meat* and *meat products* were derived have not been fed ~~protein meal~~*protein meal* derived from ruminants;

~~b~~3) the cattle from which the *fresh meat* and *meat products* were derived:

a) were subjected to an ante-mortem inspection with favourable results;

~~cb~~b) were not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to *slaughter*;

~~2~~4) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

a) the *commodities* listed in point~~s~~ 1~~)~~ ~~*a) and 1) b)*~~ of Article 11.4.14.;

b) mechanically separated *meat* from the skull ~~and~~nor or from the vertebral column ~~from~~ of cattle over 30 months of age.

Article 11.4.12.

Recommendations for importation of cattle-derived protein meal from a country, zone or compartment posing a negligible BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the cattle from which the ~~protein meal~~*protein meal* was derived ~~came from a country, *zone* or *compartment* posing a negligible BSE risk. 1)~~ ~~came from a country, *zone* or *compartment* posing a negligible BSE risk;~~

~~2~~ were ~~are~~ identified through an *animal identification system* and were born and kept in ~~the~~ a country, *zone* or *compartment* posing a negligible BSE risk, and

EITHER

1) they were born after the date from which ~~during the period when~~ the risk of ~~the~~ BSE agents being recycled ~~in~~ within the cattle 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 cattle (except ~~foetal~~ fetal blood)

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

EITHER:

~~1)~~ ~~the blood and blood products came from a country, *zone* or *compartment* posing a negligible or controlled BSE risk; and~~

~~OR~~

1~~2~~) the ~~blood and blood products came from a country, *zone* or *compartment* posing a controlled BSE risk and the~~ cattle from which the blood and blood products were derived ~~are~~ were identified through an *animal identification system* and were born and kept in ~~the~~ a country, *zone* or *compartment* posing a negligible or controlled BSE risk after the date from which ~~during the period when~~ the ~~likelihood~~ risk of ~~the~~ BSE agents being recycled ~~in~~ within the cattle population has been demonstrated to be negligible;

OR

2~~3~~) the blood and blood products were:

a) collected from cattle not subjected to a *stunning* process~~, or to any other procedure that can contaminate the blood with nervous tissue,~~ with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate the blood with nervous tissue, prior to *slaughter*; and

b) collected and processed in a manner that ensures they are not contaminated with nervous tissue.

Article 11.4.14.

Recommendations in relation to the trade of the commodities with the greatest BSE infectivity

~~1)~~ Unless covered by other articles in this chapter, the following *commodities* ~~originating from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk, and any *commodity* contaminated by them,~~ should not be traded ~~for the preparation of food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices~~:

~~a~~1~~)~~) ~~distal~~ Distal ileum from cattle of any age; ~~*b)*~~ skull, brain, eyes, vertebral column and spinal cord from cattle that were at the time of *slaughter* over 30 months of age~~.~~; or any *commodity* contaminated by them, for the preparation of protein products, food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices, which originate from a country, *zone* or *compartment* posing:

a) an undetermined BSE risk;

b) a controlled BSE risk ~~or a negligible BSE risk~~ if the *commodities* are derived from cattle born before the ~~period when~~ date from which the risk of ~~the~~ BSE agents being recycled ~~in~~ within the cattle population has been demonstrated to be negligible.

2) Protein products, food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices prepared using *commodities* listed in point~~s~~ 1~~) *a)* or 1) *b)*~~ above ~~of this article, which originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk, should not be traded~~.

3) Cattle-derived ~~protein meal~~*protein meal*~~,~~ or any *commodities* containing such product~~s,~~ which originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk~~, should not be traded~~.

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

Article 11.4.15.

Recommendations for importation of tallow (other than as defined in Article 11.4.1bis.) 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 which have been subjected to an ante-mortem inspection with favourable results, and has not been prepared using the *commodities* listed in ~~points~~point 1~~) a) and 1) b)~~ of Article 11.4.14.

Article 11.4.15bis.

Recommendations for importation of tallow derivatives (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the tallow derivatives either:

1) originate from a country, *zone* or *compartment* posing a negligible BSE risk; or

2) are derived from tallow that meets the conditions referred to in Article 11.4.15.; or

3) have been produced by hydrolysis, saponification, or transesterification that uses high temperature and pressure.

Article 11.4.16.

Recommendations for importation of dicalcium phosphate (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1) ~~the dicalcium phosphate~~ came from a country, *zone* or *compartment* posing a negligible BSE risk; or

2) ~~the dicalcium phosphate~~ is a co-product of bone gelatine.

~~Article 11.4.16bis.~~

~~**Recommendations for importation of tallow derivatives (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the tallow derivatives either:~~

~~1)~~ ~~originate from a country, *zone* or *compartment* posing that poses a negligible BSE risk; or~~

~~2)~~ ~~are derived from tallow that meets the conditions referred to in Article 11.4.15.; or~~

~~3)~~ ~~have been produced by hydrolysis, saponification or transesterification that uses high temperature and pressure.~~

Article 11.4.17.

Procedures for reduction of BSE infectivity in protein meal

The following procedure should be used to reduce the infectivity of any ~~transmissible spongiform encephalopathy~~BSE agents ~~which~~that may be present during the production of ~~protein meal~~*protein meal* containing ruminant proteins~~.~~:

1) ~~T~~the raw material should be reduced to a maximum particle size of 50 mm before heating~~.~~;

2) ~~T~~the raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

Article 11.4.18.

Surveillance

The objective of BSE *surveillance* is to detect occurrence of BSE within the cattle population.

~~1)~~ ~~*Surveillance* for BSE consists of the regular reporting of animals with clinical signs suggestive of BSE to the *Veterinary Authority* for subsequent investigation and diagnosis. The credibility of the *surveillance* programme is supported by:~~

~~a) compulsory notification of BSE throughout the whole territory by all those stakeholders involved in the rearing and production of livestock including farmers, herdsmen, *veterinarians*, transporters and *slaughterhouse/abattoir* workers;~~

~~b) an ongoing awareness programme to ensure that all stakeholders are familiar with the clinical signs suggestive of BSE as well as the reporting requirements;~~

~~c) appropriate *laboratory* investigations in accordance with the *Terrestrial Manual* and follow-up field investigation as necessary of all clinical suspects.~~

~~2~~1) BSE is a progressive, fatal disease of the nervous system of cattle that usually has an insidious onset and that is refractory to treatment. A range of clinical signs that vary in severity and between animals have been described for classical BSE:

a) progressive behavioural changes that are refractory to treatment such as increased excitability, depression, nervousness, excessive and asymmetrical ear and eye movements, apparent increased salivation, increased licking of the muzzle, teeth grinding, hypersensitivity to touch and/or sound (hyperaesthesia), tremors, excessive ~~vocalization~~vocalisation, panic-stricken response and excessive alertness;

b) postural and locomotory changes such as abnormal posture (dog sitting), abnormal gait (particularly pelvic limb ataxia), low carriage of the head, ~~(~~head shyness~~)~~, difficulty avoiding obstacles, inability to stand and recumbency;

c) ~~generalized~~generalised non-specific signs such as reduced *milk* yield, loss of body condition, weight loss, bradycardia and other disturbances of cardiac rhythm.

Some of these signs are also likely to be relevant for atypical BSE, particularly those associated with difficulty in rising and recumbency. A nervous form of atypical BSE resembling classical BSE may be observed with over-reactivity to external stimuli, unexpected startle responses and ataxia. In contrast, a dull form of atypical BSE may be observed, with dullness combined with a low head carriage and compulsive behaviour (licking, chewing, pacing in circles).

The clinical signs of BSE usually progress on a spectrum over a few weeks to several months, but ~~in~~on rare occasions cases can develop acutely and progress rapidly. ~~In the continuum of the disease spectrum, t~~The~~The~~ final stages of the disease are characterised by recumbency, coma and death.

~~Cattle displaying some of the above mentioned progressive neurological signs without signs of infectious illness, and that are refractory to treatment, are candidates for examination.~~

Since these signs are not pathognomonic for either classical or atypical BSE, all Member Countries with cattle populations ~~may~~ are likely to observe individual animals displaying clinical signs suggestive of BSE. ~~The rate at which they are likely to occur~~General statements about the likely frequency of occurrence of such animals cannot be ~~reliably predicted~~made as they will vary depending on the epidemiological situation in a particular country. ~~In addition, in~~

2) *Surveillance* for BSE consists of the reporting of all animals that ~~lie on the continuum of the~~ show ~~symptoms~~ signs of the clinical spectrum of BSE ~~spectrum~~ to the ~~*Veterinary Authority*~~*Veterinary Services* for subsequent investigation and follow-up.

In ~~those countries where cattle are intensively reared and~~production and farming systems that allow cattle 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 are not monitored as closely, situations may ~~inevitably~~ arise where an animal might be considered as a clinical suspect, yet if it ~~was~~ has not been observed for a period of time, it may only be initially seen as a downer (non-ambulatory) or found dead (fallen stock). ~~Under such circumstances, if there is an appropriate supporting~~

~~clinical history, these animals that lie on the continuum of a progressive disease from clinical suspect to downer to fallen stock may still be suitable candidates for *surveillance*.~~

The ~~investigation of potential~~ *surveillance* programme~~candidates~~ should take into account that the vast majority of BSE *cases* arise as single, isolated events. The ~~concurrent occurrence~~ concurrence of multiple animals with behavioural or neurological signs, or non-ambulatory or fallen stock is most likely associated with other causes.

The ~~following~~ animals that lie on ~~the continuum of~~ the ~~disease~~ clinical spectrum of BSE should be targeted for BSE *surveillance* and the following animals should be followed up with appropriate laboratory testing in accordance with the *Terrestrial Manual* to accurately confirm or rule out the presence of BSE agents:

a) those displaying some of the progressive clinical signs suggestive of BSE mentioned in point 1 of Article 11.4.18. ~~suggestive of BSE~~ that are refractory to treatment, and where other common causes of behavioural or neurological signs (e.g. infectious, metabolic, traumatic, neoplastic or toxic causes) have been ruled out;

b) those showing behavioural or neurological signs at ~~that have been subjected to an~~ ante-mortem inspection ~~with unfavourable results~~ at *slaughterhouses/abattoirs*;

c) those presented as downers (non-ambulatory), with an appropriate supporting clinical history (i.e. other common causes of recumbency ~~has~~ have been ruled out);

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

~~All these animals should be followed up with appropriate laboratory testing in accordance with the *Terrestrial Manual* to accurately confirm or rule out the presence of BSE agents.~~

3) The credibility of the *surveillance* programme is supported by:

a) ongoing awareness and training programmes to ensure that all those stakeholders involved in the rearing and production of livestock, including ~~farmers, herdsmen,~~ cattle owners and keepers, *veterinarians*, transporters and *slaughterhouse/abattoir* workers are familiar with the clinical signs suggestive of BSE as well as the statutory reporting requirements;

b) the fact that BSE is a compulsorily *notifiable disease* throughout the whole territory;

c) appropriate *laboratory* testing in accordance with the *Terrestrial Manual*;

d) robust, documented, evaluation procedures and protocols for:

- the identification and reporting of ~~potential candidates~~animals targeted for BSE *surveillance*,
- ~~for~~ the determination of animals to be subjected to laboratory testing,
- ~~for~~ the collection and submission of samples for laboratory testing,
- ~~and for~~the follow-up epidemiological investigations for BSE positive findings.

DRAFT CHAPTER 1.8.

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

EU position

The EU thanks the OIE for the latest version of the revised Chapter 1.8. on application for official recognition by the OIE of risk status for bovine spongiform encephalopathy and appreciates the amendments introduced in the draft to address some of the EU comments transmitted in December 2021.

The EU can support the adoption of this revised chapter as it stands.

However, the EU considers that the implementation of a ruminant-to-ruminant feed-ban should have been made a mandatory risk mitigation measure in applicant countries where livestock industry practices do not prevent cattle from being fed with ruminant-derived protein meal as there is no alternative risk mitigation measures in this case to ensure that the risk of recycling the BSE agent is negligible.

Additionally, the EU considers that full transparency will have to be ensured by the OIE on the criteria to determine and validate the "date from which the risk of BSE agents being recycled within the cattle population has been negligible" in particular for Members or zones which will be recognised under the new BSE standards once adopted. The EU will be very attentive that this date is clearly mentioned in the relevant OIE reports related to BSE risk recognition of Members.

Article 1.8.1.

Guidelines

In accordance with Article 11.4.2., the bovine spongiform encephalopathy (BSE) risk of ~~the cattle (*Bos indicus* and *Bos taurus*) population of~~ a country or *zone* is determined on the basis of a *risk assessment* that evaluates the risk of BSE agents (classical and atypical) being recycled within the cattle (*Bos indicus* and *Bos taurus*) population by identifying all potential factors associated with the occurrence of BSE, the ongoing implementation of a *surveillance* programme, and the history of occurrence and management of BSE *cases*.

In this chapter, "'BSE'" refers to both classical and atypical forms~~, unless specified otherwise~~.

The information specified in Articles 1.8.2. to 1.8.6. should be provided by OIE Member Countries in support of their application for official recognition of BSE risk status in accordance with Chapter 11.4. of the *Terrestrial Code*. The structure of the dossier should follow guidelines provided in the "'Standard Operating Procedure for official recognition of disease status and for the endorsement of national official control programmes of Member Countries'" (available on the OIE website).

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

– ~~T~~the history of occurrence and management of BSE *cases* in the country or *zone* (Article 1.8.2.)

– ~~L~~legislation (Article 1.8.3.)

– ~~V~~veterinary system (Article 1.8.4.)

– BSE risk assessment (Article 1.8.5.)

– BSE surveillance (Article 1.8.6.).

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

Article 1.8.2.

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

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

1) If a *case* of BSE has ever been diagnosed in the country or *zone*, indicate the total number of BSE *cases*, and:

   a) Provide a table of aggregated data on all *cases* of BSE encountered in the country or *zone*, by type (classical or atypical), origin (indigenous or, if imported, the country of origin), and the year of birth;

   b) For the past eight years, provide a table to indicate, for each *case*, the year of occurrence, the origin (indigenous or, if imported, the country of origin), the type (classical or atypical), and the year of birth of each indigenous *case* of classical BSE.

2) If there have been *cases* of BSE, confirm that they were excluded from the *feed* chain and describe how this was achieved. In the table under Article 1.8.3. provide details of the national legislation, regulations and *Veterinary Authority* directives that describe these procedures.

Article 1.8.3.

Legislation

Provide a table listing all relevant legislation, regulations, *Veterinary Authority* directives, legal instruments, rules, orders, acts, decrees, etc., related to BSE. For each, provide the date of promulgation and implementation as well as a brief description of the relevance to mitigating ~~against~~ the risks associated with BSE. The table should include the legislation, regulations and directives referred to in the core document of the dossier. These instruments may be provided as annexes or as weblinks to supporting documents.

Article 1.8.4.

Veterinary system

The quality of the *Veterinary Services* of a Member is important to the establishment and maintenance of confidence in its *international veterinary certificates* by the *Veterinary Services* of other Members (Article 3.2.1.). It also supports an evaluation of the BSE risk status ~~of the cattle population~~ of a country or *zone*.

1) Describe how the *Veterinary Services* of the country comply with the provisions of Chapters 1.1., 3.2. and 3.3.

2) The applicant Member may provide information on any recent (not older than five years) OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway, and highlight the results relevant to BSE.

3) Describe how the *Veterinary Services* supervise, control, enforce and monitor all BSE-related activities.

4) Provide a description of the involvement and the participation of industry; producers; ~~farmers; herdsmen;~~ cattle owners and keepers; private *veterinarians*; *veterinary paraprofessionals*; transporters; workers at livestock

markets, auctions and *slaughterhouses/abattoirs*; and other relevant non-governmental stakeholders in the control of BSE.

5) Describe the official cattle identification, registration, *traceability* and movement control system. Provide evidence of its effectiveness. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic. Indicate ~~if~~ whether there are any industry associations or organisations involved in cattle identification, registration, *traceability* and movement control systems that provide guidance, set standards or provide third party audits; include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

Article 1.8.5.

BSE risk assessment

1~~.~~) Entry assessment

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

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

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

– ~~C~~cattle~~.~~;

– ~~R~~ruminant-derived ~~protein meal~~*protein meal*~~.~~;

– ~~F~~*feed* (~~not intended for pets~~except packaged and labelled pet food) that contains ruminant-derived ~~protein meal~~*protein meal*~~.~~;

– ~~F~~fertilizers that contain ruminant-derived ~~protein meal~~*protein meal*~~.~~;

– ~~A~~any other *commodity* that either is or could be contaminated by *commodities* listed in Article 11.4.14.~~, e.g. over 30 months old cattle carcass or half carcass from which the spinal cord and vertebral column were not removed, originating from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk.~~

a) For each *commodity* listed above indicate ~~if~~ whether they were imported in the preceding eight years, and if so, from which countries.

For each *commodity* listed above describe the import requirements applied by the applicant country or *zone* and how they are related to the BSE risk status of the *exporting country* or *zone* and whether or not they are consistent with, or provide an equivalent level of assurance ~~with~~ to, the recommendations laid out in Chapter 11.4. for the importation of such a *commodity*. Where the import requirements are not consistent with the recommendations in Chapter 11.4. but are considered to provide an equivalent level of assurance, provide an explanation outlining the rationale and supporting evidence. In situations where an import requirement does not provide an equivalent level of assurance to the relevant measure in Chapter 11.4., provide an explanation of how this is likely to impact the entry assessment.

Describe the importation process for these *commodities* and how are they controlled, regulated and monitored by the *Competent Authority* with references as appropriate to the relevant legislation in the table under Article 1.8.3. Provide supporting evidence of the importation process including, where relevant, import permits or their equivalent, and examples of *international veterinary certificates* issued by *exporting countries*.

Describe the intended end use of the imported *commodities*, for example: cattle may be imported for breeding or immediate *slaughter*; rendered products may be imported for incorporation into *feed* for non-ruminant species such as pigs or *poultry*. Provide information on any systems in place ~~and their results~~ to monitor or track imported *commodities* and their results to ensure they are used as intended.

Describe the actions available under national legislation to prevent illegal introduction of the *commodities* considered above and provide information on any illegal introductions detected and the actions taken.

b) Conclusions for the entry assessment.

Given the sanitary measures applied (if any), what was the likelihood that, during the preceding eight years, any of the *commodities*, in the form that they were imported, harboured or were contaminated by the classical BSE agent?

Clearly and concisely describe the rationale leading to the conclusions reached.

2.) Exposure assessment

As emphasised in Article 11.4.1., atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population. Although uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated *feed*, this is the main route of transmission of classical BSE. Considering that atypical BSE may potentially be capable of being recycled in a cattle population if cattle were to be exposed to contaminated *feed*, it is necessary to undertake an exposure assessment regardless of the outcome of the entry assessment.

As described in Article 11.4.2., an exposure assessment evaluates the likelihood of cattle being exposed to the BSE agents either through imported *commodities* (classical BSE) or as a result of the presence of BSE agents (classical or atypical BSE) in within the indigenous cattle population of the country or *zone*.

For the purposes of undertaking an exposure assessment for the evaluation of BSE status, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.). At its discretion, the applicant Member may provide the information requested for a different period (i.e. longer than eight years for those applying for a negligible risk status, or for the time period for which they have the information if applying for a controlled risk status) to establish the period when indicate the date from which the likelihood risk of the BSE agents being recycled in within the cattle population has been demonstrated to be negligible (i.e. to determine the period of time date to be attested in point 2 of accordance with Articles 11.4.6., 11.4.7., 11.4.910., 11.4.12., and 11.4.13. and 11.4.14.).

As indicated in point 1(b) of Article 11.4.2., the first step in the exposure assessment involves an evaluation of the impact of livestock industry practices on preventing cattle from being fed ruminant-derived protein meal*protein meal* and, depending on the outcome of this step, an evaluation of the impact of specific mitigation measures on preventing cattle from being fed ruminant-derived protein meal*protein meal*.

a) Livestock industry practices.

Because oral exposure to contaminated *feed* is the principal route of transmission of the BSE agents, the exposure assessment begins with a detailed description of the cattle population and associated industry practices, with a particular emphasis on: feeding practices; disposal of dead stock animals and waste from slaughtered animals; rendering; and production, labelling, distribution and storage of *feed* that may lead to cattle being exposed to potentially contaminated *feed*.

The intent of this section is not to describe the implementation and enforcement of measures specifically targeting the exposure of the cattle population to BSE agents (such as a legislated *feed* ban) as they will be considered where relevant in Section *b) An evaluation of BSE specific mitigation measures*. The intention here is to evaluate the likelihood and extent of exposure of the cattle population to the BSE agents, given the ongoing livestock industry practices in a country or *zone*.

i) Demographics of the cattle population and production and farming systems.

Describe the composition of the cattle population and how the cattle industry is structured in the country or *zone*, considering the types of production, systems, including all that apply, such as dairy, beef rearing, feedlot, fattening and beef finishing, and the farming systems, such as intensive, extensive, semi semi-intensive, transhumant, pastoral, agropastoral, and mixed-species farming. The description should include the number and size of *herds* farms in each type of production and farming system.

ii) Feeding practices.

For each type of production system, describe the rearing and production practices related to feeding ruminants of various ages, including the types of *feed* and *feed ingredients* (animal or plant based). Where animal-based ingredients are used, describe whether or not they are derived from rendered products of ruminant or non-ruminant origin as well as the respective proportions used.

Provide an indication of the proportion of the national *feed* production prepared commercially (including local mills) or mixed on farm using either imported or domestically produced ingredients.

Describe whether or not fertili~~z~~sers containing ruminant-derived ~~protein meal~~*protein meal*, composted materials derived from fallen stock (i.e. cattle of any age which were found dead or were killed on a farm, during transportation, at livestock *markets* or auctions, or at a *slaughterhouse/abattoir*), *slaughterhouse/abattoir* waste or animals condemned at ~~ante-~~ante-mortem inspections or any other materials derived from or that incorporate ruminant protein are applied to land where cattle graze or where forage is harvested for feeding to cattle. Where such fertili~~z~~sers or composted materials are used, provide information on the extent and frequency of use.

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

iii) Slaughtering and waste management practices~~.~~

Describe the practices for fallen stock, including cattle euthanised as part of a BSE *surveillance* programme under Article 11.4.18.~~that occur on farm, during transport, at livestock *markets* or auctions or prior to *slaughter*~~, with particular reference to their transportation, disposal or destruction, including composting, burial, rendering or incineration. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Describe the places where cattle are slaughtered (for example, on farm, at a *slaughterhouse/abattoir* or *market*) together with the respective proportions and associated ages.

Describe whether or not places where animals are slaughtered are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Describe how animals condemned at ~~ante-~~ante-mortem inspection and waste declared as unfit for human consumption from slaughtered animals are processed, disposed of or destroyed, including composting, burial, rendering, incineration or other industrial uses such as salvaging and crushing bones for use in animal *feed*. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

iv) Rendering practices~~.~~

Rendering is a process by which animal material is transformed into products such as ~~protein meal~~*protein meal* that may be used in animal *feed*. It provides the pathway for the introduction of the BSE agents (classical or atypical) into the animal feed chain.

Describe whether or not there are any rendering facilities in the country or *zone*, if they are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Using tables as appropriate, for each of the preceding eight years, provide a breakdown of the number of rendering facilities operating, indicating for each facility:

– the source and types of raw materials handled;

– whether or not they receive and process material from a particular species or process mixed materials including those derived from ruminants;

– whether or not ruminant waste is segregated from non-ruminant waste and if so how segregation is maintained to avoid potential cross-contamination of non-ruminant rendered materials during processing, storage and transport of rendered products, for example through dedicated lines, storage bins or silos, transport vehicles or establishments;

– the parameters of the rendering process (time, temperature, pressure, etc.);

– the type and intended end use of the rendered products ~~produced~~. If available, provide the amount of rendered products produced annually by type and intended end use;

– if materials derived from imported cattle are managed differently, describe the process.

Indicate if there are any industry associations or organisations involved in the rendering industry that provide guidance, set standards or provide third party audits in relation to Hazard Analysis and Critical Control Points (HACCP) programmes, *good manufacturing practices*, etc. Include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

v) Feed production, labelling, distribution and storage~~.~~

Where rendered products are used as ingredients in the production of animal *feed* the exposure of cattle to the BSE agents (classical and atypical) may arise as a result of the use of rendered products containing materials of ruminant origin as ingredients in cattle *feed* or as a result of cattle *feed* being cross-contaminated when such products are used in the production of *feed* for other species.

Describe whether ~~or not~~ facilities producing *feed* for ruminant or non-ruminant livestock as well as for pets are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

For each of the preceding eight years, provide a breakdown using tables as appropriate of the number and types of facilities producing *feed*, indicating for each facility:

– ~~excluding those listed in Article 11.4.1bis.,~~ whether or not rendered ruminant products, excluding those listed in Article 11.4.1bis., were used as ingredients in *feed* for ruminants, non-ruminants and pets;

– whether or not each facility was dedicated to manufacturing *feed* for a particular species or manufactured *feed* for multiple species including ruminants.

Where facilities manufactured *feed* for multiple species including ruminants, indicate whether or not there were any practices in place to avoid ruminant *feeds* from being contaminated with rendered ruminant products during *feed* manufacture, storage and transport.

Indicate if there are any industry associations or organisations involved in *feed* production, distribution and storage that provide guidance, set standards or provide third party audits in relation to HACCP programmes, *good manufacturing practices*, etc. Include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

vi) Conclusions for livestock industry practices~~.~~

– Given the livestock industry practices described above, is the likelihood that the cattle population has been exposed to either classical or atypical BSE during the preceding eight years negligible or non-negligible?

– Clearly and concisely describe the rationale leading to the conclusion reached.

– Where the likelihood estimate is negligible, proceed to *Section 4) Risk estimation*.

– Where the likelihood estimate is non-negligible, proceed to *Section b) An evaluation of BSE specific mitigation measures*.

b) An evaluation of ~~BSE~~ BSE-specific risk mitigation measures~~.~~

For those countries that have reported classical BSE *cases* in indigenous cattle, it is apparent that their historic livestock industry practices did not prevent the recycling of the BSE agent ~~in~~ within their cattle populations. These countries, together with others whose livestock industry practices would have been conducive to recycling, may have implemented specific measures, ~~such as~~notably through a legislated *feed* ban, to ensure that the likelihood of recycling would be negligible. To qualify for official recognition

of a BSE risk status, these countries need to demonstrate that ~~the~~these measures specifically targeting BSE have been and continue to be effectively implemented and enforced.

i) The nature and scope of a feed ban~~.~~

Indicate ~~if~~ whether there is a ban on feeding ruminants with ~~protein meal~~*protein meal* derived from ruminants.

Where a *feed* ban has been implemented, clearly and concisely describe the date it was introduced, its nature and scope and how it has evolved over time.

In addition, if the *feed* ban has been implemented through national legislation, provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

ii) Commodities with the greatest BSE infectivity~~.~~

Indicate whether ~~or not~~ any of those *commodities* listed in point 1 of Article 11.4.14. are removed from the carcass at the time of *slaughter* or subsequent fabrication or processing.

If so, also:

– Describe how they are disposed of or destroyed through burial, composting, rendering, alkaline hydrolysis, thermal hydrolysis, gasification, incineration, etc.

– Describe any measures in place that ensure *slaughter* waste declared as unfit for human consumption that is rendered is not ~~cross-~~contaminated with these *commodities*.

– Describe whether these *commodities* from fallen stock and animals condemned at ~~ante-~~ante-mortem inspection are excluded from rendering and how this is done.

– Where these *commodities* are not ~~excluded~~ removed from fallen stock, animals condemned at ante-mortem inspection, or *slaughter* waste declared as unfit for human consumption, describe their final disposal ~~of this waste~~, and how it is handled and processed.

– Describe whether or not all these processes and methods are subject to approval and oversight by the *Veterinary Services* or other *Competent Authority*.

In addition, if there is specific national legislation concerning the definition, identification, removal and disposal or destruction of those *commodities* listed in point 1 of Article 11.4.14., provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

iii) Parameters of the rendering process~~.~~

Describe whether or not the parameters of the rendering process are prescribed in legislation and if they are consistent with, or provide an equivalent level of assurance to, the procedures for the reduction of BSE infectivity in ruminant-derived ~~protein meal~~*protein meal* as described in Article 11.4.17. Provide details of the legislation, if applicable, in the table under Article 1.8.3.

iv) Cross-contamination~~.~~

Describe the measures in place to prevent cross-contamination during rendering, *feed* production, transport, storage and feeding such as dedicated facilities, lines and equipment, as well as measures to prevent misfeeding, such as the use of warning labels. Provide information as to whether any of these measures are prescribed in legislation and if facilities involved in rendering and *feed* production are required to be registered or approved under the *feed* ban by the *Veterinary Services* or other *Competent Authority*.

v) Awareness programme under the scope of the feed ban~~.~~

Provide information on the existence of any ongoing awareness programmes or other forms of guidance given to all those stakeholders involved in rendering, *feed* production, transport, storage, distribution, sale and feeding under the scope of the *feed* ban. Provide examples of communication materials including publications, brochures and pamphlets.

vi) Monitoring and enforcement of the feed ban.

Describe how the *feed* ban, if implemented, has been and continues to be monitored and enforced. Provide information on:

- official oversight from the *Veterinary Authority*, other *Competent Authority* or an *approved* third party;
- training and accreditation programmes for inspectors;
- the planned frequency of inspections, and the procedures involved including manuals and inspection forms;
- sampling programmes and *laboratory* testing methods used to check the level of compliance with the *feed* ban and cross-contamination;
- options available to deal with infractions (non-compliances) such as recalls, destruction and monetary penalties.

Provide information on the ongoing results of the official inspection programme for each of the preceding eight years, using tables as appropriate:

- planned *versus* actual delivery inspections at rendering facilities, *feed* mills, farms, etc., with an explanation of any significant variance variation and how they it may have impacted the programme;
- number and type of samples taken during inspections to verify that ruminant *feed* does not contain or is not cross cross-contaminated with rendered products containing ruminant material (excluding those listed in Article 11.4.1bis.). Provide information by year, by source (rendering facility, *feed* mill or farm), indicating the *laboratory* test(s) used and the results obtained;
- the types of infractions (non-compliance) that occurred and corrective actions undertaken;
- any infractions (non-compliances) that were likely to have led to cattle being exposed to *feed* contaminated with ruminant material (excluding those listed in Article 11.4.1.bis) and how they were resolved.

vii) Conclusions for the evaluation of BSE BSE-specific risk mitigation measures.

- In evaluating the effectiveness of a *feed* ban, if implemented, for each of the preceding eight years, consideration needs to be given to:
  - the management of *commodities* listed in point 1 of Article 11.4.14., and the associated likelihood that these materials, or other materials cross cross-contaminated by them, may have entered the animal feed chain;
  - the rendering industry and the associated likelihood that rendered products containing ruminant material may retain BSE infectivity;
  - the *feed* industry, and the associated likelihood that *feed* for cattle may contain or has been cross-contaminated with ruminant-derived protein meal*protein meal*.
- Given the evaluation of BSE BSE-specific risk mitigation measures and their enforcement as described above, is the likelihood that, during the preceding eight years, the cattle population has been exposed to either classical or atypical BSE negligible or non-negligible?
- Clearly and concisely describe the rationale leading to the conclusion reached.
- Where the likelihood estimate is negligible, proceed to *Section 4) Risk estimation*.
- Where the likelihood estimate is non-negligible, proceed to *Section 3) Consequence assessment*.

3.) Consequence assessment

While uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated *feed*, it is reasonable to assume for the purposes of a consequence assessment, that the likelihood of cattle becoming infected would be similar to that for classical BSE.

As described in Article 11.4.2., a consequence assessment evaluates the likelihood of cattle becoming infected following exposure to the BSE agents (classical or atypical) together with the likely extent and duration of any subsequent recycling and amplification.

For the purposes of undertaking a consequence assessment for the evaluation of BSE risk status, the period of interest is the preceding eight years.

Considering that, for all practical purposes, oral exposure to contaminated *feed* is the principal, if not the only, route of transmission of the BSE agents, to initiate a cycle of BSE infectivity within a cattle population the following series of events would need to unfold:

– *commodities* listed in point 1 of Article 11.4.14. from an infected animal are included in raw materials that are rendered into ruminant-derived ~~protein meal~~*protein meal*;

– the rendering process does not destroy infectivity of the BSE agent(s);

– the ruminant-derived ~~protein meal~~*protein meal* is incorporated as an ingredient in cattle *feed*, or cattle *feed* is cross-contaminated during *feed* production, distribution and storage, or cattle are incorrectly fed with *feed* intended for non-ruminant species that includes the ruminant-derived ~~protein meal~~*protein meal* as an ingredient;

– one or more animals that ingest contaminated *feed* become infected;

– the infected animal survives long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically;

– *commodities* listed in point 1 of Article 11.4.14. are then included in raw materials that are rendered into ruminant-derived ~~protein meal~~*protein meal*, completing one cycle.

Recycling arises when this cycle is repeated one or more times. Any level of recycling within a given period is sufficient to conclude that the consequences of exposure to contaminated *feed* for that period within the cattle population are non-negligible.

a) Factors to consider when evaluating the likely extent of recycling of the BSE agents within a cattle population:

i) Age at exposure~~.~~

Animals less than 12 months of age are considered to be much more susceptible to *infection* than older animals, which are likely to be increasingly refractory to *infection* as they mature.

ii) Production type~~.~~

– Calves reared as replacement animals for the breeding herd~~.~~

Cattle exposed to BSE agents at less than 12 months of age and destined to enter the breeding *herd* are much more likely to become infected and survive long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically. If these materials were rendered and subsequently contaminated cattle *feed*, it is highly likely that some level of recycling would occur.

– Feedlot cattle~~.~~

Even if cattle reared in a feedlot that were destined to be slaughtered within the next two to six months were to become infected after consuming contaminated *feed*, the likelihood that they would have reached the later stages of a protracted incubation period (when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically) would essentially be negligible.

Considering that mature cattle are likely to be much more refractory to *infection* than animals within their first year of life, even if they were to consume contaminated *feed*, it is highly unlikely that those *commodities* listed in point 1 of Article 11.4.14. would pose a threat if they were rendered and subsequently contaminated cattle *feed*.

iii) The impact of livestock industry practices or the implementation of measures under a *feed* ban.

When evaluating the potential for the recycling of the BSE agents ~~in~~ within the cattle population where an infraction (non-compliance) has occurred that may have led to *feed* being ~~cross-~~contaminated, it is important to consider the impact of both the livestock industry practices and the ongoing measures under a *feed* ban. Even if an infraction that arose several years ago led to susceptible young animals becoming infected, in evaluating the likelihood of recycling in future years, consideration would need to be given to the effectiveness of the *feed* ban in subsequent years or whether or not any changes to livestock industry practices may have influenced the exposure risk.

b) Conclusions for the consequence assessment.

Where the outcome of the evaluation of livestock industry practices or the evaluation of ~~BSE~~ BSE-specific mitigation measures, that include the nature and scope of the *feed* ban and its enforcement, has concluded that there was a non-negligible likelihood that the cattle population has been exposed to the BSE agents, what is the likelihood that they have been recycled within the cattle population during the preceding eight years?

Clearly describe the rationale leading to the conclusions reached.

4.) Risk estimation

As described in Article 11.4.2., risk estimation combines the results and the conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk ~~that~~ of BSE agents ~~have been~~ being recycled ~~in~~ within the cattle population ~~through the feeding of ruminant-derived protein meal~~.

a) Provide a summary of the entry and exposure assessments and the conclusions reached.

b) If applicable, provide a summary of the consequence assessment, and the conclusions reached.

c) ~~When the condition of point 1 of Article 11.4.3. has not been met, that is, it cannot be demonstrated that for at least eight years the risk that the BSE agents have been recycled in the cattle population has been negligible, provide an explanation for the period of time within the preceding eight years for which it can be considered that the risk has been negligible. Clearly~~ Indicate the ~~period of time for~~date from which it can be considered that the risk of BSE agents being recycled ~~in~~ within the cattle population has been negligible. Provide explanations and clearly describe the rationale leading to the conclusions reached.

Article 1.8.6.

~~BSE s~~Surveillance

Article 11.4.18. describes the criteria that underpin a credible *surveillance* programme, together with an overview of the range and progression of clinical signs that cattle affected by BSE are likely to exhibit.

Requirements under point 2 of Article 11.4.18. are focused on subsets of the cattle population where ~~disease~~ BSE is more likely to be detected~~, if it is actually present~~.

The Member applying for recognition of a negligible or a controlled BSE risk status should submit documentary evidence that the provisions of point 3 of Article 11.4.18. have been effectively implemented.

For the purposes of *surveillance*, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.).

Animals that ~~lie on the continuum~~ show ~~symptoms~~ signs of the clinical ~~disease~~ spectrum of BSE (i.e. from clinically ill to non-ambulatory to fallen stock) should be targeted for BSE *surveillance* and should include those animals described in points 2(a) to 2(d) of Article 11.4.18.

1.) Awareness and training programmes (point 3(a) of Article 11.4.18.)

Ongoing awareness and training programmes are essential to ensure that all stakeholders are familiar with clinical signs suggestive of BSE (those described in point 1 of Article 11.4.8.) as well as their statutory reporting requirements.

a) Describe the stakeholder groups targeted for BSE awareness and training programmes. Describe the methods used to identify stakeholder groups within the jurisdiction and methods used to identify how, for example, the size and characteristics of the stakeholder group changes over time.

b) Describe the type(s) of awareness and training programmes implemented for specific stakeholder groups. Describe how these programmes are adapted to meet the specific obligations and activities of each stakeholder group ~~by those~~ involved in caring for livestock, as well as the protocols for sample collection and submission by *veterinarians* and animal health technicians~~)~~.

c) Provide information on the number of awareness and training activities, the stakeholder groups targeted, the number of individuals reached per activity (if available), and the geographical coverage ~~for~~ of these activities.

d) Provide a description including examples of materials used in the awareness programme ~~including~~ such as training manuals, supporting documents such as publications in local newspapers and farming magazines, pamphlets and videos (weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist).

e) Provide details on how the effectiveness of the awareness and training programmes is evaluated.

f) Provide details of any contingency or preparedness plan for BSE.

2~~.~~) Compulsory notification (point 3(b) of Article 11.4.18.)

To ensure the reporting and further investigations of any animals that ~~lie on the continuum~~ show ~~symptoms~~ signs of the clinical ~~BSE~~ spectrum of BSE, appropriate legislation, policies and incentives to support compulsory notification, investigation and verification should be in place.

a) Indicate whether the date of implementation of any supporting legislation and associated policies making notification of BSE compulsory. Indicate if a definition for a "'BSE suspect"' exists. If appropriate, outline relevant legislation in the table under Article 1.8.3.

b) Describe the supportive measures in place for notification of animals that ~~lie on the continuum~~ show ~~symptoms~~ signs of the clinical ~~BSE~~ spectrum of BSE, such as incentives, compensations or penalties.

c) Describe the guidance given to all stakeholders involved in the rearing and production of livestock including ~~farmers, herdsmen,~~ cattle owners and keepers, *veterinarians*, transporters, and workers at livestock *markets*, auctions and *slaughterhouses/abattoirs* in terms of the criteria for reporting animals that ~~lie on the continuum~~ show ~~symptoms~~ signs of the clinical ~~BSE~~ spectrum of BSE. What mechanisms are in place to ensure that these guidelines reach those stakeholders?

d) Describe the reporting framework for animals that ~~lie on the continuum~~ show ~~symptoms~~ signs of the clinical ~~BSE~~ spectrum of BSE for evaluation. Has this framework evolved over time and, if so, how?

3~~.~~) Laboratory testing (point 3(c) of Article 11.4.18.)

Provide documentary evidence that the relevant provisions of Chapter 3.4.5. of the *Terrestrial Manual* are applied, including the following:

a) If BSE samples are submitted to ~~*a laboratory*~~ *laboratories* in the country or *zone* for testing, provide an overview of ~~how many are involved in testing BSE samples,~~ how they are approved or certified, their number, location and diagnostic procedures and the time frame for reporting results.

b) If the BSE samples are not submitted to a *laboratory* in the country or *zone* for testing, or if suspicious or positive samples are referred to ~~*a laboratory*~~ *laboratories* outside the country, provide the names of the *laboratories* in other countries providing the service, as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

c) Describe the diagnostic protocol and tests used for processing samples for classical and atypical BSE and how they may have evolved over time, indicating: ~~what is~~ the primary test used~~?~~; ~~what would be~~ the series of secondary tests performed, if any, depending on the results of the primary test (i.e. negative, positive and inconclusive)~~?~~; and what test would be undertaken if discordant results arise between primary and secondary tests ~~arise~~ (e.g. primary positive result followed by a secondary negative result)~~?~~.

4.) Evaluation procedures and protocols to identify and report ~~potential candidates~~animals targeted for BSE surveillance, to determine animals to be subjected to laboratory testing, to collect and submit samples for laboratory testing, and to follow up BSE positive findings with epidemiological investigation ~~BSE positive findings~~ (point 3(d) of Article 11.4.18.)

~~Because~~ Given that the incidence of BSE is likely to be very low in Member Countries it is important that *surveillance* efforts focus on subsets of the cattle population where disease is more likely to be detected~~, if it is actually present~~. Hence, those animals described in points 2(a) to 2(d) of Article 11.4.18. must be targeted for BSE *surveillance*.

Considering that BSE is a progressive disease and that animals to be included in the *surveillance* programme may arise at the farm, the *slaughterhouse/abattoir*, or during transportation, procedures and protocols should be in place covering all points in the livestock production chain for: (1) the identification and reporting of animals potentially ~~lying on the continuum~~ showing ~~symptoms~~ signs of the clinical ~~BSE~~ spectrum of BSE (e.g. by the farmer, *animal handler*, *veterinarian*, etc.)~~,~~; (2) the criteria to determine which of these reported animals need to be tested for BSE (e.g. the criteria used by the *veterinarian* that allows the discrimination of reported animals subject to laboratory testing)~~,~~; (3) the collection and submission of samples for testing in a laboratory~~,~~; and (4) a follow-up epidemiological investigation for BSE positive findings.

It is important that appropriate procedures and protocols are in place to ensure that BSE can be definitively ruled out on the list of differential diagnoses.

a) List the common cattle disorders with clinical signs compatible with BSE in the country or *zone*. If available, provide the incidence/prevalence of these disorders, ideally by production system (e.g. dairy, beef) and by age group.

b) Describe the procedures and protocols in place for reporting animals potentially ~~lying on the continuum~~ showing ~~symptoms~~ signs of the clinical ~~BSE~~ spectrum of BSE (those described in points 2(a) to 2(d) of Article 11.4.18.) to the *Competent Authority*. For example, these procedures and protocols may include the steps that a farmer may follow once an animal with clinical signs suggestive of BSE is identified. These procedures and protocols should cover the clinical continuum of the disease spectrum ranging from clinical suspects to non-ambulatory to fallen stock.

c) Describe the procedures and protocols in place for the investigation of reported animals potentially ~~lying on the continuum~~ showing ~~symptoms~~ signs of the clinical ~~BSE~~ spectrum of BSE (those described in points 2(a) to 2(d) of Article 11.4.18.) that allow the discrimination of reported animals to be subjected to laboratory testing. For example, these procedures and protocols may include the range of clinical signs to be considered, and how the age, the clinical history of the animal and epidemiological data of the *herd* are taken into account. An evaluation procedure may, for example, be in the form of a protocol, a checklist or a decision tree, and should cover the clinical continuum of the disease spectrum ranging from clinical suspects to non-ambulatory to fallen stock.

d) Describe the methods applied to assess the age of animals investigated, such as individual identification or dentition.

e) Describe the procedures and protocols for the transport of live or dead animals for sampling, and transfer of samples to laboratories for testing, including details of the cattle identification system, the maintenance of the chain of custody of the carcass and the samples, and the reconciliation of samples with the animals they were collected from.

f) Provide the procedures and protocols for a follow-up epidemiological investigation of BSE positive results.

g) Provide a summary table for each of the preceding eight years (Table 1) of the number of animals reported and the number of animals subjected to BSE testing for each clinical presentation (those in points 2(a) to 2(d) of Article 11.4.18.).

Table 1.		
Year: _____		
Table 1 - Summary of all animals that were reported and evaluated for testing by the Veterinary Authority		
Clinical presentation (see point 2 of Article 11.4.18.)	Number of reported animals	Number of animals subjected to BSE testing

(A) Cattle displaying progressive behavioural or neurological signs suggestive of BSE that are refractory to treatment		
(B) Cattle showing behavioural or neurological signs that did not pass the ante-mortem inspection at slaughterhouses/abattoirs		
(C) Cattle presented as downers (non-ambulatory) with an appropriate supporting clinical history		
(D) Cattle found dead (fallen stock) with an appropriate supporting clinical history		

5~~.~~) Animals subjected to laboratory testing

~~a)~~ Provide in Table 2~~, for each of the preceding eight years,~~ details of all animals counted in Table 1 that were subjected to laboratory testing (see point 2 of Article 11.4.18.).

Table 2. Details of the animals that were subjected to laboratory testing~~.~~

Year notified	Laboratory identification number or individual identification number	Age (in months) at the time of reporting ~~first detection~~	Type of production system (dairy, beef, mixed, etc.)	Description of observed clinical signs	Clinical presentation (A, B, C or D)	Final diagnosis (if BSE, specify the strain)	For a BSE case, indicate the origin (indigenous or imported; if imported, indicate the country of birth)

Article 1.8.7.

~~Recovery~~ Maintenance of BSE risk status

Following the occurrence of an indigenous *case* of classical BSE in an animal born ~~within the preceding eight years~~ after the date from which the risk of BSE agents being recycled within the cattle population has been negligible occur in a country or *zone* with a negligible or controlled BSE risk status ~~of a country or *zone*~~, the outcome of the investigation together with any additional measures implemented that confirm or ensure that the risk of BSE agents being recycled within the cattle population continues to be negligible should be provided with reference to the provisions in Article 1.8.5. as appropriate. Information in relation to other sections need to only be supplied if relevant.

CHAPTER 11.10.

INFECTION WITH *THEILERIA ANNULATA*, *T. ORIENTALIS* AND *T. PARVA*

EU position

The EU thanks the OIE and supports the adoption of this revised chapter.

Article 11.10.1.

General provisions

~~*Animals* susceptible to *infection* with *Theileria* are~~ Theileriosis is a disease of bovines (*Bos indicus*, *B. taurus* and *B. grunniens*), water buffaloes *(Bubalus bubalis)*, African buffaloes *(Syncerus caffer)*, sheep *(Ovis aries)*, goats *(Capra hircus),* camels (*Camellus dromedarius* and *C. bactrianus)* and some *wild* ruminants.

~~*Infection with Theileria*~~Theileriosis can give rise to disease of variable severity and ~~to *Theileria* transmission. *Theileria*~~ the pathogenic agent may persist in ruminants for their lifetime. Such *animals* are considered carriers.

Only bovines and water buffaloes play a significant epidemiological role in the *infection* with *Theileria annulata*, *T. orientalis* and *T. parva.*

For the purposes of the *Terrestrial Code*, *infection* with *Theileria annulata*, *T. orientalis* and *T. parva* ~~are~~ is defined as a tickborne *infection* of bovines and water buffaloes with *T. annulata, T. orientalis* Ikeda, *T. orientalis* Chitose ~~and~~or *T. parva*.

For the purposes of this chapter, *Theileria* means *T. annulata, T. orientalis* Ikeda, *T. orientalis* Chitose and *T. parva.*

The following defines the occurrence of *infection* with *Theileria*:

1) *Theileria* has been identified in a sample from a bovine or water buffalo; or

2) antigen or nucleic acid specific to *Theileria* has been identified in a sample from a bovine or water buffalo showing clinical signs consistent with *infection* with *Theileria*, or epidemiologically linked to a suspected or confirmed *case*, or giving cause for suspicion of previous association with *Theileria*; or

3) antibodies specific to *Theileria*, that are not the consequence of *vaccination*, have been detected in a sample from a bovine or water buffalo ~~that either shows~~showing clinical signs consistent with *infection* with *Theileria*, or ~~is~~ epidemiologically linked to a suspected or confirmed *case* or giving cause for suspicion of previous association with *Theileria*.

For the purposes of the *Terrestrial Code*, the *incubation period* for *infection* with *Theileria* shall be 35 days.

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

Article 11.10.2.

Safe commodities

When authorising the importation or transit of the following *commodities*, *Veterinary Authorities* should not require any *Theileria*-related conditions regardless of the ~~*infection* with *Theileria*~~ health status of the *animal population* of the *exporting country* or *zone*:

1) *meat* and *meat products*;

2) *casings*;

3) *milk* and *milk products*;

4) gelatine and collagen;

5) tallow;

6) semen and embryos;

7) hooves and horns;

8) bones.

Article 11.10.3.

Country or zone free from infection with *Theileria*

1) A country or a *zone* may be considered free from *infection* with *Theileria* when the disease is notifiable in the entire country, importation of bovines and water buffaloes and their *commodities* is carried out in accordance with this chapter, and:

   a) the country or *zone* is historically free as described in Article 1.4.6.; or

   b) a *surveillance* programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with *Theileria* in the country or *zone* for at least two years; or

   c) an ongoing *surveillance* programme in accordance with Chapter 1.5. has found no competent tick *vectors* for at least two years in the country or *zone*.

2) A country or *zone* free from *infection* with *Theileria* in which ongoing *vector surveillance*, performed in accordance with Chapter 1.5., has found no competent tick *vectors* will not lose its free status through the introduction of vaccinated, test-positive or infected bovines or water buffaloes from infected countries or *zones*.

3) A country or *zone* free from *infection* with *Theileria* will not lose its status as a result of introduction of seropositive or vaccinated bovines, water buffaloes or their *commodities*, provided they were introduced in accordance with this chapter.

Article 11.10.4.

Recommendations for importation of bovines and water buffaloes from countries or zones free from infection with *Theileria*

~~For bovines and water buffaloes~~

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

1) showed no clinical sign of *infection* with *Theileria* on the day of shipment;

2) come from a country or *zone* free from *infection* with *Theileria*.

Article 11.10.5.

Recommendations for importation of bovines and water buffaloes from countries or zones not free from infection with *Theileria*

~~For bovines and water buffaloes~~

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

1) showed no clinical sign of *infection* with *Theileria* and no *infestation* with tick *vectors* on the day of shipment;

2) were kept isolated for at least 35 days prior to shipment, in an e*stablishment* where no *case* of *infection* with *Theileria* has occurred during the preceding two years;

3) were treated with a registered acaricide, the efficacy of which has been confirmed in relation to the area of origin of the *animals*, at the ~~entrance~~ time of entry ~~in~~to ~~of~~ the isolation *establishment* and then at regular intervals, according to the manufacturer's instructions, allowing continuous protection against ticks until their shipment ~~48 hours prior to entry to the *establishment*, no more than two days after entering the *establishment* and three days prior to shipment~~;

4) were subjected to serological and agent detection tests with negative results on samples taken immediately prior to ~~on~~ entry and at least 25 days after entry ~~in~~to~~to~~ the isolation *establishment*~~and five days before shipment~~.

Article 11.10.6.

Recommendations for importation of hides and skins from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products have been:

1) dry-salted or wet-salted for a period of at least 14 days prior to dispatch; or

2) treated for a period of at least seven days in salt (NaCl) with the addition of 2% sodium carbonate (Na_2CO_3); or

3) dried for a period of at least 42 days at a temperature of at least 20°C; or

4) frozen to at least -20°C for at least 48 hours.

Article 11.10.7.

Recommendations for importation of trophies derived from susceptible ~~wild~~ ruminants from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products have been processed to ensure the destruction of tick *vectors*.

TERMINOLOGY: USE OF THE TERM 'SANITARY MEASURE'

EU position

The EU supports the adoption of these revised articles.

Article 4.15.6.

Conditions for sanitation and disinfection or disinfestation of apicultural equipment

Veterinary Authorities or other *Competent Authorities* of countries are requested to regulate the use of products and means for sanitation and *disinfection* or *disinfestation* of apicultural equipment in their own country, taking into account the following recommendations.

1) Any apicultural equipment kept in an *establishment* which has been recognised as being affected with a contagious disease of bees should be subjected to ~~*sanitary measures*~~ procedures ensuring the elimination of pathogens.

2) In all cases, these ~~measures~~ procedures comprise the initial cleaning of the equipment, followed by sanitation or *disinfection* or *disinfestation* depending on the disease concerned.

3) Any infested or contaminated equipment which cannot be subjected to the above-mentioned ~~measures~~ procedures should be destroyed, preferably by burning.

4) The products and means used for sanitation and *disinfection* or *disinfestation* should be accepted as being effective by the *Veterinary Authority* or other *Competent Authority*. They should be used in such a manner as to exclude any risk of contaminating the equipment which could eventually affect the health of bees or adulterate the products of the hive.

Article 6.3.3.

Hygienic practice throughout the meat production chain

The Codex Alimentarius Code of Hygienic Practice for Meat (CHPM) constitutes the primary international standard for *meat* hygiene and incorporates a *risk*-based approach to application of ~~*sanitary measures*~~ hygiene practices and sanitation throughout the *meat* production chain. Ante-mortem inspection is described as a primary component of *meat* hygiene before *slaughter*, and post-mortem inspection is described as a primary component of process control in post-slaughter *meat* hygiene. The CHPM specifically recognises the dual objectives that *slaughterhouse/abattoir* inspection activities deliver in terms of animal and public health.

The CHPM does not provide inspection measures for specific *hazards*, which remain the responsibility of national competent authorities. The animal and public health *risks* associated with livestock populations vary across regions and animal husbandry systems, and ante- and post-mortem inspection needs to be tailored to the individual country situation and its animal and public health objectives.

The CHPM provides a platform for development of *meat* hygiene systems that are based on *risk assessment*. There are few *risk assessment* models and little relevant scientific information available on public health *hazards* derived specifically from *animals* and their products, making difficult the development of *risk*-based standards for foodborne diseases and zoonoses. While this scientific information is being accumulated, ante- and post-mortem inspection systems will remain dependent on traditional approaches.
