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 ‘double underline’ 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


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.

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.

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 (OIHLEP) 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.

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.

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.

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 comments

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.

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.

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.

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 ‘PrPBSE’ or to change to ‘PrPTSE’ 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) **The use of terms' meat-and-bone meal' and 'greaves' throughout the Terrestrial Code**

**Background**

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.

**Discussion**

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 Appendix 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.
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 Code Commission wished to note that due to the extensive number of amendments being proposed, the French and Spanish versions of Chapter 11.4. to be proposed for adoption in the French and Spanish versions of the February 2022 Code Commission report are presented as clean text only.

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.

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.

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.
# List of participants

## Members of the Code Commission

<table>
<thead>
<tr>
<th>Name</th>
<th>Title/Position</th>
<th>Organization/Address</th>
<th>Email Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Etienne Bonbon</td>
<td>President/ Senior Veterinary Advisor/ EMCAH / Animal Health Service/ Food and Agriculture Organization of the United Nations</td>
<td>Viale delle Terme di Caracalla 00153 Rome ITALY</td>
<td><a href="mailto:etienne.bonbon@fao.org">etienne.bonbon@fao.org</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><a href="mailto:e.bonbon@oie.int">e.bonbon@oie.int</a></td>
</tr>
<tr>
<td>Prof. Salah Hammami</td>
<td>Epidemiologist &amp; Virologist/ Services of Microbiology-Immunology &amp; General Pathology/ National School of Veterinary Medicine</td>
<td>Sidi Thabet -2020 TUNISIA</td>
<td><a href="mailto:hammami.salah@iresa.agrinet.tn">hammami.salah@iresa.agrinet.tn</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><a href="mailto:saleehammami@yahoo.fr">saleehammami@yahoo.fr</a></td>
</tr>
<tr>
<td>Dr Lucia Ignacio Carbajo</td>
<td>Agricultural Attaché</td>
<td>Ministry of Agriculture, Food and Environment/ Spanish Embassy in Peru</td>
<td><a href="mailto:lcarbajo@mapama.es">lcarbajo@mapama.es</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><a href="mailto:lcg968@gmail.com">lcg968@gmail.com</a></td>
</tr>
<tr>
<td>Dr Kiyokazu Murai</td>
<td>Animal Health Division</td>
<td>Ministry of Agriculture, Forestry and Fisheries/ 1-2-1 Kasumigaseki Chiyoda-ku</td>
<td><a href="mailto:kiyokazu_murai580@maff.go.jp">kiyokazu_murai580@maff.go.jp</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr Gaston Maria Funes</td>
<td>Counsellor for Agricultural Affairs/ Embassy of Argentina to the EU</td>
<td>Avenue Louise 225, (4th floor) 1050 Brussels BELGIUM</td>
<td><a href="mailto:gmfunes@magyp.gob.ar">gmfunes@magyp.gob.ar</a></td>
</tr>
<tr>
<td>Dr Bernardo Todeschini</td>
<td>Agricultural Attaché</td>
<td>Mission of Brazil to the European Union - Belgium Ministry of Agriculture, Livestock and Food Supply BRAZIL</td>
<td><a href="mailto:bernardo.todeschini@agricultura.gov.br">bernardo.todeschini@agricultura.gov.br</a></td>
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</table>

## OIE Headquarters

<table>
<thead>
<tr>
<th>Name</th>
<th>Title/Position</th>
<th>Organization/Address</th>
<th>Email Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Gillian Mylrea</td>
<td>Head/ Standards Department</td>
<td></td>
<td><a href="mailto:g.mylrea@oie.int">g.mylrea@oie.int</a></td>
</tr>
<tr>
<td>Dr Charmaine Chng</td>
<td>Chargée de mission/ Standards Department</td>
<td></td>
<td><a href="mailto:c.chng@oie.int">c.chng@oie.int</a></td>
</tr>
<tr>
<td>Dr Francisco D'Alessio</td>
<td>Deputy head/ Standards Department</td>
<td></td>
<td><a href="mailto:f.dalessio@oie.int">f.dalessio@oie.int</a></td>
</tr>
<tr>
<td>Dr Elizabth Marier</td>
<td>Chargée de mission/ Standards Department</td>
<td></td>
<td><a href="mailto:e.marier@oie.int">e.marier@oie.int</a></td>
</tr>
<tr>
<td>Dr Yukitake Okamura</td>
<td>Chargé de mission/ Standards Department</td>
<td></td>
<td><a href="mailto:y.okamura@oie.int">y.okamura@oie.int</a></td>
</tr>
<tr>
<td>Dr Leopoldo Stuardo</td>
<td>Chargé de mission/ Standards Department</td>
<td></td>
<td><a href="mailto:l.stuardo@oie.int">l.stuardo@oie.int</a></td>
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Annex 2

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

Adopted agenda

1. Welcome from the Deputy Director General
2. Meeting with the Director General
3. Adoption of agenda
4. Cooperation with other Specialist Commissions
   4.1. Scientific Commission for Animal Diseases
   4.2. Biological Standards Commission
   4.3. Aquatic Animal Health Standards Commission
5. Code Commission’s work programme except texts proposed for comments or adoption
   5.1. Ongoing priority topics (not in order of priority)
      5.1.1. Collection and processing of semen of animals (Chapter 4.6.)
      5.1.2. Revision of Section 4 Disease prevention and control (New chapter on biosecurity, revision of Chapter 4.13. on disposal of dead animals and Chapter 4.14. on disinfection)
      5.1.3. Revision of Section 5 Trade measures, import/export procedures and veterinary certification (especially Chapters 5.4. to 5.7.)
      5.1.4. Responsible and prudent use of antimicrobial agents in veterinary medicine (Chapter 6.10.)
      5.1.5. Transport of animals by sea, land and air (Chapters 7.2., 7.3. and 7.4.)
      5.1.6. Infection with Mycobacterium tuberculosis complex (Chapter 8.11.)
      5.1.7. Scrapie (Chapter 14.8.)
      5.1.8. Harmonisation of official recognition of status by the OIE: contagious bovine pleuropneumonia (Chapter 11.5.), African horse sickness (Chapter 12.1.)
      5.1.9. Mers Cov
      5.1.10. Leishmaniosis
      5.1.11. Pet food as safe commodities
      5.1.12. Honey – definitions and provisions on importation
      5.1.13. Framework for Terrestrial Code standards
      5.1.14. Safe commodities SOP
5.2. New proposals and requests

5.2.1. Request from Wildlife Working Group

5.2.2. Chapter 7.Z. Animal welfare and laying hen production systems

5.2.3. Rabbit haemorrhagic disease (Chapter 13.2.)

5.2.4. Nipah virus encephalitis and Bovine viral diarrhoea

5.2.5. Request to clarify Glossary definition for Poultry

5.2.6. Listed diseases names: Discrepancies between Chapter 1.3. and disease-specific chapters

5.2.7. OIE Standard Operating Procedure for determining if a disease should be considered as an emerging disease – Comment received

5.3. Prioritisation of items in work programme

6. Texts proposed for adoption in May 2022

6.1. Glossary A (‘Competent Authority’, ‘Veterinary Authority’, ‘Veterinary Services’, ‘Protein meal’ and ‘Stray dog’)

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

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

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

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

6.6. Infection with rinderpest virus (Chapter 8.16.)

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

6.8. Bovine spongiform encephalopathy (Chapter 11.4.) and Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy (Chapter 1.8.). Revision of the use of terms ‘meat-and-bone meal’ and ‘greaves’ throughout the Terrestrial Code

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

6.10. Trichomonosis (Chapter 11.11.)

6.11. Terminology: Use of the term ‘sanitary measure’

7. Texts circulated for comments

7.1. In September 2021 meeting report

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

7.2. Previously circulated (this is the order of priority)

7.2.1. Slaughter of animals (Chapter 7.5.)

7.2.2. Infection with rabies virus (Chapter 8.14.)
7.2.3. Infection with Rift Valley fever virus (Chapter 8.15.)
7.2.4. New chapter on infection with *Trypanosoma Evansi* (Non equine surra) (Chapter 8.X.)
7.2.5. Contagious equine metritis (Chapter 12.2.)
7.2.6. Infection with equine influenza virus (Chapter 12.6.)
7.2.7. Equine piroplasmosis (Chapter 12.7.)
7.2.8. New chapter on infection with Theileria in small ruminants and Article 1.3.3.

8. Other updates

8.1. OIE Observatory
8.2. OIE Digitalisation strategy
8.3. GBADs

9. For information / reference documents

9.1. Antimicrobial Resistance Working Group report (October 2021)
9.2. Wildlife Working Group report (December 2021)
9.3. New publication: Responsible and prudent use of anthelmintic chemicals to help control anthelmintic resistance in grazing livestock species
9.4. New publication: A key role for veterinary authorities and animal health practitioners in preventing and controlling neglected parasitic zoonoses – A handbook with focus on *Taenia solium*, *Trichinella*, *Echinococcus* and *Fasciola*

10. Meeting review

11. Date of next meeting

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GLOSSARY

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

[...]

Article 1.3.2.

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

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

[...]

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

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

[...]

Article 3.2.3.

Policy and management

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

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

This component should comprise the following specific elements:

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

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

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

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

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

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

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

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

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

[...]

Article 3.2.9.

Veterinary medicinal products

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

This article should be read in conjunction with the Terrestrial Manual, which sets standards for the production and control of vaccines and other biological products.
This component should comprise the following specific elements:

1) effective regulatory and administrative control, in accordance with Article 3.4.11., including communications and compliance programmes for:
   a) the market authorisation of veterinary medicinal products, including registration, import, manufacture, quality control and reducing the risk from illegal imports;
   b) responsible and prudent use of veterinary medicinal products, including the labelling, distribution, sale, dispensing, prescription, administration and appropriate safe storage and disposal of these products;

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

[...]
CHAPTER 3.4.

VETERINARY LEGISLATION

[...]

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 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.

ZOOONOSES TRANSMISSIBLE
FROM NON-HUMAN PRIMATES

[...]

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.:

<table>
<thead>
<tr>
<th>Disease/agent</th>
<th>Animal groups</th>
<th>Schedule</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endo- and ectoparasites</td>
<td>All species</td>
<td>At least two tests, one of which should be at the start, the other towards the end of the quarantine.</td>
<td>Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>Marmosets and tamarins</td>
<td>Two tests at an interval of 2 to 4 weeks.</td>
<td>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.</td>
</tr>
<tr>
<td>Prosimians, New World monkeys, Old World monkeys, gibbons and great apes</td>
<td>At least three tests at intervals of 2 to 4 weeks.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Disease/agent

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

Veterinary Authorities of importing countries should recognise the public health importance of zoonoses listed in the table 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.:  

<table>
<thead>
<tr>
<th>Disease/agent</th>
<th>Animal groups</th>
<th>Schedule</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuberculosis (Mycobacterium tuberculosis complex)</td>
<td>All species</td>
<td>One test.</td>
<td>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.)</td>
</tr>
<tr>
<td>Other bacterial pathogenic agents (Salmonella, Shigella and Yersinia and others as appropriate)</td>
<td>All species</td>
<td>Daily test for 3 days after arrival, and another test at least one week later.</td>
<td>Faecal culture. (See further comments in the Table of Article 6.12.4.)</td>
</tr>
<tr>
<td>Endo- and ectoparasites</td>
<td>All species</td>
<td>At least two tests, one of which should be at the start, the other towards the end of the quarantine.</td>
<td>Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.</td>
</tr>
</tbody>
</table>

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

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 fulfill. 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 improvement 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 strengthen 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 managing dog populations without causing unnecessary animal suffering 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 7.7.23

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 7.7.34

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.
Annex 9 (contd)

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 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 to local and national 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 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 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 different organisations may play in the planning and implementation of DPM programmes, at the local and national levels.

Article 7.7.7.

Competent Authority for Dog Population Management

The development and implementation of DPM programmes 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 the responsibility of a Competent Authority, which may be the Veterinary Authority. A 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 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 Dog Population 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 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 education can may play a key role in promoting responsible dog ownership and dog bite prevention programmes at school 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 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 health services or authorities, environmental control services or authorities, non-governmental organisations and the public).
Regulatory framework

DPM Legislation that addresses DPM is a key element for the sustainability and efficiency of DPM programmes. It ensures that DPM programmes are 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:

- 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;
- Authorisation and licensing of dog breeders and sellers;
- Authorisation and licensing of dog shelters, rehoming centres and holding facilities;
- Licensing practice of veterinarians, veterinary medicine, including surgery;
- Licensing preparation, use and sales 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.

Assessment, monitoring and evaluation

DPM programmes should be regularly evaluated and adapted to improve effectiveness and to respond to changes in the 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, 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 programme development by:

- Identifying qualified personnel and developing training and tools to help with implementing data collection (assessment, monitoring) and use (planning and evaluation);
- Ensuring providing the budget of DPM programmes including not only the costs for the initial assessment but also for monitoring and evaluation activities;
- 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 programmes; it should be expected that DPM programmes will also use and benefit from their own context-specific indicators and methods of measurement;
Encouraging the use of monitoring data for evaluation, learning and subsequent adaptation of DPM programmes.

Article 7.7.11.

DPM programme development and planning

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

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

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

3) Exploration of dog population dynamics in the whole dog population (not limited to the current free-roaming dog population) to identify the sources of free-roaming dogs:
   - owned dogs that roam freely;
   - dogs that have been lost or abandoned, including puppies resulting from uncontrolled breeding of owned dogs;
   - unowned dogs that roam freely and reproduce.

4) Identification of people's knowledge, attitudes and practices of regarding dog care and responsibility over owned dogs and unowned dogs. Further, 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, Vaccinate, 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 in 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: Dog 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: Household questionnaires including questions or visible inspection of whether owned dogs are confined or allowed to roam unsupervised.

- All free-roaming dogs, including both owned roaming and unowned:
  a) Direct observation of free-roaming dogs during surveys along routes designed to be representative of the area of interest and unbiased with regard to free-roaming dog density through public streets at peak roaming time; capturing these data can provide the mean number of free-roaming dogs per km of street surveyed. This can be extrapolated by the estimated total street length within the area of interest.
Annex 9 (contd)

the defined area of interest to estimate the total number of free-roaming dogs on the street at the
time of survey; some free-roaming dogs will not have been visible during the survey and so this is
an underestimate of the total free roo ming dog population [(Meunier et al., 2019)]:

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

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

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

Article 7.7.12.

DPM programme monitoring and evaluation

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

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

Indicators are the measurable sign results 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 damages to people, livestock, or property.
Article 7.7.13.

Recommendations for DPM measures

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

- Registration and identification of dogs;
- Regulation of commercial dog breeding and sale;
- Control of national and international (export and import) dog movements;
- Promoting responsible dog ownership;
- Reproductive control;
- ‘Catch, Neuter, Vaccinate and Return’;
- Reuniting and adoption;
- Access to veterinary care;
- Environmental controls;
- 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:

- supports for the enforcement of legislation through proof of ownership;
- improvement of the success rate in reuniting lost dogs with their owners;
- enabling traceability in commercial breeding and sale;
- encouragement 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 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 Commercial 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 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 dogs' 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 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 adults, and unregulated sales 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 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:

- improving the health and welfare of dogs;
- supporting the human–animal bond;
- minimising the risk that dogs pose to household members and the community;
- reducing 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:

- providing 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 protection from pain, suffering, injury, and disease) in order to meet the internationally recognised ‘five freedoms’ (see point 2 of Article 7.1.2.);

- encouraging 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.);

- preventing 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.);

- arranging 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 likely 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:

- preventing the birth of unwanted puppies;

- helping address the imbalance between reproduction and demand for dogs;

- reducing the size of the free-roaming dog population.

2) Efficient use of reproduction control does not require a limiting 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, i.e., the prevention of reproduction without the use of surgery—sterilisation or contraception, including chemical and immunological approaches;

- confinement or separation/confinedem 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** to ensure surgical sterilisation can be performed safely.

6) Castration of male dogs is generally preferred over vasectomies 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 may will need to be completed before use.

**Article 7.7.19.**

‘Catch, Neuter, Vaccination and Return’

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

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

This method is not applicable in all situations and may be illegal in countries or regions where legislation prohibits the abandonment of dogs and authorities perceive the release of sterilised dogs as a form of abandonment. Problems caused by dogs, such as noise, faecal pollution, bite injuries and traffic accidents, would not be alleviated as dogs are returned to the local community and their movements are not restricted. Where owners have limited access to affordable reproduction control for their dogs, consideration 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. 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 neutering, sterilisation and responsible ownership may be more appropriate.

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

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

- engaging local communities to understand, support, design and be an active part of ‘Catch, Neuter, Vaccination and Return’ activities and **monitoring of released dogs**, in particular in the case of dogs cared for by the community;
- use of humane methods for catching, transporting and holding dogs;
- correct surgical technique with a good standard of asepsis, anaesthesia and analgesia, followed by post-operative care (see Article 7.7.18.).
‐ disease control may include vaccination (e.g., rabies) and treatments and testing for diseases (e.g., leishmaniosis) followed, as appropriate, by treatment or euthanasia of the dog;

‐ ‘Catch, Neuter, Vaccination and Return’ 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. 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 Veterinary 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 Veterinary 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 Services 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 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 focussed 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 on appropriate bite treatment, and when necessary, including post-exposure prophylaxis where rabies is a risk, are encouraged for all age groups.

**Article 7.7.24.**

**Specific considerations for Dog Population Management 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. 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 Veterinary Services should ensure their staff and volunteers expected to handle dogs have received rabies pre-exposure vaccination where appropriate and are provided with clear protocols for treating injuries, including dog bites.
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 is supported by licensing and inspection of facilities (Barnard et al., 2014). The following minimum standards should be considered:

a1. Facilities
- sustainable finances to cover ongoing running costs;
- site selection: access to drainage, waste disposal, water and electricity are 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.

b2. Management
- provision of adequate fresh water and nutritious food;
- regular hygiene and cleaning;
- routine inspection, handling and exercise of the dogs;
- monitoring of physical and behavioural health and provision of required veterinary treatments under veterinary supervision, including routine and preventive veterinary care and euthanasia;
- policies and procedures to respect the maximum capacity for the facility and action when this is reached, assessment of dog health and behaviour, animal care, intake, treatment, adoption, sterilisation and euthanasia;
- provision of sufficient numbers of appropriately skilled staff and training of staff in safe, appropriate and positive handling of dogs;
- record keeping, animal identification and reporting to the Competent Authority;
- provision of opportunities for conspecific socialisation, human socialisation, enrichment and locomotor 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 security and animal welfare. Animal handling should also minimise distress experienced by the dog prior to loss of consciousness. Some euthanasia methods should be used with prior sedation or anaesthesia to be considered humane. Regardless of the euthanasia method used, it is advisable to perform pre-euthanasia sedation or anaesthesia to 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, CO₂ 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 following 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.
c3. Confirmation of death
For all methods of euthanasia used, death should be confirmed before animals are disposed of or left unattended.

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

d4. 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.]


Hiby E and Hiby L (2017) Direct observation of dog density and composition during street counts as a resource efficient method of measuring variation in roaming dog populations over time and between locations. Animals, 7, 57. https://doi.org/10.3390/ani7080057


CHAPTER 8.16.

INFECTION WITH RINDERPEST VIRUS

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 by 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 existing RPV-containing material, and synthesis or synthesis of RPV-containing material, is forbidden unless authorised by the FAO and OIE.

However, 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.
   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 and laboratory investigation; or
      ii) a potential case which has given a positive reaction in a diagnostic test for RPV conducted outside of an OIE Reference Laboratory for rinderpest; or
      iii) the detection of RPV-specific antibodies that are not a consequence of vaccination in a susceptible animal without clinical signs.
Annex 10 (contd)

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

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 plasmid 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.

For the purposes of this chapter:

- ‘Susceptible animals’ means domestic, feral, captive wild and wild artiodactyls.
- 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.

‘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.

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:

- 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;
- meat products in hermetically sealed containers with a F₀ value of 3 or above;
- 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 Articles 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

Ongoing surveillance post during global freedom

Article 8.16.3.

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 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 cases and the prompt identification of suspected cases.

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 whether the potential case meets the definition for a suspected case or a case of rinderpest.

Annual update on RPV-containing material

Article 8.16.4.

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

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 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.

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

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

Article 8.16.6.

Country free from rinderpest

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

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

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

Article 8.16.7.

Country infected with RPV

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

Article 8.16.8.

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

In the event of a limited outbreak within a country previously free of rinderpest, a containment zone for the purposes of disease control and eradication can should be established in accordance with Article 4.4.7. Notwithstanding the establishment of a containment zone for disease control and eradication, international trade in commodities of susceptible species from the entire country will be limited to the safe commodities listed in point 2 of Article 8.16.2. until free status is recovered 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.
Annex 10 (contd)

One of the following waiting periods is applicable:

1) when a stamping-out policy has been applied:
   a) three months after the disinfection of the last affected establishment where a stamping-out policy without vaccination and targeted surveillance in accordance with Article 8.16.11. have been applied; or
   b) three months after the disinfection of the last affected establishment and the slaughter of all vaccinated animals, where a stamping-out policy, emergency vaccination and targeted surveillance in accordance with Article 8.16.11. have been applied; or
   c) 18 months after the disinfection of the last affected establishment and the last vaccination, where a stamping-out policy, emergency vaccination not followed by the slaughter of all vaccinated animals, and targeted surveillance in accordance with Article 8.16.11. have been applied;

2) when a stamping-out policy is not practised, the above waiting periods do not apply. Instead, the country must be in compliance with the requirements below:
   a) have a record of regular and prompt animal disease reporting in accordance with Chapter 1.1.;
   b) send a declaration to the OIE stating that:
      i) there has been no case of rinderpest infection with RPV during the past 24 months;
      ii) no suspected case of infection with RPV has been found during the past 24 months;
      iii) no vaccination against rinderpest has been carried out during the past 24 months;
   c) supply documented evidence that targeted surveillance for infection with RPV in accordance with Chapter 1.4. and Article 8.16.11. is in operation and that regulatory measures for the prevention and control of rinderpest have been implemented;
   d) not have imported, since the cessation of vaccination, any animals vaccinated against rinderpest.

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

Article 8.16.10.

Recovery of global freedom

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

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

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

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

Article 8.16.11.

Surveillance for recovery of rinderpest free status

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

1) The target for surveillance should be all populations of rinderpest susceptible species animals within the country. In certain areas some wildlife populations, such as African buffaloes, act as sentinels for rinderpest infection with RPV.
2) An awareness programme should be established for all animal health professionals including veterinarians, both official and private, and livestock owners to ensure that rinderpest's clinical and epidemiological characteristics of rinderpest and risks of its recurrence are understood. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any potential case.

3) Differing clinical presentations can result from variations in levels of innate host resistance (Bos indicus breeds being more resistant than B. taurus), and variations in the virulence of the attacking strain. In the case of subacute (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.

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.

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

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, cameldid 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, 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)

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 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:

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

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

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

- 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;

- 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;

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

2. Control of infection in pigs

- 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.

- When cysticerci are detected during post-mortem *meat* inspection:
  
  - 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.;
  
  - 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.;
  
  - 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;
  
  - 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

Article 11.4.1.

General provisions

1) The recommendations in this chapter are intended to mitigate the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agents in cattle only. BSE manifests in two main forms: classical BSE and atypical BSE. Oral exposure to contaminated feed is the main route of transmission of classical BSE. Atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population. Oral exposure to contaminated feed is the main route of transmission of classical BSE. Given that cattle have been experimentally infected by the oral route with a low molecular weight type of atypical BSE (L-type BSE). 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 is not practiced.

3) For the purposes of the Terrestrial Code:

   1a) BSE is an invariably fatal neurological prion disease of cattle caused by a misfolded form of the prion protein (PrP\textsuperscript{BSE}PrP\textsubscript{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\textsuperscript{BSE}PrP\textsubscript{Sc} fragment of higher and lower molecular mass than classical BSE. The term 'BSE' includes both classical and atypical forms, unless otherwise specified.

   2b) The occurrence of a BSE case is defined by the immunohistochemical (IHC) or immunochemical detection of PrP\textsuperscript{BSE}PrP\textsubscript{Sc} in brain tissue of a bovid of the species \textit{Bos taurus} or \textit{Bos indicus}. 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) ‘Cattle’ means bovids of the species \textit{Bos taurus} or \textit{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) dicalcium phosphate (with no trace of protein or fat);
8) foetal 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 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 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.

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

a) Entry assessment

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) Cattle;
ii) Ruminant-derived protein meal;
iii) Feed (except packaged and labelled pet food not intended for pets) that contains ruminant-derived protein meal;
iv) Fertilizers that contain ruminant-derived protein meal;
v) Any other commodity that either is or could be contaminated by commodities listed in Article 11.4.14.

b) Exposure assessment

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 within the indigenous cattle population of the country, zone or compartment.

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

i) Livestock industry practices on preventing cattle from being fed ruminant-derived protein meal, taking account of:
   = demographics of the cattle population and production and farming systems;
   = feeding practices;
slaughtering and waste management practices;
rendering practices;
feed production, labelling, distribution and storage.

Depending on the outcome from this step, an evaluation of mitigation measures specifically targeting BSE may also need to be included through a consideration of the impact of:

ii) Specific risk mitigation measures on preventing cattle from being fed ruminant-derived protein meal, taking account of:

- the nature and scope of a feed ban on feeding ruminants with protein meal derived from ruminants;
- the fate of commodities with the greatest BSE infectivity (those commodities listed in point 1 of Article 11.4.14.);
- parameters of the rendering process;
- prevention of cross-contamination during rendering, feed production, transport, storage and feeding;
- an awareness programme under the scope of the feed ban;
- monitoring and enforcement of the feed ban.

Depending on the outcome of the exposure assessment, a consequence assessment (in point (c) below) may not be required.

c) Consequence assessment

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-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 recycled 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 ongoing implementation of a surveillance programme for classical BSE in the cattle population in accordance with Article 11.4.18.

3) 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 the preceding eight years:

- the current implementation of a surveillance programme for classical BSE in the cattle population in accordance with Article 11.4.18.
- the ongoing history of occurrence and management of BSE cases.
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 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 11.4.2018, 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:

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

ii) where a case was born within the preceding eight years after that date, subsequent investigations have confirmed that any identified source of infection has been mitigated and the likelihood 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 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 havinga negligible BSE risk for BSE, the status of the negligible BSE risk statuscountry 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 confirms that any identified source of infection has been mitigated and the likelihood of BSE agents being recycled within the cattle population continues to be negligible. TheIn 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 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 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 of the BSE agents being recycled within the cattle population has been demonstrated to be negligible.

OR

3) a) are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime; and

b) it is demonstrated as having that the cattle selected for export have not been fed protein meal derived from ruminants.

Article 11.4.8.

Recommendations for importation of cattle from a country or, zone or compartment posing an undetermined BSE risk

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that cattle selected for export:

1) are identified by a permanent individual through an animal identification system from birth enabling each animal to be traced throughout its lifetime;

2) it is demonstrated as having that the cattle selected for export have not been fed protein meal derived from ruminants.

Article 11.4.9.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a negligible BSE risk

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the cattle from which the fresh meat and meat products were derived:

1) came from a country, zone or compartment posing a negligible BSE risk;

2) have been subjected to an ante-mortem inspection with favourable results.

Article 11.4.10.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a negligible or controlled BSE risk

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1) the cattle from which the fresh meat and meat products were derived came from a country, zone or compartment posing a controlled BSE risk 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 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 points 1) a) and 1) b) of Article 11.4.14.;

   ii) mechanically separated meat from the skull and/or from the vertebral column from of cattle over 30 months of age.

Article 11.4.11.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing an undetermined BSE risk

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1) the cattle from which the fresh meat and meat products were derived:

a) are identified through an animal identification system;

2) it is demonstrated as having that the cattle from which the fresh meat and meat products were derived have not been fed protein meal derived from ruminants;

b) the cattle from which the fresh meat and meat products were derived:

   a) were subjected to an ante-mortem inspection with favourable results;

   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;

24) the fresh meat and meat products were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

   a) the commodities listed in points 1) a) and 1) b) of Article 11.4.14.;

   b) mechanically separated meat from the skull and/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 protein meal was derived 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 identified through an animal identification system and were born and kept in 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

12. 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 were identified through an animal identification system and were born and kept in 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

23. the blood and blood products were:
   a) collected from cattle not subjected to a stunning process, or to any other procedure that can contaminate the blood with nervous tissue, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate the blood with nervous tissue, prior to slaughter, and
   b) collected and processed in a manner that ensures they are not contaminated with nervous tissue.

Article 11.4.14.

Recommendations in relation to the trade of the commodities with the greatest BSE infectivity

1. Unless covered by other articles in this chapter, the following commodities originating from a country, zone or compartment posing a controlled or undetermined BSE risk, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices:

   a1) 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 points 1) a) or 1) b) above of this article, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk, should not be traded.

3) Cattle-derived protein meal, or any commodities containing such products, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk, should not be traded.

These points do not apply to cattle in a country or zone with a controlled BSE risk when they are born during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

Article 11.4.15.

Recommendations for importation of tallow (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the tallow:

1) came from a country, zone or compartment posing a negligible BSE risk; or

2) 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 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) came from a country, zone or compartment posing a negligible BSE risk; or

2) 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 may be present during the production of protein meal containing ruminant proteins:

1) The raw material should be reduced to a maximum particle size of 50 mm before heating.
2) 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) 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, 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 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 rare occasions cases can develop acutely and progress rapidly. In the continuum of the disease spectrum, 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 observe individual animals displaying clinical signs suggestive of BSE. The rate at which they are likely to occur cannot be reliably predicted as they will vary depending on the epidemiological situation in a particular country. In addition, in surveillance for BSE consists of the reporting of all animals that lie on the continuum of the disease spectrum to the Veterinary Authority 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, 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 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 following animals that lie on the continuum of the disease spectrum of BSE should be targeted for 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 have been ruled out);

d) those found dead (fallen stock), with an appropriate supporting clinical history (i.e. other common causes of death 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, herdsman, 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.
CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 11.4.1.

General provisions and safe commodities

1) The recommendations in this chapter are intended to manage mitigate the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (Bos taurus and B. indicus) 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. 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 considered capable of being recycled in a cattle population if cattle are orally exposed to contaminated feed. For the purposes of official BSE risk status recognition, BSE excludes atypical BSE as a condition believed to occur spontaneously in all cattle populations at a very low rate.

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

3) For the purposes of the Terrestrial Code:

   a) BSE is an invariably fatal neurological prion disease of cattle caused by a misfolded form of the prion protein (PrPSc) which includes both classical (C-type BSE) and atypical strains (H- and L-type BSE having, respectively, a PrPSc fragment of higher and lower molecular mass than classical BSE). The term 'BSE' includes both classical and atypical forms.

   b) The occurrence of a BSE case is defined by the immunohistochemical (IHC) or immunochemical detection of PrPSc in brain tissue of a bovid of the species Bos taurus or Bos indicus. 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, ‘cattle’ means bovids of the species Bos taurus or Bos indicus.

1) When authorising import or transit of the following commodities and any products made from these commodities and containing no other tissues from cattle, Veterinary Authorities should not require any BSE-related conditions, regardless of the BSE risk status of the cattle population of the exporting country, zone or compartment:

   a) milk and milk products;

   b) semen and in vivo derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

   c) hides and skins;

   d) gelatine and collagen prepared exclusively from hides and skins;

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

   f) dicalcium phosphate (with no trace of protein or fat);

   g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle which were not subjected to a stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante- and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.4.14.;

   h) blood and blood by-products from cattle which were not subjected to a stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.
2) When authorising import or transit of other commodities listed in this chapter, Veterinary Authorities should require the conditions prescribed in this chapter relevant to the BSE risk status of the cattle population of the exporting country, zone or compartment.

35) When authorising import of commodities according to the conditions prescribed in commodities are imported in accordance with this chapter, the BSE risk status of the importing country or zone of destination is not affected by the BSE risk status 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) dicalcium phosphate (with no trace of protein or fat);
7) 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 status of the cattle population of a country, zone or compartment

Owing to its specific etiological and epidemiological features, the BSE risk status of the cattle population of a country, zone or compartment should be determined on the basis of the following criteria:

1) the outcome of a BSE risk assessment, based on the provisions of the Terrestrial Code, ‘Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy’ that evaluates the risk of BSE agents being recycled within the cattle population by identifying all potential factors for BSE 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.

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

a) Entry assessment

The Entry assessment consists of assessing, through consideration of the following, evaluates the likelihood that the classical BSE agent has either been introduced into the country, zone or compartment via commodities potentially contaminated with it, or is already present in the country, zone or compartment through the importation of the following commodities in the preceding eight years:

i) cattle;
ii) ruminant-derived protein meal;
iii) feed (except packaged and labelled pet food) that contains ruminant-derived protein meal;
iv) fertilisers that contain ruminant-derived protein meal;

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

i) the presence or absence of the BSE agent in the indigenous ruminant population of the country, zone or compartment and, if present, evidence regarding its prevalence in cattle;

ii) production of meat-and-bone meal or greaves from the indigenous ruminant population;

iii) imported meat-and-bone meal or greaves;

iv) imported cattle, sheep and goats;

v) imported animal feed and feed ingredients;

vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 11.4.14. and may have been fed to cattle;

vii) imported products of ruminant origin intended for in vivo use in cattle.

The results of surveillance and other epidemiological investigations into the disposition of the commodities identified above should be taken into account in carrying out the assessment.

b) Exposure assessment

If the entry assessment identifies a risk factor, an exposure assessment should be conducted, consisting of assessing the likelihood of cattle being exposed to the BSE agent over the preceding eight years, either through imported commodities or as a result of the presence of BSE agents within the indigenous cattle population of the country, zone or compartment. The following factors should be considered:

i) recycling and amplification of the BSE agent through consumption by cattle of meat-and-bone meal or greaves of ruminant origin, or other feed or feed ingredients contaminated with these;

ii) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse/abattoir waste, the parameters of the rendering processes and the methods of animal feed manufacture;

iii) the feeding or not of ruminants with meat-and-bone meal and greaves derived from ruminants, including measures to prevent cross-contamination of animal feed;

iv) the level of surveillance for BSE conducted on the cattle population up to that time and the results of that surveillance.

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 preventing cattle from being fed ruminant-derived protein meal, taking account of:

   a) demographics of the cattle population and production and farming systems;
   b) feeding practices;
   c) slaughtering and waste management practices;
   d) rendering practices;
   e) 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 consideration of the impact of:
ii) Specific risk mitigation measures preventing cattle from being fed ruminant-derived protein meal, taking account of:

- the nature and scope of a feed ban on feeding ruminants with protein meal derived from ruminants;
- the fate of commodities with the greatest BSE infectivity (those commodities listed in point 1 of Article 11.4.14.);
- parameters of the rendering process;
- prevention of cross-contamination during rendering, feed production, transport, storage and feeding;
- an awareness programme under the scope of the feed ban;
- monitoring and enforcement of the feed ban.

Depending on the outcome of the exposure assessment, a consequence assessment (in point (c) below) may not be required.

c) Consequence assessment

The consequence assessment evaluates the likelihood of cattle becoming infected 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-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 of BSE agents being recycled within the cattle population, and to determine the date from which the risk of BSE agents being recycled within the cattle population has been negligible.

2) The ongoing awareness implementation of a surveillance programme for BSE in the cattle population in accordance with Article 11.4.16 veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Articles 11.4.20. to 11.4.22.;

3) The history of occurrence and management of BSE cases: the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;

4) the examination carried out in accordance with the Terrestrial Manual in a laboratory of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.

When the risk assessment demonstrates negligible risk, the Member Country should conduct Type B surveillance in accordance with Articles 11.4.20. to 11.4.22.

When the risk assessment fails to demonstrate negligible risk, the Member Country should conduct Type A surveillance in accordance with Articles 11.4.20. to 11.4.22.
Article 11.4.3.

Negligible BSE risk

The BSE risk Commodities from the cattle population of a country, or zone or compartment pose a can be considered to be negligible risk of transmitting the BSE agent if all the following conditions for the cattle population are met for at least the preceding eight years:

1) A risk assessment, as described in point 1 of 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 in order to identify the historical and existing risk factors, and the Member Country has demonstrated through documented evidence that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk; any identified risk factors have been adequately managed and that the risk of BSE agents being recycled within the cattle population has been negligible.

2) The Member Country has demonstrated that Type B surveillance in accordance with Articles 11.4.20. to 11.4.22. is in place and the relevant points target, in accordance with Table 1, has been met. The surveillance provisions as described in Article 11.4.18. 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 and has been completely destroyed, and
      i) the criteria in points 2 to 4 of Article 11.4.2. have been complied with for at least seven years; and
      ii) it has been demonstrated through an appropriate level of control and audit, including that of cross contamination, that for at least eight years neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;

   OR

   b) if there has been an indigenous case of classical BSE, every indigenous case was born more than 11 years ago, and

      either:
      i) all cases were born before the date from which the risk of BSE agents being recycled within the cattle population has been negligible;

      OR

      ii) where a case was born after that date, subsequent investigations have confirmed 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.

      i) the criteria in points 2 to 4 of Article 11.4.2. have been complied with for at least seven years; and

      ii) it has been demonstrated through an appropriate level of control and audit, including that of cross contamination, that for at least eight years neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;

      iii) all BSE cases, as well as:

         all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

         if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE cases,
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 Member Country or the zone will be included in the list of countries or zones posing a negligible risk for BSE only after the submitted evidence has been accepted by the OIE in accordance with Chapter 1.6. Retention on the list requires that the information for the previous 12 months on surveillance results and feed controls be resubmitted annually. Annual confirmation of the conditions in points 1 to 4 above. Documented evidence should be resubmitted annually for points 1 to 4. Any changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in accordance with Chapter 1.1.

Article 11.4.4.

Controlled BSE risk

The BSE risk Commodities from the cattle population of a country, or zone or compartment pose a can be considered to be controlled risk of transmitting the BSE agent if all of the following conditions of Article 11.4.3. are met, but one or more of these conditions has not been met for the preceding eight years:

1) a risk assessment, as described in point 1 of Article 11.4.2., has been conducted in order to identify the historical and existing risk factors, and the Member Country has demonstrated that appropriate measures are being taken to manage all identified risks, but these measures have not been taken for the relevant period of time;

2) the Member Country has demonstrated that Type A surveillance in accordance with Articles 11.4.20. to 11.4.22. has been carried out and the relevant points target, in accordance with Table 1, has been met. Type B surveillance may replace Type A surveillance once the relevant points target is met;

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 and has been completely destroyed, the criteria in points 2 to 4 of Article 11.4.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, that neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:

   i) the criteria in points 2 to 4 of Article 11.4.2. have not been complied with for seven years;

   ii) it cannot be demonstrated that controls over the feeding of meat-and-bone meal or greaves derived from ruminants to ruminants have been in place for eight years;

OR

b) there has been an indigenous case of BSE, the criteria in points 2 to 4 of Article 11.4.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, that neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants:

and all BSE cases, as well as:

— all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

— if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE cases, if alive in the country, zone or compartment, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.
Annex 14 (contd)

The Member Country or the zone will be included in the list of countries or zones posing a controlled risk for BSE only after the submitted evidence has been accepted by the OIE in accordance with Chapter 1.6. Retention on the list requires that the information for the previous 12 months on surveillance results and feed controls be re-submitted annually and annual confirmation of the conditions in points 1 to 4 of Article 11.4.3. Documented evidence should be re-submitted annually for points 1 to 4 of Article 11.4.3.

Any changes in the epidemiological situation or other significant events should be reported notified to the OIE according to the requirements 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 poses an is considered to be undetermined BSE risk if it cannot be demonstrated that it meets the requirements of another category 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 the importation of bovine commodities from a country, zone or compartment posing a negligible BSE risk

For all commodities from cattle not listed in point 1 of Article 11.4.1.

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the commodities comply with the conditions in Article 11.4.3.

Article 11.4.7.

Recommendations for the importation of cattle from a country, zone or compartment posing a negligible BSE risk but where there has been an indigenous case

For cattle selected for export

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals:

1) are identified by a permanent identification system in such a way as to demonstrate that they are not exposed to cattle as described in point 3(b)(iii) of Article 11.4.3.

2) were born after the date from which the ban on the feeding of ruminants with meat and bone meal and greaves derived from ruminants had been effectively enforced.
Article 11.4.8

Recommendations for the importation of cattle from a country, zone or compartment posing a negligible or controlled BSE risk

For cattle

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1) The cattle selected for export are identified through an animal identification system enabling them to be traced throughout their lifetime.

AND EITHER:

2) The cattle selected for export were born and kept in a country, zone or compartment posing a negligible or controlled BSE risk after the date from which the risk of BSE agents being recycled within the cattle population has been demonstrated to be negligible.

OR

3) It is demonstrated that the cattle selected for export have not been fed protein meal derived from ruminants.

1) the country, zone or compartment complies with the conditions referred to in Article 11.4.4.;

2) cattle selected for export are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3(b) of Article 11.4.4.;

3) cattle selected for export were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and grease derived from ruminants was effectively enforced.

Article 11.4.9

Recommendations for the importation of cattle from a country, or zone or compartment posing an undetermined BSE risk

For cattle

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1) The cattle selected for export are identified through an animal identification system enabling them to be traced throughout their lifetime.

2) It is demonstrated that the cattle selected for export have not been fed protein meal derived from ruminants.

1) the feeding of ruminants with meat-and-bone meal and grease derived from ruminants has been banned and the ban has been effectively enforced;

2) all BSE cases, as well as:

   a) all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or
b) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE cases, if alive in the country, zone or compartment, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed;

3) cattle selected for export:

a) are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as demonstrated in point 2 above;

b) were born at least two years after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants was effectively enforced.

Article 11.4.10.

Recommendations for the importation of fresh meat and meat products from a country, zone or compartment posing a negligible BSE risk

For fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.4.1.)

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1) the country, zone or compartment complies with the conditions in Article 11.4.3.;

2) the cattle from which the fresh meat and meat products were derived passed ante- and post-mortem inspections;

3) in countries with negligible BSE risk where there have been indigenous cases, the cattle from which the fresh meat and meat products were derived were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced.

Article 11.4.11.10.

Recommendations for the importation of fresh meat and meat products from a country, zone or compartment posing a negligible or controlled BSE risk

For fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.4.1.)

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 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 a country, zone or compartment posing a negligible or controlled BSE risk after the date from which the risk of BSE agents being recycled within the cattle population has been demonstrated to be negligible;

OR

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 1 of Article 11.4.14.;

ii) mechanically separated meat from the skull or from the vertebral column of cattle over 30 months of age.

1) the country, zone or compartment complies with the conditions referred to in Article 11.4.4.;

2) the cattle from which the fresh meat and meat products were derived passed ante- and post-mortem inspections;

3) cattle from which the fresh meat and meat products destined for export were derived were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;

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:
   i) the tissues listed in points 1 and 2 of Article 11.4.14.,
   ii) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age.

Article 11.4.1211.

Recommendations for the importation of fresh meat and meat products from a country, zone or compartment posing an undetermined BSE risk

For fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.4.1.)

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 are identified through an animal identification system;

2) it is demonstrated that the cattle from which the fresh meat and meat products were derived have not been fed protein meal derived from ruminants;

3) the cattle from which the fresh meat and meat products were derived:
   a) were subjected to an ante-mortem inspection with favourable results;
   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;

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 1 of Article 11.4.14.;
   b) mechanically separated meat from the skull or from the vertebral column of cattle over 30 months of age.

1) the cattle from which the fresh meat and meat products originate:
   a) have not been fed meat-and-bone meal or greaves derived from ruminants;
   b) passed ante- and post-mortem inspections;
   c) were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;

2) 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:
Annex 14 (contd)

a) the tissues listed in points 1 and 3 of Article 11.4.14.,

b) nervous and lymphatic tissues exposed during the deboning process,

c) mechanically separated meat from the skull and vertebral column from cattle over 12 months of age.

Article 11.4.13.

Recommendations on ruminant-derived meat-and-bone meal or greaves for importation of cattle-derived protein meal from a country, zone or compartment posing a negligible BSE risk

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the cattle from which the protein meal was derived were identified through an animal identification system and were born and kept in a country, zone or compartment posing a negligible BSE risk, and

EITHER

1) they were born after the date from which the risk of BSE agents being recycled within the cattle population has been demonstrated to be negligible;

OR

2) the protein meal was processed in accordance with Article 11.4.17.

4) Ruminant-derived meat-and-bone meal or greaves, or any commodities containing such products, which originate from a country, zone or compartment defined in Article 11.4.3., but where there has been an indigenous case of BSE, should not be traded if such products were derived from cattle born before the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced.

2) Ruminant-derived meat-and-bone meal or greaves, or any commodities containing such products, which originate from a country, zone or compartment defined in Articles 11.4.4. and 11.4.5. should not be traded between countries.

Article 11.4.13.

Recommendations for importation of blood and blood products derived from cattle (except fetal blood)

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

EITHER:

1) the cattle from which the blood and blood products were derived were identified through an animal identification system and were born and kept in a country, zone or compartment posing a negligible or controlled BSE risk after the date from which the risk of BSE agents being recycled within the cattle population has been demonstrated to be negligible.

OR

2) the blood and blood products were:

a) collected 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 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 on commodities that should not be traded in relation to the trade of the commodities with the greatest BSE infectivity

Unless covered by other articles in this chapter, the following commodities should not be traded:
1) Distal ileum from cattle of any age; 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 if the commodities are derived from cattle born before the date from which the risk of BSE agents being recycled 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 1 above.

3) Cattle-derived protein meal or any commodities containing such product which originate from a country, zone or compartment posing a controlled or undetermined BSE risk.

1) From cattle of any age originating from a country, zone or compartment defined in Articles 11.4.4. and 11.4.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other articles in this chapter) should also not be traded.

2) From cattle that were at the time of slaughter over 30 months of age originating from a country, zone or compartment defined in Article 11.4.4., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other articles in this chapter) should also not be traded.

3) From cattle that were at the time of slaughter over 12 months of age originating from a country, zone or compartment defined in Article 11.4.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other articles in this chapter) should also not be traded.

**Article 11.4.15.**

Recommendations for the importation of gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that:

1) the commodities came from a country, zone or compartment posing a negligible BSE risk;

OR

2) they originate from a country, zone or compartment posing a controlled or undetermined BSE risk and are derived from cattle which have passed ante- and post-mortem inspections; and that

   a) vertebral columns from cattle over 30 months of age at the time of slaughter and skulls have been excluded;

   b) the bones have been subjected to a process which includes all of the following steps:

      i) degreasing,

      ii) acid demineralisation,

      iii) acid or alkaline treatment,

      iv) filtration,
Annex 14 (contd)

v) sterilisation at >138°C for a minimum of 4 seconds, or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).

Article 11.4.1615.

Recommendations for the 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 of importing countries 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) it originates from a country, zone or compartment posing a controlled or undetermined BSE risk, is derived from cattle which have passed ante- and post-mortem inspections with favourable results, and has not been prepared using the tissues commodities listed in points 1 and 2 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 11.4.1716.

Recommendations for the 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 of importing countries 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) it originates from a country, zone or compartment posing a controlled or undetermined BSE risk and is a by-product co-product of bone gelatine produced according to Article 11.4.15.

Article 11.4.18.

Recommendations for the importation of tallow derivatives (other than those made from tallow as defined in Article 11.4.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that:

1) the tallow derivatives originate from a country, zone or compartment posing a negligible BSE risk; or

2) they are derived from tallow meeting the conditions referred to in Article 11.4.16.; or

3) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.
Article 11.4.1917

Procedures for the reduction of BSE infectivity in meat-and-bone meal protein meal

The following procedure should be used to reduce the infectivity of any transmissible spongiform encephalopathy BSE agents which may be present during the production of meat-and-bone meal containing ruminant proteins:

1) The raw material should be reduced to a maximum particle size of 50 mm before heating.
2) 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 11.4.2018

Surveillance: introduction

The objective of BSE surveillance is to detect occurrence of BSE within the cattle population.

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, tremors, excessive 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) 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 on rare occasions cases can develop acutely and progress rapidly. The final stages of the disease are characterised by recumbency, coma and death.

Since these signs are not pathognomonic for either classical or atypical BSE, all Member Countries with cattle populations are likely to observe individual animals displaying clinical signs suggestive of BSE. General statements about the likely frequency of occurrence of such animals cannot be made as they will vary depending on the epidemiological situation in a particular country.

2) Surveillance for BSE consists of the reporting of all animals that show signs of the clinical spectrum of BSE to the Veterinary Services for subsequent investigation and follow-up.

In production and farming systems that allow cattle to be subjected to regular observation, it is likely that animals that display clinical signs suggestive of BSE will be more readily seen. Behavioural changes, 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 production and farming systems, where cattle are not monitored as closely, situations may arise where an animal might be considered as a clinical suspect, yet if it 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).
The surveillance programme should take into account that the vast majority of BSE cases arise as single, isolated events. The concurrence of multiple animals with behavioural or neurological signs, or non-ambulatory or fallen stock is most likely associated with other causes.

The animals that lie on the 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. 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 ante-mortem inspection at slaughterhouses/abattoirs;
- c) those presented as downers (non-ambulatory), with an appropriate supporting clinical history (i.e. other common causes of recumbency have been ruled out);
- d) those found dead (fallen stock), with an appropriate supporting clinical history (i.e. other common causes of death have been ruled out).

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 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 animals targeted for BSE surveillance,
  - the determination of animals to be subjected to laboratory testing,
  - the collection and submission of samples for laboratory testing,
  - the follow-up epidemiological investigations for BSE positive findings.

1) Depending on the risk category of a country, zone or compartment with regard to bovine spongiform encephalopathy (BSE), surveillance for BSE may have one or more goals:

- a) detecting BSE, to a pre-determined design prevalence, in a country, zone or compartment;
- b) monitoring the evolution of BSE in a country, zone or compartment;
- c) monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing;
- d) supporting a claimed BSE status;
- e) gaining or regaining a higher BSE status.

2) When the BSE agent is present in a country or zone, the cattle population will comprise the following sectors, in order of decreasing size:

- a) cattle not exposed to the infective agent;
- b) cattle exposed but not infected.
c) infected cattle, which may lie within one of three stages in the progress of BSE:

i) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;

ii) some will progress to a stage at which BSE is detectable by testing before clinical signs appear;

iii) the smallest number will show clinical signs.

3) The BSE status of a country, zone or compartment cannot be determined only on the basis of a surveillance programme but should be determined in accordance with all the factors listed in Article 11.4.2. The surveillance programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.

4) With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for surveillance purposes:

a) cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);

b) cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter or downer cattle);

c) cattle over 30 months of age which are found dead or killed on farm, during transport or at a slaughterhouse/abattoir (fallen stock);

d) cattle over 36 months of age at routine slaughter.

5) A gradient is used to describe the relative value of surveillance applied to each subpopulation. Surveillance should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, zone or compartment. This approach is consistent with Articles 11.4.20. to 11.4.22.

6) When establishing a surveillance strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.

Article 11.4.21.

Surveillance: description of cattle subpopulations

1. Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all Member Countries with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

This subpopulation is the one exhibiting the highest prevalence. The accurate recognition, reporting and classification of such animals will depend on the ongoing owner/veterinarian awareness programme. This and the quality of the investigation and laboratory examination systems (Article 11.4.2.), implemented by the Veterinary Services, are essential for the credibility of the surveillance system.

2. Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casually or emergency slaughter, or downer cattle)
These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in Member Countries where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.

3. Cattle over 30 months of age which are found dead or killed on farm, during transport or at a slaughterhouse/abattoir (fallen stock)

These cattle may have exhibited some of the clinical signs listed above prior to death, but were not recognised as being consistent with BSE. Experience in Member Countries where BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.

4. Cattle over 36 months of age at routine slaughter

Experience in Member Countries where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine slaughter cattle 36 months of age or less is of relatively very little value (Table 2).

Article 11.4.22.

Surveillance activities

In order to implement efficiently a surveillance strategy for BSE, a Member Country should use documented records or reliable estimates of the age distribution of the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, zone or compartment.

The approach assigns ‘point values’ to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, zone or compartment.

A surveillance strategy should be designed to ensure that samples are representative of the herd of the country, zone or compartment, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made should be fully documented, and the documentation retained for seven years.

The points targets and surveillance point values in this chapter were obtained by applying the following factors to a statistical model:

1) the design prevalence for Type A or Type B surveillance;
2) a confidence level of 95%;
3) the pathogenesis, and pathological and clinical expression of BSE:
   a) sensitivity of diagnostic methods used;
   b) relative frequency of expression by age;
   c) relative frequency of expression within each subpopulation;
   d) interval between pathological change and clinical expression;
4) demographics of the cattle population, including age distribution and population size;
5) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;
6) percentage of infected animals in the cattle population which are not detected.
Although the procedure accepts very basic information about a cattle population, and can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect animals provide many times more information than samples from healthy or dead-of-unknown-cause animals, careful attention to the input data can substantially decrease the procedure’s cost and the number of samples needed. The essential input data are:

7) cattle population numbers stratified by age;
8) the number of cattle tested for BSE stratified by age and by subpopulation.

This chapter utilises Tables 1 and 2 to determine a desired surveillance points target and the point values of surveillance samples collected.

Within each of the subpopulations above in a country, zone or compartment, a Member Country may wish to target cattle identifiable as imported from countries or zones not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or zones not free from BSE.

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested.

4. **Type A surveillance**

   The application of Type A surveillance will allow the detection of BSE around a design prevalence of at least one case per 100,000 in the adult cattle population in the country, zone or compartment of concern, at a confidence level of 95%.

2. **Type B surveillance**

   The application of Type B surveillance will allow the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population in the country, zone or compartment of concern, at a confidence level of 95%.

   Type B surveillance may be carried out by countries, zones or compartments of negligible BSE risk status (Article 11.4.3.) to confirm the conclusions of the risk assessment, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through surveillance targeted to maximise the likelihood of identifying failures of such measures.

   Type B surveillance may also be carried out by countries, zones or compartments of controlled BSE risk status (Article 11.4.4.), following the achievement of the relevant points target using Type A surveillance, to maintain confidence in the knowledge gained through Type A surveillance.

3. **Selecting the points target**

   The surveillance points target should be selected from Table 1, which shows target points for adult cattle populations of different sizes. The size of the adult cattle population of a country, zone or compartment may be estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size.

<table>
<thead>
<tr>
<th>Adult cattle population size (24 months and older)</th>
<th>Type A surveillance</th>
<th>Type B surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;1,000,000</td>
<td>300,000</td>
<td>150,000</td>
</tr>
<tr>
<td>1,000,000</td>
<td>238,400</td>
<td>119,200</td>
</tr>
<tr>
<td>900,001-1,000,000</td>
<td>214,600</td>
<td>107,300</td>
</tr>
<tr>
<td>800,001-900,000</td>
<td>190,700</td>
<td>95,350</td>
</tr>
<tr>
<td>700,001-800,000</td>
<td>168,900</td>
<td>83,450</td>
</tr>
<tr>
<td>600,001-700,000</td>
<td>143,000</td>
<td>71,500</td>
</tr>
</tbody>
</table>
4. Determining the point values of samples collected

Table 2 can be used to determine the point values of the surveillance samples collected. The approach assigns point values to each sample according to the likelihood of detecting infection based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of surveillance described in Chapter 1.4. and the epidemiology of BSE.

Because precise aging of the animals that are sampled may not be possible, Table 2 combines point values into five age categories. The point estimates for each category were determined as an average for the age range comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the disease and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the cattle herd of the country, zone or compartment. In addition, Member Countries should sample at least three of the four subpopulations.

<table>
<thead>
<tr>
<th>Surveillance subpopulation</th>
<th>Routine slaughter¹</th>
<th>Fallen stock²</th>
<th>Casualty slaughter³</th>
<th>Clinical suspect⁴</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt; 1 year and &lt;2 years</td>
<td>0.01</td>
<td>0.2</td>
<td>0.4</td>
<td>N/A</td>
</tr>
<tr>
<td>Age &gt; 2 years and &lt;4 years (young adult)</td>
<td>0.1</td>
<td>0.2</td>
<td>0.4</td>
<td>260</td>
</tr>
</tbody>
</table>

Table 2. Surveillance point values for samples collected from animals in the given subpopulation and age category.
Annex 14 (contd)

<table>
<thead>
<tr>
<th>Age</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 4 years and &lt; 7 years (middle adult)</td>
<td>0.2</td>
</tr>
<tr>
<td>&gt; 7 years and &lt; 9 years (older adult)</td>
<td>0.1</td>
</tr>
<tr>
<td>&gt; 9 years</td>
<td>0.0</td>
</tr>
</tbody>
</table>

If a country, zone or compartment determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'casualty of emergency slaughter, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the surveillance point values accorded to the combined subpopulation would be that of 'fallen stock'.

The total points for samples collected may be accumulated over a period of a maximum of seven consecutive years to achieve the target number of points determined in Table 1.

Surveillance points remain valid for seven years (the 95th percentile of the incubation period).

Article 11.4.23.

**BSE risk assessment: introduction**

The first step in determining the BSE risk status of the cattle population of a country or zone is to conduct a risk assessment (reviewed annually), based on Section 2. of this Terrestrial Code, identifying all potential factors for BSE occurrence and their historic perspective.

1. **Entry assessment**

   Entry assessment consists of assessing the likelihood that a BSE agent has been introduced via the importation of the following commodities potentially contaminated with a BSE agent:

   a) meat-and-bone meal or greaves;
   b) live animals;
   c) animal feed and feed ingredients;
   d) products of animal origin for human consumption.

2. **Exposure assessment**

   Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

   a) epidemiological situation concerning BSE agents in the country or zone;
   b) recycling and amplification of the BSE agent through consumption by cattle of meat-and-bone meal or greaves of ruminant origin, or other feed or feed ingredients contaminated with these;
   c) the origin and use of ruminant carcasses (including fallen stock), by products and slaughterhouse/abattoir waste, the parameters of the rendering processes and the methods of animal feed manufacture;
   d) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed; thorough epidemiological investigations of any indigenous case born after the date of the implementation of feed bans should be conducted.
The following recommendations are intended to assist Veterinary Services in conducting such a risk assessment. They provide guidance on the issues that need to be addressed when conducting a country-based assessment of BSE risk. They apply equally to self-assessment in preparation of dossiers for categorisation of countries. The recommendations are supported by greater detail in the questionnaire used for the submission of data for country assessment.

**Article 11.4.24.**

The potential for the entry of the BSE agent through the importation of meat-and-bone meal or greaves

This point is irrelevant if the exposure assessment outlined below in Article 11.4.27. indicates that meat-and-bone meal or greaves have not been fed, either deliberately or accidentally, in the past eight years. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that meat-and-bone meal or greaves has not been fed to ruminants.

**Assumption:** That meat-and-bone meal or greaves of ruminant origin plays the only significant role in BSE transmission.

**Question to be answered:** Has meat-and-bone meal, greaves, or feedstuffs containing either been imported within the past eight years? If so, where from and in what quantities?

**Rationale:** Knowledge of the origin of meat-and-bone meal, greaves, or feedstuffs containing either meat-and-bone meal or greaves is necessary to assess the likelihood of entry of BSE agent. Meat-and-bone meal and greaves originating in countries of high BSE risk pose a higher likelihood of entry than that from low risk countries. Meat-and-bone meal and greaves originating in countries of unknown BSE risk pose an unknown likelihood of entry.

**Evidence required:**
- Documentation to support claims that meat-and-bone meal, greaves or feedstuffs containing either meat-and-bone meal or greaves have not been imported. OR
- Where meat-and-bone meal, greaves or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.
- Documentation on annual volume, by country of origin, of meat, greaves or feedstuffs containing them imported during the past eight years.
- Documentation describing the composition (on a species and class of stock basis) of the imported meat-and-bone meal, greaves or feedstuffs containing them.
- Documentation from the country of production, supporting why the rendering processes used to produce meat-and-bone meal, greaves or feedstuffs containing them would have inactivated, or significantly reduced the titre of BSE agent, should it be present.
- Documentation describing the fate of imported meat-and-bone meal and greaves.

**Article 11.4.25.**

The potential for the entry of the BSE agent through the importation of live animals potentially infected with BSE

**Assumptions:**
- Countries which have imported ruminants from countries infected with BSEs are more likely to experience BSE.
- Cattle pose the only known risk although other species are under study.
- Animals imported for breeding may pose a greater risk than animals imported for slaughter because of the hypothetical risk of maternal transmission and because they are kept to a greater age than animals imported for slaughter.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
Risk is proportional to volume of imports (Article 2.1.3.).

**Question to be answered:** Have live animals been imported within the past seven years?

**Rationale:** The likelihood of entry is dependent on:

- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical disease, or following active surveillance, or assessment of geographical BSE risk;
- feeding and management of the animals in the country of origin;
- use to which the commodity has been put apart from representing risk of developing clinical disease, the slaughter, rendering and recycling in meat-and-bone meal of imported animals represents a potential route of exposure of indigenous livestock even if meat-and-bone meal and greaves, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at slaughter.

**Evidence required:**

- Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the fate of imported animals, including their age at slaughter.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

**Article 11.4.26.**

The potential for the entry of the BSE agent through the importation of products of animal origin potentially infected with BSE

**Assumptions:**

- Semen, embryos, hides and skins or milk are not considered to play a role in the transmission of BSE.
- Countries which have imported products of animal origin from countries with BSEs are more likely to experience BSE.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 2.1.3.).

**Question to be answered:** What products of animal origin have been imported within the past seven years?

**Rationale:** The likelihood of entry is dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 11.4.14.);
- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical disease, or following active surveillance, or assessment of geographical BSE risk;
- feeding and management of the animals in the country of origin;
Annex 14 (contd)

The use to which the commodity has been put as apart from representing risk of developing clinical disease, the slaughter, rendering and recycling in meat-and-bone meal of imported animals represents a potential route of exposure of indigenous livestock even if meat-and-bone meal and greaves, or feedstuffs containing them, have not been imported;

species;

dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;

age at slaughter.

Evidence required:

Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.

Documentation describing origins, species and volume of imports.

Documentation describing the end use of imported animal products, and the disposal of waste.

Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.4.27.

The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of ruminant origin

Assumptions:

That the consumption by bovines of meat-and-bone meal or greaves of ruminant origin plays the only significant role in BSE transmission.

That commercially-available products of animal origin used in animal feed may contain meat-and-bone meal or greaves of ruminant origin.

Milk and blood are not considered to play a role in the transmission of BSE.

Question to be answered: Has meat-and-bone meal or greaves of ruminant origin been fed to cattle within the past eight years (see Articles 11.4.3. and 11.4.4.)?

Rationale: If cattle have not been fed products of animal origin (other than milk or blood) potentially containing meat-and-bone meal or greaves of ruminant origin within the past eight years, meat-and-bone meal and greaves can be dismissed as a risk.

Article 11.4.28.

The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production

Assumptions:

BSE has a long incubation period and insidious onset of signs, so cases may escape detection.

Pre-clinical BSE infectivity cannot reliably be detected by any method and may enter rendering, in particular if specified risk materials are not removed.

Tissues most likely to contain high titres of BSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.

BSE may manifest in sudden death, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.
BSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Article 11.4.19.

BSE agent is present at much higher titres in central nervous system and reticulo-endothelial tissues (so-called ‘Specified Risk Materials’, or SRM).

Question to be answered: How has animal waste been processed over the past eight years?

Rationale: If potentially infected animals or contaminated materials are rendered, there is a risk that the resulting meat-and-bone meal could retain BSE infectivity.

Where meat-and-bone meal is utilised in the production of any animal feed, the risk of cross-contamination exists.

Evidence required:

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.
- Documentation describing the definition and disposal of specified risk material, if any.
- Documentation describing the rendering process and parameters used to produce meat-and-bone meal and greaves.
- Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of meat-and-bone meal in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.
- Documentation describing monitoring and enforcement of the above.

Article 11.4.29.

Conclusions of the risk assessment

The overall risk of BSE in the cattle population of a country or zone is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the risk assessment to conclude that the cattle population of a country or zone is free from BSE risk, it should have demonstrated that appropriate measures have been taken to manage any risks identified.

1. See point 4 of Article 11.4.21.
2. See point 3 of Article 11.4.21.
3. See point 2 of Article 11.4.21.
4. See point 1 of Article 11.4.2
APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF RISK STATUS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

- 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:

- The history of occurrence and management of BSE cases in the country or zone (Article 1.8.2.)
- Legislation (Article 1.8.3.)
- 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; herders; 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:

- Cattle.
- Ruminant-derived protein meal.
- Feed (not intended for pet except packaged and labelled pet food) that contains ruminant-derived protein meal.
- Fertilizers that contain ruminant-derived protein meal.
- 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 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 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 within the cattle population has been demonstrated to be negligible (i.e. to determine the period of time date to be attested in point 2 of accordance with Articles 11.4.6., 11.4.7., 11.4.9, 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 and, depending on the outcome of this step, an evaluation of the impact of specific mitigation measures on preventing cattle from being fed ruminant-derived protein meal.

- a) Livestock industry practices.

Because oral exposure to contaminated feed is the principal route of transmission of the BSE agents, the exposure assessment begins with a detailed description of the cattle population and associated industry practices, with a particular emphasis on feeding practices; disposal of dead stock animals and waste from slaughtered animals; rendering; and production, 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-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 fertilizers containing ruminant-derived protein meal, composted materials derived from fallen stock (i.e. cattle of any age which were found dead or were killed on a farm, during transportation, at livestock markets or auctions, or at a slaughterhouse/abattoir), slaughterhouse/abattoir waste or animals condemned at ante-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 fertilizers 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 mortem inspection and waste declared as unfit for human consumption from slaughtered animals are processed, disposed of or destroyed, including composting, burial, rendering, incineration or other industrial uses such as salvaging and crushing bones for use in animal feed. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

iv) Rendering practices.

Rendering is a process by which animal material is transformed into products such as protein meal that may be used in animal feed. It provides the pathway for the introduction of the BSE agents (classical or atypical) into the animal feed chain.

Describe whether or not there are any rendering facilities in the country or zone, if they are required to be registered or approved by the Veterinary Services or other Competent Authority and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Using tables as appropriate, for each of the preceding eight years, provide a breakdown of the number of rendering facilities operating, indicating for each facility:

- the source and types of raw materials handled;
- whether or not they receive and process material from a particular species or process mixed materials including those derived from ruminants;
- whether or not ruminant waste is segregated from non-ruminant waste and if so how segregation is maintained to avoid potential cross-contamination of non-ruminant rendered materials during processing, storage and transport of rendered products, for example through dedicated lines, storage bins or silos, transport vehicles or establishments;
- the parameters of the rendering process (time, temperature, pressure, etc.);
- the type and intended end use of the rendered products produced. If available, provide the amount of rendered products produced annually by type and intended end use;
- if materials derived from imported cattle are managed differently, describe the process.

Indicate if there are any industry associations or organisations involved in the rendering industry that provide guidance, set standards or provide third party audits in relation to Hazard Analysis and Critical Control Points (HACCP) programmes, good manufacturing practices, etc. Include a description of their role, membership and interaction with the Veterinary Services or other Competent Authority.

v) Feed production, labelling, distribution and storage.

Where rendered products are used as ingredients in the production of animal feed the exposure of cattle to the BSE agents (classical and atypical) may arise as a result of the use of rendered products containing materials of ruminant origin as ingredients in cattle feed or as a result of cattle feed being cross-contaminated when such products are used in the production of feed for other species.
Describe whether or not facilities producing feed for ruminant or non-ruminant livestock as well as 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-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 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 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 whether there is a ban on feeding ruminants with protein meal derived from ruminants.

Where a feed ban has been implemented, clearly and concisely describe the date it was introduced, its nature and scope and how it has evolved over time.

In addition, if the feed ban has been implemented through national legislation, provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

ii) Commodities with the greatest BSE infectivity.

Indicate whether or not any of those commodities listed in point 1 of Article 11.4.14. are removed from the carcass at the time of slaughter or subsequent fabrication or processing.
If so, also:

– Describe how they are disposed of or destroyed through burial, composting, rendering, alkaline hydrolysis, thermal hydrolysis, gasification, incineration, etc.

– Describe any measures in place that ensure slaughter waste declared as unfit for human consumption that is rendered is not cross-contaminated with these commodities.

– Describe whether these commodities from fallen stock and animals condemned at ante-mortem inspection are excluded from rendering and how this is done.

– Where these commodities are not excluded 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 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 and how 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-contaminated with rendered products containing ruminant material (excluding those listed in Article 11.4.1bis.). Provide information by year, by source (rendering facility, feed mill or farm), indicating the laboratory test(s) used and the results obtained;

the types of infractions (non-compliance) that occurred and corrective actions undertaken;

any infractions (non-compliance) that were likely to have led to cattle being exposed to feed contaminated with ruminant material (excluding those listed in Article 11.4.1bis) and how they were resolved.

vii) Conclusions for the evaluation of 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-contaminated by them, may have entered the animal feed chain;

the rendering industry and the associated likelihood that rendered products containing ruminant material may retain BSE infectivity;

the feed industry, and the associated likelihood that feed for cattle may contain or has been cross-contaminated with ruminant-derived protein meal.

Given the evaluation of BSE-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.

3.4 Consequence assessment

While uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated feed, it is reasonable to assume for the purposes of a consequence assessment, that the likelihood of cattle becoming infected would be similar to that for classical BSE.

As described in Article 11.4.2., a consequence assessment evaluates the likelihood of cattle becoming infected following exposure to the BSE agents (classical or atypical) together with the likely extent and duration of any subsequent recycling and amplification.

For the purposes of undertaking a consequence assessment for the evaluation of BSE risk status, the period of interest is the preceding eight years.

Considering that, for all practical purposes, oral exposure to contaminated feed is the principal, if not the only, route of transmission of the BSE agents, to initiate a cycle of BSE infectivity within a cattle population the following series of events would need to unfold:

commodities listed in point 1 of Article 11.4.14 from an infected animal are included in raw materials that are rendered into ruminant-derived protein meal;

the rendering process does not destroy infectivity of the BSE agent(s);

the ruminant-derived protein meal is incorporated as an ingredient in cattle feed, or cattle feed is cross-contaminated during feed production, distribution and storage, or cattle are incorrectly fed with feed intended for non-ruminant species that includes the ruminant-derived protein meal as an ingredient;
Annex 15 (contd)

- one or more animals that ingest contaminated feed become infected;
- the infected animal survives long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those commodities listed in point 1 of Article 11.4.14. would begin to rise dramatically;
- commodities listed in point 1 of Article 11.4.14. are then included in raw materials that are rendered into ruminant-derived protein meal, completing one cycle.

Recycling arises when this cycle is repeated one or more times. Any level of recycling within a given period is sufficient to conclude that the consequences of exposure to contaminated feed for that period within the cattle population are non-negligible.

a) Factors to consider when evaluating the likely extent of recycling of the BSE agents within a cattle population:

i) Age at exposure.

Animals less than 12 months of age are considered to be much more susceptible to infection than older animals, which are likely to be increasingly refractory to infection as they mature.

ii) Production type.

- Calves reared as replacement animals for the breeding herd.
  Cattle exposed to BSE agents at less than 12 months of age and destined to enter the breeding herd are much more likely to become infected and survive long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those commodities listed in point 1 of Article 11.4.14. would begin to rise dramatically. If these materials were rendered and subsequently contaminated cattle feed, it is highly likely that some level of recycling would occur.

- Feedlot cattle.
  Even if cattle reared in a feedlot that were destined to be slaughtered within the next two to six months were to become infected after consuming contaminated feed, the likelihood that they would have reached the later stages of a protracted incubation period (when the levels of the BSE agent in those commodities listed in point 1 of Article 11.4.14. would begin to rise dramatically) would essentially be negligible.

  Considering that mature cattle are likely to be much more refractory to infection than animals within their first year of life, even if they were to consume contaminated feed, it is highly unlikely that those commodities listed in point 1 of Article 11.4.14. would pose a threat if they were rendered and subsequently contaminated cattle feed.

iii) The impact of livestock industry practices or the implementation of measures under a feed ban.

When evaluating the potential for the recycling of the BSE agents 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-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?
4.2 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 recycled 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 from which it can be considered that the risk of BSE agents being recycled within the cattle population has been negligible. Provide explanations and clearly describe the rationale leading to the conclusions reached.

- Article 1.8.6.

BSE 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.

1.2 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 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.
Annex 15 (contd)

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, herdsman, 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)2, 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)2.

4. Evaluation procedures and protocols to identify and report potential candidateanimals 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>
<thead>
<tr>
<th>Year: _____</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Clinical presentation (see point 2 of Article 11.4.18.)</th>
<th>Number of reported animals</th>
<th>Number of animals subjected to BSE testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Cattle displaying progressive behavioural or neurological signs suggestive of BSE that are refractory to treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(B) Cattle showing behavioural or neurological signs that did not pass the ante-mortem inspection at slaughterhouses/abattoirs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(C) Cattle presented as downers (non-ambulatory) with an appropriate supporting clinical history</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(D) Cattle found dead (fallen stock) with an appropriate supporting clinical history</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5.) Animals subjected to laboratory testing

- 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>
<thead>
<tr>
<th>Year notified</th>
<th>Laboratory identification number or individual identification number</th>
<th>Age (in months) at the time of first detection</th>
<th>Type of production system (dairy, beef, mixed, etc.)</th>
<th>Description of observed clinical signs</th>
<th>Clinical presentation (A, B, C or D)</th>
<th>Final diagnosis (if BSE, specify the strain)</th>
<th>For a BSE case, indicate the origin (indigenous or imported; if imported, indicate the country of birth)</th>
</tr>
</thead>
</table>

- 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

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 (Camelus dromedarius and C. bactrianus) and some wild ruminants.

Infection with Theileria can give rise to disease of variable severity and to transmission. 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 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 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 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;
Annex 16 (contd)

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 establishment where no case of infection with *Theileria* has occurred during the preceding two years;
3) were treated with a registered acaricide, the efficacy of which has been confirmed in relation to the area of origin of the animals, at the entrance time of entry into 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 entry and at least 25 days after entry into 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 (Na₂CO₃); or

3) dried for a period of at least 42 days at a temperature of at least 20°C; or

4) frozen to at least -20°C for at least 48 hours.

Article 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’

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.