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Organisation Mondiale de la Santé Animale | World Organisation for Animal Health | Mundial de Sanidad Animal

Annex 1

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MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION
Paris, 2–11 February 2021

PART B – Code Commission's work programme and texts circulated for comments

EU comment

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

A number of general comments on this part B of the report of the February 2021 meeting of the Code Commission are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report.

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

The OIE Terrestrial Animal Health Standards Commission (the Code Commission) held its meeting electronically from 2 to 11 February 2021. The list of participants is attached as **Annex 1**.

To facilitate the virtual 88th Annual General Session, the February 2021 meeting report of the Code Commission is being distributed in two parts: **Part A** (available on the OIE website) provides information about the new and revised texts of the *Terrestrial Code* that will be proposed for adoption at the 88th General Session; and **Part B** (herewith) provides information about other topics discussed at the Commission's February 2021 meeting including texts circulated for comments and information.

The Code Commission thanked the following Members for providing comments: Argentina, Australia, Armenia, Belize, Brazil, Canada, Chile, China (People's Republic of), Chinese Taipei, Colombia, Cuba, Dominican Republic, Ecuador, Japan, New Caledonia, New Zealand, Norway, Peru, Saudi Arabia, Singapore, Switzerland, Thailand, the United Kingdom (UK), the United States of America (USA), Zimbabwe, Members of the OIE Americas region, the Member States of 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 International Coalition for Farm Animal Welfare (ICFAW), the International Egg Commission (IEC), the World Renderers Organization (WRO), as well as various experts of the OIE scientific network.

The Code Commission reviewed the Member comments that were submitted on time and supported by a rationale, and amended relevant texts, as appropriate. The Commission did not consider comments where a rationale had not been provided or that were unclear and difficult to interpret. Due to the large volume of work, the Commission was not able to draft a detailed explanation for the reasons for accepting or not each of the comments received, and focused its explanations on the major comments. 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 amendments are presented in the usual manner by 'double underline' and '~~strikethrough~~', and are annexed to this report. In **Annexes 4, 5, 6 and 7** amendments proposed at this meeting are highlighted with a coloured background to distinguish them from those proposed previously.

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, 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 Scientific Commission's, Biological Standards Commission's, Working Group's or *ad hoc* Group's reports 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.

The reports of meetings of *ad hoc* Groups and other related documents are attached for information (**Annex 10)**.

All comments on relevant texts in this **Part B** must reach OIE Headquarters **by 9 July 2021** for them to be considered by the Code Commission at its September 2021 meeting. Comments received after the due date will not be submitted to the Commission for its consideration. In addition, the Commission would like to highlight that comments should be submitted through the OIE Delegate of Member Countries or organisations which the OIE has a Cooperative Agreement with.

All comments and related documents should be sent by email to the OIE Standards Department at **TCC.Secretariat@oie.int.**

The Code Commission again strongly encourages Members to participate in the development of the OIE's international standards by submitting comments on this report. Members are also reminded that comments should be submitted as Word files rather than pdf files because pdf files are difficult to incorporate into the working documents of the Commission. Comments should be submitted as specific proposed text changes, supported by a structured rationale or by published scientific references. Proposed deletions should be shown using '~~strikethrough~~' and additions using 'double underline'. Members should not use the automatic 'track-changes' function provided by word processing software as such changes are lost in the process of collating submissions into the Commission's working documents. Members are also requested **not** to reproduce the full text of a chapter as this makes it easy to miss comments while preparing the working documents.

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1. Introduction

The proposed agenda for the meeting 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**.

2. Cooperation with other Specialist Commissions

2.1. Scientific Commission

The opinion of the Scientific Commission was sought for relevant Member comments received. The Code Commission wished to thank the Scientific Commission for this collaborative work. Consideration of the Scientific Commission's inputs is noted under the relevant agenda items.

At this February 2021 meeting, the Bureaus (i.e. the President and two Vice-Presidents) of the Code Commission and the Scientific Commission held a meeting chaired by Dr Matthew Stone. The purpose of the meeting was to provide an occasion where the two Bureaus could be informed about the planning and coordination of relevant topics of common interest and, where necessary, prioritise them and agree on the process to manage these topics. This meeting also allowed for better alignment of relevant items on the work programmes and agendas of both Commissions.

At this Bureaus meeting, the Bureaus of the Code Commission and the Scientific Commission agreed on the approach for the following:

- Ongoing revision of Chapter 8.8, Infection with foot and mouth disease virus, (see Item 3.1.5)
- Revision of Chapter 8.15, Infection with Rift Valley fever virus, (see Item 3.1.8)
- Work on Surra and Dourine (see Item 3.1.15)
- Removal of questionnaires related to official recognition of disease status and endorsement of official control programmes from the *Terrestrial Code* and to maintain them on the OIE website (see Item 3.1.17).
- Development of case definitions for OIE listed diseases of terrestrial animals.

The Bureaus also discussed the status of the assessment on the listing/delisting of pathogenic agents currently being undertaken by the Scientific Commission for *Mycobacterium tuberculosis*, infestation of honey bees with *Acarapis woodi*, infestation of honey bees with *Tropilaelaps* spp., and to update the nomenclature and possibly expand the scope of the pathogenic agents for haemorrhagic septicaemia; and agreed that the Scientific Commission will consider the assessments for pathogenic agents previously identified for assessment in the Code Commission's work programme (i.e. West Nile fever and paratuberculosis). The Bureaus also discussed aspects related to 'temporality' in relation to 'containment zone' and 'protection zone' (see Articles 4.4.6 and 4.4.7 sent in part A of the report).

The OIE Secretariat also updated the Bureaus on an application received for an OIE Collaborating Centre for 'The Economics of Animal Health – Europe Region'.

2.2. Biological Standards Commission

The OIE Secretariat provided a brief update to the Code Commission on relevant activities of the Biological Standards Commission, including chapters in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *Terrestrial Manual*) that are being revised as well as other items of interest.

The Code Commission wished to highlight that taxonomy changes for Newcastle disease and contagious bovine pleuropneumonia would be addressed in the *Terrestrial Animal Health Code (Terrestrial Code)* once the corresponding changes in the *Terrestrial Manual* have been adopted.

The Code Commission requested the OIE Secretariat to organise a joint discussion with the Biological Standards Commission after its February 2021 meeting to facilitate a discussion on items of mutual interest.

2.3. Aquatic Animal Health Standards Commission (Aquatic Animals Commission)

The Code Commission discussed with the OIE Secretariat the need to coordinate its revision of the glossary definitions for Competent Authority, Veterinary Authority and Veterinary Services in the *Terrestrial Code* with the Aquatic Animals Commission's parallel work to revise these definitions in the glossary of the *Aquatic Animal Health Code* (the *Aquatic Code).*

The Code Commission emphasised the importance of working with the Aquatic Animals Commission to ensure alignment of these definitions in both Codes, except where differences can be justified.

Refer to item 3.1.2 for the Commission's discussion on the revision of the Glossary definitions for Competent Authority, Veterinary Authority and Veterinary Service.

3. Code Commission's work programme not including texts circulated for comments

Comments were received from Australia, New Caledonia, Switzerland, the USA, the EU, and the OIE Americas Region.

The Code Commission discussed ongoing priority topics on its work programme and considered comments and new requests received. The Commission thanked Members for general comments received and noted that specific contributions referring to ongoing topics not discussed in this meeting would be considered when the relevant discussion takes place. The Commission noted that in general, few Members submit comments on the work programme, which outlines the work areas, current and planned, to be undertaken by the Commission. The Commission strongly encouraged Members to provide feedback as to whether they agree with the topics being proposed, as well as their level of prioritisation.

In response to a comment to prioritize the revision of Chapter 8.4, Infection with *Brucella abortus, B. melitensis* and *B. suis,* notably the provisions on country or zone free from infection with *Brucella* in bovids with vaccination and without vaccination, the Code Commission noted that the Biological Standards Commission is currently working to update the relevant *Manual* chapter and agreed to wait until that work progressed to consider starting new work on this chapter.

In response to a comment to prioritize the revision of Chapter 8.11, Infection with *Mycobacterium Tuberculosis* complex, notably the provisions on country or zone free from infection with *M. tuberculosis* complex in bovids, the Code Commission noted that several discussions were currently ongoing at the Scientific Commission and the Biological Standards Commission in relation to this disease and agreed to wait until those works progressed to consider starting new work on this chapter.

In response to a comment to prioritize the revision of Chapter 14.8, Scrapie, notably the provisions on country or zone free from Scrapie, the Code Commission noted that this chapter was included in its work programme long time ago, and some issues were still pending expert advice. The Commission requested the OIE Secretariat to report back to the Commission on the status of those points at its next meeting to consider the prioritisation of this item.

3.1. Ongoing priority topics (not by order of priority)

The OIE Secretariat updated the Code Commission regarding the progress of a number of ongoing priority topics that were discussed in previous meetings and for which no new or revised text was reviewed at this meeting. The Commission noted that some topics that were included in previous reports but for which there has been no significant progress will be considered by the Commission at future meetings as they continue being part of the Commission's work programme.

3.1.1. Terminology:

a) Definition of 'swill'

Background

At its September 2019 meeting, the Code Commission agreed that the term 'swill' should be defined and added it to its work programme. The Commission had requested the OIE

Secretariat to seek the opinion of the *ad hoc* Group on African swine fever compartmentalisation on this issue.

During the *ad hoc* Group on African swine fever compartmentalisation, relevant information was gathered from the members of the *ad hoc* Group. This information highlighted that there are significant differences in the scope and definition for the term 'swill' amongst countries, and in the terminology used in national legislative texts. Noting these differences, the Code Commission considered that more precise scoping would be required to create a definition and requested the OIE Secretariat and the Commission member leading this work to continue working on this matter and report back on the progress.

Update

The Code Commission member leading this work and the OIE Secretariat updated the Commission on the progress made. The Commission noted that this work should be addressed by considering not only relevant disease-specific chapters of the *Terrestrial Code* but also Chapter 6.4, The control of hazards of animal health and public health importance in animal feed. The Commission noted also that there are some difficulties to have a clear or precise equivalent term in French and Spanish, and acknowledged that the complexities of the topic would probably not be solved by developing a single definition and requested that this work be addressed in conjunction with the work on a new chapter on biosecurity which is in its work programme (See Item 3.3).

b) Use of terms 'sanitary measure' and 'biosecurity' in the *Terrestrial Code*

Background

Following the adoption of the revised Glossary definition for 'sanitary measure' at the 87th General Session in 2019, a Member commented that there were discrepancies in the use of the term 'sanitary measure' and 'biosecurity' in the *Terrestrial Code*. At its September 2019 meeting, the Code Commission requested the OIE Secretariat to review the use of these terms and to provide an update.

Update

The Code Commission was informed that a Commission member together with the OIE Secretariat had reviewed the use of these terms throughout the *Terrestrial Code* to check for discrepancies in their use and prepared a document noting where in the *Terrestrial Code* the terms 'sanitary measure' and 'biosecurity' should be reviewed. Due to time constraints, the Commission agreed to submit its comments on the working document to the OIE Secretariat electronically, and to further discuss this item at its next meeting.

3.1.2. Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'

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

Background

In September 2018, 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 the feedback from the *ad hoc* Group that revised the PVS Tool in 2018. The Commission proposed amendments to these definitions (in parallel of Aquatic Animals Commission proposed amendments to related definitions in the *Aquatic Code*), and the revised definitions were circulated for comments in the report of its September 2018 meeting. At its February 2019 meeting, the Commission requested that the *ad hoc* Group on Veterinary Services review these comments and propose amendments as appropriate.

The *ad hoc* Group proposed new amendments, and those amended definitions were further revised by the Code Commission, the Scientific Commission and the Biological Standards Commission in September 2019, as well as by an internal OIE Headquarters Group that considered possible impacts on different OIE activities such as the OIE PVS Pathway. The revised glossary definitions were circulated for comments for the first time in the Code Commission September 2020 report.

Given the importance of aligning these definitions, as appropriate, in the *Aquatic* and *Terrestrial Codes,* the Code Commission and the Aquatic Animals Commission agreed to discuss respective proposed amendments to ensure alignment, where relevant.

Discussion

The Code Commission reviewed the comments received on the annex circulated in the Commission's September 2020 report, as well as those received by the Aquatic Animals Commission on its proposed amendments, and acknowledged that diverging views were expressed. The Commission reminded Members that these Glossary definitions are intended to provide a common understanding for the use of these terms in the context of the Codes. They are not intended to describe a hierarchy or prescribe a specific administrative organisation of a Member's governance, especially the differences between various competent authorities and veterinary organisations. The Commission noted that some comments indicated that this was not clearly understood by all Members. In addition, the Commission noted that some Members requested a lot of details to be included in these definitions that were already provided in other horizontal chapters, notably in Sections 3, 4, 5 and 6 of the Codes.

The Commission agreed that given that some of the comments had implications for the use of these terms outside the Codes, this issue needed to be discussed among a wider group of participants than the Code Commission and Aquatic Animals Commission. The Commission suggested that a working group be convened including the Presidents of the Code Commission and Aquatic Animals Commission, as well as the OIE Deputy Director General (International Standards and Science). The Commission agreed to consider comments received once the conclusions of the working group are available.

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

Background

At its February 2019 meeting, the Code Commission considered a comment requesting to review Chapter 6.10, Responsible and prudent use of antimicrobial agents in veterinary medicine, and noted that the adoption in 2018 of some revised definitions in Chapter 6.9, Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals, could have an impact on Chapter 6.10. Consequently, given that this chapter has not been significantly reviewed for some time, the Commission agreed to include it in its work programme. The Commission had requested the advice of the OIE Working Group on Antimicrobial Resistance, which met in October 2019. The Working Group recommended that amendments to Chapter 6.10 not be undertaken until work of the Codex Alimentarius Task Force on Antimicrobial Resistance (TFAMR) had progressed, in order to avoid duplication and inconsistencies.

Update

The OIE Secretariat informed the Code Commission that the proposed draft revision of the Codex Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005) is on an advanced stage of discussion, having being preliminarily adopted in November 2020 at Step 5 of the 8 step procedure established by that Organisation.

The Code Commission requested that the OIE Working Group on Antimicrobial Resistance be asked to provide their views on some aspects of the request, including expanding the scope of the chapter to non-food producing animals, and the best way to advance this work and to

designate the main areas of the chapter that would benefit from an update at its upcoming meeting. The Commission requested the OIE Secretariat to report back on the progress at the next Commission meeting.

3.1.4. Stray dog population control (Chapter 7.7)

Comments received from Australia, Canada, New Caledonia, Norway, Singapore, Switzerland, the UK, Zimbabwe, the EU, the AU-IBAR and the ICFAW.

Background

In September 2018, the Code Commission agreed to revise Chapter 7.7, Stray dog population control, to ensure it was aligned with the OIE Global Strategy to end human death due to dog-mediated rabies by 2030. An *ad hoc* Group on the Revision of Chapter 7.7, Stray dog population control, was first convened in November 2019 to review current recommendations that address the monitoring and evaluation of stray dog control schemes and responsible dog ownership, considering both rabies control and animal welfare aspects. The *ad hoc* Group also discussed additional recommendations that could support the Global Strategy and revised the chapter structure.

At its February 2020 meeting, the Code Commission reviewed the report of the *ad hoc* Group and requested that the *ad hoc* Group be reconvened to continue its work, taking into consideration the Commission's feedback. The *ad hoc* Group met several times via video conference between April and July 2020 to continue its work to revise the chapter. The Commission considered the second *ad hoc* Group report and circulated in its September 2020 report, for the first time, a revised Chapter 7.7, renamed as 'Dog population management', for Member comments.

Discussion

The Code Commission reviewed the comments received on the revised chapter circulated in its September 2020 report and requested that the *ad hoc* Group be reconvened to consider them and amend the text as appropriate. The Commission asked that the *ad hoc* Group finalise its report prior to the Commission's next meeting in September 2021.

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

Comments were received from Australia, Brazil, Canada, Chinese Taipei, Japan, New Caledonia, New Zealand, Switzerland, Thailand, the USA, Zimbabwe, the EU, the AU-IBAR, and the Members of the OIE Americas Region.

Background

At its September 2020 meeting, the Code Commission considered comments received on the version circulated for comment in its February 2017 report, as well as amendments proposed by the *ad hoc* Group on Alternatives for surveillance for demonstration of freedom from foot and mouth disease (FMD), and the Scientific Commission's opinion on selected comments. The revised chapter has been circulated three times, the last time in the Code Commission's September 2020 report.

At its September 2020 meeting, the Code Commission noted requests seeking clarification for the term 'bovine', and to review the use of the terms 'case', 'transmission', 'case with clinical signs' and 'infection' in the chapter. It was agreed that a joint taskforce with selected members from the Code Commission and Scientific Commission would be convened to consider these requests, and its recommendations will be considered by the Scientific Commission at its February 2021 meeting.

Discussion

The Code Commission acknowledged the comments received, but noted that as it was awaiting the opinion of the Scientific Commission for some points, including the recommendations of the joint taskforce, harmonisation of text relating to status recognition for alignment with Chapters 14.7, Infection with peste des petits ruminants virus, and 15.2, Infection with classical

swine fever virus, it agreed to defer its discussion of Chapter 8.8 until its September 2021 meeting.

The Code Commission also noted that at its September 2021 meeting, it will also consider the recommendations of the *ad hoc* Group on Foot and mouth disease virus that met between July – August 2020 that were endorsed by the Scientific Commission in September 2020.

3.1.6. Infection with *Mycobacterium tuberculosis* complex (Chapter 8.11)

Background

At its February 2020 meeting, the Code Commission had invited Members to provide any new scientific evidence to the OIE regarding the possibility and impact of transmission of *Mycobacterium tuberculosis* from animals to humans or other animals, to inform its decision as to whether or not *M. tuberculosis* should be listed.

At its September 2020 meeting, the Code Commission noted that a Member had provided some scientific evidence, which was referred to the Scientific Commission for consideration.

Update

The Code Commission was informed by the OIE Secretariat that the Scientific Commission had requested to obtain the views of the *ad hoc* Group on tuberculosis on the scientific evidence provided by the Member regarding the listing of *M. tuberculosis.* It agreed to defer its discussion on Chapter 8.11 until its September 2021 meeting, pending the opinion of the Scientific Commission.

3.1.7. Infection with rabies virus (Chapter 8.14)

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

Background

The last revised version of Chapter 8.14, Infection with rabies virus, was adopted in 2019. At the time of adoption, the President of the Code Commission noted that there had not been sufficient time to address some pending work because of the importance of adopting amendments to this chapter to support the global strategic plan to end human deaths from dog-mediated rabies by 2030 (i.e. the Zero by 30 initiative).

These pending issues concerned the provisions for vaccination, testing and shipment of animals (in Article 8.14.7) and the provisions on the risk mitigation measures for the importation of mammals outside of the Orders *Carnivora* and *Chiroptera* (in Articles 8.14.8 and 8.14.10). In addition, the Code Commission and the Scientific Commission had agreed to seek advice from the Working Group on Wildlife on the relevance of including specific provisions on the control of rabies in wildlife, including oral vaccination.

At its September 2020 meeting, the Code Commission considered the advice of the *ad hoc* Group on Rabies (October 2019) and the Scientific Commission (February 2020), and agreed to add a new Article 8.14.6bis on recommendations for the importation of dogs from countries or zones infected with rabies virus, and amend the title of Article 8.14.7. The Commission also agreed with a proposal by the *ad hoc* Group on the Revision of Chapter 7.7, Stray dog population control, to include a new article to provide recommendations for the implementation of a rabies vaccination programme for dogs, and requested the opinion of the Scientific Commission before proposing these amendments. The Commission also requested the OIE Secretariat to review any other pending issues and present these to the Commission at its February 2021 meeting so these can also be taken into consideration as part of this revision.

Discussion

The Code Commission considered the comments received on the new Article 8.14.6bis and the revised Article 8.14.7. The Commission agreed that given several comments referred to the rationale provided by the *ad hoc* Group on Rabies, it would request the advice of the Scientific Commission before addressing these further.

The Code Commission reviewed a background document prepared by the OIE Secretariat on the pending issue regarding the provisions on the risk mitigation measures for the importation of mammals other than dogs, cats, ferrets and laboratory animals from countries or zones infected with rabies virus (in Articles 8.14.8 to 8.14.10). The Commission noted the recommendation of the Scientific Commission (reported in its September 2018 report) and, considering the limitation of serological tests for species other than dogs and cats, the low risk of rabies transmission posed by non-carnivorous mammals, and noting that the aim of the chapter is to mitigate public and animal health risk posed by rabies, the Commission agreed not to amend articles 8.14.8 to 8.14.10 until new scientific evidence is available.

The Code Commission thanked the OIE Wildlife Working Group for their advice on the need to provide specific recommendations for the control of rabies in wildlife within this chapter. The Working Group's consensus was that there should be specific recommendations for the control of rabies in wildlife because it is an important issue relevant to public health, domestic animal health, wildlife health, animal trade, and wildlife conservation. The Working Group noted that while the significance of rabies in wildlife and the risk of human infections varies geographically, the risk to the health of domestic animals and wild animals also varies between countries depending on the level of effective control of rabies in domestic dogs, but the control of rabies in wildlife should be considered as this is an important step in the control of this disease in many countries.

Considering the need to progress the different issues under consideration for this revision, namely:

- the advice of the Scientific Commission on comments received on the rationale for the new Article 8.14.6bis and revised Article 8.14.7,
- the advice of the Scientific Commission on draft article on guidance for the implementation of rabies vaccination programmes in dogs, and
- the expert advice on draft recommendations for the control of rabies in wildlife,

the Code Commission agreed not to circulate the new Article 8.14.6bis and the revised Article 8.14.7 but rather requested the OIE Secretariat to collate all proposed amendments, in consultation with relevant experts, for the Commission's consideration at its September 2021 meeting.

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

Background

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

At its September 2020 meeting, the Code Commission acknowledged comments received and agreed to defer its discussion until it had received the Scientific Commission's opinion on selected comments.

Update

The OIE Secretariat informed the Code Commission that an *ad hoc* Group on Rift Valley fever would be convened to develop guidance for RVF surveillance during epizootic and inter-

epizootic periods, as well as the consideration of other issues such as the development of provisions for the recovery of freedom in a country or zone previously free from RVF. The Commission agreed with the Terms of Reference of the *ad hoc* Group and provided its feedback on proposed participants for the group.

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

Background

In February 2020, the Code Commission considered a request of the World Health Organization (WHO) to update Chapter 8.5, Infection with *Echinococcus granulosus*, and Chapter 15.4, Infection with *Taenia solium* (Porcine cysticercosis), as well as the corresponding chapters in the *Terrestrial Manual*, in view of recent developments in the area of vaccines and vaccination.

The Code Commission acknowledged the request and decided to wait for the opinion of the Biological Standards Commission before considering the inclusion of these topics in its work programme. In its September 2020 meeting, the Code Commission noted the amendments being proposed in the relevant chapters of the *Terrestrial Manual* and requested the OIE Secretariat to prepare amended versions of Chapters 8.5 and 15.4, for its consideration at its February 2021 meeting, taking into consideration the changes included in the *Terrestrial Manual*, and in consultation with relevant experts, if necessary.

Update

The OIE Secretariat updated the Code Commission that an electronic consultation had been conducted with some members of the *ad hoc* Group on Porcine Cysticercosis who had developed the revised draft chapter back in 2015, to draft proposed modifications to these articles, based on the modifications included in the *Terrestrial Manual*.

The Code Commission reviewed the proposed amendments to Chapters 8.5 and 15.4 and agreed to defer its discussion until its September 2021 meeting, given that time constraints did not allow for a detailed discussion.

3.1.10. Theileriosis (Chapters 11.10)

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

Background

The revised Chapter 11.10, Infection with *Theileria annulata*, *T. orientalis* and *T. parva*, and the 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. 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 *Theileria lestoquardi*, *T. luwenshuni*, *T. uilenbergi* and *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 meeting report). Given that these pathogenic agents were found to meet the criteria for listing, the Code Commission agreed to recommence work on these revised chapters.

At its September 2020 meeting, the Code Commission considered past comments on the revised Chapter 11.10, Infection with *Theileria annulata*, *T. orientalis* and *T. parva*, and circulated the revised Chapter 11.10 for comments. With regards to the new Chapter 14.X, Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi*, the Commission noted

that there were no recommendations for diagnostic tests for these pathogenic agents in the *Terrestrial Manual*. As this would impact the case definition and appropriate diagnostic tests to be recommended in the chapter, the Code Commission agreed not to progress further work on this chapter until the Biological Standards Commission progresses work on this aspect in the *Terrestrial Manual*.

Discussion

The Code Commission considered the comments received on revised Chapter 11.10, Infection with *Theileria annulata*, *T. orientalis* and *T. parva*, and deferred its discussion until its September 2021 meeting given that time constraints did not allow for a detailed discussion. The Code Commission acknowledged that selected comments had been sent to the Scientific Commission for its advice and noted that these would also be considered at its September 2021 meeting.

The Code Commission noted that the Biological Standards Commission, in its September 2020 report, had included Theileriosis in sheep and goats (infection with *Theileria lestoquardi, T. luwenshuni* and *T. uilenbergi*) in the list of chapters to be updated in the 2021/2022 review cycle. The Commission requested the OIE Secretariat to follow up on this work and report back to the Commission once that revision has progressed.

3.1.11. Trichomonosis (Chapter 11.11)

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

Background

At its September 2021 meeting, the Code Commission reviewed Articles 11.11.2, 11.11.3 and 11.11.4, following a request for clarification on the appropriate tests for the importation of bulls, given that the recommendations in this chapter differed from the corresponding *Terrestrial Manual* Chapter 3.4.15, Trichomonosis. The Code Commission had amended Articles 11.11.2, 11.11.3 and 11.11.4 based on the advice of the Reference Laboratory experts for Trichomonosis and had circulated the revised articles for comment.

Update

The Code Commission reviewed the comments received on Articles 11.11.2, 11.11.3 and 11.11.4 of Chapter 11.11, Trichomonosis, and agreed to defer its discussion until its September 2021 meeting, given that time constraints did not allow for a detailed discussion.

3.1.12. Contagious equine metritis (Chapter 12.2)

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

Background

At its February 2019 meeting, the Code Commission agreed to amend Chapter 12.2, Contagious equine metritis, to include requirements for the temporary movement of horses. In addition, given that this chapter had not been reviewed for some time, the Commission requested a comprehensive revision be undertaken. A revised draft chapter was prepared by an electronic expert consultation in 2019 and endorsed by the Scientific Commission in February 2020.

At its September 2020 meeting, the Code Commission considered the revised draft and made additional amendments, and circulated the revised chapter for comments.

Discussion

The Code Commission reviewed the comments received on the revised Chapter 12.2, Contagious equine metritis, and agreed to defer its discussion until its September 2021 meeting, given that time constraints did not allow for a detailed discussion. The Commission acknowledged that selected comments had been sent to the Scientific Commission and the Biological Standards Commission for their advice and noted that these will be considered when responding to the other comments received.

3.1.13. Infection with equine influenza virus (Article 12.6.6)

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

Background

At its February 2019 meeting, the Code Commission had proposed amendments to Article 12.6.6 based on the outcomes of work to evaluate equine influenza vaccination protocols prior to shipment of horses coordinated by an OIE Reference Laboratory for equine influenza. The revised article has been circulated four times for comments, most recently in the Code Commission's September 2020 report.

Discussion

The Commission noted that as part of the ongoing work to develop new or review existing case definitions for OIE listed diseases of terrestrial animals, the Scientific Commission considered a new draft case definition for equine influenza at its February 2021 meeting.

The Code Commission reviewed the comments received on the revised Article 12.6.6 and, noting that the proposal to revise the case definition may require other amendments to the chapter, agreed to defer its discussion until its September 2021 meeting.

3.1.14. Equine piroplasmosis (Chapter 12.7)

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

Background

At its February 2019 meeting, the Code Commission agreed to amend Chapter 12.7, Equine piroplasmosis, to include requirements for the temporary movement of horses. In addition, given that this chapter had not been reviewed for some time, the Commission requested a comprehensive revision be undertaken. A draft revised chapter was prepared by an electronic expert consultation in 2019 and endorsed by the Scientific Commission in February 2020.

At its September 2020 meeting, the Code Commission reviewed the revised draft and made additional amendments, and circulated the revised chapter for comments.

Discussion

The Code Commission reviewed the comments received on the revised Chapter 12.7, Equine piroplasmosis, and agreed to defer its discussion until its September 2021 meeting, given that time constraints did not allow for a detailed discussion. The Commission acknowledged that selected comments had been sent to the Scientific Commission and the Biological Standards Commission for their advice, and noted that these will be considered when responding to the other comments received.

3.1.15. Surra and dourine

Background

The Code Commission and the Scientific Commission had agreed that three separate chapters on animal trypanosomes with different coverage of trypanosomes species and host animals

would be developed. In addition to the development of a new draft Chapter 8.Y, Infection with animal trypanosomes of African origin, (refer to Part A of this report), a draft new Chapter 8.X, Surra, and a revised Chapter 12.3, Dourine, had been proposed and extensively discussed since 2015, in particular their respective coverage of susceptible species. Both Commissions had also agreed that notwithstanding the diagnostic issues, the scope of Chapter 8.X should address surra of multiple species including horses and that the scope of Chapter 12.3 should remain as dourine of equids.

In February 2018, both Commissions agreed to put Chapters 8.X and 12.3 on hold in light of the ongoing discussions related to Chapter 8.Y, Infection with animal trypanosomes of African origin.

Update

The Code Commission was informed that OIE experts had been consulted to develop case definitions for surra and dourine that would be considered by the Scientific Commission at its February 2021 meeting. It was also informed that an *ad hoc* Group would be convened to draft a new Chapter 8.X, Infection with *T. evansi* (surra), and amend Chapter 12.3, Infection with *T. equiperdum* (dourine). The Code Commission agreed with the Terms of Reference of the *ad hoc* Group and emphasised that the chapters should be developed in accordance with the agreed case definitions. The Commission also requested the *ad hoc* Group to consider relevant Member comments that were received in 2018.

3.1.16. Update on work of the *ad hoc* Group on the revision of *Terrestrial Code* chapters regarding the collection and processing of semen of animals

Background

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

Update

The OIE Secretariat updated the Code Commission that the *ad hoc* Group had met virtually on two occasions between November–December 2020 and would focus on Chapter 4.6 before starting any work for Chapter 4.7. The *ad hoc* Group had proposed a new draft structure for Chapter 4.6.

The Code Commission reviewed the *ad hoc* Group's report and commended the *ad hoc* Group for its work. The Commission agreed with the proposed draft structure for Chapter 4.6 and provided some further guidance on the holdings and species to be covered in the chapter.

The Code Commission requested that the *ad hoc* Group be reconvened to continue this important work and finalise its report prior to the next meeting of the Commission in September 2021.

3.1.17. Horizontal work related to official recognition of status by the OIE

a) Harmonisation plan for chapters with official recognition of status

Background

At its September 2018 meeting, the Code Commission agreed with the proposal presented by the OIE Secretariat, and endorsed by the Scientific Commission, to harmonise the requirements for official recognition and maintenance of free status, and endorsement and maintenance of official control programmes in Chapters 8.8, Infection with foot and mouth disease virus, 11.5, Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia), 12.1, Infection with African horse sickness virus, 14.7, Infection with peste des petits ruminants virus, and 15.2, Infection with classical swine fever virus. It was agreed that Chapter 14.7, Infection with peste des petits ruminants virus, would be used as the 'model chapter' to present the harmonisation work,

and based on the comments received on the 'model chapter' of PPR, changes would be similarly applied to Chapters 8.8, 11.5, 12.1 and 15.2.

Update

The Code Commission noted the revised timeline proposed by the OIE Secretariat for the harmonisation work to be undertaken, taking into account the postponement of the adoption of revised chapters due to the COVID-19 pandemic. The Commission noted that Chapters 14.7 and 15.2 would be proposed for adoption at the upcoming 88th General Session (refer to Part A of this report), and that work on revisions of Chapter 8.8 (see Item 3.3.5) is underway, and Chapters 11.5 and 12.1 are planned.

b) Plan for removing questionnaires from the Terrestrial Code

Background

At the meeting of the Bureaus of the Code Commission and the Scientific Commission in September 2019, both Commissions agreed on a plan and timeframe for the removal of the questionnaires for official recognition of animal health status and endorsement of official control programmes (Chapters 1.7 to 1.12) from the *Terrestrial Code* and to maintain them on the OIE website. This approach would be initiated by placing directly on the OIE website the questionnaire for endorsement of official control programmes for rabies.

Update

Considering the above mentioned work on the harmonisation of the provisions for the official recognition of animal health status, their maintenance and the provisions for the endorsement of official control programmes for contagious bovine pleuropneumonia, foot and mouth disease and peste des petits ruminants, as well as the ongoing revision of Chapter 11.4, Bovine spongiform encephalopathy, and Chapter 1.8, Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy (BSE questionnaire), (see Item 4.3), the Commission agreed to propose to remove all of the questionnaires at the same time, upon completion of the harmonisation work and adoption of revised Chapters 8.8, 11.4, 11.5, 12.1, 14.7 and 15.2.

In the revision of the disease-specific chapters, the Bureaus confirmed that the requirements that form the basis of the questionnaires – to declare a country or a zone free from infection, or as having a controlled or negligible BSE risk status – will be clearly captured in the respective disease-specific chapter before the questionnaires are removed from the *Terrestrial Code*, given that the questionnaires serve as a guidance for the implementation of the standards.

The Bureaus also noted that the mandatory use of questionnaires when applying for official recognition of animal health status or for OIE endorsement of official control programmes will be clearly referenced in Chapter 1.6 of the *Terrestrial Code*, as well as the relevant OIE Resolution and Standard Operating Procedures that describe the procedures for the official recognition and maintenance of animal health status.

3.1.18. Pet food

Background

At its February 2018 meeting, the Code Commission had considered a request from the Global Alliance of Pet Food Associations (GAPFA) to recommence work on the development of provisions for pet food. GAPFA had expressed willingness to provide relevant information on the treatment of ingredients used in the commercial production of pet food that might facilitate this work.

At its February 2019 meeting, the Code Commission was informed by the OIE Secretariat that GAPFA had commenced work to gather scientific information that could inform the assessment of pet food products against the criteria for assessing the safety of commodities in accordance with Chapter 2.2, Criteria applied by the OIE for assessing the safety of commodities, and would provide this information to the OIE once completed.

In 2020, GAPFA submitted its analysis for selected disease-specific chapters in the *Terrestrial Code* with the view to demonstrate that pet food could be considered as a safe commodity for trade based on Chapter 2.2. Owing to time and agenda constraints, these analyses were not considered by the Code Commission at its 2020 meetings.

Update

The Code Commission noted that GAPFA had provided a description of two pet food commodities and internationally standardised processes and treatments involved in their production to facilitate the assessment of these commodities as safe commodities.

The Code Commission thanked GAPFA for the information provided and nominated a Commission member to work with the OIE Secretariat to progress this work for further discussion at its next meeting on the approach to including these commodities in the articles on safe commodities of the various disease-specific chapters.

3.2. New proposals/requests

3.2.1. Safe commodities

The OIE Secretariat informed the Code Commission that it planned to develop an internal standard operating procedure to ensure a consistent process is applied when assessing commodities for inclusion in the lists of safe commodities in disease-specific chapters of the *Terrestrial Code*. The objective would be to define a step-by-step process that could be applied uniformly for assessing the safety of commodities against the criteria described in Chapter 2.2. The Secretariat also noted that the development of a SOP is in line with the OIE's work to ensure good regulatory practice across the organisation. The OIE Secretariat also proposed to maintain a common record of commodities assessed in the context of the *Terrestrial Code*, including information on standardised protocols.

The Code Commission supported this proposal and nominated a Commission member to work with the OIE Secretariat to progress this work, and to review progress at its next meeting.

3.2.2. Framework for *Terrestrial Code* standards

The OIE Secretariat proposed to the Code Commission that it planned to develop a framework for the development of disease-specific chapters of the *Terrestrial Code* that would define the structure and content of these chapters. Once agreed, this framework would be applied progressively to new chapters, as well as existing chapters when undergoing revision. Having a consistent approach to the structure and content of these chapters would improve the ability of Members to navigate the *Terrestrial Code*, especially given the importance of cross-referencing between chapters.

The Code Commission supported this proposal and agreed that this framework should also include a detailed description of agreed 'rules' and 'conventions' that should be used throughout the *Terrestrial Code*, based on previous decisions of the Commission. The Commission agreed that this would serve as a useful guide to ensure a consistent approach when undertaking work on the development or revision of a chapter. As there are differences in the objectives and structure of the chapters within Volume I and Volume II of the *Terrestrial Code*, and within the different sections of Volume I, the Commission requested the OIE Secretariat to begin by working on the content of disease-specific chapters, i.e. Volume II.

The Commission nominated a Commission member to work with the OIE Secretariat to progress this work, and to review progress at its next meeting.

3.2.3. Revision of Chapter 6.12, Zoonoses transmissible from non-human primates, to reflect that hepatitis B is a disease of humans

The Code Commission considered a proposal from the Scientific Commission to amend Chapter 6.12, Zoonoses transmissible from non-human primates, of the *Terrestrial Code*, in response to a request from the European Association of Zoos and Aquaria (EAZA) and following the advice of the OIE Working Group on Wildlife.

The Code Commission agreed to include this proposal in their work programme and discussed the revision of Chapter 6.12, Zoonoses transmissible from non-human primates, at this meeting (see item 4.4).

3.2.4. Transport of animals by land, sea and air (Chapters 7.2, 7.3 and 7.4)

The OIE Secretariat informed the Code Commission that during the 2019 OIE Global Animal Welfare Forum: 'Animal transport: a shared responsibility', it was agreed that there was a need to review the *Terrestrial Code* chapters on the welfare of animals during transport by land, sea and air (Chapters 7.2, 7.3 and 7.4), given that there have been significant developments in the animal welfare science, notably in the use of animal-based measures, since these chapters were last reviewed. The OIE Secretariat had developed a working document outlining the key aspects needing to be reviewed in light of scientific developments.

The Code Commission considered the working document and acknowledged the importance of ensuring that the OIE standards are up to date and fit for purpose. It agreed to include a review of these chapters on its work programme.

The Code Commission requested the OIE Secretariat to scope the work required to revise these chapters and to prepare a detailed work plan and report back to the Commission at its September 2021 meeting so the Commission can discuss how to prioritise this work amongst other items on its work plan.

3.3. Prioritisation of items in work programme

Based on a range of considerations and the progress of different topics discussed during this meeting (see sections 3 and 4 of this report) as well as the coordination with other Specialist Commissions (see section 2 of this report), the Code Commission updated its work programme and revised the order of items in each section to reflect the current level of prioritisation. In addition, the Commission decided to include the items presented below.

- Consideration of use of terms for animal-based measures/measurables
- Consideration of use of terms for enzootic/endemic/epizootic/epidemic
- Revision of Chapter 6.12, Zoonoses transmissible from non-human primates
- Development of new chapters on animal transport.

The updated work programme is presented as **Annex 3** for Member comments.

EU comment

The EU thanks the OIE and in general supports the revised work programme of the Code Commission.

Comments are inserted in the text of Annex 3.

4. Texts circulated for comments

4.1. Slaughter of animals (Chapter 7.5)

Background

The OIE *ad hoc* Group on the Revision of Chapter 7.5, Slaughter of animals, and Chapter 7.6, Killing of animals for disease control purposes, met in person in April 2018, November 2018, and June 2019, and several times via video conference between April 2020 and January 2021 to progress work on a comprehensive review of these chapters. The objective of this work was to review the structure of both chapters; address inconsistencies in the 'slaughter' and 'killing' methods described in these two chapters; and to ensure that the revised texts reflect current scientific knowledge.

At its February 2020 meeting, the Code Commission requested that the *ad hoc* Group be reconvened to address Member comments received on the new proposed structure for Chapter 7.5, and on the articles related to 'free-moving animals' arriving at the slaughterhouse that had been circulated in the Commission's September 2019 meeting report. The *ad hoc* Group was also requested to consider comments on the revised definitions related to this chapter and Chapter 7.6.

At its September 2020 meeting the Code Commission thanked the *ad hoc* Group for its commitment to addressing Member comments. The Commission agreed not to review the *ad hoc* Group's work at this meeting but rather requested that the *ad hoc* Group be reconvened to finalise the draft of articles related to animals arriving at the slaughterhouse in containers.

Discussion

The Code Commission was reminded that the *ad hoc* Group had already considered Member comments on articles related to 'free-moving animals' arriving at the slaughterhouse (as mentioned in the September 2020 report). The Commission was informed that the *ad hoc* Group worked electronically between September and November 2020 and met virtually in December 2020 and January 2021 to finalise the articles related to animals arriving at the slaughterhouse in containers. The Commission was also informed that the *ad hoc* Group did not progress the revision of the related definitions to Chapter 7.5 and Chapter 7.6 and had not yet started the revision of Chapter 7.6.

The Code Commission thanked the *ad hoc* Group for its commitment to progressing this work and agreed to present the revised Chapter 7.5, as proposed by the *ad hoc* Group, for Member comments. The Commission did not make any additional amendments.

The Code Commission also requested that the *ad hoc* Group be reconvened to finalise revisions of the definitions related to Chapter 7.5 and initiate the discussion on the revision of Chapter 7.6, and to propose options that include the animal welfare concept in the Glossary definition of 'hazard'. The Commission requested that this work be completed prior to its next meeting in September 2021.

The Code Commission encouraged Members to refer to the *ad hoc* Group report on the revision of Chapter 7.5, Slaughter of animals, and 7.6, Killing of animals for disease control purposes, for details about the *ad hoc* Group's considerations of comments received, including the rationale for changes made to the revised chapter that is being circulated for comment.

The report of the 2020 (April−July) virtual meeting of the OIE *ad hoc* Group on the Revision of Chapter 7.5., Slaughter of animals, and Chapter 7.6., Killing of animals for disease control purposes, is presented as **Annex 10** for information.

The revised version of Chapter 7.5, Slaughter of animals (renamed 'Animal welfare during slaughter'), is presented as **Annex 4** for Member comments.

EU comment

The EU thanks the OIE and supports the approach taken to revise this chapter. The EU welcomes this new version that included most of EU previous comments. The EU invites the OIE to consider some previous comments as well as new comments related to the new section on animals in containers, inserted in the text of Annex 4.

4.2. Infection with rinderpest virus (Chapter 8.16)

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

Background

At its September 2018 meeting, the Code Commission agreed to undertake a thorough review of Chapter 8.16, Infection with rinderpest virus, in response to Member requests and to update the chapter to better clarify the definitions of 'case' and 'suspected case', the reporting obligations of countries when a suspected case is detected, and measures to be taken should there be a re-emergence. In previous discussions, the Code Commission agreed with the Scientific Commission and OIE Headquarters that in this post-eradication era, the priority should be the maintenance of global freedom from rinderpest,

and its prompt recovery should there be a re-emergence. Both Commissions agreed that the structure of the chapter and trade provisions should be reviewed and revised to ensure they are aligned with this objective. To this end, both Commissions agreed to limit trade possibilities to commodities from free countries and to safe commodities.

An *ad hoc* Group on Rinderpest was convened in March 2020 to undertake this work and its report was considered by the Code Commission at its September 2020 meeting. The revised chapter was circulated for the first time for Member comments in the September 2020 report of the Commission.

Discussion

General comments

In response to comments that the proposed definitions and recovery periods in the revised Chapter 8.16 differed from those in the Global Rinderpest Action Plan (GRAP), the Code Commission clarified that the GRAP referred to the current *Terrestrial Code* chapter, and that it would be updated once the revised Chapter 8.16 has been adopted.

Article 8.16.1

In the second paragraph of point 1, in response to a comment requesting the inclusion of a footnote to the relevant OIE resolution stating that the manipulation of existing RPV-containing material, and synthesis or other forms of production of RPV-containing material is forbidden unless authorised by the FAO and OIE, the Code Commission requested the OIE Secretariat to look into how the reference could be presented in the *Terrestrial Code.*

In point 2(b)(iii), the Code Commission agreed with a comment to add 'that are not a consequence of *vaccination*' after 'antibodies', noting that this was consistent with other chapters in the *Terrestrial Code*, and although at this time all vaccinations against rinderpest are banned, this might be relevant in the event of re-emergence of rinderpest, if old animals that were previously vaccinated were still alive.

In point 2(c)(i), the Code Commission did not agree with a comment to un-italicise the word 'case', explaining that the word 'case' in 'potential case' refers to the Glossary definition of 'case', and hence an animal potentially infected with rinderpest. For consistency, the Commission proposed to italicise the word 'case' in 'potential case' and 'suspected case' throughout the text.

In point 2(c)(iii), the Code Commission agreed with a comment to add 'that are not a consequence of *vaccination*' after 'antibodies' for the same reason as given above.

Article 8.16.2bis

Noting a comment that the division of the revised chapter into two sections, one containing general provisions relevant in this era of global freedom, and another including provisions that would be relevant in the event of rinderpest re-emergence is not common practice in the *Terrestrial Code* and

could result in confusion, the Code Commission proposed to add new Article 8.16.2bis to clarify the provisions that would apply under each scenario and to delete text creating sections.

Article 8.16.3

In the third sentence of the first paragraph, the Code Commission agreed with a comment to add 'potential' before 'cases' for clarity.

In the last sentence of the second paragraph, the Code Commission agreed with a comment to include 'a case' of rinderpest.

Article 8.16.4

In the last sentence, the Code Commission agreed with a comment to add 'RPV-containing' before 'materials'. The Commission also proposed to add 'related' before 'activities' for clarity.

Article 8.16.5

In response to a comment requesting to add that immediate notification is to be done based on point 1 of Article 1.1.2 and to amend Article 1.3.1 to include 'suspected case of rinderpest' on the basis of legal certainty, the Code Commission noted that this was not in line with current *Terrestrial Code* convention and requested the OIE Secretariat to look into the legal obligation for notification and whether the text as written in the first two paragraphs of this article would be sufficient.

In the same two paragraphs, the Code Commission agreed with a comment to add 'of infection with RPV after 'suspected case' for clarity.

In the second sentence of the third paragraph, the Code Commission agreed with a comment requesting to specify that samples should be sent to the OIE Reference Laboratory for confirmation even if confirmed by a national laboratory. Therefore, it proposed to add 'or if there is a positive reaction in a diagnostic test for RPV conducted outside of an OIE Reference Laboratory for rinderpest' after 'cannot be ruled out', for consistency with the wording used in point 2(c)(ii) of Article 8.16.1.

In the first paragraph of point 2, the Code Commission did not agree with a comment to add 'in accordance with Article 1.1.3' as it considered this to be implied.

In the first two paragraphs of point 2, the Code Commission agreed with a comment to add 'of infection with RPV' after 'case' for clarity. This was applied throughout the text for consistency.

In the third paragraph of the same point, the Code Commission did not agree with a comment to add 'FAO/OIE approved Rinderpest Holding facility' after 'OIE Reference Laboratory for rinderpest'. It explained that confirmation of infection with RPV should be undertaken by an OIE Reference Laboratory for rinderpest, which has a different agreement from institutions holding RPV-containing material.

The Code Commission did not agree with a comment to delete the fifth paragraph of the same point noting that the option for vaccination had been discussed extensively between the OIE, FAO and Members. The Commission highlighted that there were Members who wished to have the option of vaccination as a control measure in the event of re-emergence of rinderpest. Although this approach would jeopardise the rapid recovery of global freedom, it agreed that it should be considered as an option and therefore included in the chapter.

Article 8.16.6

In the first paragraph, the Code Commission noted a comment proposing a timeframe for the submission of the risk assessment to the OIE and referred the comment to OIE Headquarters for further advice.

In the same paragraph, the Code Commission did not agree with a comment to add 'of infection with rinderpest virus' after 'case' as it considered this to be implied.

With regard to a comment querying what was meant by 'risk assessment', the Code Commission explained that it referred to an assessment of the risk of introduction of RPV to a free country following a re-emergence of rinderpest in another country. The risk assessment should thus look at epidemiological and ecological linkages to infected countries, for instance through animal movements or geographical factors.

In the second paragraph, the Code Commission agreed with a comment to add 'with RPV' after 'infection' for clarity.

Article 8.16.8

In the first sentence, the Code Commission did not agree with a comment to replace 'can' with 'may'. It proposed to replace 'can' with 'should' to emphasise the recommendation of establishing a containment zone, should rinderpest re-emerge.

Article 8.16.9

While the Code Commission agreed with a comment that an efficient and rapid stamping-out policy should be advocated for the prompt recovery of free status, it noted that the provisions in the chapter have to be inclusive of Members that would not be able to apply a stamping-out policy therefore should include provisions for a scenario where a stamping-out policy is not practised.

Article 8.16.10

In point 2, the Code Commission did not agree with a comment to refer to a stamping-out policy as described in points 1(a) and 1(b) of Article 8.16.9 as it was of the view that there was no need to detail how such an outbreak would need to be managed, noting that further guidance and recommendations would be provided, in particular through the GRAP, should there be a re-emergence of rinderpest.

In response to a comment to include provisions on the pathway to recovery of individual country freedom or to make reference to the relevant provisions of the 2010 edition of the chapter, including reference to Article 1.4.6 on the rinderpest questionnaire, the Code Commission was of the view that there was no need to specify exact provisions at this time noting that it would depend on the nature of the re-emergence of rinderpest.

Article 8.16.12

The Code Commission agreed with a comment to delete 'except safe commodities in point 2 of Article 8.16.2' in the title of the article, and proposed to add this text to point 2 instead for clarity. It considered this clarification to be important in view that Article 8.16.2 has two points, one to be applied during global freedom, and the other during re-emergence of rinderpest.

In points 1, 2, 3(a) and 4(a), the Code Commission did not agree with a comment to change the residency period from '30 days' to '42 days', which represents two incubation periods. The Commission highlighted that one incubation period is normally used to define the residency period in a free country or zone, unlike provisions concerning the reinstatement of free status or isolation period for animals imported from infected countries or zones, which is usually based on two incubation periods. The Commission noted the rationale in the report of the *ad hoc* Group on rinderpest that met in March 2020 that 30 days is based on the incubation period for rinderpest plus an allowance of a safety margin.

Article 8.16.13

The Code Commission agreed with a comment that countries whose free status have been suspended in accordance with the first paragraph of Article 8.16.6 should be covered by this article, and thus proposed to replace 'infected with' with 'not free from' in the title.

The Code Commission proposed to replace 'in the event of re-emergence of rinderpest' with 'from countries not free from rinderpest' for clarity.

Revised Chapter 8.16, Infection with rinderpest virus, is presented as **Annex 5** for Member comments.

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter.

Comments are inserted in the text of Annex 5.

4.3. Bovine spongiform encephalopathy (Chapter 11.4) and application for official recognition by the OIE of free status for bovine spongiform encephalopathy (Chapter 1.8)

Comments were received from Argentina, Australia, Brazil, Canada, China (People's Republic of), Chinese Taipei, Japan, New Caledonia, New Zealand, Switzerland, Thailand, the USA, the EU and the WRO.

Background

In February 2018, the Code Commission and the Scientific Commission had agreed on 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) *ad hoc* Group on BSE risk assessment, which met twice, ii) *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. The Code Commission, at its September 2019 meeting, reviewed the four *ad hoc* Group reports and the opinion of the Scientific Commission regarding the draft revised chapter, and circulated the revised chapter for comments for the first time.

In February 2020, the Code Commission considered comments received and while it addressed some comments it also identified comments that needed further expert advice and requested that the joint *ad hoc* Group on BSE risk assessment and surveillance be reconvened to address these comments. In June 2020, the joint *ad hoc* Group was convened to address relevant comments and to also review the draft revisions for Chapter 1.8, Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy, to ensure alignment.

In September 2020, the Code Commission reviewed the joint *ad hoc* Group report and circulated the revised chapters for comments.

Discussion

a) Chapter 11.4, Bovine spongiform encephalopathy

General comments

In response to a comment to propose to systematically add the word 'status' in several article titles and text throughout the chapter where BSE risk is specified, the Commission considered the current text to be clear as written.

In response to a comment to request to distinguish the requirements for importing commodities between countries with negligible risk and countries with controlled risk, the Code Commission reminded Members to refer to its September 2020 report and June 2020 report of the *ad hoc* Group on BSE risk assessment and surveillance.

In response to a comment that although classical BSE cases born after the total feed ban indicate that the feed ban has not been fully implemented, the revised chapter only considers the feed ban as a risk assessment factor for BSE in Article 11.4.2 and does not take the feed ban as a mandatory requirement for international trade, the Code Commission reiterated that the occurrence of classical BSE cases born after the total feed ban does not necessarily mean gaps or failures in the effective enforcement of feed ban and reminded Members to refer to the relevant parts of July 2018 report of the *ad hoc* Group on BSE risk assessment.

The Code Commission acknowledged comments that once this revised chapter is adopted, the 'period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible' will be critical information for the implementation of recommendations described in this chapter, and thus the relevant period for each Member which has recognition of a BSE status should be well communicated to Members by the OIE. The Commission requested the OIE Secretariat to explore how to communicate this information to Members.

The Code Commission did not agree with a comment to refer to 'cattle/bovine' wherever 'ruminant' is used as it considered that, without a ruminant-to-ruminant feed ban, ruminants other than cattle could not be regarded as being epidemiologically insignificant.

Article 11.4.1

In point 1, the Code Commission did not agree with a comment to add 'agent' after 'a low molecular weight type of atypical BSE' as it considered that the 'type' implies 'agent' and this would not provide any additional value.

In the same point, the Code Commission did not agree with a comment stating that if measures to avoid oral exposure of cattle to feed contaminated with classical BSE were applied, it would be unlikely that atypical BSE be recycled. The Commission reiterated its view that atypical BSE is potentially capable of being recycled in a cattle population if cattle is exposed to contaminated feed. The Commission encouraged Members to refer to the relevant parts of the March 2019 report of the *ad hoc* Group on BSE risk assessment and surveillance.

In point 3(a), the Code Commission did not agree with a comment to delete 'for respectively having a protease-resistant PrP^{BSE} fragment of higher and lower molecular mass than classical BSE' as the Commission considered it was necessary for completeness. In the same point, the Commission agreed with a comment to delete 'unless otherwise specified' as it considered that when appropriate, classical or atypical is specified throughout the text. In the same point, the Commission agreed with comments to explain that the abnormality of the causative agent by adding 'a misfolded form of prion protein (PrP^{sc}) which includes both classical and atypical BSE' for clarity.

In point 4(b), the Code Commission noted a reservation regarding the new definition for 'protein meal' proposed for inclusion in the chapter, and reminded Members that the rationale for this proposal was provided in the March 2019 report of the *ad hoc* Group on BSE risk assessment and surveillance. In addition, the Commission proposed to include the new definition for 'protein meal' in the Glossary and explained that once the revised chapter and the proposed new Glossary definition are adopted, it will review the use of terms 'meat-and-bone meal' and 'greaves' throughout the *Terrestrial Code* and consider where these terms should be replaced with 'protein meal'.

In the same point, the Commission did not agree with a comment to add 'including meat-and-bone meal, greaves and processed animal protein, etc.' after 'animal tissues are rendered' as it considered the addition would not provide any additional value.

Article 11.4.1bis

In point 4, comments were received seeking clarification on the rationale for the removal of detailed information on processing of gelatine and collagen and to propose that only certain types of commodities be considered as safe commodities. The Code Commission recalled that this issue had been addressed in the June 2020 report of the *ad hoc* Group on BSE risk assessment and surveillance and it encouraged Members to refer to the relevant parts of that report.

Article 11.4.2

In the title of this article, the Code Commission agreed with a comment to delete 'of the cattle population' as it considered that this was in line with the proposed approach that would allow for two different subpopulations to be differentiated within a country, zone or compartment recognised as either negligible or controlled risk. This differentiation would be based on the date of birth of the cattle relative to the period when the risk of BSE agents being recycled in the cattle population had been demonstrated to be negligible. This amendment was also applied to relevant text in Articles 11.4.4 and 11.4.5.

In response to a comment requesting that the flowchart of risk assessment steps (presented in Figure 1 of the June 2020 report of the *ad hoc* Group on BSE risk assessment and surveillance) should be included in this article, the Code Commission reiterated that they had agreed that this should be placed somewhere on the OIE website for Members' information once the revised chapter is adopted. This is in line with the general approach taken throughout the whole *Terrestrial Code* in relation with charts, figures and tables. The Commission did not agree with a proposal to modify the flowchart as the Commission considered it to be clear as currently presented.

In point 1, the Code Commission noted a comment querying how the proposed system on risk assessment will actually apply in the case of an applicant country wishing to claim that the 'period when the risk of BSE agents being recycled in the cattle population has been demonstrated to be negligible' is more than eight years. The Commission explained that a Member applying for official recognition of a negligible BSE risk status for a country or zone may be able to demonstrate that the likelihood of the BSE agent being recycled in the cattle population has been negligible for more than eight years, for which the Member should demonstrate compliance with all four steps of the risk assessment for the years wishing to be covered. Furthermore, the Commission reminded Members that in the third paragraph of point 2 (Exposure assessment) of Article 1.8.5 it is explicitly described that the applicant Member may provide the information for a period of longer than eight years.

In the same point, in response to a comment seeking clarification on the information required to submit for annual reconfirmation of the negligible or controlled BSE risk status, the Commission reminded Members to refer to the relevant parts of the March 2019 report of the *ad hoc* Group on BSE risk assessment and surveillance. The Commission also explained that, at its September 2020 meeting, it requested the OIE Secretariat to revise the form for the annual reconfirmation of BSE risk status to ensure alignment with this revised chapter, once adopted.

In points 1(a), 1(b) and 1(c), the Code Commission did not agree with a comment to replace 'likelihood' with 'risk' throughout the chapter. The Commission reminded Members that the risk estimation described in point 1(d) is the result of addressing three key components: entry assessment (described in point 1(a) to assess the likelihood (probability) that an agent is introduced via importations), exposure assessment (described in point 1(b) to assess the likelihood [probability] that animals are exposed to the agent), and consequence assessment (described in point 1(c) to assess the likelihood of infection following exposure, and the likely extent and duration of any subsequent recycling and amplification within the cattle population. These concepts are aligned with those described in Chapter 2.1, Import risk analysis.

In point 1(a), the Code Commission did not agree with a comment to delete the list of commodities that should be considered in the entry assessment. The Commission reminded Members to refer to the relevant parts of the June 2020 report of the *ad hoc* Group on BSE risk assessment and surveillance and reiterated that Chapter 11.4 focuses on defining the requirements applicable to the official recognition of BSE risk status, whereas Chapter 1.8 provides a tool in the form of a questionnaire for Members to submit the relevant information and demonstrate how they fulfil the requirements described in Chapter 11.4.

In the same point, in response to a comment to delete 'classical', the Code Commission emphasised that it is impossible to evaluate the likelihood that atypical BSE agent has been introduced as atypical BSE is assumed to occur spontaneously in any country (and therefore the occurrence of a case of atypical BSE would not impact a country's BSE risk status by itself). On the other hand, the Commission reiterated that the recycling of atypical BSE agent should be avoided and therefore it is important to consider the potential recycling of all BSE agents, including atypical BSE, in the exposure assessment. The Commission noted this response would apply to similar comments submitted in some other articles.

In point 1(a)(i), in response to a comment to add 'sheep and goats' in the commodities that should be considered in the entry assessment, the Code Commission requested the OIE Secretariat to seek expert advice, taking into consideration that point 2 of Article 11.4.1 says '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.'

In point 1(b), the Code Commission did not agree with a comment to delete the list of factors that should be considered in the exposure assessment for the same reason provided above for point 1(a).

In point 1(b)(i), the Code Commission did not agree with a comment to add 'intentionally' before 'fed', and to add 'or unintentionally exposed to' before 'ruminant-derived protein meal' as it considered that 'being fed ruminant-derived protein meal' implies both intentional and unintentional exposure.

In point 1(b)(i), under the fifth indent, the Code Commission agreed with a comment to add 'labelling' as it considered that labelling would be a potential risk and therefore it should be included.

In point 1(c), the Code Commission did not agree with a comment to delete the list of factors that should be considered in the consequence assessment for the same reasons provided above in points 1(a) and 1(b).

In point 1(d), in response to a comment to delete 'through the feeding of ruminant-derived protein meal, with indigenous cases arising', the Code Commission requested the OIE Secretariat to seek expert advice as to whether a description for other pathway should be included in this point. In the same point, the Commission did not agree with a comment to add 'and to precise the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible' as it considered that this point should focus on central element of the risk estimation, while addressing the comment in point 4(c) of Article 1.8.5.

Article 11.4.3

In the title of the article, the Code Commission did not agree with a comment to add 'status' after 'Negligible BSE risk' as it considered it would not provide additional value. This response also applies to similar comments submitted in some other articles.

In point 1, the Code Commission did not agree with comments seeking to reinstate requirements described in points 1(a) and 1(b) as it considered they are covered in points 1(b)(i) and (ii) of Article 11.4.2. In the same point, the Commission did not agree with a comment to replace 'that has identified' with 'which identifies' as it considered the current text to be clear as written.

In point 4, in response to a comment that all cohort animals should be killed when an indigenous case of classical BSE is identified, the Code Commission reiterated that killing of those animals would not provide a significant gain in risk reduction. The Commission reminded Members to refer to the relevant parts of the July 2018 report of the *ad hoc* Group on BSE risk assessment.

Article 11.4.3bis

In the first paragraph, the Code Commission did not agree with a comment to add '(or compartment)' before 'recognised as posing a negligible risk for BSE'. The Commission noted that this article describes the conditions to recover a negligible BSE risk status recognised by the OIE, and recalled that when a compartment loses its status, all the initial conditions for status recognition should apply. For clarity and consistency with the other chapters for diseases with official recognition of animal health status, the Commission agreed to include a new Article 11.4.4bis dedicated to 'compartment with negligible or controlled BSE risk'.

Article 11.4.4

In the first paragraph, the Code Commission agreed with a proposal to edit the text for clarity. In the same paragraph, the Commission partially agreed with a comment and deleted 'at least' as the Commission considered it was redundant.

The Code Commission did not agree with a comment proposing to add a new paragraph stating that 'Countries that have a suspended status under clause 11.4.3.bis are also considered to have a controlled BSE risk.' The Commission considered that this addition might be perceived by Members as the status being automatically downgraded, noting that this situation only applies under very specific circumstances, i.e. only during the period between the confirmation of an indigenous case of classical BSE and confirmation that the risk of recycling remains negligible.

Deleted previous Article 11.4.6

In response to a comment to propose development of an article for 'recommendations for importation of cattle from a country, zone or compartment posing a negligible BSE risk without cases' and an article for 'recommendations for importation of cattle from a country, zone or

compartment posing a negligible or controlled BSE risk with cases', the Code Commission recalled the opinion of the *ad hoc* Group that met in March 2019, that it was no longer relevant to provide such recommendations given that the revised Article 11.4.3 clearly defines the conditions related to the occurrence of an indigenous case. This response also applies to similar comments submitted in some other articles.

Article 11.4.7

In response to a comment that the merging of negligible and controlled risk seems to devalue the benefit of country's efforts to obtain a negligible risk status, the Code Commission stressed that the new approach is scientifically sound as proposed by the *ad hoc* Group on BSE risk assessment and surveillance in the June 2020 report of its meeting.

The Code Commission did not agree with comments to move the text on animal identification from point 1 to point 3 as it considered that BSE concerns the lifespan of an animal and animal identification enables the Veterinary Authority to trace the origin of animals for the purpose of effective control. Nevertheless, the Commission noted that point 1 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. The Commission clarified that the animal identification system should enable the Veterinary Authority to demonstrate compliance with the conditions of point 2 or point 3, and amended the text for clarity.

In point 2, the Code Commission did not agree with a comment to add 'and constantly raised' after 'born', and 'or in countries, zones or compartments' after 'in the country, zone or compartment' as the Commission considered the comment to be too stringent and prescriptive considering the reality of the current global situation on BSE, noting that the records of the animal's movements could be monitored through the animal identification system described in point 1. This response also applies to similar comments submitted in some other articles.

Article 11.4.10

In point 1, the Code Commission did not agree with a comment to add 'enabling each animal to be traced throughout its lifetime' after 'an animal identification system', as this was not intended by the recommendations. The Commission reiterated that the animal identification system should be sufficient for the Veterinary Authority to demonstrate compliance with the conditions of point 3 or point 4 of the article, irrespective of the chosen methodology. This response also applies to similar comments submitted in some other articles.

In point 3, the Code Commission did not agree with a comment to add 'and 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 the commodities listed in points 2 of Article 11.4.14' at the end of the sentence, as this points refers to as the cattle population with negligible risk.

Article 11.4.11

The Code Commission did not agree with a comment to propose to merge points 1 and 3 as it considered the text clear as written.

Article 11.4.12

The Code Commission did not agree with a comment to delete point 2. The Commission considered the point relevant and feasible, and reiterated that the animal identification system described in the point, as defined in the Glossary, does not necessarily mean 'individual' identification system, but that the system enables the Veterinary Authority to demonstrate that the cattle were born in the country, zone or compartment during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

Article 11.4.13

In point 3(a), the Code Commission agreed with a comment to move ‘or to any other procedure that can contaminate the blood with nervous tissue’ to the end of the sentence for improved clarity.

Article 11.4.14

In point 1(b), the Code Commission did not agree with a comment to add ‘with cases of BSE’ after ‘negligible BSE risk’. The Commission emphasised that Members without cases of (indigenous classical) BSE could show a much longer ‘period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible’ than Members with cases of indigenous classical BSE, if they can show ‘negligible likelihood of exposure’ through the assessment of livestock industry practices in the exposure assessment.

In response to a comment requesting to restructure the article, the Code Commission reminded Members that this article lists commodities that should not be traded and there is no reason to introduce more stringent conditions than provided in the current Article 11.4.14, which was adopted in 2016, during the tail of the epidemic.

Article 11.4.16bis

In point 1, the Code Commission proposed an amendment for consistency with this wording throughout the chapter.

In point 3, in response to comments to seek clarification on the requirements (temperature, time and pressure) of the methods used to safely produce tallow derivatives, the Code Commission requested the OIE Secretariat to seek expert advice.

Article 11.4.17

In the chapeau paragraph, the Code Commission did not agree with a comment to revert ‘BSE’ to ‘transmissible spongiform encephalopathy’ as this chapter pertains to BSE, not all TSEs.

Article 11.4.18

In response to a comment that introducing the word ‘continuum’ to the article adds unneeded complexity, the Code Commission partially agreed and proposed alternative amendments for clarity.

In point 2, in response to a comment that it is critical to assess the quality and reliability of passive surveillance when granting the BSE status and therefore a criteria for assessing passive surveillance system in Members applying for the BSE risk status as well as the submitted result of the surveillance should be established, the Code Commission reminded Members that the four pillars to ensure the credibility of the surveillance programme are listed in point 3 of this article and the details of these pillars are described in Article 1.8.6.

In point 2(a), 2(b), 2(c) and 2(d), the Code Commission did not agree with comments to propose including age limits (minimum age) for the animals to be tested as it considered that the age threshold is no longer justified by data at the peak of the epidemic. The Commission encouraged Members to refer to the relevant parts of the October 2018 report of the *ad hoc* Group on BSE surveillance for a more detailed rationale.

In point 2(b), the Code Commission agreed with a comment to delete ‘that have been subjected to an’ and ‘with unfavourable results’ in order to avoid confusion and make the meaning clear.

In point 2(c) and 2(d), in response to a comment that it is too restrictive to target downers and fallen stock only ‘with an appropriate supporting clinical history’, the Code Commission explained that an ‘appropriate supporting clinical history’ would imply that other common causes, such as infectious, metabolic, traumatic, neoplastic or toxic causes, have been ruled out, and amended the text for clarity.

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

General comments

The Code Commission did not agree with a comment that the word 'likelihood' be systematically replaced by 'risk'. Refer to the rationale provided above in Article 11.4.2.

In response to a comment that the 'period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible' for each Member which has recognition of a BSE risk status should be well communicated to Members by the OIE, once adopted, the Code Commission requested the OIE Secretariat to explore how to communicate this information to Members.

The Code Commission reminded Members that it had been agreed that Chapters 1.7 to 1.12 will be removed from the *Terrestrial Code* and be maintained on the OIE website (see Item 3.1.18).

Article 1.8.1

In the first paragraph, the Code Commission did not agree with a comment to delete 'the risk of' as the Commission considered it clear as written.

In second paragraph, the Code Commission agreed with a comment to delete 'unless specified otherwise' as it considered that classical or atypical is specified throughout the text as appropriate.

Article 1.8.2

In point 1(b), the Code Commission did not agree with a comment to delete 'classical' at the end of the sentence for the same reason given above (in Article 11.4.2). This response also applies to similar comments submitted in some other articles.

In the same point, the Code Commission did not agree with a comment to delete 'of each indigenous case of classical BSE' as it considered that the data of birth is only relevant for the indigenous cases of classical BSE, noting that the impact on the status of a Member will be based on whether such case was born within the last eight years or not.

Article 1.8.4

In the chapeau paragraph, the Code Commission proposed to delete 'of the cattle population' for consistency with changes proposed in Chapter 11.4 (see details in Article 11.4.2 noted above).

Article 1.8.5

In point 1, under the fifth indent, the Code Commission agreed with a comment to delete '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' as it agreed that the example may be confusing.

In point 2, under the second paragraph, the Code Commission did not agree with comments to delete '(classical BSE)' and '(classical or atypical BSE)'. The Commission emphasised that it is difficult to assess the likelihood that an atypical BSE agent has been introduced, as atypical BSE is assumed to occur spontaneously (and therefore the occurrence of a case of atypical BSE would not impact a country's BSE risk status by itself). On the other hand, the Commission reiterated that the recycling of atypical BSE should be avoided and therefore it is important to consider the potential recycling all BSE agents, including atypical BSE, in the exposure assessment.

In point 2(a), in the first paragraph, the Code Commission proposed to replace 'dead stock' with 'dead animals' for consistency with the language used in the *Terrestrial Code*.

In point 2(a)(i), the Code Commission agreed with a comment to restructure the list of production systems for consistency with Chapter 7.9, Animal welfare and beef cattle production systems, but did not agree with a comment to delete 'and mixed species farming' as the Commission considered it to be a relevant farming system. Furthermore, the Commission agreed with a comment to add 'The description should include the number and size of farms in each type of production system' as it considered this information is necessary to provide a clear picture of the structure of the livestock industry in a country.

In point 2(a)(iii), in response to a comment to add 'and cattle euthanised as part of a BSE surveillance programme under Article 1.8.6' after 'fallen stock', the Code Commission partially agreed for clarity, and proposed new text and moved 'at livestock markets or auctions' to the third paragraph in point 2(a)(ii).

In point 2(a)(iv), under the last paragraph, the Code Commission did not agree with a comment to add 'The Competent Authority can do both or delegate the set of a guidance, the set of standards and/or audits in relation to HACCP programs and good manufacturing practices to the rendering industry' as it considered that it is not necessary to specify who can provide guidance, set standards or provide third party audits in relation to HACCP.

In the title of point 2(a)(v), the Code Commission proposed to add 'labelling' for consistency with a change proposed in Chapter 11.4 (see Article 11.4.2).

In point 2(a)(v), in the first indent, the Code Commission agreed with a comment to move 'excluding those listed in Article 11.4.1bis' within the sentence, for improved clarity.

In point 2(b), the Code Commission did not agree with a comment to reinstate 'ruminant-to-ruminant feed ban' as a condition for the recognition of the negligible or controlled BSE risk status. Refer to the Commission's response detailed in Article 11.4.3 for a similar comment.

In point 2(b)(ii), under the third indent, in response to a comment to add 'with slaughter waste declared as unfit for human consumption' after 'rendering', the Code Commission proposed to add 'fallen stock or' before 'slaughter waste declared as unfit for human consumption' under the fourth indent for improved clarity.

In point 3(a)(iii), the Code Commission did not agree with a comment to add 'to a feed ban' after 'an infraction (non-compliance)' as it considered that this is self-evident and that infractions to the other regulation should also be considered. In the same point, the Commission agreed with a comment to delete 'cross-' for clarity.

In point 4(c), the Code Commission agreed with a comment to replace the point with 'Indicate the period of time for which it can be considered that the risk of BSE agents being recycled in the cattle population has been negligible. Provide explanations and clearly describe the rational leading to the conclusions reached', reiterating that the period of time is essential information for this new approach. For the rationale refer to Article 11.4.2 above.

The Code Commission reminded Members that, in the third paragraph of point 2 (Exposure assessment) of the revised Article 1.8.5, it is explicitly described that the applicant Member may provide the information for a period of longer than eight years. Furthermore, regarding the annual reconfirmation of the negligible or controlled BSE risk status, the Commission reminded Members to refer to the relevant parts of the March 2019 report of the *ad hoc* Group on BSE risk assessment and surveillance, and also reiterated that, at its September 2020 meeting, the Commission had requested the OIE Secretariat to revise the form for the annual reconfirmation of BSE risk status to ensure alignment with this revised chapter, once adopted.

The Code Commission noted a comment querying how the proposed system on risk assessment will actually apply in the case of an applicant country wishing to claim that the 'period when the risk of BSE agents being recycled in the cattle population has been demonstrated to be negligible' is more than eight years. The Commission explained that a Member applying for official

recognition of a negligible BSE risk status for a country or zone, may be able to demonstrate that the likelihood of the BSE agent being recycled in the cattle population has been negligible for more than 8 years and, in that case, the Member should demonstrate compliance with all four steps of the risk assessment for the years wishing to be covered. Furthermore, the Commission reminded Members that, in the third paragraph of point 2 (Exposure assessment) of Article 1.8.5, it is explicitly described that the applicant Member may provide the information for a period of longer than eight years.

In response to a comment seeking clarification on the information required to submit the annual reconfirmation of the negligible or controlled BSE risk status, the Code Commission reminded Members to refer to the relevant parts of the March 2019 report of the *ad hoc* Group on BSE risk assessment and surveillance, and also explained that, at its September 2020 meeting, the Commission requested the OIE Secretariat to revise the form for the annual reconfirmation of BSE risk status to ensure alignment with this revised chapter, once adopted.

Article 1.8.6

In response to a comment that once this chapter is adopted, sufficient time for implementation of changes must be guaranteed to Members, the Code Commission explained that the process of status recognition will be revised taking this into account.

In the second paragraph, the Code Commission agreed with a comment to delete 'if it is actually present' for clarity. The Commission explained that these provisions refer to the investigation of potential surveillance candidates by detection of clinical signs which are relevant for suspicion irrespective of the previous detection of the disease, and noted that, as stated in Article 11.14.18, they would also be relevant to atypical BSE. The Commission agreed to make this amendment elsewhere in the text. Also, in the same paragraph, the Commission proposed to replace 'disease' with 'BSE' for clarity.

In the fifth paragraph (and other relevant text in this article), the Code Commission proposed to replace 'lie on the continuum' with 'show symptoms' for better clarity and consistency with the changes proposed in Article 11.4.18.

In the point 4, in the third paragraph, the Code Commission did not agree with a comment to add 'classical' before 'BSE positive findings' as it considered that all BSE cases need to be followed up in order to properly address the risk of BSE agents being recycled.

In the point 4(c), the Code Commission did not agree with a comment to add 'and animals excluded from laboratory testings' as it considered it clear as written.

In the point 4(g) and 5(a), the Code Commission agreed with a comment to replace 'each year' with 'each of the preceding years' to improve clarity.

In the point 4, in the Table 1, in response to a comment to propose including age limits (minimum age) for the animals to be tested, the Code Commission reiterated that the age threshold is no longer justified by data at the peak of the epidemic. The Commission reminded Members to refer to the relevant parts of the October 2018 report of the *ad hoc* Group on BSE surveillance.

In the point 5(a), in Table 2, the Code Commission acknowledged a comment that filling out the table would be a disproportionate administrative burden. The Commission reiterated that this chapter should be used as the basis for applications for the recognition of a BSE risk status and reminded Members that the Commission at its September 2020 meeting requested the OIE Secretariat to revise the form for the annual reconfirmation of BSE risk status to ensure alignment with this revised chapter, once adopted.

Article 1.8.7

In response to a comment to improve the clarity of the text, the Code Commission partially agreed and proposed amended text.

The revised Chapters 11.4, Bovine spongiform encephalopathy, and Chapter 1.8, Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy, and the proposed Glossary definition for 'protein meal' are presented as **Annex 6**, **Annex 7** and **Annex 8** respectively, for Member comments.

EU comment

The EU thanks the OIE and in general supports the proposed changes to Chapters 11.4. and 1.8.

Comments on these chapters, as well as on the proposed change to the glossary, are inserted in the text of Annexes 6, 7 and 8.

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

Background

In February 2019, in response to a request, the Scientific Commission had requested the Working Group on Wildlife to conduct a review of the potential transmission of hepatitis B from gibbons to humans. In the March 2020 meeting report of the Working Group on Wildlife, it had concluded that hepatitis B was a disease of humans, 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 September 2020 meeting, the Scientific Commission agreed with the recommendations of the Working Group on Wildlife and proposed that Article 6.12.4 of Chapter 6.12, Zoonoses transmissible from non-human primates, of the *Terrestrial Code* be amended to reflect that hepatitis B is a disease of humans. The Scientific Commission had also recommended that Chapter 3.9.11 of the *Terrestrial Manual* be updated to ensure differentiation between hepatitis B virus in humans and other viruses of the *Hepadnaviridae* Family. The relevant amendments to the *Terrestrial Manual* were proposed by the Biological Standards Commission at its September 2020 meeting, and circulated for Member comments with the view for adoption in May 2021.

Discussion

The Code Commission considered the Scientific Commission's proposal to amend Chapter 6.12, Zoonoses transmissible from non-human primates, of the *Terrestrial Code*, and agreed to amend the chapter, as relevant. The Commission introduced relevant amendments to the text of Articles 6.12.4, 6.12.6 and 6.12.7 and agreed to circulate the revised chapter for Member comments noting that the scope of this revision was limited to the deletion of references to hepatitis B in gibbons and great apes.

Revised Articles 6.12.4, 6.12.6 and 6.12.7 of Chapter 6.12, Zoonoses transmissible from non-human primates, are presented as **Annex 9** for Member comments.

EU comment

The EU in general supports the proposed changes to this chapter.

Comments are inserted in the text of Annex 9.

5. Other updates

5.1. OIE Wildlife Health Management Framework

The OIE Secretariat updated the Commission on progress on the development of the OIE Wildlife Health Management Framework. The OIE Secretariat reported that a concept note has been developed in consultation with the OIE Wildlife Working Group, OIE regional and sub-regional representations, relevant stakeholders and partners, including the United Nations Environment Programme (UNEP), the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), and the International Union for Conservation of Nature (IUCN). In addition, the OIE had surveyed all its Members to collect their views on this topic, in particular the role of Veterinary Services in wildlife

health management, priorities and the needs of Veterinary Services to better support wildlife health management. Some of this information was used in the development of the Concept Note and ensured that OIE Members were engaged in this work.

The Code Commission commended the work done and recognised the value that these developments would have in future work considerations of the Commission. The Commission reiterated its views on the importance of strengthening the role of Veterinary Services in improving wildlife health management, and on the value of engaging with Members to assess their needs and priorities.

The Commission expressed its willingness to consider relevant aspects of this work if the inclusion of new content in the *Terrestrial Code* chapters is considered necessary. The Commission requested that it be kept informed of ongoing progress of this work.

5.2. Standard Operating Procedure for determining if a disease should be considered as emerging disease

The OIE Secretariat informed the Code Commission of the ongoing work been undertaken by OIE Headquarters to develop the Standard Operating Procedure for determining if a pathogenic agent of terrestrial animals meets the *Terrestrial Code* definition for an emerging disease, which will describe the sequence of steps for the determination of an emerging disease by the OIE, as well as the subsequent tracking of an emerging disease to one of the end-points described in Article 1.1.4.

The Code Commission recognised the value of this work to facilitate a consistent approach in the reporting of emerging diseases of terrestrial animals by Members. Furthermore, the Commission requested to also consider the role that the OIE should play to collect scientific and epidemiological information to identify a potential ‘emerging disease’ even before an assessment is specifically requested, and noted that this could be achieved by encouraging Members to provide the OIE with relevant animal health information in accordance with Article 1.1.6 of the *Terrestrial Code* or through its Reference Centre network.

6. Date of next meeting

To be confirmed after the election of the Code Commission members in May 2021.

Annex 3

WORK PROGRAMME FOR
THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

EU comment

The EU thanks the OIE and in general supports the revised work programme of the Code Commission.

In particular, we welcome that work will now be initiated on the revision Chapter 6.10., as indicated in Item 3.1.3. of this report. Reference is made to the proposals submitted by the EU to the OIE in December 2018 (available here https://ec.europa.eu/food/horizontal-topics/international-affairs/international-standards/world-organisation-animal-health/eu_en). The EU stands ready to provide expert advice and further input on this important topic.

Furthermore, the EU would encourage the Code Commission to embark on a thorough revision of Section 5 of the Code, relating to Trade measures, import/export procedures and veterinary certification. Indeed, many of the chapters in that section have not been revised in more than 10 years (with Chapter 5.7. dating back to 1968), yet these are crucial for safe international trade. This is particularly true for bilateral trade based on the concept of zoning applied in non-disease free countries, which has now become widely accepted by trade partners and is further gaining importance compared to trade based on the concept of country freedom from (a) certain disease(s). Special attention in this regard should be given to veterinary procedures at border posts. Despite its already heavy workload, the EU would therefore support adding the revision of the chapters in Section 5 of the Code to the work programme of the Code Commission.

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments post-meeting)
Horizontal chapters		
General aspects	1) Work with AAHSC towards harmonisation, as appropriate, of the horizontal parts of the *Codes,* notably Glossary, User's Guide, Section 4 on Disease prevention and control and Section 5 on Trade measures, import/export procedures and veterinary certification	Ongoing
	2) Work with BSC and SCAD for accurate disease description and diagnostic in the *Manual* and case definitions in the *Code* and names of diseases and country and zone disease status	Ongoing – Approach to the issue of 'case definitions' and listing diseases was agreed
	3) Revision and formatting of chapters (articles numbering, tables and figures)	Ongoing – Plan to develop standard framework for a *Terrestrial Code* chapter
	4) Revision of the Users' Guide	Ongoing – Last amendments were proposed for adoption in May 2021

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments post-meeting)
	5) Use of terms: – biosecurity / sanitary measures – disease / infection / infestation – animal health status – animal-based measures / measurables – enzootic / endemic / epizootic / epidemic – notify / 'notifiable disease', 'report' / 'reportable disease'	Ongoing
Glossary	1) 'Epidemiological unit'	Proposed for adoption in May 2021 (Sep 2018/4th)
	2) 'Poultry'	Proposed for adoption in May 2021
	3) 'Captive wild [animal]', 'feral [animal]' and 'wild [animal]'	Proposed for adoption in May 2021 (Sep 2018/3rd)
	4) 'Competent Authority', 'Veterinary Authority', 'Veterinary Services'	Sent for comments (Sep 2018/2nd)
	5) – 'Death', 'euthanasia', 'slaughter' and 'stunning' – New definitions for 'distress', 'pain' and 'suffering'	AHG to address Member comments (Sep 2019/2nd)
	6) 'Case'	Preliminary discussion
	7) New definitions for 'animal product', 'product of animal origin' and 'animal by-product'	Preliminary discussion
	8) New definition for 'swill'	Preliminary discussion

Annex 3 (contd)

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments post-meeting)
Horizontal issues not yet in the *Code*		
Section 3. Veterinary Services	1) New introductory CH in Section 3	Proposed for adoption in May 2021 (Sep 2019/3rd)
Section 4. Disease control	1) New CH on official control programmes for listed and emerging diseases	Proposed for adoption in May 2021 (Feb 2017/ 7th)
	2) New CH on biosecurity	Preliminary discussion: – Work in progress regarding guideline on ASF compartmentalisation; – swill feeding to be considered
	3) New CH on application of zoning	Preliminary discussion
Section 7 Animal welfare	1) New CH on animal welfare and laying hen production systems	Proposed for adoption in May 2021 (Sep 2017/5th)

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments post-meeting)
Horizontal chapters in need of revision		
Section 1. Animal disease diagnosis, surveillance and notification	1) CH 1.6 on procedures for publication of a self-declaration of disease freedom, recognition of an official animal health status and endorsement of an official control programme by the OIE	Proposed for adoption in May 2021 (Feb 2018/5th)
	2) CH 1.1 on notification of diseases, infections and infestations, and provision of epidemiological information	Proposed for adoption in May 2021 (Sep 2018/4th)
	3) CH 1.3 on listed diseases: • Avian influenza	Proposed for adoption in May 2021
	4) CH 1.3 on listed diseases: • MERS-CoV • Trypanosomes	Proposed for adoption in May 2021 (Sep 2019/3rd)
	5) CH 1.3 on listed diseases: • *Mycobacterium tuberculosis* (in *Mycobacterium tuberculosis* complex) • Theileriosis (*T. lestoquardi*, *T. luwenshuni*, *T. uilenbergi* and *T. orientalis*) • West Nile fever • *M. paratuberculosis*	Ongoing
Section 3. Veterinary Services	1) CH 3.4 on veterinary legislation	Proposed for adoption in May 2021 (Sep 2018/4th)
	2) CHs 3.1 and 3.2 on Veterinary Services	Proposed for adoption in May 2021 (Sep 2019/3rd)

Annex 3 (contd)

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments post-meeting)
Section 4. Disease control	1) CH 4.4 on zoning and compartmentalisation	Proposed for adoption in May 2021 (Feb 2020/2nd)
	2) CH 4.6 on general hygiene in semen collection and processing centres	Ongoing – AHG convened to progress with the work
	3) CH 4.7 on collection and processing of semen: – including resolving the lack of clarity of the text on brucellosis (Article 4.7.4)	Ongoing – AHG convened to progress with the work
	4) CH 4.9 on collection and processing of oocytes and *in vitro* produced embryos from livestock and horses: – including inclusion of BVD in CH 4.9 – amendment of Article 4.9.5	Ongoing
	5) CH 4.8 on collection and processing of *in vivo* – derived embryos: – categorisation of bluetongue (Article 4.8.14)	Ongoing
	6) CH 4.14 on disinfection: – consideration as to whether Glossary definition for 'disinfection' should be revised	Preliminary discussion
Section 5. Trade measures	1) CHs 5.4 to 5.7 on measures applicable at departure and on arrival	Preliminary discussion
	2) CH 5.11 on model certificates for dogs	Preliminary discussion (in relation to the revision of chapter on rabies)
	3) CH 5.12 on model certificates for competition horses	Preliminary discussion and pending revision of CHs on horse diseases
Section 6. Veterinary public health	1) CH 6.10 on responsible and prudent use of antimicrobial agents in veterinary medicine	Ongoing
	2) CH 6.12 on zoonoses transmissible from non-human primates	Sent for comments (Feb 2021/1st)
	3) CH 6.2 on the role of Veterinary Services in food safety systems	Pending discussion on definitions of VS, VA and CA
	4) CH 6.3 on meat inspection	Pending revision of definitions of VS, VA and CA
Section 7. Animal welfare	1) CH 7.7 on stray dog population control	Sent for comments (Sep 2020/1st)
	2) CH 7.5 on slaughter and CH 7.6 on killing of animals	Ongoing
	3) Chapters on animal transport	Preliminary discussion
Diseases not yet in the *Code*		
Disease-specific chapters	1) New CH on animal trypanosomoses of African origin	Proposed for adoption in May 2021 (Sep 2019/3rd)
	2) New CH on surra	AHG to be convened
	3) New CH on MERS-CoV	Ongoing work on case definition

Annex 3 (contd)

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments post-meeting)
Disease-specific chapters (contd)	4) New CH on leishmaniosis (listed disease without chapter)	Ongoing work on case definition
	5) New CH on Crimean Congo hemorrhagic fever (MCs comments, listed disease without chapter)	Ongoing work on case definition
Listed disease chapters/articles in need of revision		
Sections 8 to 15	1) CH 10.4 on avian influenza	Proposed for adoption in May 2021 (Sep 2018/4th)
	2) CH 14.7 on peste des petits ruminants (Harmonisation of articles regarding official status recognition by the OIE)	Proposed for adoption in May 2021 (Feb 2019/3rd)
	3) CH 15.2 on classical swine fever	Proposed for adoption in May 2021 (Feb 2017/4th)
	4) CH 10.5 on avian mycoplasmosis	Proposed for adoption in May 2021 (Feb 2020/2nd)
	5) CH 9.4 on *Aethina tumida* (Small hive beetle)	Proposed for adoption in May 2021 (Feb 2020/2nd)
	6) CH 12.6 on equine influenza	Sent for comments (Sep 2019/3rd)
	7) CH 11.4 on bovine spongiform encephalopathy and CH 1.8 Questionnaire	Sent for comments (Feb 2015/3rd)
	8) CH 8.15 on Rift Valley fever virus	Sent for comments (Feb 2019/3rd)
	9) CH 8.8 on foot and mouth disease	Sent for comments (Sep 2015/2nd)
	10) CH 8.16 on rinderpest	Sent for comments (Sep 2020/2nd)
	11) CH 11.10 on Theileriosis and new CH 14.X on infection with *Theileria* in small ruminants	CH 11.10 – sent for comments (Sep 2017/2nd) CH 14.X – pending development of guidance in the Manual (Sep 2017/1st)
	12) CH 12.2 on contagious equine metritis	Sent for comments (Sep 2020/1st)
	13) CH 12.7 on equine piroplasmosis	Sent for comments (Sep 2020/1st)
	14) CH 11.11 on trichomonosis	Sent for comments (Sep 2020/1st)
	15) CH 8.14 on rabies	Sent for comments (Sep 2020/1st)
	16) CH 12.3 on dourine	AHG to be convened
	17) CH 14.8 on scrapie	Pending expert advice

Annex 3 (contd)

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments post-meeting)
Sections 8 to 15 (contd)	18) CH 8.11 on *Mycobacterium tuberculosis* complex	Ongoing
	19) CH 15.4 on porcine cysticercosis (request from WHO)	Ongoing
	20) CH 8.5 on infection with *Echinococcus granulosus* (request from WHO)	Ongoing
	21) Pet food (for certification or safe commodities)	Ongoing
	22) Revision of safe commodities list to add lactose	On hold
	23) Revision of Article 15.3.9 on import of semen from countries not free from PRRS	Pending expert advice
	24) CH 11.5 Infection with contagious bovine pleuropneumonia	Preliminary discussion
	25) CHs on equine encephalomyelitis (Eastern, Western, Venezuelan) – inclusion of case definitions	Preliminary discussion
	26) CH 8.13 Paratuberculosis	Preliminary discussion
	27) CH 10.3 Avian infectious laryngotracheitis	Preliminary discussion
	28) CH 10.9 Infection with Newcastle disease virus	Preliminary discussion

List of abbreviations	
AAHSC	Aquatic Animal Health Standards Commission
AHG	*Ad hoc* Group
BSC	Biological Standards Commission
CA	Competent Authority
CH	Chapter
MERS-CoV	Middle East respiratory syndrome coronavirus
SCAD	Scientific Commission for Animal Diseases
VA	Veterinary Authority
VS	Veterinary Services
WHO	World Health Organization

Annex 4

DRAFT CHAPTER 7.5.

ANIMAL WELFARE DURING SLAUGHTER

EU comment

The EU thanks the OIE and supports the approach taken to revise this chapter. The EU welcomes this new version that included most of EU previous comments. The EU invites the OIE to consider some previous comments as well as new comments related to the new section on animals in containers.

Article 7.5.1.

Introduction

Providing good welfare to the animals at *slaughter* is ethically and economically beneficial. The implementation of animal welfare measures in addition to giving value to the product directly for ethical reasons, contributes to the improvement of workers' safety and product quality~~, and is essential for~~ (including food safety) and consequently to the improvement of economical returns [Blokhuis *et al.*, 2008; Lara and Rostagno, 2018].

Article 7.5.2.

Scope

This chapter identifies potential *animal welfare hazards* during *slaughter* and provides recommendations for arrival and *unloading*, *lairage*, handling, *restraint*, *stunning* and bleeding of animals in ~~*slaughterhouses*~~*/abattoirs*. It provides animal-based measures to assess the level of welfare and recommends remedial actions to be applied, when necessary.

EU comment

The EU suggest to not delete the word 'slaughterhouses' from the following sentence :

"This chapter identifies potential *animal welfare hazards* during *slaughter* and provides recommendations for arrival and *unloading*, *lairage*, handling, *restraint*, *stunning* and bleeding of animals in *slaughterhouses*/*abattoirs*."

Justification
For consistency with the rest of this chapter where *"slaughterhouses/abattoirs" is* used.

This chapter applies to the *slaughter* in *slaughterhouses/abattoirs* of free-moving animals ~~the following domestic animals~~, e.g. cattle, buffalo, bison, sheep, goats, horses, donkeys, mules~~,~~ and pigs, and animals in *containers* (e.g. rabbits and *poultry*)~~.~~ ~~, hereafter referred as "animals". Recommendations consider whether animals arrive at the *slaughterhouse/abattoir* in *containers* or are free-moving.~~

This chapter should be read with the guiding principles for *animal welfare* provided in Chapter 7.1. and relevant provisions of Chapters 6.2. and 6.3.

EU comment

The EU suggest amending the sentence as follows:

"This chapter should be read with the guiding principles for animal welfare provided in Chapter 7.1. and relevant provisions of Chapters 6.2., ~~and~~ 6.3 and 7.14."

Justification
The Chapter 7.14 on *the killing of reptiles for their skins, meat and other products* is also relevant to mention since some of them are killed for human consumption.

The principles underpinning these recommendations may also apply to the *slaughter* of other species and those slaughtered in other places.

Article 7.5.3.

Definition for the purpose of this chapter

Bleeding means the act of severing major blood vessels that supply the brain, to ensure *death*.

Article 7.5.4.

Animal welfare hazards

Hazards to *animal welfare* during each of the pre-slaughter stages have a~~n additive~~ cumulative effect on the stress of the animals [Moberg and Mench, 2000].

At the *slaughterhouses/abattoirs*, animals are exposed to *animal welfare hazards* including fasting and water deprivation, mixing of unfamiliar *animals*, handling by humans, exposure to a novel environment (e.g. noise, lighting, flooring), forced movement ~~physical exercise~~, limited space allowance, extreme weather conditions and ineffective ~~inadequate~~ *stunning* and bleeding. These *hazards* can have negative impacts on the welfare of the animals that can be assessed through animal-based measures. In addition resource-based measures and management-based measures may be used as a substitute. *Animal welfare hazards* can be minimised by appropriate design of premises and choice of equipment, and through good management, training and competency of personnel.

Article 7.5.5.

Criteria (or measures)

The welfare of animals at *slaughter* should be assessed using outcome-based measures. Although consideration should be given to the resources provided as well as the design and management of the system, animal-based criteria are preferential.

The routine use of these outcome-based measures and the appropriate thresholds should be adapted to the different situations in which animals are managed at a *slaughterhouse/abattoir*. It is recommended that target values or thresholds for *animal welfare* measurables be based on current scientific knowledge and appropriate national, sectorial or regional standards.

Article 7.5.6.

Management

The *slaughterhouse/abattoir* operator is responsible for the development and enforcement of a dedicated operating plan that should consider the following:

– training and competency of personnel;

– design of premises and choice of equipment;

– ~~training and competency of personnel;~~

– throughput (number of animals slaughtered per hour);

– maintenance and cleaning procedures;

– contingency plans;

– operating procedure and corrective actions.

Article 7.5.7.

Training and competency of personnel

Animal handlers and other personnel have a crucial role to play in ensuring good *animal welfare* conditions from the time of arrival of the animals at the *slaughterhouse/abattoir* through to their *death*. Training for all personnel should emphasise the importance of *animal welfare* and their responsibility in contributing to the welfare of the animals that come through the *slaughterhouse/abattoir*.

Animal handlers should understand the behavioural patterns of animals they are working with and their underlying principles to carry out the required tasks whilst ensuring good *animal welfare*. They should be experienced and competent in handling and moving the animals with knowledge about animal behaviour and physiology and able to identify signs of stress, fear, pain and suffering. Personnel in charge of *restraint* and of *stunning* and bleeding operations should be familiar with the relevant equipment, their key working parameters and procedures. Personnel *stunning*, shackling and bleeding animals should be able to identify effective *stunning* of the animal and signs of recovery of consciousness, should be able to detect if an animal is still alive prior to dressing or scalding and should be able to take corrective actions, if necessary [EFSA, 2013a; EFSA 2013b].

EU comment

The EU suggests moving the third sentence to the start of the paragraph and amending the resulting text as follows:

"Slaughterhouse/abattoir personnel ~~in charge of *restraint* and of *stunning* and bleeding operations~~working with live animals should be familiar with the relevant equipment, their key working parameters and procedures. ~~*Animal handlers*~~Personnel handling, restraining or stunning animals should understand the behavioural patterns of animals they are working with and their underlying principles to carry out the required tasks whilst ensuring good *animal welfare*. They should be experienced and competent in handling and moving the animals with knowledge about animal behaviour and physiology and able to identify signs of stress, fear, pain and suffering. Personnel *stunning*, shackling and bleeding animals should be able to identify effective *stunning* of the animal and signs of recovery of consciousness, should be able to detect if an animal is still alive prior to dressing or scalding and should be able to take corrective actions, if necessary [EFSA, 2013a; EFSA 2013b]."

Justification
All slaughterhouse personnel having contact with live animals (incl. restrained/stunned) should know the relevant equipment, working parameters and procedures (e.g. personnel in lairage area needs to be familiar with handling aids and drinking devices, max. number of animals per compartment etc). Furthermore, being familiar with animal behaviour/handling is also necessary for restraining and stunning (e.g. how to approach an animal for manual electrical or mechanical stunning).

Competencies may be gained through a combination of formal training and practical experience. These competencies should be assessed by the *Competent Authority* or by an independent body recognised by the *Competent Authority*.

Only the personnel actively working on the slaughter line should be present in areas where animals are handled. The presence of visitors or other personnel should be limited in those areas in order to prevent unnecessary noise, shouting or movement.

Article 7.5.8.

Design of premises and choice of equipment

The design of premises and the choice of equipment used in a *slaughterhouse/abattoir* have an important impact on the welfare of animals. They should consider the animals' needs, in terms of their physical comfort including thermal comfort ~~conditions~~, ease of movement, protection from injury, ~~protection from sudden or excessive noise~~ fear and ability to perform natural and social behaviours as well as watering and feeding needs. Premises should be designed to eliminate distractions that may cause approaching animals to stop, baulk or turn back. Flooring should be non-slip to prevent injury and stress due to slipping.

The design of the *slaughterhouse/abattoir* and choice of equipment should take into consideration the species, categories, quantities, ~~and~~ size or weight and age of the animals. *Restraint*, *stunning* and bleeding equipment is critical for the welfare of an animal at the time of *slaughte*r. Appropriate back-up equipment should be available for immediate use in case of failure of the *stunning* equipment initially used.

Article 7.5.9.

Throughput (number of animals slaughtered per hour)

The throughput of the *slaughterhouse/abattoir* should never exceed the maximum specification of the design of the facilities or equipment. ~~and may~~ The *slaughterhouse/abattoir* operators should continuously monitor throughput and adjust it to any operational changes, such as staff numbers or line breakdowns. It may also need to be reduced depending on the welfare outcomes.

Personnel allocation should be adequate for the anticipated throughput and be sufficient to implement the *slaughterhouse/abattoir* operating plan as well as ante and post-mortem inspections.

Article 7.5.10.

Maintenance and cleaning procedures

All equipment should be clean and well maintained in accordance with manufacturer's instructions in order to ensure *animal welfare* ~~and safety of personnel~~.

Maintenance and cleaning of handling, *unloading*, *lairage* and moving facilities contribute to ensuring that animals are handled smoothly, preventing pain and fear.

Maintenance and cleaning of *restraining*, *stunning* and bleeding equipment are essential to ensure reliable and efficient *stunning* and *slaughter*, thereby minimising pain, fear and suffering.

Article 7.5.11.

Contingency plans

Contingency plans should be in place at the *slaughterhouse/abattoir* to protect the welfare of the animals in the event of an emergency. The contingency plans should consider the most likely emergency situations given the species slaughtered and the location of the *slaughterhouse/abattoir.*

Contingency plans should be documented and communicated to all responsible parties.

Each personnel who has a role to play in implementing contingency plans should be well trained on the tasks they have to perform in case of emergency.

Article 7.5.12.

Arrival of free-moving animals

On arrival at the *slaughterhouse/abattoir*, animals will already have been exposed to *hazards* that may have negative impacts on their welfare. Any previous *hazards* will have a cumulative effect that may affect the welfare of the animals throughout the *slaughter* process. Therefore, animals should be transported to the *slaughterhouse/abattoir* in a manner that minimises adverse animal health and welfare outcomes, and in accordance with Chapters 7.2. and 7.3.

1. Animal welfare concerns:

Delay in *unloading* of animals is a major ~~the main~~ *animal welfare* concern at arrival [NAMI, 2017].

Animals in *vehicles* have smaller space allowances than on farm, undergo water and *feed* deprivation, may have suffered from an injury, ~~and~~ may be exposed to ~~thermal stress due to~~ adverse weather conditions. In addition, stationary *vehicles* may have insufficient ventilation. Delays in *unloading* animals will prolong or exacerbate the impact of these *hazards*. Under these circumstances, injured or sick animals requiring urgent attention ~~will~~ may not be identified or dealt with appropriately and therefore the duration of their suffering will be increased.

2. Animal-based and other measurables include:

It can be difficult to assess animal-based measures while animals are in the *vehicle*. Some measurables that may be assessed include animals with injuries, or those that are sick or have died. Panting, shivering and huddling may indicate thermal stress. Drooling and licking may indicate prolonged thirst.

Animals dead on arrival or condemned on arrival should be recorded and monitored as an indicator of *animal welfare* prior to and during transport.

EU comment

The EU suggest amending the sentence as follows:

"Animals dead or emergency-killed (see Article 7.5.19) on arrival ~~or condemned on arrival~~ should be recorded and monitored as an indicator of *animal welfare* prior to and during transport."

Justification
On arrival at the slaughterhouse, animals may also be discarded for animal health or food hygiene reasons, which is not necessarily relevant for animal welfare. The word 'condemned' seems inappropriate in this context because of its ambiguity.

Time from arrival to *unloading* and the environmental temperature and humidity can be used to establish relevant thresholds for corrective action.

3. Recommendations:

Animals should be unloaded promptly on arrival. This is facilitated by scheduling the arrival of the animals at the *slaughterhouse/abattoir* to ensure that there are sufficient personnel and adequate space in the *unloading* or *lairage* area.

Consignments of animals assessed to be at greater risk of *animal welfare hazards* should be unloaded first. When no space is immediately available, creating space should be a priority. Provisions should be made to provide shelter, shade or additional ventilation during waiting periods, or animals transported to an alternative nearby location where such provision ~~is~~ available.

Animals should be provided water as soon as possible after *unloading*.

Special consideration should be given to animals that have undergone long or arduous journey times, lactating or pregnant animals and young animals.

EU comment

The EU suggests adding the following sentence:

"Mortalities and injuries should be reported to the competent authority of the slaughterhouse and of the place of departure."

Justification

This previous EU comment was not accepted "*as this corresponds to a recommendation not an animal-based measure*" according to the ad hoc report (Annex 10). Therefore, the EU suggest adding it in the recommendations section.

In addition, the information related to mortalities and injuries are important for the competent authorities to monitor the level of animal welfare during transport and at arrival.

4. Species-specific recommendations:

Pigs are especially sensitive to extreme temperatures and therefore special attention should be taken when dealing with delays in *unloading* this species.

Shorn sheep might be especially sensitive to extreme temperatures and therefore special attention should be taken when dealing with delays in *unloading*.

Lactating animals should be given special attention and given priority when *unloading* and processing.

Unweaned animals are especially sensitive to extreme temperatures and can find it difficult to regulate their body temperature. They are very susceptible to dehydration, illness and stress after transportation and handling. These animals must be given special attention and be given priority when *unloading* and processing.

Article 7.5.13.

~~Displacements~~ Handling of free-moving animals

This article addresses the handling of animals during *unloading* and *lairage,* and in the killing area.

1. Animal welfare concerns:

During *unloading,* animals are exposed to similar *hazards* to those encountered when being loaded (see Chapters 7.2. and 7.3). Inappropriate equipment in the *vehicle* or the *slaughterhouse/abattoir*, such as a lack of lateral protection when *unloading*, excessively steep ramps or an absence of foot battens, may result in animals slipping, falling or being trampled, causing injuries. The absence of ramps or lifts can result in animals being pushed or thrown off the vehicle. These *hazards* can also be associated with inappropriate handling and forced physical movement of animals that are unable to move independently as a result of weakness or injuries. Exposure to novel environments (e.g. noise, lighting, flooring) will cause fear and reluctance to move, or turning back.

2. Animal-based and other measurables include:

a) animals running, slipping and falling;

b) animals with broken or otherwise injured limbs;

c) animals turning-back, attempting to escape and reluctant to move;

d) animal vocalisation and frequency of vocalisation especially for pigs and cattle;

~~d~~ e) animals that are unable to move by themselves;

~~e~~ f) animals that strike against the facilities;

~~f~~ g) frequency of use of excessive force by personnel;

EU comment

The EU proposes to delete:

"g) ~~frequency of use of excessive force by personnel~~;"

and to replace it by the following:

"g) number of cases where personnel uses excessive force."

Justification
The wording "frequency" may be understood as an acceptable practice at a certain frequency, while the use of excessive force should not be admitted even at a low frequency. The wording "number of cases" is more neutral.

~~g~~ h) frequency of use of electrical prods.

Animals are safely handled when these measures are below an acceptable threshold.

3. Recommendations:

Ramps should be provided and used. Ramps should be positioned so that the animals can be handled safely. There should be no gap between the *vehicle* and the ramp, the gradient should not be too steep preventing animals from voluntarily moving, and solid side barriers should be in place.

EU comment

The EU proposes the following revision:

"Ramps or lifts should be provided and used. Ramps or lifts should be positioned so that the animals can be handled safely."

Justification

The ad hoc group report (Annex 10) does not seem to have considered this previous comment as there is no explanation why it was not accepted.

The use of lifts is an alternative option for handling animals, not requiring them to engage in a ramp.

Design of the facilities should promote the natural movements of animals, and, as far as possible, with a minimal human interaction.

Preventive measures such as foot battens, rubber mats and deep groove flooring can help animals to avoid slipping.

The *unloading* area and raceways should be well lit so that animals can see where they are going.

The design of *unloading* areas and raceways should aim to minimise the potential for distractions that may cause animals to stop, baulk or turn back when being unloaded (e.g. shadows, changes in flooring, moving objects, loud or sudden noises). For details refer to Chapters 7.2. and 7.3.

Animals that are injured, sick or unable to rise require immediate action and, when necessary, emergency killing should be performed ~~euthanised~~ without moving them and without delay. Refer to Articles 7.5.19. and 7.5.2~~0~~1. Such animals should never be dragged, nor should they be lifted or handled in a way that might cause further pain, suffering or exacerbate injuries.

Personnel should be calm and patient, assisting the animals to move using a soft voice and slow movements. They should not shout, kick, or use any other means that is likely to cause fear or pain to the animals. Under no circumstances should *animal handlers* resort to violent acts to move animals (see Article 7.5.20.).

Personnel should not stand between an animal and where they want it to move to as this may cause the animal to baulk.

Mechanical aids ~~and electric goads~~ should be used in a manner to encourage and direct movement of the animals without causing distress and pain. Preferred mechanical aids include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles.

Electric goads should only be used in extreme cases and not on a routine basis to move animals.

The use of electric goads should be limited to battery-powered goads applied to the hindquarters of adult pigs and large ruminants, and never to sensitive areas such as the eyes, mouth, ears, ano-genital region or belly. Such instruments should not be used on equids, sheep and goats of any age, or on calves or piglets.

EU comment

The EU proposes the following revision:

"The use of electric goads should be limited to battery-powered goads applied to the hindquarters of adult pigs and large ruminants which refuse to move, and only when they have room ahead of them in which to move. The shocks shall be adequately spaced and shall only be applied to the muscles of the hindquarters. Shocks shall not be used repeatedly if the animal fails to respond. Electric goads should never be applied to sensitive areas such as the eyes, mouth, ears, ano-genital region or belly. Such instruments should not be used on equids, sheep and goats of any age, or on calves or piglets."

Justification

The ad hoc group report (Annex 10) does not seem to have considered this previous comment as there is no explanation why it was not accepted.

The current paragraph implies that electric goads can be used indiscriminately in any adult pig or large ruminant's hindquarter. This should never be the case as this may have severe welfare consequences and not result in improved handling. The additional text intends to ensure there are additional safeguards to prevent indiscriminate use.

~~Mechanical~~ Handling aids ~~and electric goads~~ should not be used as a substitute for good facility design and handling. They should not be used repeatedly if an animal fails to respond or move. In such cases it should be determined whether some physical or other impediment is preventing the animal from moving.

~~Electric goads should only be used in extreme cases and not on a routine basis to move animals.~~

~~The use of electric goads should be limited to battery-powered goads applied to the hindquarters of adult pigs and large ruminants, and never to sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.~~

The manual lifting of animals should be avoided; if it is necessary, animals should not be grasped or lifted in a manner which causes pain or suffering and physical damage (e.g. bruising, fractures, dislocations). (See Article 7.5.20.).

4. Species-specific recommendations:

None identified.

Article 7.5.14.

Lairage of free-moving animals

1. Animal welfare concerns:

Animals during *lairage* may be exposed to several *animal welfare hazards* including:

a) food and water deprivation leading to prolonged hunger and thirst,

b) absence of protection against ~~extremes~~ adverse ~~in~~ weather or climate conditions leading to thermal stress,

c) sudden or excessive noises, including from personnel, leading to fear,

d) insufficient space to lie down and move freely leading to fatigue and aggressive behaviour,

e) poor design and maintenance leading to distress and injuries,

f) mixing of unfamiliar animals leading to aggressive behaviour,

g) limited access to resources (e.g. drinkers, bedding) leading to aggressive behaviour;

h) exposure to hard or abrasive surfaces leading to injury or lameness.

2. Animal-based and other measurables include:

a) thermal stress (e.g. panting, sweating, shivering, huddling behaviour),

b) space allowance,

c) excessive soiling with faeces,

d) injuries (e.g. lameness, open wounds, fractures),

e) illness (e.g. limping, diarrhoea, coughing),

f) aggressive behaviours (e.g. mounting, fighting),

g) frequency of vocalisation especially for pigs and cattle.

3. Recommendations:

Animals should have constant access to clean water. Water supply points should be designed according to the species and age of the animal, with environmental conditions that allow for effective consumption. The number and location of the water supply points should minimise competition.

~~Animals should be provided with *feed* in *lairage* if the duration between loading and expected time for *slaughter* exceeds 24 hours~~. Animals which are not expected to be slaughtered after 12 hours of arrival should be fed as appropriate for the species and should be given moderate amounts of food at appropriate intervals.

EU comment

The EU proposes to revise the sentence as follows:

"Animals which are not expected to be slaughtered after 12 hours of arrival should be fed as appropriate for the species and ~~should be given moderate amounts of food~~ at appropriate intervals."

Justification
The meaning of "moderate amounts of food" is vague without adding concrete additional guidance.

The *lairage* should provide animals with protection against adverse weather conditions including shade.

Animals should be protected from excessive and sudden noise (e.g. ventilation fans, alarms, or other indoor or outdoor equipment).

Lairage areas should be free from sharp edges and other *hazards* that may cause injury to animals.

The *lairage* should provide enough space for all animals to lie down at the same time, to move freely and to move away in case of aggressive behaviours.

Lairage areas should have adequate lighting levels to allow inspection of the animals.

Animals from different groups (or different species) should not be mixed.

4. Species-specific recommendations:

~~None identified.~~ Pigs should be kept in small groups (up to 15) when resting in lairage, when moving to the stunner and when stunned.

Article 7.5.15.

Restraint for stunning or bleeding (free-moving animals)

1. Animal welfare concerns:

The purpose of *restraint* is to facilitate the correct application of the *stunning* or bleeding equipment. Incorrect *restraint* may not only lead to ineffective *stunning* or bleeding, but also cause pain and distress.

Other *hazards* include:

a) slipping or falling of animals entering the restraining area;

b) struggling or escape attempts caused by insecure *restraint*;

c) injuries and pain caused by excessive force of *restraint*;

d) fear caused by prolonged *restraint*, which may exacerbate insecure or excessive *restraint*.

In addition, *slaughter* without *stunning* increases the risk of pain and fear due to the need for robust *restraint* of conscious animals for neck cutting, especially if animals are turned on their sides or backs [von Holleben *et al.*, 2010; Pleiter, 2010].

2. Animal-based and other measurables include:

a) animal slipping or falling;

b) struggling;

c) escape attempts;

d) vocalisation (cattle and pigs);

e) reluctance to enter the restrainer;

f) frequency of use of electric goads.

3. Recommendations:

Where individual restraint is used, ~~T~~the restrainer should be narrow enough that the animals cannot move ~~either~~ backwards ~~or~~ , forwards or turn around.

The restrainer being used should be appropriate to the size of the animals and the restrainer should not be loaded beyond its design capacity.

In case of *slaughter* without *stunning*, the restrainer should restrain the head appropriately and should support the body of the animal appropriately.

The restraining should be maintained until the animal is unconscious.

When restrainers are used that hold an animal with its feet off the floor, the animal must be held in a balanced, comfortable, upright position.

When a restrainer is used to rotate an animal from an upright position, the body and head must be securely held and supported to prevent struggling and slipping within the device.

Restrainers should not have sharp edges.

Non-slip flooring should be used to prevent animals from slipping or falling.

Flooring and handling that intentionally cause loss of balance, slip or fall - i.e. a box with a floor that rises on one side upon entry to the box – should not be used.

Distractions (e.g. movements of equipment or people, loose chains or objects, shiny surfaces or floors) should be minimised to prevent baulking ~~balking~~ and improve ease of entry into the restrainer.

No animals should enter the restrainer until equipment and personnel are ready to slaughter that animal.

No animals should be released from the restrainer until the operator has confirmed loss of consciousness.

Animals should not be left in conveyor style restrainers during work breaks, and in the event of a breakdown animals should be removed from the conveyor promptly.

The restrainer should be in a clean and non-slip condition.

EU comment

The EU proposes adding the following text:

"The restrainer should be in a clean and non-slip condition, and in a well maintained working condition."

Justification
Maintenance of the restraining equipment is also an important aspect to ensure reliable stunning.

4. Species-specific recommendations:

Gondolas for gas *stunning* of pigs should not be overloaded and pigs should be able to stand without being on top of each other.

Head *restraint* is recommended for cattle.

Article 7.5.16.

Stunning of free-moving animals

EU comment

For the sake of clarity and easy reference, the EU suggests redrafting this section in order to separate the different stunning methods (mechanical, electrical and controlled atmosphere) and include separate sub-sections to cover:

- method description;

- key parameters;

- hazards;

- indicators and;

- recommendations.

For example, the EU finds essential having parameters for electrical stunning and would like to ask the OIE to provide them.

Justification

This approach was taken for animals containers and it would be consistent to keep the same structure for both parts.

1. Animal welfare concerns:

The main *animal welfare* concern associated with *stunning* is 'ineffective *stunning*' which results in pain, distress or fear during induction of unconsciousness and possible recovery before *death*.

The most common methods for *stunning* are mechanical, electrical and exposure to controlled atmosphere.

Stunning prior to *slaughter* decreases or avoid pain and suffering to animals and also improves workers' safety.

EU comment

The EU suggests deleting part of the sentence as follows:

"*Stunning* prior to slaughter decreases or avoids pain and suffering to animals. ~~and also improves workers' safety~~."

Justification
The chapter is about animal welfare and the worker safety is not an animal welfare concern. This proposed change is in line with the change proposed by the Code Commission under Article 7.5.10 where the reference to safety of personnel has been deleted.

Mechanical *stunning* is divided into penetrating *stunning* and ~~non-penetrating~~ non-penetrative percussive *stunning* applications. Both applications use different types of devices aimed to induce immediate loss of consciousness as the impact of the bolt on the skull results in concussion and disruption of normal brain function [Daly *et al.*, 1987; EFSA, 2004]. Penetrative *stunning* devices propel a bolt which penetrates the

skull and enters the cranium damaging the brain. Non-penetrative percussive *stunning* devices propel a blunt bolt which does not penetrate the skull, but results in rapid loss of consciousness from impact. The main *hazards* preventing effective mechanical *stunning* are incorrect shooting position and incorrect direction of the impact. These may cause ineffective *stunning* and pain or short-lasting unconsciousness. Poor maintenance of the equipment, ~~L~~low bolt velocity, misuse of cartridge ~~Low bolt velocity~~, narrow bolt diameter or short length of bolt leading to shallow penetration~~,~~ may also affect the effectiveness of *stunning*. In older animals with a thicker skull, low bolt velocity may result in an ineffective stun. In ~~non-penetrating~~ non-penetrative percussive *stunning* applications, high bolt velocity may cause fracture of the skull and ineffective *stunning* [Gibson *et al.*, 2014]. If not applied correctly, fracture of the skull and ineffective *stunning* are more likely to occur with young animals such as calves, when a higher bolt velocity is used.

Electrical *stunning* involves application of an electric current to the brain of sufficient magnitude to induce immediate unconsciousness [EFSA, 2004; Grandin, 1980]. The main *hazards* preventing effective electrical *stunning* are: incorrect electrode placement, poor contact, dirty or corroded electrode, low voltage/current or high frequency [EFSA, 2004].

Controlled atmosphere *stunning* methods involve the exposure to high concentrations of carbon dioxide (hypercapnia), low concentration of oxygen (hypoxia) or a combination of the two (hypercapnic hypoxia). Loss of consciousness is not immediate following exposure of animals to controlled atmosphere *stunning*. The main *hazards* causing increased distress during induction of unconsciousness are irritant or aversive gas mixtures, low gas temperature and humidity. The main *hazards* causing ineffective controlled atmosphere *stunning* are incorrect gas concentration and short gas exposure time [Anon, 2018; EFSA, 2004; Velarde *et al.*, 2007].

Gases or gas mixtures that are painful to inhale should preferably not be used to stun or kill pigs.

EU comment

The EU suggests deleting:
~~" - gases or gas mixtures that are painful to inhale should preferably not be used to stun or kill pigs."~~

Justification
This wording is better placed under the recommendations section where it is already mentioned.

2. Animal-based and other measurables include:

Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, just before and during bleeding until death occurs ~~neck cutting, and during bleed-out~~ [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

EU comment

The EU proposes amending the sentence as follows:

"Effectiveness of stunning should be monitored at different stages: immediately after stunning, just before and during bleeding until death ~~occurs~~ is confirmed ~~neck cutting, and during bleed-out~~."

Justification
The wording "occurs" does not imply a verification while the proposed wording "is confirmed" implies that death is verified by an operator, a wording that is coherent with the section on animal-based measurables.

No ~~single~~ indicator should be relied upon alone.

Mechanical *stunning:*

An effective stun is characterised by the presence of all the following signs: immediate collapse; apnoea; tonic seizure; absence of corneal reflex; absence of eye movements.

The presence of any of the following signs ~~may~~ indicate ~~an~~ a high risk of ineffective stun or recovery of consciousness: rapid eye movement or nystagmus, vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

Electrical *stunning:*

An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex.

The presence of any of the following signs may indicate an ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

EU comment

The EU proposes amending the sentence as follows:

"The presence of any of the following signs ~~may~~ indicates ~~an~~ a high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing."

Justification
For consistency sake, the same wording used for mechanical stunning should also be used here.

Gas *stunning*:

An effective stun is characterised by the presence of all the following signs: loss of posture; apnoea; absence of corneal reflex; absence of muscle tone.

The presence of any of the following signs may indicate an ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

EU comment

The EU proposes amending the sentence as follows:

"The presence of any of the following signs ~~may~~ indicates ~~an~~ a high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing."

Justification
For consistency sake, the same wording used for mechanical stunning should also be used here.

3. Recommendations:

Animals should be stunned as soon as they are restrained.

When a two-step electrical stun-kill method is used, the electrical current must reach the brain before it reaches the heart otherwise the animal will experience cardiac arrest while still conscious.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be cleaned, maintained and stored following manufacturer's recommendations.

EU comment

The EU proposes amending the sentence as follows:

"*Stunning* equipment should be used, cleaned, maintained and stored following manufacturer's recommendations."

Justification
It is as important that stunning equipment is used, cleaned and maintained in accordance with manufacturer's instructions.

Regular calibration of the equipment according to the manufacturer's procedure are recommended. Effectiveness of the *stunning* should be monitored regularly.

*Slaughterhouses/abattoir*s should have standard operating procedures that define key operating parameters or follow the manufacturer's recommendations for *stunning*, such as:

a) Mechanical:

- position and direction of the shot [AVMA, 2016];
- grain of the cartridge or air pressure appropriate to the type of animal (captive bolt) [Gibson 2014];
- length and diameter of the bolt (captive bolt);
- calibre and type of gun and ammunition (free bullet).

b) Electrical:

- shape, size and placement of the electrodes [AVMA, 2016];
- ~~pressure~~ contact between electrode and head;
- electrical parameters (current, voltage and frequency);
- visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors and displays voltage and applied current.

c) Controlled atmosphere:

- gas concentrations and exposure time;
- temperature and humidity;
- rate of decompression (law atmospheric pressure system for *stunning*);

EU comment

The EU suggests the following revision:
"rate of decompression (l~~a~~ow atmospheric pressure system for stunning);"

Justification

Typographical.

– gases or gas mixtures that are painful to inhale should preferably not be used to stun or kill pigs.

4. Species-specific recommendations:

Non-penetrating captive bolt should not be used in mature cattle and pigs [Finnie, 1993 and Finnie *et al.*, 2003].

The *Competent Authority* should determine effective electrical parameters, based on scientific evidence for different types of animals.

EU comment

The EU suggests providing species-specific electrical parameters as it was done in the past version of the chapter or at least precise technical and scientific references for the competent authorities to determine effective electrical parameters.

Justification
The EU understands that establishing technical parameters is delicate in an international context. However, a range of values or references to external documents could be valuable for the competent authorities in order to determine these parameters until the OIE has adopted complementary guidance documents.

Article 7.5.17

Bleeding of free-moving animals

1. Animal welfare concerns:

The main *animal welfare* concern at the time of bleeding following *stunning* is the recovery of consciousness due to prolonged stun-to-stick interval or due to incomplete severance of the main blood vessels.

Bleeding without prior *stunning* increases the *risk* of animal suffering because the incision to sever blood vessels results in substantial tissue damage in areas well supplied with nociceptors. The activation of these nociceptors causes the animal to experience pain [Gregory, 2004; Gibson *et al.*, 2009]. Loss of consciousness due to bleeding is not immediate and there is a period during which the animal can feel fear, pain and distress [Gregory, 2004; Johnson *et al.*, 2015].

Absence of or ineffective *stunning* may result in animals being released from the *restraint*, shackled, and further processed while they are still conscious or have the potential to recover consciousness.

2. Animal-based and other measurables include:

The main animal-based measurable is the blood flow (rate and duration).

For animal-based and other measurables of return of consciousness after *stunning*, see Article 7.5.16.

In cases of bleeding without *stunning* the animal-based and other measurables that indicate loss of consciousness include all the following: absence of muscle tone; absence of corneal reflex; absence of rhythmic breathing. In addition, cessation of bleeding can be used as an indicator of *death*.

EU comment

The EU suggests amending the sentence as follows:

"In addition, cessation of bleeding after a continuous and rapid blood flow can be used as an indicator of *death*."

Justification
This wording is in line with the recommendation under 3b. Cessation of bleeding itself, if not preceded by continuous and rapid blood flow, may not necessarily indicate death.

3. Recommendations:

a) both carotid arteries or the blood vessels from which they arise should be severed;

~~a~~ b) continuous and rapid blood flow should be assured after bleeding;

~~b~~ c) ~~cessation of blood flow~~ death should be assured before further processing;

~~c~~ d) bleeding knives should be sharpened for each animal.

In addition, the following should be considered:

Slaughter with *stunning*:

a) the stun-to-stick interval should be short enough to ensure that the animal will die before recovering consciousness;

b) unconsciousness should be confirmed before bleeding.

Slaughter without *stunning*:

a) bleeding should be carried out by a single incision; any second intervention should be recorded and analysed to improve procedures.

4. Species-specific recommendations

~~None identified.~~

Cattle are at risk of prolonged bleed out times and regaining consciousness if the bilateral vertebral arteries are not cut during a neck cut. If they are not cut, the vertebral arteries will continue to provide blood to the brain and can cause occlusion of the cut major arteries, slowing exsanguination. Therefore, bleeding with a cut of the brachiocephalic trunk should always be preferred in cattle.

Article 7.5.18.

Slaughter of pregnant free-moving animals

1. Animal welfare concerns:

Foetuses in the uterus cannot achieve consciousness [EFSA, 2017; Diesch *et al.*, 2005]. However, if removed from the uterus the foetus may perceive pain or other negative impacts.

EU comment

The EU suggests amending the sentence as follows:

"Foetuses in the uterus most probably cannot achieve consciousness [EFSA, 2017; Diesch et al., 2005]."

Justification

The EFSA opinion is not so conclusive to completely exclude possible consciousness. The EFSA's panel first assessed whether and when livestock foetuses of different animal species experience pain. The scientists agreed that the animals do not experience pain in the first two thirds of gestation because the relevant physical and neurological structures develop only during the last part of gestation.
The experts estimated the probability that foetuses experience pain during the final third of gestation. They concluded that the most probable scenario is that they don't experience pain due to the presence of a series of inhibitory mechanisms in the body of the foetus. They do not completely exclude the risk that they experience pain.

2. Animal-based and other measurables include:

   None identified.

3. Recommendations:

   Under normal circumstances, pregnant animals that would be in the final 10% of their gestation period at the planned time of *unloading* at the *slaughterhouse/abattoir* should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that pregnant females are handled separately.

   The foetus should be left undisturbed in utero for at least 30 minutes after the *death* of the dam [EFSA, 2017; Anon, 2017]. The uterus could be removed as a whole, clamped and kept intact such that there is no possibility to the foetus to breathe.

   In cases where the foetus is removed before 30 minutes has elapsed euthanasia (captive bolt followed by bleeding) should be carried out immediately.

4. Species-specific recommendations:

   None identified.

Article 7.5.19.

Emergency killing of free-moving animals

This article addresses animals that show signs of severe pain or other types of severe suffering before being unloaded or within the *slaughterhouse/abattoir*. These animals may correspond to animals unfit to travel as listed in Article 7.3.7. Principles described below may also apply to animals that are not suitable for *slaughter* for commercial reasons, even if they do not present signs of pain or suffering.

1. Animal welfare concerns:

   Some animals can arrive at *slaughterhouses/abattoirs* with injuries or severe illnesses that can cause undue pain and suffering. This is more likely in animals of low economic value.

2. Animal-based and other measurables include:

   Animals requiring emergency *killing* are unable to walk independently or present severe injuries such as fractures, large open wounds, or prolapses. They may also present clinical signs of serious illness or being in a state of extreme weakness. New-born animals or animals that gave birth within the last 48 hours may also belong to this category.

3. Recommendations:

   Animals should not be moved unless it can be done without causing further pain or suffering.

   Animal handlers should euthanise the animal as soon as possible.

   Emergency *killing* should be systematically recorded and analysed in order to improve procedures and prevent recurrences.

4. Species-specific recommendations:

None identified.

Article 7.5.20.

Methods, procedures or practices unacceptable on animal welfare grounds for free-moving animals

1) None of the following practices for handling animals are acceptable and should not be used:

EU comment

The EU suggests deleting and replacing the sentence with the following:

"~~None of~~ The following practices for handling animals are not acceptable and should not be used :"

Justification
For clarity sake.

a) crushing or breaking tails of animals;

b) applying pressure using an injurious object or applying an irritant substance ~~to sensitive areas such as eyes, mouth, ears, anogenital region or belly~~;

c) hitting animals with instruments such as large sticks, sticks with sharp ends, ~~metal~~ piping, stones, fencing wire or leather belts;

d) kicking, throwing or dropping animals;

e) grasping, lifting or dragging animals only by some body parts such as their tail, head, horns, ears, limbs, wool or hair;

f) dragging animals by any body part with chains or ropes.

EU comment

The EU suggest adding the sentence as follows:

"g) forcing animals to walk over other animals."

Justification
Cases of such practices have been reported and it is important to underline that it is unacceptable.

2) None of the following practices for restraining animals are acceptable and should not be used:

EU comment

The EU suggests deleting and replacing the sentence with the following:

"~~None of~~ The following practices for restraining animals are not acceptable and should not be used :"

Justification
For clarity sake.

a) mechanical clamping of the legs or feet of the animals as the sole method of *restraint*;

b) breaking legs, cutting leg tendons or blinding animals;

c) severing the spinal cord, by using for example a puntilla or dagger;

d) applying electrical current that does not span the brain;

e) suspending or hoisting conscious animals by the feet or legs;

f) severing brain stem by piercing through the eye socket or skull bone;

g) forcing animals to the ground by one or more handlers jumping on and lying across the animal's back.

3) Breaking the neck while the animal is still conscious during bleeding is also an unacceptable practice.

Article 7.5.21.

Arrival of animals in containers

On arrival at the *slaughterhouse/abattoir*, animals will already have been exposed to *hazards* that may have negative impacts on their welfare. Any previous *hazards* will have a cumulative effect that may impair the welfare of the animals throughout the *slaughter* process. Therefore, animals should be transported to the *slaughterhouse/abattoir* in a manner that minimises adverse animal health and welfare outcomes, and in accordance with Chapters 7.2. and 7.3.

1. Animal welfare concerns:

Animals in *containers* have smaller space allowances than on farm, undergo water and *feed* deprivation, and may be exposed to thermal stress due to adverse weather conditions. In addition, stationary *vehicles* may have insufficient ventilation. Delays in *unloading containers* will prolong or exacerbate the impact of these *hazards*. Under these circumstances, injured or sick animals requiring urgent attention will not be identified and therefore the duration of their suffering will be increased.

2. Animal-based and other measurables include:

It can be difficult to assess animal-based measures while animals are in the *containers* and especially when the *containers* are on the vehicle. Some measurables that may be assessed include animals with injuries, or those that are sick or have died. Panting, shivering and huddling may indicate thermal stress. In rabbits drooling and licking may indicate prolonged thirst.

EU comment

The EU suggests amending the sentence as follows:

"It can be difficult to assess animal-based measures while animals are in the containers and especially when the containers are on the vehicle or when many containers are stacked on top of each other."

Justification
The difficulty to check animals in containers is not limited to when they are in vehicles.

Time from arrival to *unloading* and slaughter, the environmental temperature and humidity can be used to establish relevant thresholds for corrective action.

3. Recommendations:

Animals should be slaughtered as soon as they arrive at the *slaughterhouse/abattoir*. If not possible, *containers* should be unloaded, or vehicles should be placed in lairage or in sheltered and adequately ventilated area, promptly on arrival. This is facilitated by scheduling the arrival of the animals at the *slaughterhouse/abattoir* to ensure that there are sufficient personnel and adequate space in the *lairage* area.

Consignments of animals assessed to be at greater risk of *animal welfare hazards* (e.g. from long journeys, prolonged lairage, end of lay hens) should be unloaded first or should be considered for prioritised *slaughter*. When no available space is immediately available, creating space should be a priority. Provisions should be made to provide shelter, shade or additional ventilation during waiting periods, or animals should be transported to an alternative nearby location where such provision ~~i~~s available.

EU comment

The EU proposes to add the following sentence:

"Mortalities and injuries should be reported to the competent authority of the slaughterhouse and of the place of departure."

Justification

Same as the one provided in Article 7.5.12 on free moving animals.

4. Species-specific recommendations:

Poultry is especially sensitive to extreme temperatures and therefore special attention should be taken when dealing with delays in *unloading* this species in extreme temperatures.

Birds may get trapped or their wings or claws may get caught in the fixtures, mesh or holes in poorly designed, constructed or maintained transport systems. Similarly, rabbits may trap their paws in the fixtures mesh or holes in poorly designed, constructed or maintained transport systems. Under these situations, operators *unloading* birds or rabbits should ensure gentle release of trapped animals.

Article 7.5.22

Moving of animals in containers

This article addresses the handling of containerised animals during *unloading* and *lairage,* and into the killing area.

1. Animal welfare concerns:

During *unloading* and moving *containers* animals can be exposed to pain and fear due to tilting, dropping or shaking of the *containers*.

2. Animal-based and other measurables include:

a) animals with broken limbs;

b) animals that strike against the facilities;

c) animals vocalizing;

d) body parts (i.e. wings or heads) stuck between *containers*;

e) animals injured by sharp projections inside *containers.*

3. Recommendations:

Containers in which animals are transported should be handled with care, moved slowly, and should not be thrown, dropped or knocked over. Where possible, they should be horizontal while being loaded or unloaded mechanically and stacked to ensure ventilation. In any case, *containers* should be moved and stored in an upright position as indicated by specific marks.

Animals delivered in *containers* with perforated or flexible bottoms should be unloaded with particular care to avoid injury by crushing or jamming of body parts.

Animals that are injured, jammed or sick require immediate action and, when necessary, should be taken from the *containers* and euthanised without delay. Refer to Articles 7.5.8, 7.5.9., 7.6.8 and 7.6.17.

Staff should routinely inspect the *containers* and remove the broken *containers* that should not be re-used.

4. Species-specific recommendations:

None identified.

Article 7.5.23

Lairage of animals in containers

1. Animal welfare concerns:

Animals during *lairage* may be exposed to several *animal welfare hazards* including:

a) food and water deprivation leading to prolonged hunger and thirst,

b) absence of protection against extremes in climate leading to thermal stress,

c) sudden or excessive noises, including from personnel, leading to fear,

d) insufficient space to lie down and move freely leading to fatigue and aggressive behaviour.

EU comment

The EU proposes adding the following sentence:

"e) not being able to inspect all animals and perform emergency killing when necessary."

Justification

As mentioned in the previous article, the difficult to check animals is an additional welfare concern. Animals in distress are unlikely to be properly treated or euthanised.

2. Animal-based and other measurables include:

a) thermal stress (e.g. panting, shivering, huddling behaviour),

b) space allowance,

c) excessive soiling with faeces,

d) injuries (e.g. splay leg, open wounds, fractures),

e) dead animals.

3. Recommendations:

Animals should be slaughtered upon arrival at the *slaughterhouse/abattoir*.

The *lairage* should provide animals with protection against adverse weather conditions.

Animals should be protected from excessive noise (e.g. ventilation fans, alarms, or other indoor or outdoor equipment).

4. Species-specific recommendations:

None identified.

Article 7.5.24.

Unloading animals from containers

1. Animal welfare concerns:

Animals are removed manually or automatically by tilting (poultry) from the transport *containers*.

When the *containers* with birds are mechanically emptied by tipping, animals fall on to conveyors. Dumping, piling up and shock might happen, especially for the last birds which are often removed by mechanical shaking of the *containers*.

Other *hazards* include:

a) narrow openings or doors of the *containers*;

b) *containers* placed too far away from the place of *stunning*;

c) incorrect design of tipping equipment that cause animals falling from high and conveyor belts that are running too fast or too slow resulting in piling or injured animals.

EU comment

The EU proposes amending sentence as follows:

"c) incorrect design of tipping equipment that cause animals falling from high and conveyor belts that are too steep or running too fast or too slow resulting in piling or injured animals."

Justification

Very steep conveyor belts also result in piling animals and possible increasing of the risk of injuries.

2. Animal-based and other measurables include:

a) animal falling;

b) struggling, including wing flapping;

c) escape attempts;

d) vocalisation;

e) injuries, dislocation, fractures;

f) pilling-off of animals.

3. Recommendations:

Removal of animals from the *containers* in a way that cause pain, e.g. by one leg, wings, neck or ears, should be avoided.

Animals should be removed from *containers* by the body or by both legs using both hands and one animal at a time. Animals should not be grabbed and lifted by one leg, the ears, wings or fur and they should not be thrown swing or dropped.

Modular systems that involve tipping of live birds are not conducive to maintaining good animal welfare. These systems, when used, should be incorporated with a mechanism to facilitate birds sliding out of the transport system, rather than being dropped or dumped on top of each other from heights of more than a metre.

4. Species-specific recommendations:

Birds with broken bones and/or dislocated joints should be humanely killed before being hung on shackles for processing.

Article 7.5.25.

Restraint for stunning animals from containers

1. Animal welfare concerns:

The purpose of *restraint* is to facilitate the correct application of the *stunning* or bleeding equipment. Incorrect *restraint* cause pain and distress and may lead to ineffective *stunning* or bleeding.

Other *hazards* include:

a) Inversion can provoke compression of the heart and lungs by the viscera and might compromise breathing and cardiac activity. This might cause pain and fear in conscious birds.

b) Shackling hanging birds upside down by inserting both legs into metal shackles. During shackling, the birds are also subjected to compression of their legs and wing flapping by their neighbour(s), possibly leading to pain and fear.

c) Inappropriate shackling may lead to pain and fear when shackles are too narrow or too wide, when the birds are hung by one leg, or when one bird is shackled on two different adjacent shackles.

d) Drops, curves and inclination of shackle line or high speed of the slackline create fear and possible pain due to the sudden changes in position as well as increase effects of inversion.

2. Animal-based and other measurables include:

a) struggling;

b) escape attempts;

c) vocalisation (poultry);

d) injuries and pain caused by excessive force of restraint or shackling;

e) fear caused by prolonged restraint, which may exacerbate insecure or excessive restraint.

3. Recommendations:

Animals should be handled and restrained without provoking struggle or attempts to escape.

Avoid inversion of conscious animals.

Avoid shackling of conscious animals but there is no real way to prevent or correct shackling, however, as it is a part of some of the *stunning* methods most commonly used in slaughter plants.

Shackle lines must be constructed and maintained so they do not jolt birds as this is likely to stimulate flapping. Shackle line speeds must be optimised so that they do not cause the birds to struggle.

To minimise wing flapping, breast support should be provided to the birds from the shackling point up to the stunner.

Inappropriate shackling such as too narrow or too wide shackles, birds being pushed into the shackles with force, birds shackled by one leg, or shackled on two different adjacent shackles, should be avoided.

Inappropriate shackling can be prevented by training staff to handle birds with care and compassion, shackle birds gently by both legs and kill injured birds before shackling, by rotating staff at regular intervals to avoid boredom and fatigue and by using shackles that are appropriate to the species and size of the birds.

4. Species-specific recommendations:

Rabbits:

Restraining for head-only electrical *stunning* is manual and involves holding the rabbit with one hand supporting its belly, and the other hand guiding the head into the *stunning* tongs or electrodes.

Rabbits should not be lifted or carried by the ears.

Poultry:

Shackling should not be used with heavy birds like parent *flocks* or with birds that are more susceptible to fractures like end-of-lay hens.

Article 7.5.26.

Head only electrical stunning

1. Animal welfare concerns:

Electrical *stunning* involves application of an electric current to the brain of sufficient magnitude intensity to induce immediate unconsciousness [EFSA, 2004; Grandin, 1980]. The main *hazards* preventing effective electrical *stunning* are: incorrect electrode placement, poor contact, dirty or corroded electrode, inappropriate electrical parameters (low voltage/current or high frequency [EFSA, 2004]).

2. Animal-based and other measurables include:

Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, just before and during bleeding until death occurs [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

EU comment

The EU proposes amending the sentence as follows:

"Effectiveness of stunning should be monitored at different stages: immediately after stunning, just before and during bleeding until death ~~occurs~~is confirmed."

Justification
Same as for Article 7.5.16 (2)

No indicator should be relied upon alone.

An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex.

The presence of any of the following signs indicate a high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

3. Recommendations:

Animals should be stunned as soon as they are restrained.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be cleaned, maintained and stored following manufacturer's recommendations.

EU comment

The EU proposes amending part of the sentence as follows:

"*Stunning* equipment should be used, cleaned, maintained and stored following manufacturer's recommendations."

Justification
Same as for the comment under Article 7.5.16. (3).

Regular calibration of the equipment according to the manufacturer's procedure are recommended. Effectiveness of the *stunning* should be monitored regularly.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters or follow the manufacturer's recommendations for *stunning*, such as:

– shape, size and placement of the electrodes [AVMA, 2016];

– contact between electrode and head;

– electrical parameters (current intensity, voltage and frequency);

– visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors and displays voltage and applied current.

4. Species-specific recommendations:

The *Competent Authority* should determine effective electrical parameters, based on scientific evidence for different types of animals.

EU comment

The EU suggests providing species-specific electrical parameters as it was done in the past version of the chapter or at least precise technical and scientific references for the competent authorities to determine effective electrical parameters.

Justification
Same as for Article 7.5.16 (4).

Article 7.5.27.

Electrical water-bath stunning

1. Animal welfare concerns:

In electrical water-bath *stunning* poultry are inverted and hung by the legs from a shackle line. The bird's head has direct contact with the water-bath, and an electric current is passed from the water through the bird to the leg shackle. *Hazards* that may prevent effective electrical *stunning* are: lack of contact between head and water, pre-stun shocks due to wings contacting water before the head, and the use of inappropriate electrical parameters (low voltage/current or high frequency [AVMA 2016]).

2. Animal-based and other measurables include:

Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, just before and during bleeding until death occurs [EFSA, 2019, EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

No indicator should be relied upon alone.

An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex.

The presence of any of the following signs indicate a high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

3. Recommendations:

The height of the water-bath stunner must be adjusted so that the birds cannot pull themselves up and avoid the stunner. Avoid distractions such as people walking under the birds can cause birds to pull up.

EU comment

The EU suggest adding the following revision:

"Avoid distractions such as people walking under the birds that can cause birds to pull up."

Justification
Editorial suggestion.

Personnel should watch for short or stunted birds as these birds will not be able to make contact with the water and will not be stunned.

The rail of the shackle line should run smoothly. Sudden movement such as jolts, drops or sharp curves in the line may cause birds to flap and avoid the stunner.

Pre-stun shocks can be reduced by having a smooth shackle line and by adjusting the water level of the bath.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be cleaned, maintained and stored following manufacturer's recommendations.

EU comment

The EU proposes amending part of the sentence as follows:

"*Stunning* equipment should be used, cleaned, maintained and stored following manufacturer's recommendations."

Justification

Same as for the comment under Article 7.5.16. (3).

Regular calibration of the equipment according to the manufacturer's procedure are recommended. Effectiveness of the *stunning* should be monitored regularly.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters or follow the manufacturer's recommendations for *stunning*, such as:

– water level;

– contact between water and head;

EU comment

The EU proposes amending the sentence as follows:

"contact between water and head, as well as between the legs and the leg shackle;"

Justification
The added variable is just as important for sufficient current flow and dependent on the procedures in place (humidification, matching birds and shackle size/form)

– electrical parameters (current intensity, voltage and frequency);

– visual or auditory warning system to alert the operator to proper or improper function. such as a device that monitors and displays voltage and applied current.

Ensure an optimum combination of voltage and frequency during electrical water bath *stunning* practices, to maximize the effectiveness of *stunning*.

4. Species-specific recommendations:

The *Competent Authority* should determine effective electrical parameters, based on scientific evidence for different types of birds.

EU comment

The EU suggests providing species-specific electrical parameters as it was done in the past version of the chapter or at least precise technical and scientific references for the competent authorities to determine effective electrical parameters.

Justification
Same as for Article 7.5.16 (4).

Article 7.5.28.

Mechanical stunning

The mechanical methods described here are captive bolt, percussive blow to the head, cervical dislocation and decapitation.

EU comment

The EU suggests adding the following:

The mechanical methods described here are captive bolt (<u>penetrative and non-penetrative</u>), percussive blow to the head, cervical dislocation and decapitation.

Justification
This is to clarify the distinction between non-penetrative captive bolt and the percussive blow to the head where recommendations differ.

Effective mechanical *stunning* requires a severe and immediate damage to the brain by the application of mechanical force. For that reason, cervical dislocation and decapitation cannot be considered as *stunning* methods.

1. <u>Animal welfare concerns:</u>

Mechanical methods required precision and often physical strength to restrain and stun the animals. A common cause for misapplication of these methods is the lack of proper skill and the operator fatigue.

Captive bolt

An incorrect shooting position or incorrect captive bolt parameters will mis-stunned the animal leading to serious wounds and consequently pain and fear.

EU comment

The EU proposes amending the sentence as follows:

"An incorrect shooting position or incorrect captive bolt parameters will mis-stun~~ned~~ the animal leading to serious wounds and consequently pain and fear."

Justification
Editorial suggestion.

Improper captive bolt parameters may be linked to the use of improper gun (diameter), improper cartridges, overheated or badly maintained gun.

Percussive blow to the head

An incorrect application of the blow, by not hitting the brain with sufficient force will also mis-stunned the animals leading to serious wounds and consequently pain and fear.

EU comment

The EU proposes amending the sentence as follows:

"An incorrect application of the blow, by not hitting the brain with sufficient force will also mis-stun~~ned~~ the animals leading to serious wounds and consequently painand fear."

Justification
Editorial suggestion.

In addition, the blow might not be consistently effective when delivered to an animal held upside down by its legs (part of the energy is dissipated by the movement of the body instead of damaging the brain).

Cervical dislocation and decapitation

Because neither method apply to the brain, the loss of consciousness is not immediate and, in some cases, when the method is not properly applied the pain and fear of the animal might be prolonged.

EU comment

The EU proposes amending the sentence as follows:

"Because neither method apply~~y~~ies to the brain, the loss of consciousness is not immediate and, in some cases, when the method is not properly applied the pain and fear of the animal might be prolonged.
"

Justification
Editorial suggestion.

In addition, decapitation is associated with an open wound leading to intense pain.

2. Animal-based and other measurables include:

Captive bolt and percussive blow to the head

With birds, severe convulsions (wing flapping and leg kicking) occur immediately after shooting. This is due to the loss of control of the brain over the spinal cord. Since mechanical *stunning* is applied on individual animals, its efficacy can be assessed immediately after the stun.

EU comment

The EU proposes amending the sentence as follows:

With birds, severe convulsions (wing flapping and leg kicking) occur immediately after shooting/blowing.

Justification
Relevant to be mentioned in the context of percussive blow to the head.

Cervical dislocation and decapitation

Death can be confirmed from several indicators: permanent absence of breathing, absence of corneal or palpebral reflex, dilated pupil, or relaxed carcass [EFS, 2013].

3. Recommendations:

Captive bolt and percussive blow to the head should only be used as backup or for small-scale slaughtering as in small *slaughterhouses/abattoirs* or on-farm slaughter.

EU comment

The EU suggests amending the sentence as follows:

"Captive bolt and percussive blow to the head should only be used as backup or for small-scale slaughtering as in small slaughterhouses/abattoirs or on-farm slaughter or for emergency killing."

Justification
Emergency-killing requires urgent action and it is usually occasional so such method is acceptable in that context.

Captive bolt

The captive bolt gun should be cleaned, maintained and stored following manufacturer's recommendations.

EU comment

The EU proposes amending part of the sentence as follows:

"The captive bolt gun should be used, cleaned, maintained and stored following manufacturer's recommendations."

Justification
Same as for the comment under Article 7.5.16. (3).

Effectiveness of the *stunning* should be monitored regularly.

Because it requires precision, this method should only be applied with proper restrain of the head of the animals. In addition, in the case of birds, they should be restrained in a bleeding cone to contain wing flapping.

The captive-bolt should be pointing perpendicularly on the parietal bones of birds.

Placement is different for birds with or without combs:

Without comb

The placement of the device should be directly on the midline of the skull and at the highest/widest point of the head with the captive bolt aimed directly down toward the brain [AVMA, 2020]

With comb

As far as captive bolt in chickens (and poultry with comb development) is concerned, the placement should be directly behind the comb and on the midline of the skull with the captive bolt aimed directly down [AVMA, 2020].

Rabbits

The device should be placed in the centre of the forehead, with the barrel in front of the ears and behind the eyes. The device should be discharged twice in rapid succession at the pressure recommended for the age and size of the rabbit. [Walsh *et al.,* 2017].

The power of the cartridge, compressed air line pressure or spring should be appropriate for the species and size of birds. Cartridges should be kept dry and the gun regularly inspected and maintained.

As an indication for broiler chickens, the appropriate specifications for captive bolt *stunning* are a minimum of 6-mm bolt diameter driven at an air pressure of 827 kPa to a penetration depth of 10 mm [Raj and O'Callaghan, 2001].

There should be sufficient bolt guns such that they are allowed to cool between operations, and they should be cleaned and maintained according to manufacturer's instructions.

EU comment

The EU proposes amending part of the sentence as follows:

"There should be sufficient bolt guns such that they are allowed to cool between operations, ~~and they should be cleaned and maintained according to manufacturer's instructions."~~

Justification
Repetition from (2) 2nd paragraph

Percussive blow to the head

This method should be dealt with a single sufficiently strong hit placed in the frontoparietal region of the head resulted in loss of auditory evoked potentials in broilers and broiler breeders.

EU comment

The EU proposes amending part of the sentence as follows:

"~~This method~~ <u>The blow</u> should be dealt with a single sufficiently strong hit placed in the frontoparietal region of the head ~~resulted~~ <u>resulting</u> in loss of auditory evoked potentials in broilers and broiler breeders."

Justification
For the sake of clarity and making the text more straight forward.

Fatigue of the operator can lead to inconsistency in application, creating concern that the technique may be difficult to apply humanely to large numbers of birds. It should not be done with the animal's head hanging down since inversion is stressful and part of the energy of the blow will be dissipated by the movement of the body.

Considering that the application of this method is entirely manual and prone to error, percussive blow might be used only when no other *stunning* method is available and, by establishing a maximum number of animals per operator in time to avoid errors due to operator fatigue.

It should not be used as a routine method and should be limited as a back-up method limited to small size animals (e.g. up to 3kg liveweight manually and up to 5 kg mechanical).

EU comment

The EU proposes deleting as follows:

"It should not be used as a routine method and should be limited as a back-up method limited to small size animals (e.g. up to 3 kg live weight ~~manually and up to 5 kg mechanical~~)."

Justification
There is no mechanical blow to the head.

This method should not be used in rabbits because of the difficulties to apply this method efficiently.

Cervical dislocation

Cervical dislocation should be avoided since it does not render the animal unconscious immediately.

It should not be used as a routine method and should be limited as a back-up method limited to small size animals (e.g. up to 3kg liveweight manually and up to 5 kg mechanical).

Mechanical dislocation should be preferred to manual dislocation as the efficiency of the first is less dependent on the operator's strength than the later.

Decapitation

Decapitation should not be used.

4. Species-specific recommendations:

Because of their size, heavy animals such as turkeys, geese or mature rabbits should not be stunned through percussive blow to the head or cervical dislocation.

EU comment

The EU adding the following:

"Turkeys and geese may be properly stunned by non-penetrative captive bolt."

Justification
To clearly distinguish between the blow to the head and the non-penetrative captive bolt.

Article 7.5.29.

Controlled atmosphere stunning

Animals may be exposed to controlled atmosphere *stunning* methods either directly in crates or after being unloaded on a conveyor belt. Animals are not subject to restraint. Controlled atmosphere *stunning* includes exposure to carbon dioxide, inert gases or low atmosphere pressure.

EU comment

The EU suggests amending the sentence as follows:

"Animals may be exposed to controlled atmosphere stunning methods either directly in crates or after being unloaded on a conveyor belt. Animals are not subject to restraint. Controlled atmosphere stunning includes exposure to carbon dioxide, inert gases, mixtures of carbon dioxide with inert gases, or low atmosphere pressure."

Justification
Mixture of carbon dioxide with inert gases has been tested also to use carbon dioxide at low concentration.

Animal welfare concerns:

A common concern of all controlled atmosphere *stunning* methods is the risk of insufficient exposure of animals to the modified atmosphere, which can result in animals consciousness before bleeding. The insufficient exposure to modified atmosphere may be due to either a too short exposure time, a too low concentration of gas or a combination of these variables.

EU comment

The EU suggests amending the sentence as follows:

"A common concern of all controlled atmosphere stunning methods is the risk of insufficient exposure of animals to the modified atmosphere, which can result in animals ~~returning to~~ recovering consciousness before bleeding."

Justification
In the context of consciousness, recovering is more appropriate to consider.

These variables are critical because animals being stunned in large groups need special attention to ensure unconsciousness prior to neck cutting. For this reason, the duration of unconsciousness induced needs to be longer than required by other *stunning* methods to ensure animals do not recover prior to being killed.

Furthermore, in the case of exposure to carbon dioxide, there is a risk that animals are exposed to a too high concentration of this gas, leading to pain. Exposure of conscious animals to more than 40% carbon dioxide (CO_2) will cause painful stimulation of the nasal mucosa and aversive reactions.

Low atmospheric pressure systems (LAPS) should not be confused with decompression. LAPS utilise a slow removal of air where animals exhibit minimal to no aversive behaviours. Decompression is a fast process that is associated with induction of pain and respiratory distress.

1. Animal-based and other measurables include:

It may be difficult to monitor the effectiveness of controlled atmosphere *stunning* due to limited access to observation of animals during the *stunning* process. All chamber-type systems should have either windows or video cameras so that problems with induction can be observed. If problems are observed, there is a need to take immediately any corrective measure that could alleviate the suffering of the animals concerned.

Therefore, it is essential that the death of animals is confirmed at the end of the exposure to the controlled atmosphere.

Death can be confirmed from permanent absence of breathing, absence of corneal or palpebral reflex, dilated pupils and relaxed carcass.

Since animal-based measures are difficult to monitor, resource-based measures should be used such as gas concentration, exposure time and decompression rate (for low atmosphere pressure).

2. Recommendations:

Conscious animals should not be exposed to carbon dioxide exceeding 40%.

The duration of exposure and the gas concentration should be designed and implemented in such a way that all animals are dead before being shackled.

Gas concentrations and exposure time, temperature and humidity must be monitored continuously at the level of the animal inside the chamber.

In case of low atmosphere pressure *stunning* decompression rate should be monitored continuously. The decompression rate should not be greater than or equivalent to a reduction in pressure from standard sea level atmospheric pressure (760 Torr) to 250 Torr in not less than 50 s. During a second phase, a minimum atmospheric pressure of 160 Torr shall be reached within the following 210 s.

Annex 4 (contd)

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

3. Species-specific recommendations:

Low atmosphere pressure *stunning* has only been scientifically studied on commercial broilers and therefore should not be used for other animals until further information is available.

The recommended CO_2 displacement rate for rabbits is 50-60% of the chamber or cage volume/min as this results in a significantly shorter time to insensibility and death (Walsh *et al.*, 2016, AVMA 2020). Exposure to CO_2 at high concentrations can reduce pre-stun handling and produce irreversible *stunning* in rabbits. With a stun to stick interval of up to 2 min, 200 s of exposure at 80%, 150 s at 90% and 110 s at 98% are recommended (Dalmau *et al.*, 2016). While there are advantages to high CO_2 exposure in rabbits, it is not without welfare concerns (aversion, vocalisation).

EU comment

The EU suggests deleting the entire paragraph:

"~~The recommended CO2 displacement rate for rabbits is 50-60% of the chamber or cage volume/min as this results in a significantly shorter time to insensibility and death (Walsh et al., 2016, AVMA 2020). Exposure to CO2 at high concentrations can reduce pre-stun handling and produce irreversible stunning in rabbits. With a stun to stick interval of up to 2 min, 200 s of exposure at 80%, 150 s at 90% and 110 s at 98% are recommended (Dalmau et al., 2016). While there are advantages to high CO2 exposure in rabbits, it is not without welfare concerns (aversion, vocalisation).~~"

Justification
It is not logical to keep this paragraph and stating under the general recommendation that:
"Conscious animals should not be exposed to carbon dioxide exceeding 40%." The paragraph recognises indeed that exposure to high concentration is aversive for rabbits.
However, the maximum of 40% CO_2 may have to be differentiated by animal species. And EFSA concluded that *further research is needed* to elicit the CO_2 concentration with the minimum aversion in rabbits (Stunning methods and slaughter of rabbits for human consumption - 2020 - EFSA Journal - Wiley Online Library).

Article 7.5.30.

Bleeding in animals arriving in containers

EU comment

The EU suggests amending the sentence as follows:

Bleeding ~~in~~ of animals arriving in containers

Justification
Editorial suggestion.

1. Animal welfare concerns

In poultry, the most common animal welfare concern at the time of bleeding is recovery of consciousness due to ineffective electric water bath *stunning* practices. There are a lot of factors that determine the efficacy of a *stunning* procedure such as type of chicken (broiler, breeder, layer), animal weight, voltage, frequency, impedance and duration of *stunning* [Zulkifli *et al.*, 2013; Raj, 2006; Wotton & Wilkins, 2004].

Improper *stunning* practice leads to the risk of animal suffering from pain, during and after *slaughter* if they regain consciousness. There is also an additional risk of injury on bones (coracoid and scapula), wings and joints due to flapping if birds regain consciousness.

Bleeding without prior *stunning* increases the risk of animal suffering because the incision to sever blood vessels results in substantial tissue damage in areas well supplied with nociceptors. The activation of these nociceptors causes the animal to experience pain [Gregory, 2004; Gibson et al., 2009]. Loss of consciousness due to bleeding is not immediate and there is a period during which the animal can feel fear, pain and distress [Gregory, 2004; Johnson *et al.*, 2015].

In case of bleeding without *stunning*, higher cases of injury, bruises, haemorrhage and broken body parts are expected to occur due to wing flapping and violent muscular contractions [McNeal *et al.*, 2003).

Bleeding duration also plays an integral part in processing, where animals that have not undergone a sufficient bleeding period (min 40 sec), may still be alive upon reaching the scalding tank. Live and conscious birds, if not removed prior to scalding, will then be subjected to additional pain stimulators from the heat inside the scalding tank.

2. Animal-based and other measurables include:

The main animal-based measurable is the blood flow (rate and duration). For animal-based and other measurables of return of consciousness after *stunning*, see Article 7.5.16.

One of the most common parameters in determining bleeding efficiency is the percentage of blood loss, where the amount of blood loss is estimated through the difference between pre-slaughter weight and post-slaughter weight [Velarde *et al.*, 2003; Sabow *et al.*, 2015].

The effectiveness of a *stunning* procedure on birds can be seen through the following signs: absence of corneal reflex, loss of posture tonic-clonic seizures and apnoea. Presence of one or more signs during bleeding may be the result of ineffective *stunning* procedure.

EU comment

The EU suggests amending the sentence as follows:

"Presence of one or more of these signs during bleeding may be the result of ineffective *stunning* procedure."

Justification
For the sake of clarity.

3. Recommendations:

The *slaughterhouse/abattoir* operators should ensure that:

– qualified personnel take random samples of birds between the end of *stunning* and before bleeding to ensure birds are not showing signs of consciousness;

– qualified personnel right after bleeding check that the jugular veins, carotid artery and windpipe were cut thoroughly, guaranteeing a well bleeding process afterwards;

– the slaughter line speed allows a minimum bleeding period of 40 seconds (for chickens) so that there is minimum blood loss of 60 percent before reaching the scalding tank or other potentially painful operation;

– qualified personnel check that at the bleeding line, especially before scalding, birds are completely dead. Birds that are still alive need to be removed from shackle.

EU comment

The EU suggests amending the sentence as follows:

"- qualified personnel check that at the bleeding line, especially before scalding, birds are ~~completely~~ dead. Birds that are still alive need to be euthanized immediately ~~removed from shackle~~.

Justification
Birds could be dead or not and for this reason we prose to remove completely. Removing the animals from shackle is not sufficient and animals should be euthanized.

Decapitation should not be used as a bleeding technique because it does not allow monitoring possible return of consciousness.

4. Species-specific recommendations

None identified.

Article 7.5.31

Emergency killing on animals arriving in containers

This article addresses animals that show signs of severe pain or other types of severe suffering before being unloaded or within the *slaughterhouse/abattoir*. These animals may correspond to animals unfit to travel as listed in Article 7.3.7. Principles described may also apply to animals that are not suitable for *slaughter* for commercial reasons, even if they do not present signs of pain or suffering.

1. Animal welfare concerns:

Some animals can arrive at *slaughterhouses/abattoirs* with injuries or severe illnesses that can cause undue pain and suffering.

2. Animal-based and other measurables include:

Animals requiring emergency *killing* are those with severe injuries such as fractures, bone dislocations, and large open wounds.

EU comment

The EU suggests adding the following sentence:

"They may also present clinical signs of serious illness or being in a state of extreme weakness."

Justification
This wording is already used under Article 7.5.19 for free moving animals and could apply for animals in containers.

3. Recommendations:

Animal handlers should euthanise the animal as soon as they are identified at arrival, during lairage or at the time of shackling.

Emergency *killing* should be systematically recorded and analysed to improve procedures and prevent recurrences.

4. Species-specific recommendations:

None identified yet.

Article 7.5.32.

Methods, procedures or practices unacceptable on animal welfare grounds for animals arriving in containers

1) None of the following practices for handling animals are acceptable and they should not be used:

EU comment

The EU suggests deleting and replacing the sentence with the following:

"~~None of~~ The following practices for handling animals are not acceptable and should not be used:"

Justification
Same as provided for Article 7.5.20 (1).

a) applying pressure using an injurious object or applying an irritant substance to any part of the body of the animal;

b) hitting animals with instruments such as large sticks, sticks with sharp ends, metal piping, stones, fencing wire or leather belts;

EU comment

The EU suggests amending the sentence as follows:

"b) hitting animals with instruments such as large sticks, sticks with sharp ends, ~~metal~~ piping, stones, fencing wire or leather belts;"

Justification
To be in line with the changes proposed under Article 7.5.20 for free moving animal.

c) throwing or dropping animals;

EU comment

The EU suggests amending the sentence as follows:

"kicking, throwing or dropping animals;"

Justification
To be in line with the changes proposed under Article 7.5.20 for free moving animal.

d) grasping, lifting or dragging animals only by some body parts such as their tail, head, ears, limbs, hair or feathers.

2) None of the following practices for restraining animals are acceptable and should not be used:

EU comment

The EU suggests deleting and replacing the sentence with the following:

"~~None of~~ The following practices for restraining animals are not acceptable and should not be used:"

Justification
Same as provided for Article 7.5.20 (1).

a) mechanical clamping of the legs or feet of the animals as the sole method of restraint;

b) breaking legs, cutting leg tendons or blinding animals;

c) applying electrical current that does not span the brain such as the use of the electrical *stunning* method with a single application leg-to-leg;

d) severing brain stem by piercing through the eye socket or skull bone;

In poultry, electro-immobilisation for neck-cutting or preventing wing flapping during bleeding, or the method of brain piercing through the skull without prior *stunning*.

References

Anonymous (2017). Animal welfare aspects in respect of the slaughter or killing of pregnant livestock animals (cattle, pigs, sheep, goats, horses). EFSA Journal 15:4782.

Anonymous (2018). Scientific Opinion on monitoring procedures at slaughterhouses for bovines. EFSA Journal 11:3460.

Anonymous (2018). Technical Note No 19 Carbon Dioxide cx and Killing of Pigs. Humane Slaughter Association, UK. https://www.hsa.org.uk/downloads/technical-notes/tn19-carbon-dioxide-stunning-and-killing-of-pigs.pdf

AVMA Guidelines for the Humane Slaughter of Animals (2016). Available from: https://www.avma.org/KB/Resources/Reference/AnimalWelfare/Documents/Humane-Slaughter-Guidelines.pdf

Dalmau, A., Pallisera, J., Pedernera, C., Muñoz, I., Carreras, R., Casal, N., Mainau, E., Rodríguez, P., Velarde, A.. (2016). Use of high concentrations of carbon dioxide for stunning rabbits reared for meat production. World Rabbit Science, 24: 25-37.

Daly, C.C., Gregory, G. and Wotton, S.B. (1987). Captive bolt stunning of cattle: effects on brain function and role of bolt velocity. British Veterinary Journal 143 574-580.

EFSA (2004). Welfare aspects of animal stunning and killing methods. Scientific Report of the Scientific Panel for Animal Health and Welfare on a request from the Commission related to welfare aspects of animal stunning and killing methods. Available from: http://www.efsa.europa.eu/de/scdocs/doc/45.pdf.

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare) (2013a). Scientific opinion on monitoring procedures at slaughterhouses for bovines. EFSA Journal 2013. 11, 3460. Available from: http://dx.doi.org/10.2903/j.efsa.2013.3460.

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare) (2013b). Scientific opinion on monitoring procedures at slaughterhouses for sheep and goats. EFSA Journal 2013. 11, 3522. Available from: http://dx.doi.org/10.2903/j.efsa.2013.3522.

EFSA AHAW Panel (EFSA Panel on Animal Health and Animal Welfare) (2017) Scientific Opinion on the animal welfare aspects in respect of the slaughter or killing of pregnant livestock animals (cattle, pigs, sheep, goats, horses). EFSA Journal 2017;15(5):4782, 96 pp. Available from : https://doi.org/10.2903/j.efsa.2017.4782

EFSA AHAW Panel (EFSA Panel on Animal Health and Animal Welfare) (2019) Scientific Opinion on the Slaughter of animals: poultry. EFSA Journal 2019;17(11):5849, 91 pp. Available from : https://doi.org/10.2903/j.efsa.2019.5849

Finnie, J.W. (1993). Brain damage caused by captive bolt pistol. J. Comp. Patholo. 109:253–258.

Finnie, J.W, J. Manavis, G.E. Summersides and P.C. Blumbergs. (2003). Brain Damage in Pigs Produced by Impact with a Non-penetrating Captive Bolt Pistol. Aust. Vet. J. 81:153-5.

Gibson, T.J, Johnson, C.B, Murrell, J.C, Hulls, C.M., Mitchinson, S.L., Stafford, K.J., Johnstone, A.C. and Mellor, D.J. (2009). Electroencephalographic responses of calves to slaughter by ventral neck incision without prior stunning. New Zealand Veterinary Journal 57 77-83.

Gibson, T.J., Mason, C.W., Spence, J.Y., Barker, H. and Gregory, N.G. (2014). Factors Affecting Penetrating Captive Bolt Gun Performance. Journal of Applied Animal Welfare Science 18 222-238

Grandin, T. (1980). Mechanical, electrical and anesthetic stunning methods for livestock. International Journal for the Study of Animal Problems, 1(4), 242-263

Gregory, N.G.(2004). Physiology and Behaviour of Animal Suffering. Blackwell Science, Oxford, p. 227. ISBN: 0-632-06468-4.

Johnson, C.B., Mellor, D.J., Hemsworth, P.H. and Fisher, A.D (2015). A scientific comment on the welfare of domesticated ruminants slaughtered without stunning. New Zealand Veterinary Journal 63 58-65.

Mellor, D.J., Diescha, T.J., Gunn, A.J. and Bennet, L. (2005). The importance of 'awareness' for understanding fetal pain. Brain Research Reviews 49 (2005) 455–471.

Moberg, G. and Mench, J. (2000). The Biology of Animal Stress: Basic Principles and Implications for Animal Welfare, CABI.

Recommended Animal Handling Guidelines & Audit Guide: A Systematic Approach to Animal Welfare (2017). Rev. 1, North American Meat Institute (NAMI).

Annex 4 (contd)

Pleiter, H. (2010). Review of Stunning and Halal Slaughter. Meat and Livestock Australia.

von Holleben, K., von Wenzlawowicz, M., Gregory, N., Anil, H., Velarde, A., Rodriguez, P., Cenci Goga, B., Catanese, B., Lambooij, B. (2010). Report on good and adverse practices—animal welfare concerns in relation to slaughter practices from the viewpoint of veterinary sciences. Dialrel report. Deliverable. 1, 3. http://www.dialrel.eu/images/veterinary-concerns.pdf

Lara, L. and Rostagno M. (2018). Animal welfare and food safety in modern animal production, in Advances in Agricultural Animal Welfare, Food Science, Technology and Nutrition, Pages 91-108.

Blokhuis, H., Keeling, L., Gavinelli, A. and Serratosa, J. (2008) Animal welfare's impact on the food chain. Trends in Food Science & Technology, 19 (2008), 79-88.

Walsh JL, Percival A, Turner PV. Efficacy of blunt force trauma, a novel mechanical cervical dislocation device, and a non-penetrating captive bolt device for on-farm euthanasia of pre-weaned kits, growers, and adult commercial meat rabbits. Animals (Basel) 2017;7:100.

Annex 5

CHAPTER 8.16.

INFECTION WITH RINDERPEST VIRUS

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter.

Comments are inserted in the text below.

Article 8.16.1.

General provisions

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

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

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

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

However, RPV-containing material including live vaccines continue to be held in a number of institutions around the world and this poses a *risk* of virus re-introduction into susceptible animals. Therefore, manipulation of existing RPV-containing material, and synthesis or other forms of production of RPV-containing material, is forbidden unless authorised by the FAO and OIE.

EU comment

We note with appreciation that further to our previous comment, the OIE Secretariat has been asked to look into how a reference to the relevant resolution could be included in the text of the paragraph above, in relation to the prohibition of manipulation of RPV-containing material unless authorised by FAO and OIE. While it may indeed be unusual to refer to resolutions in the Code, it would indeed be relevant in this context as such prohibition is not included in the text of this chapter. We look forward to proposals on this in the report of the September 2021 meeting of the Code Commission.

As sequestration and destruction of virus stocks proceed, the *risks* of re-occurrence of *infection* are expected to progressively diminish. 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.

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 or 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 with or without clinical signs.

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

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

3) For the purposes of this chapter:

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

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

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

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

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

Article 8.16.2.

1. Safe commodities during global freedom

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

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

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

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

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

c) gelatine.

Article 8.16.2bis.

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

Articles 8.16.5. to 8.16.13. apply in the event of re-emergence of rinderpest.

~~First section: applicable during global freedom~~

Article 8.16.3.

Ongoing surveillance post global freedom

All countries in the world, whether or not Member Countries of the OIE, have completed all the procedures necessary to be recognised as free from rinderpest *infection,* and annual re-confirmation of rinderpest absence 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 for routine checking. Countries should also maintain national contingency plans for responding to events suggestive of rinderpest including the checking of potential *case*s and the prompt identification of suspected *case*.

EU comment

For reasons of consistency with amendments highlighted in yellow in this draft chapters concerning use of "free from rinderpest" vs. "infection with RPV" (e.g. Articles 8.16.6 and 8.16.9), the EU suggests deleting the word "infection" after "free from rinderpest" in the 2nd line of the paragraph above.

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 and recover from a rinderpest *outbreak*. If needed, expertise from the region or continent, or international organisations may be requested to provide resources to help confirm or rule out if the potential *case* meets the definition for a suspected *case* or a *case* ~~of rinderpest~~.

Article 8.16.4.

Annual update on RPV-containing material

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

EU comment

The EU notes that the paragraph above refers to "annual reports" to be submitted "each year", and suggests OIE consider revising the wording to avoid redundancy.

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

Article 8.16.5.

Response to a recurrence of rinderpest

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

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

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

EU comment

The EU notes with appreciation that the OIE Secretariat has been asked to look into the legal obligations of member countries in relation to immediate notification of suspected cases of infection with RPV, further to our previous comments. We look forward to the outcomes and possible proposals on this in the report of the September 2021 meeting of the Code Commission.

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 be established in accordance with Article 8.16.8.

EU comment

For consistency with the changes proposed in Article 8.16.8., we would suggest replacing "may be established" with "should be established" also in the paragraph above. Consideration could also be given to add wording such as "without delay" or "timely", as it seems important to encourage countries as much as possible to rapidly establish a containment zone in the event of a limited outbreak of rinderpest.

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.

EU comment

The EU suggests clarifying how and when the free status of a country will be reinstated, after it has been suspended in accordance to the paragraph above. Indeed, this is relevant for recovery of global freedom in accordance with Article 8.16.10. However, there are no provisions for such reinstatement of suspended country status anywhere in this chapter, and Article 8.16.9. on recovery of free status does not apply to countries that have not had any case of infection with RPV.

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.

Article 8.16.9.

Recovery of free status for a country

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

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

One of the following waiting periods is applicable:

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

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

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

   c) 18 months after the *disinfection* of the last affected *establishment* and the last *vaccination*, where a *stamping-out policy*, emergency *vaccination* not followed by the *slaughter* of all vaccinated animals,

and targeted *surveillance* in accordance with Article 8.16.11. have been applied;

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

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

b) send a declaration to the OIE stating that:

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

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

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

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

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

In the scenarios mentioned in points 1a), 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 submitted evidence has been accepted by the OIE.

EU comment

The EU queries whether it is clear enough from the paragraph above that the favourable outcome of both the international expert mission and the review of documented evidence by the OIE is necessary for regaining free country status. Indeed, the second sentence only refers to acceptance by the OIE of submitted evidence, not to the outcomes of the expert mission.

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.

EU comment

There is no mention in the paragraph above of countries whose free status has been suspended in accordance with Article 8.16.6. Reference is made to the EU comments inserted in that article.

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*.

EU comment

Given the definition of "potential *case*" in point 3(b) of Art. 8.16.1., another term should perhaps be used at the end of point 2 above. Indeed, farmers and workers would be expected to report suspect clinical signs, irrespective of epidemiological considerations or laboratory investigations.

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

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

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

Article 8.16.12.

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

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

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

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

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

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

Article 8.16.13.

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

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

Annex 6

CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

EU comment

The EU thanks the OIE for the latest version of the revised Chapter 11.4. on bovine spongiform encephalopathy. The EU appreciates that sufficient explanations have been provided, or appropriate amendments introduced in the draft, to address some of the comments lodged in December 2020.

However:

- it remains critical for the EU that total transparency is ensured on the 'period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible' (hereafter "the period"). The EU will therefore pay a lot of attention to the expected feedback from the OIE Secretariat on the validation process of the period and on how to communicate this information to the Members;

- the EU is concerned with the exclusion of blood and blood products from the definition of 'protein meal' in Article 11.4.1, point 4b);

- the EU still looks forward to the experts' opinion on Articles 11.4.2.1 point d) and 11.4.16bis point 3;

- the EU would like to insist that cattle and products imported from a negligible or controlled risk country should not only be born, but also have stayed continuously, in a country during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible, if the absence of feeding with protein meal is not to be explicitly required. This addition is necessary to ensure that the animals have not been exposed to a possible contamination during the period between birth and export or slaughter;

- the EU would very much appreciate some further clarification of the notion of 'appropriate supporting clinical history' in Article 11.4.18., points 2.c) and 2.d).

- finally, the EU remains strongly concerned with, and therefore keeps a reservation on, the fact that the future chapter will allow a Member to be recognised with BSE negligible risk or controlled risk without enforcing the minimum ruminant-to-ruminant feed ban that is required by the current Code.

Detailed comments are provided below.

EU comment

The EU notes that the following expressions appear in the chapter:
- the risk of BSE being recycled within the cattle population;
- the risk of BSE being recycled in the cattle population;
- the risk of BSE agents being recycled in the cattle population;
- the risk of the BSE agents being recycled in the cattle population.

The EU considers that consistency should be ensured throughout the text.

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. 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~~,~~), 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*:

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

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

EU comment

We suggest adjusting the last sentence of point b) as follows:

'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:

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

~~4~~b) '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.

EU comment

The EU is concerned with the proposed exclusion of blood and blood products from the definition of protein meal.

We note that the proposed definition is about "final or intermediate products". Considering that blood is an 'animal tissue' and not a 'product', contrary to 'blood products' or 'peptides', the EU is of the opinion that it is not appropriate nor consistent to mention 'blood' in the exclusions.

Moreover, the proposed definition is not species-specific, and is therefore meant to apply also to protein meal derived from cattle. The fact that blood products are not listed in Article 11.4.1bis as a safe commodity, and that specific recommendations for its trade are laid down in Article 11.4.13., demonstrate that there is a risk of BSE associated to

ruminant blood and blood products, which requires mitigation. However, we note that there is no mention of blood products in Article 11.4.2. nor in Chapter 1.8., which focus entirely on protein meal as the source of risk through feed.

Excluding blood products from the definition of protein meal therefore appears to introduce a loophole, where the risk of feeding cattle with potentially contaminated blood products is just not considered. Blood products derived from ruminants should definitely not be excluded from the definition of protein meal.

We therefore request the adjustment of point b) as follows:

'b) '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.'

Alternative option:

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

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

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

Article 11.4.1bis.

Safe commodities

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

1) *milk* and *milk products*;

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

3) hides and skins;

4) gelatine and collagen;

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

~~6) tallow derivatives;~~

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

7) foetal 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 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 being recycled within the cattle population by identifying all potential factors associated with the occurrence of BSE and their historic perspective. Member Countries should review the *risk assessment* annually to determine whether the situation has changed.

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

   a) Entry assessment

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

      i) Cattle;

      ii) Ruminant-derived protein meal;

      iii) *Feed* (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

      ~~An~~The exposure assessment evaluates the likelihood of cattle being exposed to BSE during the preceding eight years, either through imported *commodities* or as a result of the presence of BSE agents in 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 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;

– awareness programme under the scope of the *feed* ban;

– monitoring and enforcement of the *feed* ban.

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

c) Consequence assessment

~~A~~The consequence assessment evaluates the likelihood of cattle becoming infected ~~with~~ following exposure to the BSE agents together with the likely extent and duration of any subsequent recycling and amplification within the cattle population during the preceding eight years. The factors to be considered in the consequence assessment are:

i) age at exposure;

ii) production type;

iii) the impact of cattle industry practices or the implementation of BSE 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 BSE agents have been recycled in the cattle population through the feeding of ruminant-derived protein meal, with indigenous *cases* arising ~~as a consequence~~;

EU comment

In December 2020, we expressed the opinion that:

- 'the feeding of ruminant-derived protein meal' is too restrictive and does not cover the whole range of events that could result in the BSE agents being recycled;

- the addition of 'with indigenous cases arising' is not necessary and could even be confusing, particularly if no such case has been detected.

We therefore requested the deletion of 'through the feeding of ruminant-derived protein meal, with indigenous cases arising'.

We note in the report of the last meeting of the Code Commission that the OIE Secretariat has been requested to seek expert advice on this question.

We maintain our comment and look forward to hearing back from the experts.

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:

1) A *risk assessment* as described in Article 11.4.2. that has identified all potential risk factors associated with the occurrence of BSE has been conducted, and the Member Country has demonstrated through documented

evidence that the ~~likelihood~~risk of BSE agents being recycled in 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.~~

EU comment

In December 2020, the EU proposed the addition of the following point 1a) as an additional condition to be met to be granted the negligible BSE risk status (for the preceding 8 year) or the controlled BSE risk status in accordance with Article 11.4.4.

'1a) Protein meal derived from ruminants has not been fed to ruminants.'

The rational for this addition was detailed in the EU comment provided in December 2020. We regret that the Code Commission did not agree with this proposal.

We would like to reiterate that the EU remains strongly concerned with the possibility that a Member be recognised with BSE negligible risk or controlled risk without enforcing the minimum ruminant-to-ruminant feed ban currently required across the board.

2) The *surveillance* provisions as described in Article 11.4.~~20~~18. have been implemented.

3) EITHER:

   a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported or has been diagnosed as atypical BSE as defined in this chapter;

   OR

   b) if there has been an indigenous *case* of classical BSE:

      EITHER:

      i) all *cases* were born at least eight years ago;

      OR

      ii) where a *case* was born within the preceding eight years, subsequent investigations have confirmed that the ~~likelihood~~risk of BSE being recycled within the cattle population has continued to be negligible.

4) Any *cases* of BSE that have been detected have been completely destroyed or disposed of to ensure that they do not enter the animal *feed* chain.

The country or the *zone* will be included in the list of countries or *zones* posing a negligible risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1 to 4 above. Documented evidence should be resubmitted annually for points 1 to 4 above.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

Article 11.4.3bis.

Recovery of negligible BSE risk status

~~When~~Should an indigenous *case* of classical BSE ~~is reported~~ in an animal born within the preceding eight years occur in a country or *zone* recognised as ~~having~~posing a negligible ~~BSE~~ risk for BSE, the status~~,~~ of the ~~negligible BSE risk status~~country or *zone* is suspended~~ and the recommendations for controlled BSE risk status apply, pending~~. The status may be recovered when the outcome of subsequent investigations ~~confirming~~confirms that the ~~likelihood~~risk of BSE being recycled within the cattle population continues to be negligible. ~~The~~In the interim, the provisions for a country or *zone* ~~will regain~~with a controlled BSE risk status apply.

The negligible BSE risk status of the country or *zone* will be reinstated only after the submitted evidence has been accepted by the OIE.

Article 11.4.4.

Controlled BSE risk

The BSE risk ~~of the cattle population~~ of a country or~~,~~ *zone* ~~or *compartment*~~ can be considered to be controlled provided all of the conditions of Article 11.4.3. are met, but at least one 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, *zone* or *compartment* is considered to be undetermined if it cannot be demonstrated that it meets the requirements for negligible or controlled BSE risk.

EU comment

To ensure consistency with the first paragraphs of Article 11.4.3. (negligible BSE risk) and 11.4.4. (controlled BSE risk), and for the same reasons, the EU suggests the deletion of the reference to compartments in this article, and its rewording as follows:

> **'The BSE risk 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 11.4.6.~~

~~**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 in the country, *zone* or *compartment* during the period when the ~~likelihood~~risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

EU comment

In December 2020, the EU placed the following comment:

"The EU would like to point out that the above-proposed wording of point 2) seems to imply that the cattle have to be born in the country where "the cattle selected for export came from" (see point 1); in addition, the proposed wording does not address the risk of contamination between the date of birth and the latest period of life of the cattle, should it be sold initially in a country at a time when the risk of recycling is not negligible there. The EU considers the provision should allow for the cattle to be born and raised in different countries, provided they have always remained in a country during the period when the risk of recycling was negligible in that country.

The EU therefore suggests that point 2) is amended as follows:

> **'2) the cattle selected for export were born and constantly raised in a~~the~~ country, zone or compartment, or in countries, zones or compartments, during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible' "**

The Code Commission did not agree, judging "*the comment to be too stringent and prescriptive considering the reality of the current global situation on BSE, noting that the records of the animal's movements could be monitored through the animal identification system described in point 1*".

The EU respectfully disagrees with the Code Commission's position.

The certification that a cattle is exported from a country with negligible or controlled risk and was born in a country during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible (=the period) does not appear to be a sufficient guarantee. Please consider for example the following scenario: a cattle is born in country A during the period; it is exported at the age of 1 or 2 weeks to country B before the start of the period, where it is raised; country B is later granted the controlled risk status; the adult cattle is then exported by country B to country C. In this scenario, fully compatible with the wording of Article 11.4.7. as proposed, the cattle will have been raised before export in a country where there is a risk of recycling of the BSE agents at an age when it was fully susceptible to BSE, with

no guarantee that it has not been fed protein meal. The EU considers that the risk for the importing country C would not be appropriately mitigated.

The EU insists that the Code Commission should adequately address this issue. The same comment also applies to Article 11.4.10. point 3 and 11.4.13. point 2).

OR

3)-

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

~~b)~~ ~~are~~ it 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, zone or compartment posing an undetermined BSE risk

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

1) the cattle selected for export are identified ~~by a permanent individual~~ through an *animal identification system* ~~from birth~~ enabling ~~each *animal*~~ them to be traced throughout ~~its~~ their lifetime;

2) ~~are~~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~~negligible or controlled BSE risk and are identified through an *animal identification system*;

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

AND EITHER:

3) they were born in the country, *zone* or *compartment* during the period when the ~~likelihood~~ risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

EU comment

The comment lodged in Article 11.4.7., point 2, also applies here, resulting in the suggested rewording of point 3 as follows:

'3) they were born and constantly raised in a~~the~~ country, zone or compartment, or in countries, zones or compartments, during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;'

OR

4) the *fresh meat* and *meat products*:

a) derived from cattle not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to *slaughter*; and

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

i) the *commodities* listed in point~~s~~ 1~~)~~ ~~a) and 1) *b)*~~ of Article 11.4.14.;

ii) mechanically separated meat from the skull ~~and~~nor or from the vertebral column from 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*~~3) the cattle from which the *fresh meat* and *meat products* were derived:

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

~~c~~b) were not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to *slaughter*;

~~2~~4) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

a) the *commodities* listed in point~~s~~ 1~~)~~ ~~a) and 1) *b)*~~ of Article 11.4.14.;

b) mechanically separated meat from the skull ~~and~~nor or from the vertebral column from cattle over 30 months of age.

Article 11.4.12.

Recommendations for importation of cattle-derived protein meal from a country, zone or compartment posing a negligible BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the cattle from which the protein meal was derived ~~came from a country, *zone* or *compartment* posing a negligible BSE risk.~~ :

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

2) are identified through an *animal identification system* and were born in the country, *zone* or *compartment* during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

Article 11.4.13.

Recommendations for importation of blood and blood products derived from cattle (except foetal 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~~

2) the ~~blood and blood products came from a country, *zone* or *compartment* posing a controlled BSE risk and the~~ cattle from which the blood and blood products were derived are identified through an *animal identification system* and were born in the country, *zone* or *compartment* during the period when the ~~likelihood~~ risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

EU comment

The comment lodged in Article 11.4.7., point 2, also applies here, resulting in the suggested rewording of point 2 as follows:

'2) the cattle from which the blood and blood products were derived are identified through an animal identification system and were born and constantly raised in a~~the~~ country, zone or compartment, or in countries, zones or compartments, during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;'

OR

3) the blood and blood products were:

   a) collected from cattle not subjected to a stunning process~~, or to any other procedure that can contaminate the blood with nervous tissue,~~ with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate the blood with nervous tissue, prior to *slaughter*; and

   b) collected and processed in a manner that ensures they are not contaminated with nervous tissue.

Article 11.4.14.

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

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

~~a~~1*)* ~~distal~~ Distal ileum from cattle of any age; ~~*b)*~~ skull, brain, eyes, vertebral column and spinal cord from cattle that were at the time of *slaughter* over 30 months of age~~.~~; or any *commodity* contaminated by them, for the preparation of protein products, food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices, which originate from a country, *zone* or *compartment* posing:

a) an undetermined BSE risk;

b) a controlled BSE risk or a negligible BSE risk if the *commodities* are derived from cattle born before the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

EU comment

As evidenced in Article 1.8.5. point 2.b)ii), the notion of 'commodities with the greatest BSE infectivity' applies not only to slaughtered animals, but also to fallen stock and animals condemned at ante-mortem inspection. The EU therefore suggests to amend point 1 as follows:

'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* or death 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:'

2) Protein products, food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices prepared using *commodities* listed in point~~s~~ 1~~) *a)* or 1) *b)*~~ above ~~of this article, which originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk, should not be traded~~.

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

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

Article 11.4.15.

Recommendations for importation of tallow (other than as defined in Article 11.4bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

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

2) ~~the tallow~~ is derived from cattle which have been subjected to an ante-mortem inspection with favourable results, and has not been prepared using the *commodities* listed in ~~points~~point 1~~) a) and 1) b)~~ of Article 11.4.14.

Article 11.4.16.

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

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

1) ~~the dicalcium phosphate~~ came from a country, *zone* or *compartment* posing a negligible BSE risk; or

2) ~~the dicalcium phosphate~~ is a co-product of bone gelatine.

Article 11.4.16bis.

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

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

1) originate from a country, *zone* or *compartment* posing ~~that poses~~ a negligible BSE risk; or

2) are derived from tallow that meets the conditions referred to in Article 11.4.15.; or

3) have been produced by hydrolysis, saponification or transesterification that uses high temperature and pressure.

EU comment

In December 2020, the EU lodged the following comment:

"In order to clarify that the expression 'that uses high temperature and pressure', in point 3, only applies to the transesterification process, the EU would like to propose the following adjustment:

'3) have been produced by hydrolysis, saponification, or by transesterification that uses high temperature and pressure.' "

We note in the report of the last meeting of the Code Commission that the OIE Secretariat has been requested to seek expert advice on this question.

We maintain our comment and look forward to hearing back from the experts.

Article 11.4.17.

Procedures for reduction of BSE infectivity in protein meal

The following procedure should be used to reduce the infectivity of any ~~transmissible spongiform encephalopathy~~BSE agents ~~which~~that may be present during the production of protein meal 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

~~1)~~ ~~*Surveillance* for BSE consists of the regular reporting of animals with clinical signs suggestive of BSE to the *Veterinary Authority* for subsequent investigation and diagnosis. The credibility of the *surveillance* programme is supported by:~~

~~a)~~ ~~compulsory notification of BSE throughout the whole territory by all those stakeholders involved in the rearing and production of livestock including farmers, herdsmen, *veterinarians*, transporters and *slaughterhouse/abattoir* workers;~~

~~b)~~ ~~an ongoing awareness programme to ensure that all stakeholders are familiar with the clinical signs suggestive of BSE as well as the reporting requirements;~~

~~c)~~ ~~appropriate *laboratory* investigations in accordance with the *Terrestrial Manual* and follow-up field investigation as necessary of all clinical suspects.~~

~~2~~1) BSE is a progressive, fatal disease of the nervous system of cattle that usually has an insidious onset that is refractory to treatment. A range of clinical signs that vary in severity and between animals have been described for classical BSE:

a) progressive behavioural changes that are refractory to treatment such as increased excitability, depression, nervousness, excessive and asymmetrical ear and eye movements, apparent increased salivation, increased licking of the muzzle, teeth grinding, hypersensitivity to touch and/or sound (hyperaesthesia), tremors, excessive ~~vocalization~~vocalisation, panic-stricken response and excessive alertness;

b) postural and locomotory changes such as abnormal posture (dog sitting), abnormal gait (particularly pelvic limb ataxia), low carriage of the head (head shyness), difficulty avoiding obstacles, inability to stand and recumbency;

c) ~~generalized~~generalised non-specific signs such as reduced *milk* yield, loss of body condition, weight loss, bradycardia and other disturbances of cardiac rhythm.

Some of these signs are also likely to be relevant for atypical BSE, particularly those associated with difficulty in rising and recumbency. A nervous form of atypical BSE resembling classical BSE may be observed with over-reactivity to external stimuli, unexpected startle responses and ataxia. In contrast, a dull form of atypical BSE may be observed with dullness combined with a low head carriage and compulsive behaviour (licking, chewing, pacing in circles).

The clinical signs of BSE usually progress on a spectrum over a few weeks to several months, but ~~in~~on rare occasions cases can develop acutely and progress rapidly. ~~In the continuum of the disease spectrum, t~~The ~~The~~ final stages of the disease are characterised by recumbency, coma and death.

~~Cattle displaying some of the above mentioned progressive neurological signs without signs of infectious illness, and that are refractory to treatment, are candidates for examination.~~

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

2) *Surveillance* for BSE consists of the reporting of all animals that ~~lie on the continuum of the~~ show symptoms of the clinical BSE spectrum to the *Veterinary Authority* for subsequent investigation and follow-up.

In those countries where cattle are intensively reared and subjected to regular observation, it is likely that ~~such~~ animals that display clinical signs suggestive of BSE will be more readily seen. Behavioural changes, that 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 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 not observed for a period of time, it may only be initially seen as a downer (non-ambulatory) or found dead (fallen stock). ~~Under such circumstances, if there is an appropriate supporting clinical history, these animals that lie on the continuum of a progressive disease from clinical suspect to downer to fallen stock may still be suitable candidates for *surveillance*.~~

The investigation of potential *surveillance* candidates should take into account that the vast majority of BSE cases arise as single, isolated events. The concurrent occurrence of multiple animals with behavioural or neurological signs, non-ambulatory or fallen stock is most likely associated with other causes.

The following animals that lie on ~~the continuum of~~ the ~~disease~~clinical spectrum should be targeted for BSE *surveillance*:

a) those displaying some of the progressive clinical signs mentioned in point 1 of Article 11.4.18. suggestive of BSE that are refractory to treatment, and where other common causes of behavioural or neurological signs (e.g. infectious, metabolic, traumatic, neoplastic or toxic causes) have been ruled out;

b) those showing behavioural or neurological signs at ~~that have been subjected to an~~ ante-mortem inspection ~~with unfavourable results~~ at *slaughterhouses/abattoirs*;

c) those presented as downers (non-ambulatory), with an appropriate supporting clinical history (i.e. other common causes of recumbency has been ruled out);

d) those found dead (fallen stock), with an appropriate supporting clinical history (i.e. other common causes of death has been ruled out).

EU comment

The EU thanks the Code Commission for taking into consideration the EU comment made in December 2020 and proposing a rewording of points c) and d). However, we are of the opinion that the text still lacks clarity, or may be too restrictive. In particular, we consider that the expression 'clinical history' can only refer to the clinical signs possibly shown by an animal before it is presented as a downer or it is found dead. Consequently:

- **as regards point c), where the animal is still alive, we suggest adding a reference to the current 'clinical condition' of the animal, rather than indirectly explain with the parenthesis that the expression 'clinical history' may include the current state of recumbency where there was no previous clinical sign.**
- **as regards point d), we propose to consider the clinical history on the one hand, and on the other hand, where there is no clinical history (i.e. where no sign has been shown or noticed before the animal was found dead) the cause of death, if identified. We also suggest including for more clarity a copy/paste of the examples of other common causes already mentioned in point a).**

The EU therefore proposes amending the wording of points c) and d) as follows:

'c) those presented as downers (non-ambulatory), with an appropriate supporting clinical history or clinical condition ~~(i.e. other common causes of recumbency has been ruled out)~~;

d) those found dead (fallen stock), with an appropriate supporting clinical history or where ~~(i.e.~~ other common causes of death (e.g. infectious, metabolic, traumatic, neoplastic or toxic causes) ~~has~~ have been ruled out~~)~~.'

All these animals should be followed up with appropriate laboratory testing in accordance with the *Terrestrial Manual* to accurately confirm or rule out the presence of BSE agents.

3) The credibility of the *surveillance* programme is supported by:

a) ongoing awareness and training programmes to ensure that all those stakeholders involved in the rearing and production of livestock including farmers, herdsmen, *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 for BSE *surveillance*, for determination of animals to be subjected to laboratory testing, for the collection and submission of samples for laboratory testing, and for follow-up epidemiological investigation for BSE positive findings.

EU comment

Considering that Article 11.4.18. is dedicated to surveillance and that the management of a BSE case is covered in Article 11.4.3. point 4, the EU is of the opinion that the purposes of the epidemiological investigation mentioned in point d) are above all to identify the source of the contamination and if other animals should be investigated, which are irrelevant in case of atypical BSE.

The EU therefore considers that the scope of the provision relating to an epidemiological investigation, in Article 11.4.18. point 3.d), should be restricted to classical BSE cases only, and proposes the following amendment:

'd) robust, documented, evaluation procedures and protocols for the identification and reporting of potential candidates for BSE surveillance, for determination of animals to be subjected to laboratory testing, for the collection and submission of samples for laboratory testing, and for follow-up epidemiological investigation for classical BSE positive findings.'

A similar comment is also lodged in Article 1.8.6. point 4.

Annex 7

DRAFT CHAPTER 1.8.

APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF RISK STATUS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

EU comment

The EU thanks the OIE for the latest version of the revised Chapter 1.8. on the questionnaire for BSE status. The EU is overall satisfied with this draft chapter.

However,

- the EU expects that the Code Commission will follow up on the EU comment in Article 1.8.6. point 4(g) and ensure a proper alignment of the wording with Article 11.4.18.;

- the EU insists that total transparency must be ensured on the "period of time for which it can be considered that the risk of BSE agents being recycled in the cattle population has been negligible" in a given Member. We therefore look very much forward to hearing about the solution to be proposed by the OIE Secretariat on the way to communicate this information to the Members;

- finally the EU remains strongly concerned with, and therefore keeps a reservation on, the fact that, as reflected in the present version of Chapter 1.8. and in line with the last proposal for Chapter 11.4., a Member could be recognised with BSE negligible risk or controlled risk without enforcing the minimum ruminant-to-ruminant feed ban that is required by the current Code.

Detailed comments are provided below.

EU comment

The EU notes that the following expressions appear in the chapter:
- the risk of BSE agents being recycled within the cattle population;
- the likelihood of the BSE agents being recycled in the cattle population;
- the risk of BSE agents being recycled in the cattle population;
- the risk of BSE being recycled within the cattle population.

The EU considers that consistency should be ensured throughout the text.

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 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.

EU comment

The EU is of the opinion that the notions of ‘indigenous case’ and ‘imported case’ are mutually exclusive. The EU therefore suggests rewording point b) as follows:

‘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 3.1.1.). 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., 3.1. and 3.2.

2) The applicant Member may provide information on any recent (not older than five years) OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway, and highlight the results relevant to BSE.

3) Describe how the *Veterinary Services* supervise, control, enforce and monitor all BSE-related activities.

4) Provide a description of the involvement and the participation of industry; producers; farmers; herdsmen; 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 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 pets) 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 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* 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 the indigenous cattle population of the country or *zone*.

For the purposes of undertaking an exposure assessment for the evaluation of BSE status, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.). At its discretion, the applicant Member may provide the information requested for a different period (i.e. longer than eight years for those applying for a negligible risk status, or for the time they have the information if applying for a controlled risk status) to establish the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible (i.e. to determine the period of time to be attested in point 2 of Articles 11.4.6., 11.4.7., 11.4.9., 11.4.12. and 11.4.13.).

EU comment

The EU would like to draw once again the attention of the Code Commission on the need to adjust, in the above paragraph, the cross-references with Chapter 11.4.

As indicated in point 1b) 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, 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 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 farms in each type of production 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 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) programs, *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 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 programs, *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 estimatio*n.

– 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.

EU comment

In December 2020, the EU commented in Article 11.4.3. about the need to maintain the ruminant-to-ruminant feed ban a condition to be granted the negligible or controlled BSE risk status, with a subsequent alignment of Article 1.8.5.

The rational for this request was detailed in the EU comment provided in December 2020 on Article 11.4.3. We regret that the Code Commission did not agree with this proposal.

We would like to reiterate that the EU remains strongly concerned with the possibility that a Member be recognised with BSE negligible risk or controlled risk without enforcing the minimum ruminant-to-ruminant feed ban currently required across the board.

For those countries that have reported classical BSE *cases* in indigenous cattle, it is apparent that their historic livestock industry practices did not prevent the recycling of the BSE agent in their cattle population. These countries, together with others whose livestock industry practices would have been conducive to recycling may have implemented specific measures, such as through a legislated *feed* ban to ensure that the likelihood of recycling would be negligible. To qualify for official recognition of a BSE risk status, these countries need to demonstrate that the measures specifically targeting BSE have been and continue to be effectively implemented and enforced.

i) The nature and scope of a feed ban.

Indicate if 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 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 or *slaughter* waste declared as unfit for human consumption, describe the final disposal of this waste, and how it is handled and processed.

EU comment

The EU considers that the second, third and fourth bullet points above still lack clarity.

As regards the second bullet point, the EU suggests better aligning with Article 11.4.14.1 by using the word 'contamination' instead of 'cross-contamination'.

Both the third and fourth bullet points are about the exclusion of these *commodities*, but from a process (i.e. rendering) in the third, and from other material (fallen stock / slaughter waste) in the fourth.

In the third, if the issue is about excluding the *commodities* from rendering, then the *commodities* from slaughter waste declared as unfit for human consumption should probably be covered as well.

If the fourth is related to the third, which is suggested by the latest addition of "fallen stock or", it would seem that "animals condemned at ante mortem inspection" should also be added. The word "excluded" could be replaced by "removed".

The EU therefore suggests the adjustment of these three bullet points as follows:

'- 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 and slaughter waste declared as unfit for human consumption are excluded from rendering and how this is done.

- Where these *commodities* are not ~~excluded~~ removed from fallen stock, animals condemned at ante mortem inspection or slaughter waste declared as unfit for human consumption, describe the 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 a third party;
- training and accreditation programmes for inspectors;
- the planned frequency of inspections, 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 they 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-compliances) that were likely to have led to cattle being exposed to *feed* contaminated with ruminant material (excluding those listed in Article 11.4.1.bis) and how they were resolved.

vii) Conclusions for the evaluation of BSE 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. 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 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;
- 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 in 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?

Clearly describe the rationale leading to the conclusions reached.

4. Risk estimation

As described in Article 11.4.2., risk estimation combines the results and the conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk that BSE agents have been recycled in the cattle population through the feeding of ruminant-derived protein meal.

a) Provide a summary of the entry and exposure assessments and the conclusions reached.

b) If applicable, provide a summary of the consequence assessment, and the conclusions reached.

c) ~~When the condition of point 1 of Article 11.4.3. has not been met, that is, it cannot be demonstrated that for at least eight years the risk that the BSE agents have been recycled in the cattle population has been negligible, provide an explanation for the period of time within the preceding eight years for which it can be considered that the risk has been negligible. Clearly~~ Indicate the period of time for which it can be considered that the risk of BSE agents being recycled in 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 of the disease spectrum (i.e. from clinically ill to non-ambulatory to fallen stock) should be targeted for BSE *surveillance* and include those animals described in points 2a) to 2d) of Article 11.4.18.

1. Awareness and training programmes (point 3a) of Article 11.4.18.)

   Ongoing awareness and training programmes are essential to ensure that all stakeholders are familiar with clinical signs suggestive of BSE (those described in point 1 of Article 11.4.8.) as well as their statutory reporting requirements.

   a) Describe the stakeholder groups targeted for BSE awareness and training programmes. Describe the methods used to identify stakeholder groups within the jurisdiction and methods used to identify how, for example, the size and characteristics of the stakeholder group changes over time.

   b) Describe the type(s) of awareness and training programmes implemented for specific stakeholder groups. Describe how these programmes are adapted to meet the specific obligations and activities of each stakeholder group by those involved in caring for livestock, as well as the protocols for sample collection and submission by *veterinarians* and animal health technicians).

   c) Provide information on the number of awareness and training activities, the stakeholder groups targeted, the number of individuals reached per activity (if available), and the geographic coverage for these activities.

   d) Provide a description including examples of materials used in the awareness programme including training manuals, supporting documents such as publications in local newspapers and farming magazines, pamphlets and videos (weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist).

   e) Provide details on how the effectiveness of the awareness and training programmes is evaluated.

   f) Provide details of any contingency or preparedness plan for BSE.

2. Compulsory notification (point 3b) of Article 11.4.18.)

   To ensure the reporting and further investigations of any animals that ~~lie on the continuum~~ show symptoms of the BSE spectrum, appropriate legislation, policies and incentives to support compulsory notification, investigation and verification should be in place.

   a) Indicate 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 of the BSE spectrum, such as incentives, compensations or penalties.

   c) Describe the guidance given to all stakeholders involved in the rearing and production of livestock including farmers, herdsmen, *veterinarians*, transporters, workers at livestock *markets*, auctions and *slaughterhouses/abattoirs* in terms of the criteria for reporting animals that ~~lie on the continuum~~ show symptoms of the BSE spectrum. 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 of the BSE spectrum for evaluation. Has this framework evolved over time and, if so, how?

3. Laboratory testing (point 3c) 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* 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 suspicious or positive samples are referred to a *laboratory* outside the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

c) Describe the diagnostic protocol and tests used for processing samples for classical and atypical BSE and how they may have evolved over time, indicating: what is the primary test used?; what would be the series of secondary tests performed, if any, depending on the results of the primary test (i.e. negative, positive and inconclusive)?; and what test would be undertaken if discordant results between primary and secondary tests arise (e.g. primary positive result followed by a secondary negative result)?

4. Evaluation procedures and protocols to identify and report potential candidates for BSE surveillance, to determine animals to be subjected to laboratory testing, to collect and submit samples for laboratory testing, and to follow up with epidemiological investigation BSE positive findings (point 3d) of Article 11.4.18.)

Because 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 2a) to 2d) 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 of the clinical BSE spectrum (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.

EU comment

The EU expressed the opinion, in December 2020, that no epidemiological investigation is necessary in case of atypical BSE positive findings, and such investigation should be required only in case of classical BSE.

The Code Commission did not agree with the EU proposal, considering "that all BSE cases need to be followed up in order to properly address the risk of BSE agents being recycled".

The EU does not disagree with the fact that "all BSE cases need to be followed up in order to properly address the risk of BSE agents being recycled". However, this concern, which relates to the practical management of BSE cases, is appropriately covered in Article 1.8.2., point 2) and is not related to surveillance, which is what Article 1.8.6. is about. The EU is of the opinion that the purposes of the epidemiological investigation mentioned here are above all to identify the source of the contamination and if other animals should be investigated, which are irrelevant in case of atypical BSE.

Therefore, the EU respectfully insists that the title of point 4 and the above paragraph should be amended as follows:

> **'4. Evaluation procedures and protocols to identify and report potential candidates for BSE surveillance, to determine animals to be subjected to laboratory testing, to collect and submit samples for laboratory testing, and to follow up with epidemiological investigation <u>of classical</u> BSE positive findings (point 3d) of Article 11.4.18.)**
>
> **…**
>
> **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 of the BSE spectrum (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 <u>classical</u> BSE positive findings.'**

A similar comment is lodged in Article 11.4.18., point 3.d).

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~~ <u>showing symptoms</u> of the <u>clinical</u> BSE spectrum (those described in points 2a) to 2d) 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~~ <u>showing symptoms</u> of the BSE spectrum (those described in points 2a) to 2d) 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 2a) to 2d) of Article 11.4.18.).

Table 1.		
Year: _____		
Table 1 - Summary of all animals that were reported and evaluated for testing by the Veterinary Authority		
Clinical presentation (see point 2 of Article 11.4.18.)	Number of reported animals	Number of animals subjected to BSE testing
(A) Cattle displaying progressive behavioural or neurological signs suggestive of BSE that are refractory to treatment		
(B) Cattle showing behavioural or neurological signs that did not pass the ante-mortem inspection at slaughterhouses/abattoirs		
(C) Cattle presented as downers (non-ambulatory) with an appropriate supporting clinical history		
(D) Cattle found dead (fallen stock) with an appropriate supporting clinical history		

EU comment

The EU notes that the Code Commission did not align the wording of the lines (C) and (D) in Table 1 with the wording in Article 11.4.18., points 2.c) and 2.d), as last amended.

The EU therefore requests that the wording in lines (C) and (D) of Table 1 is aligned with that in Article 11.4.18. point 2.c) and 2.d). In line with the latest EU comment lodged in Article 11.4.18., points 2.c) and 2.d), the EU considers that the lines (C) and (D) of Table 1 should read as follows:

'(C) Cattle presented as downers (non-ambulatory) with an appropriate supporting clinical history or clinical condition;

(D) Cattle found dead (fallen stock) with an appropriate supporting clinical history or where other common causes of death (e.g. infectious, metabolic, traumatic, neoplastic or toxic causes) have been ruled out.'

5. Animals subjected to laboratory testing

a) Provide in Table 2, for each of the preceding eight years, details of all animals counted in Table 1 that were subjected to laboratory testing (see point 2 of Article 11.4.18.).

Table 2. Details of the animals that were subjected to laboratory testing.							
Year notified	Laboratory identification	Age (in	Type of production	Description of observed	Clinical presentation (A,	Final diagnosis	For a BSE case,

	number or individual identification number	months) at first detection	system (dairy, beef, mixed, etc.)	clinical signs	B, C or D)	(if BSE, specify the strain)	indicate the origin (indigenous or imported; if imported, indicate the country of birth)

EU comment

In December 2020, the EU expressed concerns about the fact that filling out this table would be a disproportionate administrative burden in the EU Member States, where more than 1 million cattle are tested each year in the framework of the EU BSE monitoring.

The EU noted that the Code Commission acknowledged the concern, but did not amend the wording of this point 5, suggesting that it should be addressed by OIE Secretariat when it will revise the form for the annual reconfirmation of BSE risk status.

The EU would appreciate some stronger commitment from the OIE that, should this chapter be adopted with the current wording, the EU Members will not be expected, in practise, to provide these details for each tested animal.

Article 1.8.7.

Recovery of BSE risk status

Following the occurrence of an indigenous *case* of classical BSE in an animal born within the preceding eight years in a country or *zone* with a negligible 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 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.

Annex 8

GLOSSARY

EU comment

Reference is made to the EU comment on the definition of protein meal included in point 4b of Article 11.4.1. (see Annex 6).

We note that the definition of protein meal proposed for inclusion in the glossary is the same as the one included for the purposes of Chapter 11.4. in point 4b of Article 11.4.1.

Inclusion in the glossary of that new definition is warranted as that term is also used in draft Chapter 1.8. (where it is not defined).

However, to avoid an unnecessary duplication that could cause confusion, we would suggest deleting that definition from point 4b of Article 11.4.1. as soon as the definition is included in the glossary.

Ideally, both the revised glossary and draft Chapters 11.4. and 1.8. should be adopted simultaneously, with the definition of protein meal included only in the glossary.

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.

Annex 9

CHAPTER 6.12.

ZOONOSES TRANSMISSIBLE FROM NON-HUMAN PRIMATES

EU comment

The EU in general supports the proposed changes to this chapter.

Comments are inserted in the text below.

[…]

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 a *laboratory* approved for this purpose;

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

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

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

Annex 9 (contd)

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

EU comment

In relation to the entry for "Tuberculosis (Mycobacterium tuberculosis complex)" in the table above, the EU suggests the following changes:

(1) The indication of specific animal groups (in the column "Animal groups") should be replaced by "<u>All species</u>".

Rationale: Tuberculosis as a zoonosis is a general health issue for all non-human primates. The differentiation of New World monkeys and Old World monkeys is not relevant here.

(2) The text in the column "Schedule" should be replaced by the following (in relation to "All species"):

"<u>Three negative tests with two weeks intervals, the last 10 days before transfer to the new institution.</u>"

Rationale: The differentiation between New World monkeys and Old World monkeys in terms of testing intervals is not helpful and is not supported by the scientific literature.

See also "Guidelines for the prevention and control of tuberculosis in non-human primates: recommendations of the European Primate Veterinary Association Working Group on Tuberculosis" (Bushmitz *et al*. 2009. J Med Primatol). The guidelines do not differentiate between wild caught and accredited breeders as well as recommendations are given for all NHPs. Three tuberculin skin tests incorporated into the routine at 2-week intervals last 10 days prior transport (Figure 1, Bushmitz *et al*. 2009. J Med Primatol). This is further supported in Nonhuman Primates in Biomedical Research: Biology and Management, Chapter 12: Kramer *et al*. 2012. Preventative Medicine in Nonhuman Primates. Elsevier. Where tuberculin skin tests are requested at interval of two weeks for at least two inoculations.

(3) The text in the column "Methods" should be replaced by the following:

"<u>Generally, a combination of different tests is advised for the in vivo-diagnosis of tuberculosis in non-human primates. In addition to the standard procedure of</u>

tuberculinization with mammalian old tuberculin (MOT) or purified protein derivates (PPD), it is advisable to perform an interferon-gamma assay where whole blood samples are used. Other methods include radiology of the chest, serology, sample staining for acid fast bacteria, nucleic-acid amplification tests and microbial cultivation of faecal or bronchiolar lavage fluid. The combination of different tests is important as some species, e.g., orang utans (*Pongo* spec.), are known to have notorious false positive skin test results."

Rationale: The text as proposed is in parts confusing and does not address the major obstacles of in vivo tuberculosis testing in non-human primates. These are based on immunological species differences and also on some difficulties associated with ~~different~~ test methods. New World monkeys can equally be tested using intra-skin eyelid inoculation of tuberculin. Many primate centres and zoos are using this diagnostic method even in marmosets and tamarins. It makes it easier to identify a positive reaction without handling the animal a second time. It is to be noted ~~here~~ that some prosimians are smaller in body size than e.g. marmosets.

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

EU comment

The EU suggests inserting the words "and B" after "Hepatitis A" in the paragraph above. This is to compensate for the deletion of that disease from the revised table above and to keep the disease mentioned in the document.

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.

EU comment

The EU suggests replacing the words "in primate species" with "in their natural host, but can be fatal to other primate species including humans (e.g. Macacine herpesvirus1)".

Rationale: The proposed new wording improves the text by being more specific with respect to the risk of symptomatic infections and by giving an example.

[…]

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

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

Chapter 4.16.:

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.