Annex 28

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FIFTH MEETING OF THE OIE *AD HOC* GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT AND SURVEILLANCE

Paris, 8, 9, 12 and 15–19 June 2020

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The OIE *ad hoc* Group on bovine spongiform encephalopathy (BSE) risk assessment and surveillance (hereinafter referred to as the Group) met on 8, 9, 12 and 15 to 19 June 2020 through video-conference to address Members' comments received on the revised draft Chapter 11.4, Bovine spongiform encephalopathy, of the *Terrestrial Animal Health Code* (hereinafter referred to as the *Terrestrial Code*) circulated for the first time in the Terrestrial Animal Health Standards Commission (hereinafter referred to as the Code Commission) September 2019 report.

This work is a continuation of the work to revise Chapters 1.8 and 11.4. in the *Terrestrial Code* initiated by the *ad hoc* Group on BSE risk assessment which met in July[1] and November 2018[2], the *ad hoc* Group on BSE surveillance which met in October 2018[3], and the *ad hoc* Group on BSE risk assessment and surveillance which met in March 2019[4].

1. Opening

Dr Matthew Stone, OIE Deputy Director General for International Standards and Science, welcomed the Group members, and the representatives from the Scientific Commission for Animal Diseases (hereafter the Scientific Commission) and the Code Commission on behalf of Dr Monique Eloit, Director General of the OIE.

Dr Stone emphasised that the revision of the BSE standards was considered a priority for OIE Members, and that this meeting aimed to address the many Members' comments received on the revised draft Chapter 11.4.

Dr Stone explained that the Code Commission had addressed some Members' comments at its February 2020 meeting. However, given the nature and significant number of comments received, the Code Commission had requested that an *ad hoc* Group be convened to review comments that needed further expert advice, and to revise draft Chapters 11.4 and 1.8. He noted that the Code Commission would review the Group's report at its next meeting in September 2020. Dr Stone acknowledged the significant achievements made to date in the revision of the BSE standards and underlined the importance of continuing open discussions based on scientific evidence for provisions to be risk-based. He thanked the experts for their time and commitment to address the terms of reference for this meeting, and their involvement in the standard-setting process. All experts have signed the forms for undertaking of confidentiality and declaration of conflicts of interest. No potential conflict of interest in the revision of BSE Standards was declared.

[1] The July 2018 report of the meeting of the OIE *ad hoc* group on BSE risk assessment can be found here: https://www.oie.int/fileadmin/SST/adhocreports/Bovine%20spongiform%20encephalopathy/AN/A_AHG_BSE_risk_assessment_July2018_web.pdf

[2] The November 2018 report of the meeting of the OIE *ad hoc* group on BSE risk assessment can be found here: https://www.oie.int/fileadmin/SST/adhocreports/Bovine%20spongiform%20encephalopathy/AN/A_AHG_2nd_BSE_risk_assessment_Web.pdf

[3] The October 2018 report of the meeting of the OIE *ad hoc* group on BSE surveillance can be found here: https://www.oie.int/fileadmin/SST/adhocreports/Bovine%20spongiform%20encephalopathy/AN/A_AHG_BSEsurv_DSD_Oct2018_Web.pdf

[4] The March 2019 report of the meeting of the OIE *ad hoc* group on BSE risk assessment and surveillance can be found here: https://www.oie.int/fileadmin/SST/adhocreports/Bovine%20spongiform%20encephalopathy/AN/A_AhG_BSEsurv_RiskAss_Mar2019.pdf

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2. Adoption of the agenda and appointment of Chairperson and Rapporteur

The work of this Group was undertaken in two parts. The sessions on surveillance were held on 8, 9 and 12 June, and Dr Alicia Cloete was appointed Chair and Dr Ángel Ortiz-Pelaez Rapporteur with the support of the OIE Secretariat. The sessions on risk assessment were held from 15 to 19 June, and Dr Ximena Melón was appointed Chair and Dr Alicia Cloete Rapporteur with the support of the OIE Secretariat. The proposed agenda for the meeting was endorsed by the Group.

The terms of reference, agenda and list of participants are provided as Appendices I, II and III, respectively.

3. Review of comments to Chapter 11.4, Bovine spongiform encephalopathy

Comments were received from Australia, Brazil, Canada, People's Republic of China, Chinese Taipei, Japan, Republic of Korea, New Zealand, Singapore, South Africa, Switzerland, Thailand, United States of America (USA), the Member States of the European Union (EU) and the International Meat Secretariat (IMS).

At its February 2020 meeting, the Code Commission addressed some of these comments and referred those that needed further expert advice to this Group for its consideration. The Group was updated on the opinion of the Code Commission on various comments, which were preliminarily addressed by the Code Commission at its February 2020 meeting. The Group considered comments received and made amendments to the text of the chapters, where appropriate. In addition, the Group proposed amendments for clarity, consistency, and improved readability.

3.1. Draft Article 11.4.1. General provisions

The Group agreed with the amendments made by the Code Commission at its February 2020 meeting and did not propose further amendments to the draft text.

3.2. Draft Article 11.4.1.bis. Safe commodities

The Group discussed Members' comments stating that gelatine and collagen made from bones (including vertebral column and skull), in contrast to those made from hides and skins, should not be considered a safe commodity. The Group noted that these Members did not provide any scientific evidence to support their claims, and referred the Members to the conclusions expressed in the report of its March 2019 meeting[5], where the Group agreed with the conclusions of an EFSA report[6] that the steps listed in current point 2(b) of Article 11.4.15 were sufficient to ensure that "the relative human exposures due to gelatine produced from bones including the skull and vertebral column sourced from cattle of any age are very low ($<10^{-5}$) and do not support the continuation of the restriction prohibiting the inclusion of skull and vertebral column" in the production of gelatine and collagen. The Group noted that the Code Commission agreed to include 'gelatine and collagen' in draft Article 11.4.1bis at its September 2019 meeting given that point 2(a) of current Article 11.4.15 was considered unjustifiable and that point 2(b) describes industrial practices that were not specifically directed against BSE. The Group agreed with the Code Commission that tallow derivatives should be considered safe commodities if made from tallow with a maximum level of insoluble impurities of 0.15% in weight, and consequently agreed with the reinstatement of current Article 11.4.18 as draft Article 11.4.16bis to provide recommendations for importation of tallow derivatives other than those listed in draft Article 11.4.1bis.

[5] See the March 2019 report of the meeting of the OIE *ad hoc* group on BSE risk assessment and surveillance.
[6] EFSA Panel on Biological Hazards. Opinion of the Scientific Panel on biological hazards (BIOHAZ) on the "Quantitative assessment of the human BSE risk posed by gelatine with respect to residual BSE [1]". The EFSA Journal. 2006; 4(1):312, 1–29 doi:10.2903/j.efsa.2006.312

In response to a comment made by a Member, the Group considered whether foetal blood could be included in the list of safe commodities in this article. The Group noted that current scientific evidence indicated that BSE infectivity had not been detected in blood from infected bovine adults. The results of a long-term study[7], assessing the presence of BSE prions in the blood of clinical end-stage cases of BSE in cattle through cattle-to-cattle blood transfusions, indicated that no clinical signs or seeding activity were observed in blood recipients after 10 years-post-transfusion. The Group concluded that bovine blood and blood products were considered free of BSE infectivity. The Group further noted that even in the highly unlikely case that prions were present in blood, the placental barrier of bovines would make BSE maternal transmission unlikely and that there is no risk of cross contamination with potentially infected tissues from the cow during foetal blood collection. In light of this evidence, the Group supported the inclusion of 'foetal blood' as a safe commodity in this article.

3.3. Draft Article 11.4.2. The BSE risk of the cattle population of a country, zone or compartment

The Group discussed two Members' comments requesting a clearer alignment between draft Article 11.4.2 provisions and those of Chapter 2.1. on import risk analysis. The Group considered that there was no inconsistency between the two chapters in either terminology or in the risk assessment steps described. The risk assessment steps described in draft Chapter 11.4 were adapted from provisions in Chapter 2.1, which provides a sufficiently broad and flexible framework to accommodate the requirements of BSE. The Group agreed, however, that having more guidance on the nature of each step of the risk assessment could be useful to Members, some of which are described in more detail in draft Chapter 1.8. Therefore, the Group provided further elaboration on the aspects to consider under the entry assessment, exposure assessment and consequence assessment, based on the provisions in draft Chapter 1.8.

The Group edited the introductory sentences to highlight that the BSE risk of a country, zone or compartment is based on an evaluation of the risk posed by its cattle population. The Group stressed that this is especially important for trade purposes since there could be cattle in the population posing different risks at the same time.

In addition, the Group added a specific reference to the time period for which the risk assessment needed to be conducted for (i.e., the preceding eight years). This was in accordance with the time frame discussed and agreed in its November 2018 meeting (i.e., for at least the 95th percentile of the incubation period, plus one year).

Under the exposure assessment, the Group inserted text to clarify that all applicant Members have to include an evaluation of livestock industry practices. Based on the outcome from this step, an evaluation of mitigation measures specifically targeting BSE may also need to be considered. The Group further stated that, as per point 2 of Article 2.1.4, the consequence assessment step may not be required if the exposure assessment concluded that the likelihood of exposure to the BSE agents had been negligible. Figure 1 illustrates the risk assessment steps described in draft point 1 of Article 11.4.2.

[7] Bannach, O., Reinartz, E., Henke, F., Dressen, F., Oelschlegel, A., Kaatz, M., ... & Birkmann, E. (2013). Analysis of prion protein aggregates in blood and brain from pre-clinical and clinical BSE cases. *Veterinary microbiology*, *166*(1-2), 102-108. https://www.sciencedirect.com/science/article/pii/S0378113513003039

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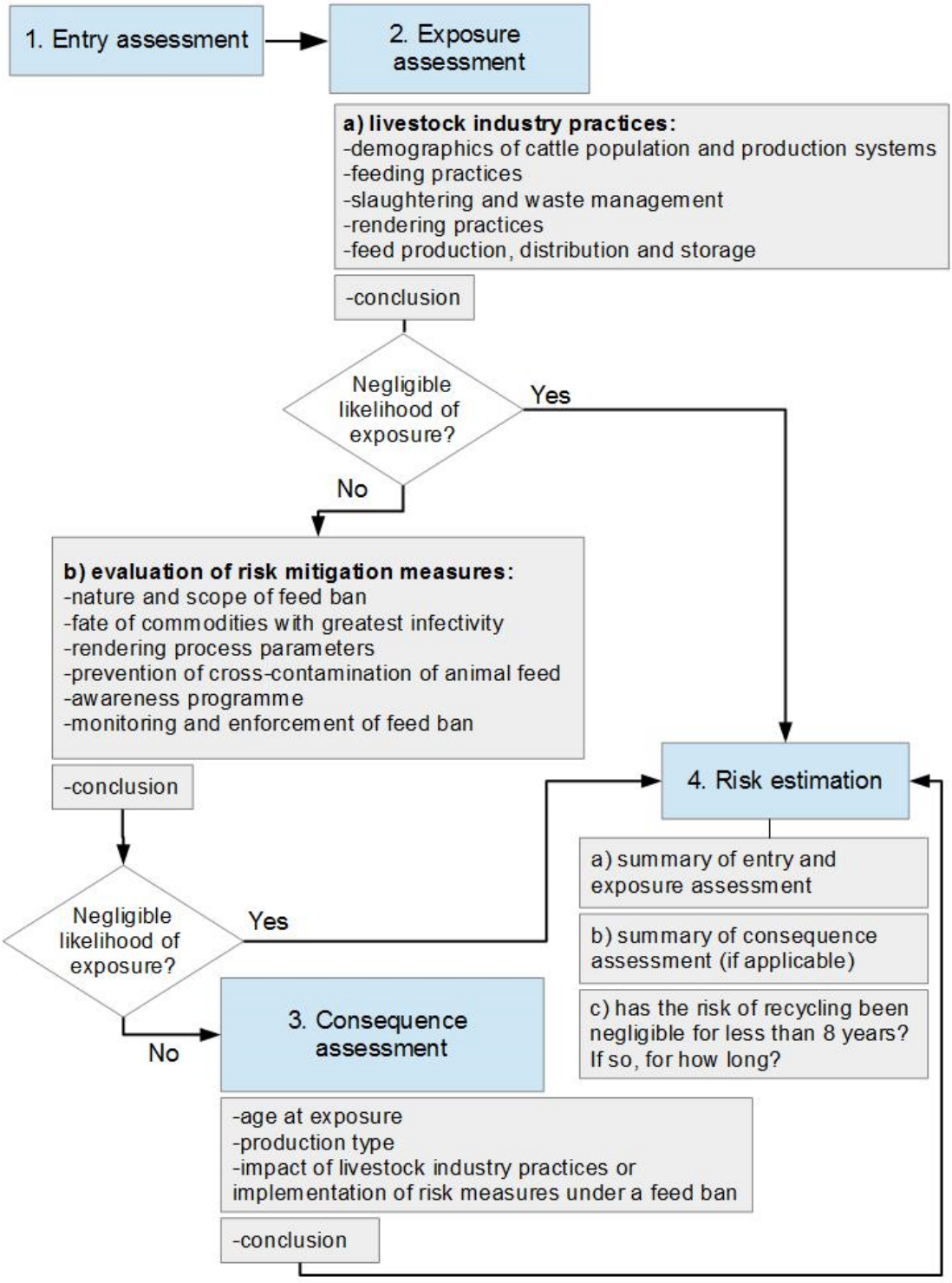

Figure 1. Schematic representation of the risk assessment steps described in Article 11.4.2.

For clarity, the Group replaced the term "likelihood" with the word "risk" in the risk estimation step.

Regarding the Code Commission's request to clarify the use of the term 'feed ban' in Chapter 11.4, the Group explained that a feed ban is defined as the "ban on feeding ruminants with protein meal derived from ruminants" under point 1(bii) of draft Article 11.4.2. The Group added that the scope of the ban of feeding ruminants with meat-and-bone meal and greaves (now 'protein meal'[8]) derived from ruminants or with other feed or feed ingredients contaminated with these has not changed and that applicant Members should provide documented evidence that ruminant protein meal has not been fed to ruminants. The Group clarified that a feed ban may not always need to be legislated to provide an appropriate level of assurance.

Finally, in response to a question from the Code Commission, the Group clarified that the term 'livestock industry practices' is more accurate than 'cattle industry practices' given that from the list of factors to be evaluated during the exposure assessment (i.e., demographics of the cattle population and production systems; feeding practices; slaughtering and waste management; rendering; and feed production, distribution and storage) not all of them relate solely to cattle. In particular, the exposure of cattle to the BSE agents may arise as a result of cross contamination of cattle feed with feed intended for other species and produced with materials of ruminant origin.

3.4. Draft Article 11.4.3 Negligible BSE risk

The Group amended the introductory sentence to clarify that the focus of the assessment was the cattle population, as per the amendments made in draft Article 11.4.2.

Given that the two pathways whereby the BSE risk of the cattle population of a country or zone can be considered to pose a negligible risk (based on livestock industry practices and the implementation of appropriate measures to mitigate risk factors) are captured in draft Article 11.4.2, the Group agreed that it was not necessary to refer to these again in draft Article 11.4.3.

In response to a Member's comment stating that the occurrence of an indigenous case of classical BSE in an animal younger than eight years indicated that the control measures were not effectively implemented, the Group commented that this was not necessarily true in all instances, as isolated pockets of residual infectivity in a complex network of rendering, feed production, distribution and storage may account for rare, sporadic opportunities of exposure with negligible consequences in terms of recycling of infectivity, particularly considering the ongoing implementation of a feed ban[9]. The Group emphasised that investigations should be carried out after the occurrence of such BSE cases to assess whether the risk of recycling has continued to be negligible or not.

3.5. Draft Article 11.4.3bis Recovery of negligible BSE risk status

The Group made only minor edits to the provisions of this draft article to improve clarity. The wording was strengthened to indicate that after suspension, the outcome of the investigations should confirm that the risk of BSE being recycled within the cattle population continues to be negligible (i.e., there was no interruption or breach in the implementation of BSE control measures).

The Group considered a Member's comment asking whether the new provisions would be applicable to cases confirmed before the revised Chapter 11.4 is adopted by Members. The Group noted the explanation of the Secretariat that the revised chapters become effective once adopted and that the provisions for recovery would also apply to Members where BSE cases were reported on a date prior to the date of adoption of these new provisions. Furthermore, in accordance with the 'Standard Operating Procedures (SOP) on suspension, recovery or withdrawal of officially recognised disease status of Members'[10], the outcome of the investigation would have to be favourably assessed by the Scientific Commission, within a maximum of two years after the detection of the case, for the status to be re-instated.

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[8] The rationale for using the term 'protein meal' rather than 'meat-and-bone meal and greaves' can be found in the March 2019 report of the meeting of the OIE *ad hoc* group on BSE risk assessment and surveillance.

[9] The supporting evidence and rationale for the conclusion that isolated, residual pockets may have negligible consequences can be found in the July 2018 report of the meeting of the OIE *ad hoc* group on BSE risk assessment.

[10] The "SOP for suspension / recovery / withdrawal / containment zone" is available from: https://www.oie.int/animal-health-in-the-world/official-disease-status/official-recognition-policy-and-procedures/ in the three OIE languages.

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The Group considered a comment recommending the inclusion of cross-reference to Chapter 1.8 to provide guidance on the requirements for the recovery of a negligible BSE risk status. The Group concurred with the Secretariat that, as with other diseases with official status recognition, the OIE would direct the Member not only to the relevant article for recovery of status in Chapter 1.8 (the BSE questionnaire) (i.e., draft Article 1.8.7.) but also to follow the applicable SOP, once a case was reported.

3.6. Draft Article 11.4.4 Controlled BSE risk

The Group made no amendments to the provisions of this draft article.

3.7. Draft Article 11.4.5 Undetermined BSE risk

The Group made no amendments to the provisions of this draft article.

3.8. Deleted draft Article 11.4.6 Recommendations for importation of cattle from a country, zone or compartment posing a negligible BSE risk

The Group noted that in September 2019, the Code Commission had proposed amendments to this article, as well as to draft Articles 11.4.7 and 11.4.8 on the basis of having a gradation in the risk mitigation measures corresponding to the change in BSE risk (from negligible to controlled to undetermined). In doing so, the only requirement for cattle importation from a country, zone or compartment posing a negligible BSE risk was for cattle to come from such a place, regardless of the birth date of the animals selected for trade.

The Group did not agree with the amendments made by the Code Commission to draft Article 11.4.6 and explained that the risk posed by the cattle population born *during* 'the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible' is different from that posed by the cattle population born *before* that same period. The Group clarified that a country or zone can show that the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible could be longer than the minimum eight years for negligible risk, increasing the proportion of cattle in this category. By taking into consideration the time of birth of the cattle selected for export on the importation requirements, the proportion of the cattle population that could be traded would be greater in countries or zones with negligible than with controlled BSE risk status. This was because this period would be greater in countries and zones with a negligible BSE risk status, hence including a greater proportion of their cattle population compared to those with a controlled BSE risk status. This would represent a gradation in the import requirements. Therefore, the Group supported its initial proposal to include a recommendation that the cattle were born during the period when the risk of recycling BSE agents has been demonstrated to be negligible.

Because a gradation of risk approach was provided in the provisions of draft Article 11.4.7, the Group considered that the text on the import requirements for a negligible or controlled BSE risk could be drafted similarly. The Group has therefore proposed to delete draft Article 11.4.6 and amend draft Article 11.4.7 (see Section 3.9 of this report) to include provisions for both negligible and controlled statuses.

3.9. Draft Article 11.4.7 Recommendations for importation of cattle from a country, zone or compartment posing a negligible or controlled BSE risk

The provisions of this article were merged with those from 'Recommendations for importation of cattle from a country, zone or compartment posing a negligible BSE risk' (see Section 3.8 of this report).

The Group agreed with amendments made by the Code Commission in September 2019 related to the mandatory individual identification of cattle to be able to differentiate animals born during the period when the risk of recycling is negligible from those born before that period.

3.10. Draft Article 11.4.8 Recommendations for importation of cattle from a country, zone or compartment posing an undetermined BSE risk

The Group made no amendments to the provisions of this draft article.

3.11. Deleted draft Article 11.4.9 Recommendations for importation of meat and meat products from a country, zone or compartment posing a negligible BSE risk

The Group noted that amendments made by the Code Commission at its September 2019 meeting to draft Articles 11.4.9 to 11.4.11 were based on a gradation in the risk mitigation measures corresponding to the change in BSE risk (from negligible to controlled to undetermined). For consistency with the reasoning expressed in Section 3.8 of this report, the Group deleted draft Article 11.4.9.

3.12. Draft Article 11.4.10 Recommendations for importation of meat and meat products from a country, zone or compartment posing a negligible or controlled BSE risk

Consistent with the rationale provided in Sections 3.8 and 3.9 of this report, the Group amended this draft article to include provisions for both negligible and controlled BSE risk statuses.

For consistency with draft Article 11.4.7, the Group added a requirement on the mandatory individual identification of cattle from which the meat and meat products derived.

The Secretariat included edits proposed by the Scientific Commission at its September 2019 meeting for the Code Commission consideration. These amendments related to the inclusion of procedures other than stunning with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to slaughter.

3.13. Draft Article 11.4.11 Recommendations for importation of meat and meat products from a country, zone or compartment posing an undetermined BSE risk

The Group concluded that identification through an animal identification system of the animal from which the fresh meat and meat products were derived was a pre-requisite to allow demonstration that an individual animal had never been fed protein meal derived from ruminants.

3.14. Draft Article 11.4.12 Recommendations for importation of cattle-derived protein meal from a country, zone or compartment posing a negligible BSE risk

Consistent with the rationale in Section 3.8 of this report, the Group reaffirmed its position that the age of the cattle used to produce protein meal should be taken into consideration to ensure that they were born during the period when the risk of the BSE agent being recycled in the cattle population was negligible and added a new point 2.

The Group did not agree with Members' suggestions to include a provision forbidding the trade of protein meal originating from areas where there had been an indigenous BSE case and from cattle born during the period prior to implementation of a ruminant-to-ruminant feed ban. The Group clarified that the occurrence of indigenous cases[11] was already considered in draft Article 11.4.3 provisions ('Negligible BSE risk') and therefore no particular recommendations for trade of commodities from places with a history of BSE was needed.

[11] For more details, see the March 2019 report of the meeting of the OIE *ad hoc* group on BSE risk assessment and surveillance.

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3.15. Draft Article 11.4.13 Recommendations for importation of blood and blood products derived from cattle (except foetal blood)

The Group agreed with Code Commission edits and also edited the title of this draft article to exclude foetal blood, which was proposed to be listed as a safe commodity (see Section 3.2 of this report).

For consistency with importation requirements for cattle and meat and meat products, the Group amended the recommendations related to the mandatory individual identification of cattle to differentiate animals born during the period when the risk of recycling is negligible from those born before that period.

3.16. Draft Article 11.4.14 Recommendations in relation to the trade of commodities with the greatest BSE infectivity

The Group considered a Member's comment to replace 'distal ileum' with 'the last four metres of the small intestine'. The Group noted that this would ensure that the distal ileum, which is the anatomical area of the intestine posing a BSE risk, is included within those four meters, regardless of the variation that could arise from the breed, age or size of the animal. The Group was however of the view that this could be overly prescriptive, as each Member would have their own standard protocol for describing the area to be removed, as long as the distal ileum is included. The Group left the decision to the consideration of the Code Commission.

The Group noted that the last paragraph of draft Article 11.4.14 of the version circulated to Members in 2019 would allow Members with a controlled BSE risk status to trade commodities with the greatest BSE infectivity as long as animals were born during the period when the risk of recycling has been demonstrated to be negligible. In response to a Member's comment proposing to apply such standards to only cattle-derived protein meal rather than to all the commodities listed in this draft Articles, the Group affirmed that, due to the particularly high risk that all commodities listed in this draft Article pose, they should not be traded from areas posing a controlled or undetermined BSE risk, and therefore deleted the above mentioned paragraph. While a Member with a controlled BSE risk status may be able to demonstrate that the risk of recycling has been negligible, it would be for less than eight years (i.e., for less than the 95th percentile of the incubation period, plus one year), which would not be a sufficient period of time to build a sufficient level of confidence, despite the effectiveness of the measures.

3.17. Draft Article 11.4.15 Recommendations for importation of tallow (other than as defined in Article 11.4.1.bis) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

The Group made no amendments to the provisions of this draft article.

3.18. Draft Article 11.4.16 Recommendations for importation of dicalcium phosphate (other than as defined in Article 11.4.1.bis) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

The Group made no amendments to the provisions of this draft article.

3.19. Draft Article 11.4.16bis Recommendations for importation of tallow derivatives (other than as defined in Article 11.4.1.bis) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

The Group supported the proposal of the Code Commission to re-instate current Article 11.4.18 as draft Article 11.4.16bis.

3.20. Draft Article 11.4.17 Procedures for the reduction of BSE infectivity in protein meal

The Group made no amendments to the provisions of this draft Article.

3.21. Draft Article 11.4.18. Surveillance

a) Member's comments on the general characteristics of the proposed surveillance system and on the need for a minimum number of cattle to be tested

Whilst some Members were in favour of the proposed new approach for BSE surveillance and the elimination of the 'point system', some other Members raised concerns on the absence of provisions requiring a minimum number of animals to be tested for BSE every year.

In view of this, the Group edited point 2 of draft Article 11.4.18 to improve the clarity that the cattle that should be part of the BSE surveillance programme are those that lie on the continuum of the disease spectrum: (1) cattle with behavioural or neurological signs described in point 1 of draft Article 11.4.18 that are refractory to treatment and where other common causes of neurological signs such as trauma and infectious, metabolic, neoplastic and toxic causes have been ruled out, (2) cattle with behavioural or neurological signs that do not pass ante-mortem inspection at a slaughterhouse or abattoirs, (3) downers (non-ambulatory) that have an appropriate clinical history compatible with BSE and (4) fallen stock (found dead) that have an appropriate clinical history compatible with BSE. The Group noted that whilst having information on the clinical history and its progression is very important to detect a clinical suspect on farm, it is also essential to include animals that lie on the whole continuum of the disease spectrum (i.e., from clinically ill to non-ambulatory to fallen stock). The determination of potential suspect BSE cases should take into account that the vast majority of BSE cases arise as single, isolated events. The occurrence of multiple animals showing behavioural or neurological signs, multiple downers or multiple fallen stock is most likely associated with a variety of causes other than BSE.

Considering that the disease is progressive and that animals to be included in the surveillance programme may arise at the farm, the slaughterhouse, or during transportation, the Group determined that 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 to determine if the reported animal qualifies for BSE testing as part of the BSE surveillance), (3) the collection and submission of samples for testing in a laboratory, and (4) a follow-up epidemiological investigation for BSE positive findings. Therefore, the Group strengthened the surveillance provisions by adding point 3(d) to draft Article 11.4.18.

Although the specific details of the above mentioned procedures and protocols should be defined by each Member, the Group highlighted the importance of documenting them and ensuring that they are readily available to guide stakeholders. They could be captured in the form of a decision tree or a checklist and would be part of the Member's dossier when applying for a BSE risk status. As an example, the Group described an instance where an animal with clinical signs suggestive of BSE is initially identified by a farmer and brought to the attention of a veterinarian. If appropriate (i.e., if animal is indeed showing signs suggestive of BSE), this clinical suspect should then be reported or notified to the competent authority (e.g., the Veterinary Authorities), who would then be responsible for undertaking a thorough examination. When this examination confirms that the clinical presentation and history are indeed indicative of BSE (i.e., the animal matches the criteria of points 1 and 2 of draft Article 11.4.18), the animal should be targeted for BSE surveillance. All these animals should be followed up with adequate laboratory testing as described in Chapter 3.4.5 of the *Terrestrial Manual* to accurately confirm or rule out the presence of the BSE agent. The competent authority would also be responsible for conducting a follow-up epidemiological investigation if the animal is positive.

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The Group considered that having stepwise procedure and protocols in place would enhance the credibility of and confidence in the Members' surveillance programme. The details of the procedures and protocols and the corresponding results would be part of the Member's dossier when applying for an official BSE risk status. In light of this, the Group drafted the requirements to be included in the BSE questionnaire for Members to demonstrate compliance with the newly added point 3(d) of draft Article 11.4.18.

In addition, the Code Commission questioned during the meeting whether the requirement to conduct laboratory tests described in the *Terrestrial Manual* should be maintained under draft Article 11.4.18 given that reference to diagnostic tests was already made under draft Article 11.4.1 (i.e., 'Standards for diagnostic tests are described in the *Terrestrial Manual*'). In response, the Group noted that such a reference is conventional in the *Terrestrial Code,* but nonetheless highlighted the importance of explicitly denoting in draft Article 11.4.18 that samples must be tested for BSE using the laboratory methods specifically described for that purpose in the *Terrestrial Manual* (similarly to what is stated in other chapters of the *Terrestrial Code* such as 4.15, 8.8, 11.5 and 15.2). Therefore, the Group concluded that this was a requirement for a robust surveillance system and did not remove point 3(c) of draft Article 1.4.18.

Given the apparent concerns from Members regarding the evaluation of a surveillance programme, the Group clarified that a rigorous assessment would continue to be undertaken by the OIE following Member's application for a BSE risk status, and that their surveillance and awareness programmes would be reviewed annually for status maintenance purposes.

Finally, the Group discussed the potential impact of these new provisions on those Members that already have a BSE risk status and concluded that evidence of compliance with the new requirements for surveillance could be provided during the annual reconfirmation campaign.

b) Member's comment requesting the consideration of surveillance as a monitoring tool of the correct implementation of a feed ban

The Group noted a Member's comment stating that the proposed amendments on the surveillance programme do not sufficiently consider the consequences of an ineffective implementation of BSE control measures, such as the inadequate implementation of a ruminant-to-ruminant feed ban. The Group highlighted that monitoring the implementation of a feed ban through surveillance is not a strategy that can be presently recommended given the current state of the BSE epidemic. Firstly, monitoring the effectiveness of measures through testing of individual animals to estimate prevalence of disease can be prohibitively expensive as very large sample sizes are required to detect a case of BSE at a set prevalence of 1 per 1,000,000 cattle. Secondly, due to the prolonged BSE incubation period[12], the time required to detect a relapse in the prevalence of the disease due to a breach in the feed ban and the implementation of corrective actions can be too lengthy. Consequently, the ongoing efforts and resources would be more appropriately channelled into directly maintaining and monitoring the rigorous and continuous implementation of the various mitigation measures in the field.

The Group further remarked that surveillance programmes implemented over many years in those Members with classical BSE have provided critical insights into the evolution of BSE and have convincingly demonstrated the effectiveness of mitigation measures, particularly those associated with a ruminant-to-ruminant feed ban, as evidenced by the sustained decline in the incidence of classical BSE. The Group reiterated its conclusion from its meeting in October 2018 - that since the relevant control measures for BSE are well-established and that sufficient evidence has been accumulated, the goals associated with monitoring the evolution of BSE and demonstrating the effectiveness of mitigation measures through surveillance have now been met.

[12] The upper 95th percentile incubation period for classical BSE is estimated to be seven years.

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c) Member's comments requesting provisions for a minimum number of clinical suspects to be tested and for the assessment of initial recognition and maintenance of BSE risk status when a Member reports no clinical suspects

In response to a comment requesting the incorporation of a minimum, mandatory number of cattle to be tested, the Group noted the inadequacy of a minimum testing requirement applicable to all Members. The BSE epidemic has now reached its tail and only sporadic cases are detected by Members[13], suggesting that the BSE prevalence throughout the world is now very low.

The Group concluded that to impose quotas for minimum clinical suspects to be reported and tested based on statistical assumptions for a disease that, if present, would be at very low level, would be disproportionate to the risk. The Group conducted sample size simulations and noted that a very large number of animals would have to be tested to achieve an adequate confidence level in the sample size results. The Group calculated the number of animals that would need to be tested (sample size) to detect at least one infected animal, assuming a very low prevalence and applying a risk-based sample size calculation. For example, assuming a prevalence of 1 in 100,000, a relative risk of 4 in emergency slaughter or with observations at ante-mortem inspection (2% of the population) compared to the general population, and assuming that 5,000 animals are tested from these two risk groups combined and none were tested from the rest of the cattle population, with a 80% prior confidence of freedom, the surveillance sensitivity (the probability that the surveillance system would detect at least one infected animal if disease was present at 1/100,000) would only be 17%, and the confidence of freedom 82.8%, with a 99% sensitive test[14]. Consequently, the number of tested risk animals required would be prohibitively large for the size of the cattle population of many Members.

The Group further discussed whether to use cattle population numbers as a proxy for an 'expected' number of BSE clinical suspects by year, but concluded this was very variable and difficult to predict for all Members, especially considering the large variability in cattle husbandry systems.

The Group remarked that the proper implementation of ongoing awareness and training programmes should be maintained to ensure that all stakeholders are capable of identifying animals showing clinical signs suggestive of BSE and that they are familiar with their statutory reporting obligations. The Group clarified that, for both initial recognition and maintenance of a BSE risk status, Members will need to provide documented evidence that the awareness programme has been implemented in accordance with the provisions of draft Article 11.4.18 point 3(a) and draft Article 1.8.6 point 1.

In addition, the Group strengthened the provisions of draft Article 11.4.18 point 3(a) so that the awareness and training programmes reach all stakeholders involved in the rearing and production of livestock, from farm to abattoir, such as farmers, herdsmen, veterinarians, transporters and abattoir staff.

[13] [1] European Food Safety Authority (2019). The European Union summary report on surveillance for the presence of transmissible spongiform encephalopathies (TSE) in 2018. EFSA Journal 17(12):5925.; [2] Arnold ME, Simons RR, Hope J, Gibbens N, Adkin AL. (2017) Is there a decline in bovine spongiform encephalopathy cases born after reinforced feed bans? A modelling study in EU member states. Epidemiology & Infection 145(11):2280-2286.

[14] Calculation of surveillance sensitivity was carried out using EpiTools website ('Surveillance with simple risk-based sampling' option): https://epitools.ausvet.com.au/riskbasedsesimple

Annex 28 (contd)

d) Members' comments requesting distinct surveillance provisions for Members with a history of BSE cases or with a controlled BSE risk status

The Group discussed two comments proposing (1) to request mandatory testing of all fallen stock in countries or zones with a history of BSE cases, on top of testing all clinical suspects, or (2) to maintain active surveillance in countries or zones with a controlled BSE risk status. The Group explained that provisions under draft points 3 and 4 of Article 11.4.3, draft Article 11.4.3bis and draft Article 11.4.4 already clearly identify the impact and the way to address BSE cases not only for the initial recognition but also for the maintenance of a BSE risk status.

The Group reaffirmed its conclusion that as long as measures to prevent recycling and amplification of the BSE agents have been continuously and effectively implemented, and an effective surveillance system for the detection and investigation of suspected cases is in place, to have distinct surveillance provisions for different Members would neither be proportionate to the risk nor provide a gain in risk reduction. The Group stressed that the new provisions now clearly established that subpopulations of cattle not passing the ante-mortem inspection at abattoirs, and downers (non-ambulatory) and fallen stock (found dead) with an appropriate clinical history were to be included in the surveillance programme (Section 3.21.a of this report).

The Secretariat further referred Members to Section 4.1 of the report of the October 2018[15] meeting where the probability of detection of a case was provided for various cattle population groups as well as an example to illustrate that current surveillance on distinct cattle subpopulations could no longer be justified as the level of investment required could not be considered to be cost effective and likely beyond the means of many countries.

e) Member's comment requesting addition of further criteria for defining a clinical suspect

The Group addressed a comment requesting a stricter definition of clinical suspect given the non-specific nature of BSE clinical signs. The Group highlighted that a key feature of BSE is that it produces non-pathognomonic signs characterized by behavioural or neurological signs that are progressive[16] and refractory to treatment. Thus, it was not possible to characterize high, medium or low clinical suspects.

f) Member's comment requesting reassessment of requirements for compulsory notification of BSE

Current provisions in point 3 of Article 11.4.2. require BSE to be a compulsorily notifiable disease in the whole territory. Under revised provisions, compulsory notification should apply to all stakeholders involved in the rearing and production of livestock (see draft point 1(a) of Article 11.4.18 of the version circulated for comments in September 2019[17]).

A Member requested the reassessment of the requirements for compulsory notification in support of the surveillance programme, arguing these to be overly prescriptive. The Group explained that those who closely interact with animals (farmers, herdsmen, etc.) should not only be able to recognise clinical signs (based on the BSE awareness programme in place) but also should report animals to the competent authority to strengthen the credibility and efficacy of the BSE surveillance programme. The Group agreed however that for consistency with other chapters, such an extensive listing of the relevant stakeholders was not necessary and amended the provisions of draft Article 11.4.18 point 3(b) accordingly.

[15] See the October 2018 report of the meeting of the OIE *ad hoc* group on BSE surveillance.
[16] That is, with continuous worsening from onset of clinical signs to death.
[17] Annex 26 of the Report of the September 2019 meeting of the OIE Terrestrial Animal Health Standards Commission.

In addition, the Group recognised that draft Article 11.4.18 point 3(b) is using the word 'notification' (a term that, if in italics, would have a meaning in the *Terrestrial Code* not intended for this provision[18]). After a suggestion from the Code Commission during the meeting to re-word this point, the Group underlined the relevance of not confusing this requirement with the act of reporting an outbreak to the OIE. The Group highlighted that the purpose of this provision is to require BSE to be a compulsorily *notifiable disease* in the whole territory as defined in the Glossary of the *Terrestrial Code* (i.e., *notifiable disease* means a disease listed by the Veterinary Authority, and that, as soon as detected or suspected, should be brought to the attention of this Authority, in accordance with national regulations). The Group noted that many other diseases are required to be notifiable[19]. The Group proposed to either use the word 'notification' without italics[20] or to somehow modify the sentence to include the term 'compulsorily *notifiable disease*'.

g) Member's comment requesting the OIE to provide an assessment of the current surveillance provisions in terms of its cost-effectiveness

In response to a comment requesting the Group to provide the details of the assessment of the current surveillance provisions, including its cost-effectiveness, its advantages and disadvantages, and its achievements, the Group made reference to the report of the Group that met in October 2018[21] where the Group provided a thorough historical perspective of the current provisions (Section 3.2) and identified the significant drawbacks that have arisen over the years that pointed to the need to review the current BSE surveillance provisions (Section 3.3). Likewise, the Group recalled the study showing that the likely investment required to implement an active surveillance programme would by far exceed that of a passive programme, and that for very little additional gain in the likely time required to detect disease re-emergence (from 17 to 15 years) (also in the above mentioned report, Section 4).

h) Member's comment requesting evaluating the capacity and competence of the Veterinary Service and Veterinary Authority through a Performance of Veterinary Services (PVS) evaluation

In response to a comment requesting the evaluation of the capacity and competence of the veterinary service and the veterinary authority through a Performance of Veterinary Services (PVS) evaluation in particular, given that some Members could be granted a BSE risk status due to their livestock industry practices, the Group made reference to the report of the Group that met in November 2018. Back then, the Group amended draft Article 1.8.4. to request that recent (i.e., not older than five years) PVS Evaluation Reports, Follow-up Reports and Gap Analyses be provided, if available, as part of the application. The Group reaffirmed its position.

4. Revision of Chapter 1.8 (the BSE questionnaire) of the *Terrestrial Code*

Draft Chapter 1.8 was circulated for Members' information (i.e., not for comments) in the Code Commission September 2019 report. The Group further revised Chapter 1.8. to address any remaining matters emerging from the revision of Chapter 11.4., ensuring full consistency between the BSE questionnaire and the draft Chapter 11.4.

[18] *Notification* (in italics) means the procedure by which: a. the Veterinary Authority informs the Headquarters, b. the Headquarters inform the Veterinary Authority, of the occurrence of disease, infection or infestation in accordance with Chapter 1.1.

[19] E.g., Article 14.8.5. "the disease is compulsorily notifiable"; Article 8.1.1. "Anthrax should be notifiable in the whole country". Other diseases include Aujeszky's disease, acarapisosis, bluetongue, epizootic hemorrhagic disease, lumpy skin disease, etc.

[20] The word 'notification' (without italics) is used in various articles of the *Terrestrial Code*, including Articles 3.2.7, 3.2.8, 4.3.3, 4.5.7, 10.4.28, and 14.8.2.

[21] See the October 2018 report of the meeting of the OIE *ad hoc* group on BSE surveillance.

Annex 28 (contd)

4.1. Draft Article 1.8.5 point 2. Exposure assessment

The Group edited the text to further emphasise that the evaluation of livestock industry practices should focus on the identification of all potential risk factors associated with feeding cattle with protein meal derived from ruminants. Accordingly, the risk mitigation practices should focus on the elimination of such risks, if present. The subheadings of points (v) and (vi) were edited to clarify that the awareness programmes and monitoring and enforcement activities should relate to the feed ban.

4.2. Draft Article 1.8.5 point 3. Consequence assessment

The Group edited the text to clarify that not only the extent, but the duration, of any recycling and amplification occurrences should be determined.

4.3. Draft Article 1.8.5 point 4. Risk estimation

The Group expanded this point to highlight that the purpose of the risk estimation (i.e., 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). Point (b) was deleted for conciseness.

4.4. Draft Article 1.8.6 BSE surveillance

The Group edited the text to reflect the amendments made in draft Article 11.4.18 for consistency.

Two tables were added to assist Members to provide a consistent summary of the number of cattle that were reported and the number that were subjected to testing in a given year. Table 1 is stratified by the types of cattle targeted for investigation according to point 2 of Article 11.4.18.

5. Recommendations for the consideration of the OIE

The Group once more emphasised that training by the OIE on the procedures and requirements for the official recognition of the BSE risk status of a country or zone would be beneficial for Members upon the adoption of the revised provisions.

6. Finalisation and adoption of the report

The Group reviewed and adopted the draft report.

Annex 28 (contd)

Annex I

FIFTH MEETING OF THE OIE *AD HOC* GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT AND SURVEILLANCE

Paris, 8, 9, 12 and 15–19 June 2020

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Terms of Reference

Purpose

The purpose of this *ad hoc* Group is to provide independent analysis and advice to OIE in response to the comments received from the Members regarding the revision of the surveillance and risk-based provisions applicable to the recognition and maintenance of BSE risk status as well as the recommendations for international trade.

Functions

This *ad hoc* Group will report to the Director General of the OIE, and approved reports will be considered by the relevant Specialist Commissions (the Scientific Commission for Animal Diseases and the Terrestrial Animal Health Standards Commissions) when necessary, in accordance with the OIE Basic Texts.

Experts' contributions will be solicited in preparation of this meeting under the coordination of the OIE Secretariat.

During this meeting, this *ad hoc* Group will:

1. Further revise Chapter 11.4 taking into consideration the latest scientific knowledge, the previous work done by four *ad hoc* Groups on the revision of BSE standards, the opinion of the Specialist Commissions (Scientific and Code) provided in September 2019, the comments submitted by Members in December 2019, and the proposals of the Code Commission from February 2020.
2. Further revise Chapter 1.8 (the BSE questionnaire) to address any remaining matters emerging from the revision of Chapter 11.4, ensuring full consistency between the BSE questionnaire and the draft Chapter 11.4.
3. Revise the draft form in support of the annual reconfirmation of BSE risk status. Ensure full consistency between the reconfirmation form and draft Chapter 11.4.

- Should the Group not be able to complete its Terms of Reference during this meeting, experts' contributions will be solicited after the meeting, including by teleconference(s) if needed.

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Annex 28 (contd)

Annex II

FIFTH MEETING OF THE OIE *AD HOC* GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT AND SURVEILLANCE

Paris, 8, 9, 12 and 15-19 June 2020

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Agenda

1) Opening.

2) Adoption of the agenda and appointment of chairperson and rapporteur.

3) Review of the Terms of Reference (ToRs) and definition of the work plan:
   - Revision of Members' comments;
   - Further revise Chapter 11.4 (point 1 of the ToR);

4) Revision of Chapter 1.8 (the BSE questionnaire) of the *Terrestrial Code*
   - Further revise Chapter 1.8 (point 2 of the ToR).

5) Recommendations for the consideration of the OIE

6) Finalisation and adoption of the report.

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Annex 28 (contd)

Annex III

FIFTH MEETING OF THE OIE *AD HOC* GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT AND SURVEILLANCE

Paris, 8, 9, 12 and 15–19 June 2020

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