Annex 26

Original: English
April–July 2020

OIE *AD HOC* ON THE REVISION OF CHAPTER 7.7 STRAY DOG POPULATION CONTROL

Paris, April–July 2020

1. Introduction

Due to the COVID-19 sanitary crisis, the OIE *ad hoc* Group on the Revision of Chapter 7.7 Stray dog population control (hereafter referred to as the *ad hoc* Group) met via video conference (i.e., Zoom) between April and July 2020.

The *ad hoc* Group met eleven times via Zoom during the first semester of 2020 (16th April, 6th May, 5, 17 and 18th June, 6, 7, 16, 17, 28 and 30th July) to finalise the revision of the chapter in accordance with the advice of the OIE Terrestrial Animal Health Standards Commission (hereafter referred to as the Code Commission) from their February 2020 meeting. The participants in the Zoom meetings are presented in Annex I. During the first meeting of the *ad hoc* Group, the Secretariat explained the modus operandi for the review of Chapter 7.7 in the context of the sanitary crisis.

The OIE would like to thank the *ad hoc* Group members and acknowledge the important effort they made by working under such difficult conditions to deliver their expert opinion.

The work of this *ad hoc* Group started after 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. The first meeting of this *ad hoc* Group was held at the OIE Headquarters on 5–7 November 2019. During that meeting, the *ad hoc* Group reviewed current recommendations that address the monitoring and evaluation of stray dog control schemes and responsible dog ownership and discussed additional recommendations that could support the Global Strategy.

2. Update on the February 2020 Code Commission meeting

During the first meeting, the OIE Secretariat informed the *ad hoc* Group of the outcomes of the February 2020 Code Commission meeting. The *ad hoc* Group members provided the following answers to the Code Commission's recommendations:

To restructure Chapter 7.7, as proposed in the terms of reference and to update the text in line with current scientific information; to include in the revision of Chapter 7.7 the practical minimum recommendations for population control measures such as dog catching, housing or restraint.

- The *ad hoc* Group restructured the chapter to help the reader navigate through the content. The terminology was updated and clarified to improve understanding and accessibility of the guidance. The *ad hoc* Group proposed new recommendations throughout the chapter (including on dog capture, handling, and housing), revised the definitions, clarified the roles and responsibilities, and added the concept of animal-based measures to the chapter. The *ad hoc* Group aligned the chapter with and referred to the recommendations in Chapters 8.14 and 8.5.

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To keep the focus on animal welfare and move the animal and public health recommendations to other relevant chapters; to add cross-references in other relevant chapters, notably animal health related ones.

- The *ad hoc* Group removed the new proposed content providing guidance on rabies vaccination and revised the text to keep other measures together in Chapter 7.7 to achieve animal welfare and public health impacts. The *ad hoc* Group considered difficult to separate out measures purely for public health.

- The *ad hoc* Group edited the 'Euthanasia section' (new Article 7.7.27) to make it more focused on welfare. Specifically, the *ad hoc* Group defined a short list of recommended and unacceptable methods and suggested to delete the table of euthanasia methods.

To include information on rabies vaccination strategies in Chapter 8.14 Infection with rabies virus; consequently, the *ad hoc* Group was requested to provide a proposal regarding suitable text to be included in Chapter 8.14.

- The *ad hoc* Group developed a draft text on how to implement rabies vaccination programme for the Code Commission to consider its inclusion in Chapter 8.14, Infection with rabies virus. The text proposed by the *ad hoc* Group is presented in Annex III. The *ad hoc* Group also proposed text to keep in Chapter 7.7. (e.g., Articles 7.7.1 and 7.7.21) that explains the contribution of Dog Population Management (DPM) to rabies control.

To provide further justification for the proposal to change the title and if changed, to expressly include the concept of welfare within it.

- The *ad hoc* Group proposed to change the title of the chapter from 'Stray dog population control' to 'Dog Population Management' (DPM). Effective management of dog populations is hampered by a misunderstanding that solely the control of the current stray dog population is needed to achieve successful management. A common source of stray dogs is the owned dog population. Owned dogs allowed to roam freely become lost or are abandoned by their owners. Due to poor responsible dog ownership, owned dogs may breed haphazardly, and their offspring abandoned which adds to the free-roaming or stray dog population. A dog population is composed of different subpopulations depending on dog's ownership and restriction status. This system is normally open, interactive and dynamic and dogs may move even several times between subpopulations throughout their lifespan. Consequently, to implement dog populations management measures effectively and sustainably, the wider dog population, and not just the current strays, must be considered. The current chapter title reflects this misguided focus on stray dogs, whilst the proposed new title encourages consideration of the wider population and all potential sources of future stray dogs.

  Dog population management is becoming more widely used and recognised as a term for humane management of dogs. For example, International Companion Animal Management Coalition (ICAM) uses the term 'Humane Dog Population Management' in the title of 2019 edition, the World Health Organization (WHO) uses the term 'dog population management' within their 2018 Expert Consultation on Rabies and the Food and Agriculture Organization of the United Nations (FAO) used 'Dog Population Management' for their 2014 report on an expert meeting on the subject.

  Including the term 'welfare' within the title does not seem necessary due to being part of Section 7 'Animal Welfare', and Dog Population Management has public health as well as animal welfare benefits. However, if the Code Commission prefers to include the concept of welfare within the title, the *ad hoc* Group suggests 'Animal Welfare and Dog Population Management' as a title.

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To clarify the rationale for the *ad hoc* Group to propose to change the use of 'Stray dog' to 'Free-roaming dog' in the text and clarify its proposed new definition in the Glossary.

- The *ad hoc* Group proposed to change the use of 'Stray dog' to 'Free-roaming dog' in the text and the Glossary. The term 'stray dog' has many meanings around the world. For example, in the United Kingdom a 'stray dog' is an owned dog that has been lost, whilst in Bhutan a 'stray dog' is a dog that is unowned. These different definitions create unavoidable assumptions about how DPM should be done. Therefore, the *ad hoc* Group decided to use a different term that does not have the same long-standing connotations and varied definitions. 'Free-roaming dog' is a term that describes the behaviour of a dog, one that is currently roaming without restriction, but it does not imply ownership status. 'Free-roaming dog' is also a term that is used in other texts on the same or related subjects; for example, the WHO uses 'free-roaming dogs' in their 2018 Expert Consultation on Rabies.

- The proposed new definition for 'Free roaming dog' is presented for consideration in Annex IV for the convenience of the Code Commission.

3. Revision of Chapter 7.7 Stray dog population control

The Code Commission agreed to convene an *ad hoc* Group to revise the content of Chapter 7.7, Stray dog population control, to ensure it was aligned with and contained the relevant recommendations to support the OIE Global Strategy to end human death due to dog-mediated rabies by 2030.

The *ad hoc* Group considered Chapter 7.7 and proposed amendments to the structure, terminology, scope, objectives, and content as recommended in the terms of references. The revised Chapter 7.7, Stray dog population control, is presented in Annex II.

a) Chapter structure: In this revised structure, articles were either added or reorganised to improve the flow of the recommendations and to address the wider scope of the chapter. In particular, the articles on roles and responsibilities were rewritten to reflect the various entities who may have a role in DPM.

b) Terminology: The terminology used throughout the chapter and title was harmonised to be consistent with the terminology used in other texts and with other chapters.

c) Scope and Context: The scope was redefined to focus on the welfare of dogs when implementing dog population management programme.

d) Objectives: The objectives of this chapter were reworded and updated to take into consideration the OIE's activities around dog-mediated human rabies.

e) Chapter content: As for the structure, the content of each article was revised to ensure most up-to-date guidance on DPM.

4. Any other business

None.

5. Next steps

The *ad hoc* Group members agreed to continue their work on Chapter 7.7, Stray dog population control, pending feedback from the Code Commission after its September 2020 meeting.

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Annex I

MEETING OF THE OIE *AD HOC* GROUP ON THE REVISION OF CHAPTER 7.7 STRAY DOG POPULATION CONTROL

Paris, April–July 2020

List of participants

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Annex II

[Note: this Annex has been replaced by Annex 17 to the report of the meeting of the OIE Terrestrial Animal Health Standards Commission which was held on 1–10 September 2020.]

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Annex III

[Note: this Annex is being considered by the Code Commission. Details on these considerations can be found under item 7.2. of the report of the meeting of the OIE Terrestrial Animal Health Standards Commission which was held on 1–10 September 2020.]

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Annex IV

REVISED GLOSSARY DEFINITION

~~STRAY DOG~~ FREE-ROAMING DOG

means any dog not under direct control ~~by a person~~ or not prevented from roaming. Types of ~~stray dog~~ free-roaming dog include:

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

b) free-roaming dog with no owner,

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

Annex 27

Original: English
March 2020

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON RINDERPEST

24–26 March 2020

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The meeting of the OIE *ad hoc* Group on Rinderpest was held by video conference from 24 to 26 March 2020.

1. Welcome and background information

The OIE Secretariat welcomed participants to the virtual meeting and thanked the *ad hoc* Group members for their pre-meeting work to review Chapter 8.16., Infection with rinderpest virus, of the *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code)*. The Secretariat explained that due to confinement and travel restrictions arising from the Covid-19 pandemic, the meeting had to be held by video conference.

Dr David Ulaeto, the Chairperson, together with the OIE Secretariat (rapporteur) presented the background information that led to the revision of Chapter 8.16. They noted that the chapter was last revised in 2013 to ensure it was relevant for the status of global freedom, following the declaration of rinderpest eradication in 2011. They noted that the current Chapter 8.16 requires that countries wishing to recover freedom after rinderpest re-emergence through vaccination should slaughter animals which have been vaccinated. During regional rinderpest tabletop exercises to test the Global Rinderpest Action Plan1, concerns were raised that the provisions of the current chapter were not inclusive of countries that had a vaccinate-to-live policy. Subsequent discussions with the Code Commission, Scientific Commission and FAO-OIE Joint Advisory Committee for Rinderpest (JAC) highlighted further gaps in the chapter. Given the importance of having a chapter that was fit for purpose, the OIE Director General agreed that an *ad hoc* Group be convened to address these issues.

2. Adoption of the agenda

The draft agenda was adopted by the *ad hoc* Group. The adopted agenda and list of participants are presented as Appendix I and II, respectively. The Terms of Reference for the *ad hoc* Group are presented as Appendix III.

3. Revision of Chapter 8.16 of the *Terrestrial Code*

a) Definitions for suspected case and confirmed case

Given that the finding of a suspected case of rinderpest is notifiable to the OIE, the *ad hoc* Group acknowledged that the current definition for a ‘suspected case’, based on ‘stomatitis-enteritis syndrome’, was too broad and non-specific for it to be used meaningfully by Member Countries for notification purposes. The *ad hoc* Group noted that this could jeopardise early warning in the event of re-emergence of rinderpest. The *ad hoc* Group was aware that the notification of a ‘suspected case’ would trigger international scrutiny and therefore due diligence should be exercised to rule out other differential diagnoses which could also present as ‘stomatitis-enteritis syndrome’. In this regard, the *ad hoc* Group recommended that the chapter include a gradation in the level of suspicion and proposed the following definitions:

[1] http://www.fao.org/documents/card/en/c/CA1965EN/

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- 'Potential case' of rinderpest, refers to an animal with clinical signs consistent with 'stomatitis-enteritis syndrome' (i.e., definition of 'suspected case' in the 2019 *Terrestrial Code* chapter) which cannot be ascribed to another disease compatible with stomatitis-enteritis syndrome by epidemiological considerations or appropriate laboratory investigation;
- 'Suspected case' of rinderpest, refers to a potential case where all relevant differential diagnoses for stomatitis-enteritis syndrome have been ruled out, or which has produced a positive rinderpest test result outside an OIE Reference Laboratory (such as with a local diagnostic test that is not indicative of confirmation but provides stronger grounds of suspicion). Such a case shall be notified to the OIE; and
- 'Case' of rinderpest refers to an animal where infection with rinderpest has been confirmed by an OIE Reference Laboratory for rinderpest. Such a case shall be notified to the OIE.

For consistency with the other disease-specific chapters of the *Terrestrial Code*, these proposed definitions have been moved to Article 8.15.1. In discussing these definitions, the *ad hoc* Group stressed the importance of Member Countries maintaining the capacity to perform first-line tests to facilitate the detection of suspected cases of rinderpest, such as through RT-PCR and AGID. The *ad hoc* Group agreed that Member Countries should refer to the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereafter referred to as the *Terrestrial Manual*) for information about diagnostic tests for rinderpest, including local tests that may be used. Member Countries are also encouraged to establish ongoing links with OIE Reference Laboratories to guide testing. The *ad hoc* Group recommended that the OIE work with the JAC to provide advice on strengthening in-country capacity for rinderpest testing.

The *ad hoc* Group also considered the possible pathways for the re-emergence of rinderpest and agreed that while proximity to known and unknown facilities possessing rinderpest virus containing material (RVCM) is a clear risk factor, it emphasised that suspected cases should not be limited to the vicinity of institutions holding RVCM.

b) Articles for free country, infected country, free zone, containment zone and infected zone

The *ad hoc* Group recognised that contrary to other listed diseases in the *Terrestrial Code*, in this post eradication era, all countries are considered to be free of rinderpest unless proven otherwise through the detection of a case.

Country or zone free from rinderpest (Article 8.16.6)

The *ad hoc* Group proposed that in the event of re-emergence of rinderpest (i.e., when a country has notified a case of rinderpest), other Member Countries may continue to be recognised as free from rinderpest so long as they do not have a confirmed case(s). However, given the risk pathways for infection, including through movement of animals, the *ad hoc* Group was of the view that additional assurance would have to be provided by countries or zones where, although no case of rinderpest has been detected, there are significant epidemiological and ecological linkages to infected countries or zones.

Therefore, the *ad hoc* Group recommended that in the event of re-emergence of rinderpest, all Member Countries would have to perform a risk assessment for rinderpest and submit this to the OIE. The rinderpest free status of Member Countries would be suspended if the risk assessment is not accepted by the OIE. The *ad hoc* Group proposed the concept of countries at a 'heightened risk', where targeted surveillance, in addition to the ongoing surveillance requirements of the post-eradication era, must be performed to provide confidence in the ability to detect infection. Notwithstanding, the *ad hoc* Group emphasised that all Member Countries should still perform surveillance to facilitate early warning.

Country or zone infected with RPV (Article 8.16.7)

As explained in the preamble of 3(ii), the *ad hoc* Group proposed that the definition of country or zone infected with RPV be based on the occurrence of a case of rinderpest.

Establishment of a containment zone within a country or zone previously free from rinderpest (Article 8.16.8)

The *ad hoc* Group noted that the priority for Chapter 8.16 in this post-eradication era is the maintenance of global freedom and its prompt recovery should there be a re-emergence of rinderpest. In discussing the provisions for establishing a containment zone, the *ad hoc* Group kept in mind that the objective of its establishment, unlike other disease-specific chapters, would be for the purposes of disease control and subsequent eradication and not to facilitate continued international trade. Therefore, the *ad hoc* Group proposed additional text to clarify that international trade in commodities from the entire country would be limited to the safe commodities listed in Article 8.16.2 until free status is recovered.

c) Safe commodities and trade provisions in the event of re-emergence of rinderpest

Safe commodities (Article 8.16.2)

In developing a list of safe commodities for this chapter, the *ad hoc* Group referred to the 2010 edition of the *Terrestrial Code* and identified semi-processed hides and skins to be safe commodities for rinderpest.

The *ad hoc* Group also proposed to include gelatin and meat in a hermetically sealed container with a Fo value of 3 or above in this article, given that in accordance with Chapter 2.2, Criteria applied by the OIE for assessing the safety of commodities, standard manufacturing processes would inactivate RPV in these commodities.

The *ad hoc* Group also proposed additional text to Article 8.16.2 to clarify that the list of safe commodities would apply in the event of re-emergence of rinderpest to avoid confusion with this post-eradication era, where all susceptible animals and their products are considered safe with respect to rinderpest.

Trade provisions (Article 8.16.12)

In reviewing the trade provisions applicable to countries free from rinderpest in the 2010 edition of the *Terrestrial Code*, the *ad hoc* Group noted inconsistencies in the residency period required of animals prior to exportation or the harvesting of products (e.g., 3 months for semen collection and 30 days for susceptible animals). The *ad hoc* Group further noted that there was no residency period stipulated for donor animals of *in vivo* embryos. In view of the 21-day incubation period for rinderpest and considering the allowance of a safety margin, the *ad hoc* Group recommended to have a 30-day residency period in a country free of rinderpest for susceptible animals and animals from which products were derived or harvested. The *ad hoc* Group noted that oocytes may also be harvested from susceptible animals, and therefore proposed provisions for this in the draft chapter.

Instead of having separate articles for each commodity as per the convention in the *Terrestrial Code*, the *ad hoc* Group recommended incorporating all the provisions into one article for conciseness given that the focus of the chapter is on post-eradication and not trade in the event of re-emergence.

d) Provisions for recovery of freedom to ensure timelines for recovery of country freedom and global freedom are compatible

Recovery of global freedom (Article 8.16.10)

The OIE Secretariat drew the *ad hoc* Group's attention to the incompatibilities between the waiting periods for recovery of country freedom, and the reinstatement of global freedom status in the current chapter. The time limit of six months for the reinstatement of global freedom (if global freedom was not reinstated within six months, the global freedom status would be 'lost') after the confirmation of an outbreak was not a practical timeframe as it was unachievable in the event infected countries did not employ stamping-out as a control measure.

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Separately, the *ad hoc* Group also discussed the significance of a loss of global freedom status and agreed that this would imply that the status of all non-infected countries would become undetermined, and these countries would need to submit an application to the OIE for the official recognition of free status, in addition to the risk assessment that should have been previously submitted to the OIE. The *ad hoc* Group advised that the contents of the questionnaire for the assessment of country status be developed by the OIE Headquarters with possible consultation of experts, although the questionnaire may be abbreviated for countries that have been free of rinderpest since its eradication in 2011.

The *ad hoc* Group considered that the re-initiation of the official status recognition framework for all countries may not be warranted if the outbreak was confined to a limited area and effectively contained. Therefore, considering this and the impracticality of the six-month timeframe for the reinstatement of global freedom after the confirmation of an outbreak, the *ad hoc* Group recommended abolishing the time limit for the reinstatement of global freedom, and proposed the concept of global freedom status suspension provided:

- The outbreak is limited to a country or zone without any further outbreaks outside the ecosystem of the first outbreak.
- The outbreak is handled in a prompt and efficient manner shown to be successful in mitigating the spread of rinderpest and reducing its incidence.

During a period of global freedom status suspension, the requirement would be for Member Countries to submit a risk assessment as described in point 3(ii) above, thereby easing the administrative burden on Member Countries that are at low risk of infection in the event of re-emergence of rinderpest. To ensure that global freedom status suspension does not go on indefinitely, the *ad hoc* Group proposed a period of 12 months for the infected country(s) to demonstrate that the control measures are being effective, failing which global freedom status would be lost. Notwithstanding, an obvious failure of control measures during the period of 12 months could lead to an immediate loss of global freedom. Likewise, as the *ad hoc* Group also pointed out, evidence of a wider spread of rinderpest at the outset would justify the loss of global freedom status, in lieu of its suspension.

The *ad hoc* Group considered that global rinderpest freedom may be recovered from a suspended status once the infected country(s) has recovered freedom. In the event of loss of global rinderpest freedom, an additional requirement for recovery is for all countries to be officially recognised by the OIE as free from rinderpest.

The table below illustrates the concept and implications of global rinderpest freedom suspension and loss:

	Global freedom status suspended	**Global freedom status lost**
Time of commencement	Confirmation of first case of rinderpest in post-eradication era, provided conditions in Article 8.16.6 are met.	When conditions in Article 8.16.6 are not met. This could be within 12 months of the suspension of global freedom status or immediately if, upon confirmation of first case, there is already evidence of wider dissemination.
End time	Until such time infected countries have regained freedom (i.e., global freedom recovery).	Until such time infected countries have regained freedom and all countries have undergone official recognition for free status (i.e., global freedom recovery).

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Requirements	All Member Countries to submit risk assessments to the OIE. Member Countries identified to be at 'heightened risk' required to perform additional surveillance to provide confidence in ability to detect cases. Expert mission to infected countries to verify containment and eradication measures.	Official status recognition procedure reinstated; all Member Countries required to submit dossiers for freedom recognition (abbreviated version possible for countries that have been free of rinderpest since its eradication in 2011). Expert mission to infected countries to verify containment and eradication measures.

Recovery of free status for a country or zone (Article 8.16.9)

The *ad hoc* Group referred to recommendations in the current and 2010 editions of the *Terrestrial Code* for the control measures to be applied and the corresponding waiting periods for the recovery of free status for a country or zone.

In point 1(a), which referred to the application of a stamping-out policy, the *ad hoc* Group agreed that three months is a reasonable time period as it encompasses a minimum of two incubation periods and provides a conservative buffer considering experience from previous rinderpest outbreaks where larger ecosystems and animal populations were involved, rather than in closed herds where outbreaks could be relatively contained.

In point 1(b), which referred to the application of a stamping-out policy and emergency vaccination followed by the slaughter of animals, the *ad hoc* Group agreed that the waiting period of three months is appropriate as per the rationale in point 1.

In point 1(c), which referred to the application of a stamping-out policy and emergency vaccination not followed by the slaughter of vaccination animals (i.e. vaccinate-to-live), the *ad hoc* Group did not agree with the waiting period of six months, because of the possibility of interference by maternal antibodies with serological surveillance. The *ad hoc* Group noted maternal antibodies may persist for up to 10 months, and thus recommended a conservative waiting period of 18 months.

In point 2, which referred to when stamping-out was not applied, the *ad hoc* Group agreed with the waiting period of 24 months, which is the period used in the OIE pathway.

The *ad hoc* Group noted that guidance was available to Member Countries for the control of animal diseases2 and further concurred with the importance of international expert missions to ascertain the successful application of containment and eradication measures.

e) Provisions on surveillance

Surveillance for recovery of rinderpest free status (Article 8.16.11)

Given that rinderpest can produce different clinical presentations and clinical surveillance alone could fail to detect mild cases of the disease, the *ad hoc* Group recommended including a provision for serological surveillance to complement clinical surveillance. However, the *ad hoc* Group also noted that there was no DIVA (differentiating infected from vaccinated animals) technology for rinderpest, and thus recommended that, for the purposes of serological surveillance, the target population should exclude vaccinated animals and animals with maternal antibodies. For this reason, the *ad hoc* Group also noted that serological surveillance for the purposes of demonstrating freedom should only take place after the cessation of vaccination.

[2] https://www.oie.int/scientific-expertise/specific-information-and-recommendations/animal-disease-control/

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The *ad hoc* Group noted that, at the current time, there are no assays available for serological surveillance for rinderpest antibodies and this will become of critical importance in the event of a re-emergence of rinderpest.

In revising the chapter, the *ad hoc* Group also made changes to the order of some articles to ensure alignment with other disease-specific chapters in the *Terrestrial Code*. In addition, given the extensive nature of the revisions the *ad hoc* Group only provided a 'clean' version of the revised draft chapter.

The revised draft Chapter 8.16, Infection with rinderpest virus, is attached as Appendix IV.

4. Next steps

The *ad hoc* Group was informed that its report, including the amended draft Chapter 8.16, will be considered by the Code Commission at its next meeting in September 2020.

5. Adoption of the report

The *ad hoc* Group reviewed the draft report provided by the rapporteur and agreed to circulate it electronically for comments before the final adoption.

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Appendix I

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON RINDERPEST

24–26 March 2020

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Agenda

1) Welcome and background information

2) Adoption of the agenda

3) Revision of Chapter 8.16 of the *Terrestrial Code*

   a) Definitions for suspected case and *case*

   b) Articles for free country, infected country, free zone, containment zone and infected zone

   c) Safe commodities and trade provisions in the event of re-emergence of rinderpest

   d) Provisions for recovery of freedom to ensure timelines for recovery of country freedom and global freedom are compatible

   e) Provisions on surveillance

4) Next steps

5) Adoption of the report

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Appendix II

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON RINDERPEST

24–26 March 2020

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Appendix III

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON RINDERPEST

24–26 March 2020

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Terms of reference

Background

Following the declaration of rinderpest eradication in 2011, Chapter 8.16, Infection with rinderpest virus, of the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) underwent a major revision in 2013 to reflect the global freedom status.

However, it became evident that further work on the chapter was needed when concerns were expressed by some Member Countries that the recovery of global freedom, should the disease re-emerge, would be impeded if infected countries chose not to stamp-out sick animals, or slaughter vaccinated animals. Subsequent issues were raised by the FAO-OIE Joint Advisory Committee for Rinderpest which further highlighted discrepancies in the chapter.

The OIE Headquarters is coordinating the review of this chapter, which seeks to address the afore-mentioned concerns and, at the same time, to ensure that the provisions in the chapter are compatible with the objective of maintenance of global freedom and its prompt recovery should there be a re-emergence.

Purpose

The *ad hoc* Group on Rinderpest will revise the scientific and technical aspects of Chapter 8.16 of the *Terrestrial Code*, in light of the guidance provided by the OIE Secretariat, the relevant Specialist Commissions and the FAO-OIE Joint Advisory Committee for Rinderpest.

Terms of Reference

The *ad hoc* Group will provide input to the following areas:

1) Propose revised definitions for suspected case and *case* (presently in Article 8.16.5);
2) Propose articles for *free country, infected country, free zone, containment zone* and *infected zone*;
3) In revising the trade provisions, develop a list of *safe commodities* in accordance with criteria in Chapter 2.2 for trade with infected countries, in case of an outbreak[3];
4) Review the current provisions on recovery of freedom in Article 8.16.6 to ensure that the timelines for recovery of country freedom and global freedom are compatible, in particular for the scenario where stamping-out is not practised;
5) Review the current provisions on surveillance in Articles 8.16.3 and 8.16.8 and the provisions on surveillance in the 2010 edition of the rinderpest chapter and propose any amendments, if necessary.

Expected outputs of the *ad hoc* Group

1) An *ad hoc* Group report for consideration by the OIE Terrestrial Animal Health Standards Commission at its September 2020 meeting.

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[3] In the event of re-emergence of rinderpest, only safe commodities may be traded.

Annex 28

Original: English
March 2020

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[4] and November 2018[5], the *ad hoc* Group on BSE surveillance which met in October 2018[6], and the *ad hoc* Group on BSE risk assessment and surveillance which met in March 2019[7].

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.

[4] 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

[5] 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

[6] 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

[7] 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

Annex 28 (contd)

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[8], where the Group agreed with the conclusions of an EFSA report[9] 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.

[8] See the March 2019 report of the meeting of the OIE *ad hoc* group on BSE risk assessment and surveillance.

[9] 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[10], 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.

[10] 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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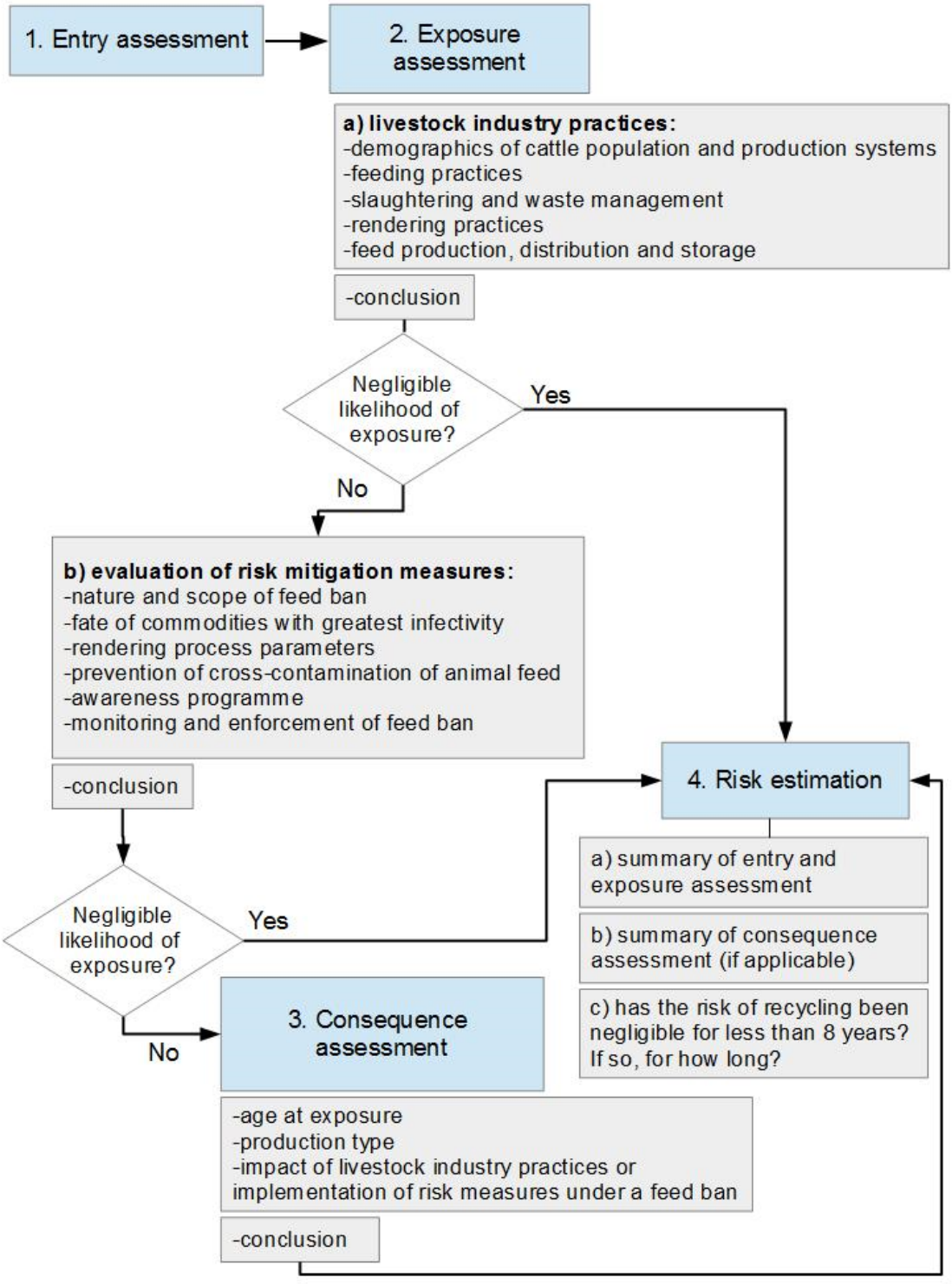

Figure 1. ***Schematic representation of the risk assessment steps described in Article 11.4.2.***

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'[11]) 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[12]. 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'[13], 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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[11] 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.

[12] 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.

[13] 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.

Annex 28 (contd)

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[14] 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.

[14] 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.

Annex 28 (contd)

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.

Annex 28 (contd)

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[15], 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.

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

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[16], 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[17]. 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.

[16] [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.

[17] 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[18] 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[19] 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[20]).

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.

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

[19] That is, with continuous worsening from onset of clinical signs to death.

[20] 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[21]). 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[22]. The Group proposed to either use the word 'notification' without italics[23] 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[24] 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.

[21] *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.

[22] 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.

[23] 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.

[24] 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 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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