

Ad hoc Group on the revision of bovine spongiform encephalopathy (BSE) standards and the maintenance of official BSE risk status

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22 to 24 June 2022

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A virtual meeting of the *ad hoc* Group on the revision of bovine spongiform encephalopathy (BSE) standards and the maintenance of official BSE risk status (the Group) was held from 22 to 24 June 2022 to finalise the assessment of the impact of the revised BSE provisions on the Members having an officially recognised BSE risk status by WOAAH. The Group also further revised the draft annual reconfirmation form for maintenance of official BSE risk status.

This is a continuation of the work initiated by the *ad hoc* Group on the revision of BSE standards and the impact of this revision on official status recognition which met in June 2021¹.

1. Opening

Dr Min Kyung Park, Head of the Status Department, welcomed the Group on behalf of Dr Monique Eloit, Director General of WOAAH. Dr Park thanked the experts of the Group for their time, commitment and valuable contribution to the revision of BSE standards, as well as assessing their impact on the recognition and maintenance of Members' official BSE risk status. Dr Park informed the Group regarding the postponement of the proposal for adoption of the revised BSE standards to the WOAAH General Session of May 2023 and underlined the importance to conclude this work as soon as possible.

Dr Park thanked the experts for having signed the forms for undertaking of confidentiality and declaration of interests. No potential conflict of interests was identified in relation to the Terms of Reference (ToR) of this meeting.

Dr Park provided a brief overview of the ToR and provisional agenda of the meeting and introduced the members of the Secretariat supporting the work of the Group. Finally, Dr Park and the experts welcomed Dr Olivier Andreoletti as a new member of the Group.

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

The Group was chaired by Dr Noel Murray, and Dr Alicia Cloete acted as rapporteur, with the support of the Secretariat. The Group endorsed the proposed agenda.

The ToR, agenda and list of participants are provided as [Appendices I, II and III](#), respectively.

3. Assessment of the impact that the revised BSE provisions may have on the maintenance of officially recognised BSE risk status of three Members

Following the BSE *ad hoc* Group that convened in June 2021 that initiated the evaluation of Members or zones that were granted an official BSE risk status based on a negligible risk of entry despite a non-negligible exposure assessment, and follow-up conducted during the 2021 annual reconfirmation campaign to clarify questions and gaps noted, the Scientific Commission for Animal Diseases (the Commission) concluded at its February 2022 meeting that five of the eight Members adequately closed the gaps identified by the BSE *ad hoc* Group. However, based on the nature and scope of the submitted information, as well as the length of the dossiers and time constraints of the virtual meeting in February 2022, the Commission proposed to refer the information from the three remaining Members to a BSE expert group to discuss the recommendations of the experts at its September 2022 meeting.

Upon this decision of the Commission to refer the three dossiers, this Group evaluated the information provided by the three Members. For one Member having a negligible BSE risk status, the Group concluded that its exposure assessment could be considered negligible.

For two Members having a negligible BSE risk status, the Group could not conclude whether the exposure risk (i.e., likelihood of recycling and amplification of BSE agent, if it were present in the cattle population) could be considered negligible. Based on the assessment report and recommendations, the Group requested that these two Members submit additional information to continue the evaluation.

4. Revision of the draft annual reconfirmation form for maintenance of official BSE risk status.

The Group revised the annual reconfirmation form that was first drafted by the *ad hoc* Group on the revision of BSE standards and the impact of this revision on the official status recognition in June 2021.

The proposed amendments on the draft annual reconfirmation form were aimed at eliminating redundancies, clarifying the questions and providing guidance on the type of information/evidence expected from Members when reconfirming their BSE risk status in accordance with the revised BSE provisions of the Terrestrial Code. The questions were further clarified

¹ The report of this meeting of the *ad hoc* Group can be found [here](#).

to assess the potential change in the risk of entry and exposure of the BSE agent in the cattle population and, if any changes noted, mitigation measures to be described according to the change of risk.

The Group decided to defer the revision of the questions related to BSE surveillance to future meetings considering the on-going work on the development of guidelines for BSE surveillance. Finally, the Group made editorial changes in line with the latest version of the draft revised Chapter 11.4. The amended draft annual reconfirmation form can be found in [Appendix IV](#) of this report.

5. Consideration of a Member comment on the draft revised Chapter 11.4.

At its September 2021 meeting, the Terrestrial Animal Health Standards Commission (the Code Commission) agreed with a comment on point 3 of Article 11.4.1. of the revised draft Chapter 11.4. Bovine spongiform encephalopathy, to replace PrPBSE with PrPSc in order to align with the corresponding Chapter 3.4.5. in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual). At its February 2022 meeting, the Code Commission did not agree with a new Member comment to revert PrPSc to PrPBSE or to change to PrPTSE and reiterated the need to ensure alignment with the corresponding Terrestrial Manual Chapter. The Code Commission requested that this comment be forwarded to the Biological Standards Commission for its advice. WOAHS Secretariat agreed to take the opportunity of this meeting to seek the opinion of the BSE *ad hoc* Group on this comment.

The Group stated that PrPBSE or PrPTSE are less commonly used terminologies and that despite various proposals to modify the nomenclature in the prion field, PrPSc for abnormal PrP associated with prion replicative agents (regardless of the species) has remained the most largely admitted terminology. In addition, the Group agreed with the Code Commission that there should be consistency in the terminology used in both the Terrestrial Code and the Terrestrial Manual. Therefore, the Group disagreed with the comment to replace PrPSc with PrPBSE or to change to PrPTSE. The Group was of the opinion this particular issue about terminology or abbreviation is not major as long as it is defined when it is first used in a document.

6. Finalisation and adoption of the report

The Group reviewed the draft report and agreed to circulate it electronically for comments before the final adoption. Upon circulation, the Group agreed that the report adequately captured its discussion.

.../Appendices

Appendix 1 Terms of reference

VIRTUAL MEETING OF THE *AD HOC* GROUP ON THE IMPACT OF THE REVISION OF BSE STANDARDS AND THE MAINTENANCE OF OFFICIAL BSE RISK STATUS

22 to 24 June 2022

Terms of reference

Purpose

The purpose of this *ad hoc* Group (the Group) is to finalise the assessment performed by the *ad hoc* Group in June 2021 on the impact of the revised bovine spongiform encephalopathy (BSE) standards on the maintenance of official BSE risk status of three Members, and to further revise the annual reconfirmation form for maintenance of official BSE risk status.

Background

In February 2018, the Terrestrial Animal Health Standards Commission (Code Commission) and the Scientific Commission for Animal Diseases (Scientific Commission) agreed on an in-depth review of Chapters 1.8. Application for official recognition by the World Animal Health Organisation (WOAH) of risk status for BSE and 11.4. BSE. Since then, six *ad hoc* Groups have been convened to complete the revision of BSE standards as well as to assess the potential impact of the revised provisions on the already officially recognised BSE risk status of Members.

The BSE *ad hoc* Group that convened in June 2021 conducted an impact assessment of 18 Members which were identified to have been granted an official BSE risk status based on a negligible risk of entry despite a non-negligible exposure assessment. The BSE risk status of these Members may be affected because the revised BSE standards require conducting an exposure assessment with demonstration of negligible risk of BSE agents being recycled in the cattle population, regardless of the outcome of the entry assessment. The BSE *ad hoc* Group concluded that the exposure risk could not be considered negligible for seven Members or zones having a negligible BSE risk status and for one Member having a controlled BSE risk status and recommended these eight Members submit additional information when reconfirming their BSE risk status in November 2021.

The Scientific Commission, at its February 2022 meeting, reviewed the information provided by these eight Members in response to the questions raised by the BSE *ad hoc* Group of June 2021. Based on the nature and scope of the submitted information, the Scientific Commission referred the dossiers of three Members to the Group to request its assessment and recommendations to be considered at the September 2022 meeting of the Scientific Commission.

In addition, the same *ad hoc* Group of June 2021 drafted and proposed a template of the annual reconfirmation form for maintenance of BSE risk status according to the draft revised BSE standards at that time. This draft template of the annual reconfirmation form for BSE risk status was endorsed by the Scientific Commission at its September 2021 meeting while noting that further adjustments may be necessary. The Group is requested to continue the revision of the annual reconfirmation form in line with the latest version of the draft revised BSE standards.

Pre-requisites

Group members should:

- Sign the Undertaking on Confidentiality of information (if not done already);
- Complete the Declaration of Interest form.
- Understand that the membership of the Group may be retained between *ad hoc* Group meetings to ensure continuity of the work.

Actions to deliver

The members of this Group will conduct the following actions:

1. Continue the assessment of the impact that the revised BSE provisions may have on the maintenance of officially recognised BSE risk status of three Members

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- Before the start of the meeting, after receiving the working documents by the WOAHA secretariat, review the recommendation made by the BSE *ad hoc* Group that conducted the impact assessment in June 2021 and assess the information submitted during the 2021 annual reconfirmation campaign.
 - Draft a report on the assessment including recommendations on the next steps with regard to the maintenance of the official BSE risk status.

2. Revise the template of the annual reconfirmation form for maintenance of BSE risk status.

Revise the annual reconfirmation form for maintenance of BSE risk status drafted by the BSE *ad hoc* Group in June 2021. Provide clear guidance on the expected type of information that Members should submit to substantiate their responses for reconfirming their BSE risk status in accordance with the latest version of the revised BSE standards.

3. Provide their expert opinion on any additional request made by the secretariat relevant to the revision of the BSE standards.

Deliverables

The Group is expected to produce a detailed report with recommendations to the Scientific Commission on the following outcomes:

- Evaluation of the information submitted by three Members taking into account the report of the BSE *ad hoc* Group that conducted the impact assessment in June 2021 to address whether all remaining gaps have been resolved or if there are any points to be followed-up in the 2022 annual reconfirmation campaign.
- Revision of the draft annual reconfirmation form for maintenance of BSE risk status based on the latest version of the revised BSE standards.

Reporting / Timeline

WOAHA will circulate the draft report no more than seven days after the virtual meeting (not later than 1 July 2022) and the Group will finalise its report within the following week (deadline: 8 July 2022).

Appendix 2 Agenda

VIRTUAL MEETING OF THE *AD HOC* GROUP ON THE IMPACT OF THE REVISION OF BSE STANDARDS AND THE MAINTENANCE OF OFFICIAL BSE RISK STATUS

22 to 24 June 2022

AGENDA

1. Opening
 2. Adoption of the agenda and appointment of Chair and Rapporteur
 3. Assessment of the impact that the revised BSE provisions may have on the maintenance of officially recognised BSE risk status of three Members
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 6. Finalisation and adoption of the report
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Appendix 3 List of Participants

VIRTUAL MEETING OF THE *AD HOC* GROUP ON THE IMPACT OF THE REVISION OF BSE STANDARDS AND THE MAINTENANCE OF OFFICIAL BSE RISK STATUS

22 to 24 June 2022

List of Participants

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Appendix 4 Revised draft form for the annual reconfirmation of BSE risk status

**Revised draft form for the annual reconfirmation of
bovine spongiform encephalopathy (BSE) risk status of WOAAH Members**

QUESTION		YES	NO	
1.	Have any cases of BSE occurred in the past 12 months?			
2.	Have all cases of BSE that have been detected within the past 12 months been completely destroyed and disposed of?			
		N/A		
3.	Have any modifications in the legislation regarding BSE been made during the past 12 months?			
4.	Has the risk assessment for BSE in accordance with Article 11.4.2 been reviewed by the Competent Authority of the country/zone through incorporation of documented evidence for the past 12 months?			
5.	a) Have there been any imports of the following commodities?	i. Cattle		
		ii. Ruminant derived protein meal		
		iii. Feed (not intended for pets) that contains ruminant derived protein meal		
		iv. Fertilizers that contain ruminant derived protein meal		
		v. Any other commodity that either is or could be contaminated by commodities listed in Article 11.4.14.		
	b) Have there been any changes to the import requirements of the following commodities?	i. Cattle		
		ii. Ruminant derived protein meal		N/A
		iii. Feed (not intended for pets) that contains ruminant derived protein meal		N/A
		iv. Fertilizers that contain ruminant derived protein meal		N/A
		v. Any other commodity that either is or could be contaminated by commodities listed in Article 11.4.14.		N/A
6.	a) Have there been any changes in the livestock industry practices in the last 12 months as described under Point 1.b.i of Article 11.4.2.?			
	b) Have there been any changes to the BSE specific risk mitigation measures in the last 12 months as described under Point 1.b.ii of Article 11.4.2.?			
7.	a) Has the surveillance programme continued to report and test all animals that show signs of clinical BSE during the past 12 months as described under Point 2 of Article 11.4.18.? Please provide supportive information by completing Table 1 below.			
	b) Have the awareness and training programmes for the different stakeholder groups continued to be implemented during the past 12 months as described under Point 3 of Article 11.4.18.?			
	c) Has BSE continued to be compulsorily notifiable through the whole territory during the past 12 months?			
	d) Have all tests for BSE been conducted in accordance with the <i>Terrestrial Manual</i> during the past 12 months?			

*Please provide relevant documented evidence substantiating your answers to questions 3 to 7.

*Note: according to Articles 11.4.3 (Negligible BSE risk) and 11.4.4 (Controlled BSE risk) of the *Terrestrial Code*, retention on the list requires that supportive information be provided on risk assessment, surveillance, and occurrence and disposal of BSE cases.

Table 1 - Summary of all cattle with clinical signs suggestive of BSE that were reported and evaluated by the Veterinary Services

Please provide the approximate number of the country's cattle population over 24 months:

Clinical presentation (see Article 11.4.18 point 2)	Number reported	Number tested for BSE
Cattle displaying progressive neurological signs suggestive of BSE that are refractory to treatment		
Cattle showing neurological signs that did not pass the ante-mortem inspection at slaughterhouses/abattoirs		
Cattle presented as downers (non-ambulatory) with an appropriate supporting clinical history		
Cattle found dead (fallen stock) with an appropriate supporting clinical history		
