Ad hoc Group on the review of Bovine spongiform encephalopathy (BSE) surveillance guidelines

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A virtual meeting of the *ad hoc* Group on the review of the Bovine spongiform encephalopathy (BSE) surveillance guidelines (the Group) was held on 25 October 2022 to peer-review the draft BSE surveillance guidelines to support WOAH Members in the revision of their surveillance programmes in accordance with the revised BSE standards.

1. Opening

Dr Montserrat Arroyo, WOAH Deputy Director General for International Standards and Science, welcomed the Group. Dr Arroyo thanked the experts of the Group for their time, commitment and valuable contribution to this work and highlighted the importance of this task which aims to support WOAH Members in the revision of their surveillance programmes and practical implementation in the field in accordance with the revised BSE provisions on surveillance of the *Terrestrial Animal Health Code* (*Terrestrial Code*). Dr Arroyo briefly informed the Group of the achievements made to date on the revision of the BSE standards and the next steps in the development of the BSE surveillance guidelines. Dr Arroyo emphasised that the objective of the meeting was to critically review the draft guidelines and encouraged the Group to maintain this focus.

Dr Arroyo thanked the experts for signing the confidentiality undertaking and declaration of interest forms. No potential conflict of interest was identified in relation to the Terms of Reference (ToR) of this meeting.

Dr Min-Kyung Park, Head of the Status Department, provided a brief overview of the ToR and provisional agenda of the meeting and introduced the Secretariat supporting the Group's work.

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

Dr Alicia Cloete chaired the Group, and Dr Ximena Melon 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. Peer-review the draft BSE surveillance guidelines to support WOAH Members in the revision of their surveillance programmes in accordance with the revised BSE standards

Following the ongoing revision of BSE standards that started in February 2018, several WOAH Members recently expressed their concerns regarding the level of BSE surveillance to be considered appropriate for recognition or maintenance of an official BSE risk status and requested WOAH to provide additional guidance on the practical implementation of the revised BSE surveillance provisions of the *Terrestrial Code*. In light of this and upon the recommendation of the Scientific Commission for Animal Diseases (the Scientific Commission), WOAH developed surveillance guidelines for BSE (the guidelines) and convened a BSE *ad hoc* Group to peer-review them.

The Group highlighted the importance of the guidelines being aligned, but not being redundant, with the revised chapters 11.4. and 1.8. of the *Terrestrial Code* and Chapter 3.4.5. of the *Manual of Diagnostics Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*). There was a consensus that the guidelines should solely focus on surveillance for BSE to complement Chapter 1.4. 'Animal Health Surveillance' of the *Terrestrial Code*, and any allusion to areas other than surveillance could be reduced to references to the relevant *Terrestrial Code* and *Terrestrial Manual* chapters to avoid duplication of information and potential confusion. The Group recommended revising the guidelines to ensure that the terminology used is consistent with those in the above-mentioned chapters. These guidelines are not a WOAH standard as are the revised chapters but are a complementary document to facilitate Members' understanding and implementation of the revised standards.

The Group emphasised that the key objective of the guidelines should be to support Members in developing or revising their surveillance system focusing on the animals that lie on the clinical spectrum for BSE that should be targeted as specified under the four categories described in points 2a to 2d of the draft revised Article 11.4.18. As such, the guidelines should elaborate further on the spectrum of BSE signs that is consistent with the revised Chapter 11.4 and provide additional information to assist Members in that regard. The Group highlighted that although the guidelines should focus on supporting Members to implement surveillance targeting the four categories of animals that lie on the clinical spectrum of BSE, they should also include further elaboration on point 3 of the draft revised Article 11.4.18 and points 1 and 2 of Article 1.8.6, including evaluation of the credibility of the surveillance system. The Group also acknowledged that the objective of the revised BSE provisions is to encourage Members to demonstrate the robustness of their surveillance system in their own production and farming systems and epidemiological situation. Thus, the Group recommended that a section on how to assess the robustness and effectiveness of the system could be included in the guidelines. The Group suggested various indicators that could be considered by Members to be included in the guidelines. The Group appreciated the inclusion of decision trees and flow diagrams to support the decision-making process to identify animals targeted for BSE surveillance but recommended that these diagrams be presented for each of the four categories targeted for surveillance as specified under points 2a to 2d of the draft revised Article 11.4.18. To facilitate the reading of the guidelines

alongside the revised provisions for BSE surveillance, the Group recommended to re-organise them so that the structure follows that of the draft revised Article 11.4.18. and Article 1.8.6.

The Group agreed that although information regarding atypical BSE should remain in the guidelines, it should be clear that classical and atypical BSE cannot be distinguished clinically and that an effective surveillance system for BSE should be able to identify any clinical case of BSE. The four categories of animals that surveillance should target, described in point 2 of draft revised Article 11.4.18. cover both classical and atypical forms of BSE.

The Group agreed that the guidelines should not include a minimum number of animals to be tested per year, for reasons explained in the report of the June 2020 *ad hoc* Group meeting on BSE risk assessment and surveillance¹. As explained in the aforementioned report, the Group insisted on the importance of including all animals on the clinical spectrum of BSE in the surveillance system rather than meeting/imposing quotas for minimum clinical suspects to be reported and tested based on statistical assumptions for a disease that, if present, would be at a very low level. The Group agreed that applying a statistical criterion would be disproportionate to the risk. 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 that it was very variable and difficult to predict for all Members, especially considering the large variability in the livestock industry practices. The Group was of the opinion that the guidelines should provide the relevant information to Members to allow them to design their own surveillance systems adjusted to their needs using, for example, parameters and indicators to help to plan and monitor the effectiveness of their BSE surveillance system.

The Group took the opportunity to emphasise that the risk mitigation measures in place to negate the risk of recycling and amplification of the BSE agent, if it were present in the cattle population, are just as important as any surveillance system in place. A BSE surveillance system does not only serve to test or confirm the efficacy of mitigation measures but should be complementary to the control programme as a whole. The Group recalled the extensive deliberations on this topic during the June 2020 *ad hoc* Group meeting on BSE risk assessment and surveillance¹ and encouraged Members to consult that meeting report for further information. Finally, the Group agreed to circulate their comments and electronically review an updated version of the guidelines.

4. Finalisation and adoption of the report

The Group agreed to circulate the draft report electronically for additional comments before the final submission to the Scientific Commission. Upon circulation, the Group agreed that the report captured the discussions.

.../Appendices

¹ The report of this *ad hoc* Group meeting can be found in the report of the September 2020 meeting of the Scientific Commission available <u>here</u>.

Appendix 1 Terms of reference

VIRTUAL MEETING OF *AD HOC* GROUP ON THE REVIEW OF BSE SURVEILLANCE GUIDELINES 25 October 2022

TERMS OF REFERENCE

Purpose

The purpose of the *ad hoc* Group on the review of BSE surveillance guidelines (the Group) is to peer-review the draft BSE surveillance guidelines to support WOAH Members in the revision of their surveillance programmes in accordance with the revised BSE standards.

Background

Following several Members' requests, in February 2018, the Terrestrial Animal Health Standards 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 WOAH of risk status for bovine spongiform encephalopathy (BSE) and 11.4. Bovine spongiform encephalopathy. The revised Chapters will be proposed for adoption at the next General Session of the World Assembly of WOAH Delegates in May 2023.

During the revision of the Chapters, experts of the BSE *ad hoc* Groups on surveillance noted that the current provisions of the *Terrestrial Animal Health Code* (*Terrestrial Code*) were based on:

- i. A set design prevalence for achieving and maintaining negligible (1 per 50,000 cattle) or controlled (1 per 100,000 cattle) BSE risk status,
- ii. Four sub-populations identified as routine slaughter, fallen stock, casualty slaughter, and clinical suspects and sampling at least three of them;
- iii. Surveillance points assigned to each sample based on age of cattle and subpopulation from which the sample was collected: and
- iv. A minimum number of points to be collected over a maximum of seven consecutive years to substantiate a prevalence of BSE as in i) above.

The experts agreed that the current provisions were outdated because they were developed at a time of great uncertainty about the global distribution of BSE and its prevalence within the cattle population of a country, and highlighted the challenges posed by Members when applying such provisions and the impact they have on the official recognition and maintenance of BSE risk status. In light of this, the experts of the BSE *ad hoc* Groups determined that an on-going, robust, and comprehensive passive surveillance programme for BSE should be in place and proposed modifications accordingly in the draft provisions of both Chapters.

Based on the requests from WOAH Members to be provided with additional guidance on the practical implementation of the revised BSE surveillance provisions and concerns regarding the level of BSE surveillance to be considered appropriate for recognition or maintenance of their official BSE risk status, the Scientific Commission recommended: i) the development of guidelines on BSE surveillance to support WOAH Members in the revision of their surveillance programmes in accordance with the revised BSE Chapters, and ii) such guidelines to be peer-reviewed by the BSE ad hoc Group and endorsed by the Scientific Commission at its February 2023 meeting. The finalisation and publishing of the guidelines on WOAH's website shall be in line with the timeline of the revision of the BSE standards.

Specific issues to be addressed

The Group will peer-review the draft BSE surveillance guidelines and provide comments and proposals for further improvement of the guidelines before they are forwarded to the Scientific Commission for its consideration.

Prerequisites

The 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 its meetings to ensure continuity of the work.

Actions to deliver

Before the meeting

The Status Department (SD) highlights and extracts relevant areas from current and revised Chapters 1.8. and 11.4. of the *Terrestrial Code* for the discussion of the Group on the assessment of the BSE surveillance guidelines.

The SD will send the working documents to the Group (drafted guidelines, current and revised BSE chapters), at least three weeks before the Group meeting (4 October 2022).

The Group will revise, provide comments and suggest amendments on the draft guidelines, which will be shared in a format allowing for active exchange of opinions, until the meeting date of the Group.

The experts can request support from the SD at any time.

The SD suggests the nomination of a Chair and Rapporteur for the Group's consideration.

The SD can suggest a preparatory meeting with the Chair, the Rapporteur or all experts to address specific points in advance, if needed.

The experts are expected to:

- Be familiar with revised and current Chapters 1.8. and 11.4. of the Terrestrial Code;
- Review and study in detail the draft BSE surveillance guidelines provided by WOAH;
- Take into account any other information available in the public domain that is considered pertinent for the revision of the guidelines;
- Draft and submit questions, comments and proposals to further improve the draft BSE surveillance guidelines.

During the meeting

- Agree on the appointment of the Chair and Rapporteur of the meeting (the Chair will lead the discussion and the Rapporteur will ensure that the report reflects the discussion and captures the keys recommendations to the guidelines);
- Contribute to the discussions;
- Provide a detailed report with key recommendations and suggested amendments for the consideration of the Scientific Commission.

The Chair is responsible for coordinating the finalisation of the task and for ensuring that the views of all members of the Group are taken into consideration.

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 meeting if needed.

After the meeting

The SD will circulate the draft report after the meeting is over. Experts are expected to contribute to the finalisation of the report within approximately one week.

The SD will circulate the final version of the report to the Group once endorsed by the Scientific Commission and is published online.

Deliverables

A detailed report highlighting key recommendations and suggested amendments for consideration by the Scientific Commission.

Reporting / timeline

WOAH will circulate the draft report no more than seven days after the meeting (no later than 1 November 2022) and the Group will finalise its report within ten days (indicative deadline: 11 November 2022).

Appendix 2 Agenda

VIRTUAL MEETING OF THE *AD HOC* GROUP ON THE REVIEW OF BSE SURVEILLANCE GUIDELINES 25 October 2022

AGENDA

- 1. Opening
- 2. Adoption of the agenda and appointment of Chair and Rapporteur
- 3. Peer-review the draft BSE surveillance guidelines to support WOAH Members in the revision of their surveillance programmes in accordance with the revised BSE standards
- 4. Finalisation and adoption of the report

Appendix 3 List of Participants

AD HOC GROUP ON THE REVIEW OF BSE SURVEILLANCE GUIDELINES 25 October 2022

List of Participants

MEMBERS

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