OIE AD HOC GROUP ON THE EVALUATION OF BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS OF MEMBERS

Virtual meeting, 16 to 19 November 2021

TERMS OF REFERENCE

Purpose

The purpose of the *ad hoc* Group on the evaluation of bovine spongiform encephalopathy (BSE) risk status of Members (the Group) is to evaluate applications for official recognition of BSE risk status of Members, and to propose the criteria to be used by Members having an official BSE risk status by the OIE for determining the starting date when the risk of the BSE agents being recycled within the cattle population has been demonstrated to be negligible.

Background

In accordance with the OIE procedure for official recognition of animal health status, OIE Members can be officially recognised by the OIE as having a negligible or controlled BSE risk status by the OIE through the adoption of a resolution by the World Assembly of Delegates of the OIE (the Assembly) in May every year. A Member wishing to apply for the official recognition of its BSE risk status by the OIE should complete and submit the relevant questionnaire laid out in Chapter 1.8 of the OIE Terrestrial Animal Health Code (Terrestrial Code) and comply with all requirements specified in the Terrestrial Code. The OIE Scientific Commission for Animal Diseases (Scientific Commission) is responsible for undertaking, on behalf of the Assembly, the assessment of OIE Members' applications for their compliance with OIE standards. The assessment carried out by the Scientific Commission is based on the recommendations formulated by a relevant ad hoc Group. Ad hoc groups are convened under the authority of and report to the OIE Director General.

In February 2018, the Terrestrial Animal Health Standards Commission (Code Commission) and the Scientific Commission agreed on an in-depth review of Chapter 11.4, Bovine Spongiform Encephalopathy (BSE). Since then, five *ad hoc* Groups have been convened to complete the revision of BSE standards and the impact that the revised provisions might have on currently officially recognised Members. The revised provisions recommend Members to trade certain commodities based on the risk of BSE agents being recycled in the cattle population. That is, the risk of certain commodities are different if they originate from animals born before the date when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible compared to those originating from animals born after that date.

The BSE *ad hoc* Group, that convened in June 2021, proposed an approach to determine this starting date for Members having a negligible BSE risk status; however, they could not agree on a proposal for Members having a controlled BSE risk status. The Scientific Commission, at its September 2021 meeting, agreed that it would be up to the Member demonstrate this starting date, if beyond the years covered by the revised BSE standard, in trade negotiations between Members. In order to support the Members in their bilaterial discussions, the Scientific Commission recommended that the BSE *ad hoc* Group develop criteria to guide Members in determining the starting date.

Specific issues to be addressed

- 1. The Group will evaluate Members' applications in detail on their compliance with the requirements specified in the *Terrestrial Code* for BSE.
- 2. The Group will propose criteria for determining the date when the risk of the BSE agents being recycled within the cattle population has been demonstrated to be negligible (the 'starting date').

Based on the evaluations of the Members' applications and the criteria for Members to determine the starting date, the Group will provide its conclusions and recommendations to the Scientific Commission.

Prerequisites

The Group members should:

- Sign the OIE Undertaking on Confidentiality of information;
- 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

Upon reception of an application from a Member, the Status Department (SD) conducts a preliminary screening to check the conformity of the dossier (structure of the dossier in accordance with the SOP and with the questionnaire under Chapter 1.8 of the *Terrestrial Code*, main sections of the questionnaire, regular notification to the OIE, payment of the fee, OIE Performance of Veterinary Services (PVS) report, etc.). If an information gap is identified, the SD requests additional information from the Member.

As the PVS reports are bound by the OIE rules on confidentiality of information, the SD and experts will consider for the evaluation the available PVS report(s) if not obsolete (PVS reports from more than five years ago) or confidential.

The SD highlights and extracts relevant areas from Chapters 1.8. and 11.4. of the *Terrestrial Code* for the discussion of the Group on the assessment of the criteria to determine the 'starting date'.

The SD will send the working documents to the Group, including the dossiers received from applicant Members, at least one month before the Group meeting (i.e., 18 October 2021).

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 the current and revised Chapters <u>1.8</u> and <u>11.4</u> of the *Terrestrial Code*;
- Evaluate and study in detail all dossiers provided by the OIE;
- Take into account any other information available in the public domain that is considered pertinent for the evaluation of the dossiers;
- Summarise the dossiers according to the *Terrestrial Code* requirements by completing the summary tables provided by the SD (the summary tables will be provided at a later stage along with the working documents for the meeting). Experts are expected to capture and summarise in each corresponding section of the summary table the main gaps as well as strengths identified during the assessment of the dossiers, using extracted texts or reference to pages/annexes from the application;
- Draft questions to the applicant Members whenever the analysis of the dossiers identifies incomplete or unclear information;
- Submit to the SD the completed summary tables for each application together with possible questions for the applicant Members at least 10 days before the teleconference and preferably by 5 November 2021;

The SD will compile the summary tables and the questions to be forwarded to the applicant Members before the teleconference. All subsequent information and material provided by a Member will be forwarded to the Group.

<u>During the meeting</u>

- 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 detailed assessment of the dossiers);
- Mention any potential conflict of interest and, if relevant, withdraw him/herself from the discussion;
- Contribute to the discussions;
- Provide a detailed report in order to recommend, to the Scientific Commission, the Members and/or zone(s) to be recognised (or not) as having a controlled or negligible BSE risk status, indicate any information gaps or specific areas that should be addressed in the future by the applicant Members, and a criteria for Members already having a controlled or negligible BSE risk status to determine the starting date.

If during the teleconference the Group decides that additional information should be requested from an applicant Member before an informed conclusion can be drawn, the SD can request it and forward the additional information to the Group at a later date. The Chair is responsible for coordinating the finalisation of the assessment 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 teleconference if needed.

After the meeting

The SD will circulate the draft report after the teleconference 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 to recommend to the Scientific Commission whether an applicant Member(s) should be (or not) recognised with an official BSE risk status, and the criteria to determine the starting date for Members already having a BSE risk status. The report should indicate any information gaps or specific areas that should be addressed in the future by the Members.

Reporting / timeline

The OIE will circulate the draft report no more than seven days after the teleconference (no later than 26 November 2021) and the Group will finalise its report within ten days (indicative deadline: 6 December 2021).