Annex 7

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REPORT OF THE VIRTUAL MEETING OF THE OIE *AD HOC* GROUP ON THE EVALUATION OF BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS OF MEMBERS

16 to 19 November 2021

A virtual meeting of the OIE *ad hoc* Group on the evaluation of bovine spongiform encephalopathy (BSE) risk status of Members (hereafter the Group) was held from 16 to 19 November 2021.

1. Opening

Dr Montserrat Arroyo, Deputy Director General for International Standards and Science of the OIE, welcomed the Group. She thanked the experts for their availability and contribution to the work of the OIE and extended her appreciation to their institutes and national governments for allowing their participation in this meeting. Dr Arroyo acknowledged the amount of work achieved before, during and after the meeting in reviewing the dossiers and writing the report. Dr Arroyo thanked the Group for its commitment and support to the OIE in fulfilling the mandates given by Members.

Dr Arroyo highlighted the importance of the quality of the report to be scrutinised by Members before adopting the proposed list of countries/zones with a risk status for BSE. She also encouraged the Group to continue providing detailed feedback to Members with a negative outcome to support them in identifying the main gaps and points for improvement to achieve their desired BSE risk status, as well as providing informative recommendations to those Members with positive outcomes for further improvement in maintenance of their BSE risk status.

The Group and the OIE welcomed Dr Fabien Schneegans as a new member of the Group.

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

Dr Alicia Cloete was appointed Chair and Dr Mark Stevenson acted as rapporteur with the support of the OIE Secretariat. The Group endorsed the proposed agenda.

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

3. Evaluation of an application from a Member for the official recognition of its negligible BSE risk status

3.1 France

In accordance with the established procedures, the participating expert working for the European Commission expressed a possible conflict of interest and withdrew from all discussions of the Group on France's dossier.

France was recognised as having a controlled BSE risk status in May 2008 and was later recognised as having a negligible BSE risk status in May 2015. After an indigenous case of classical BSE in a five-year-old bovine was reported to the OIE in March 2016, a controlled BSE risk status was reinstated.

In September 2021, France submitted a dossier seeking its recognition as a country presenting a negligible BSE risk status.

The Group requested additional information and received clarification from France. Points specifically discussed by the Group are summarised below:

a. Section 1: Risk Assessment — Article 11.4.2. point 1

- Risk assessment for entry of the BSE agent

  Regarding importations of live cattle, the Group noted that in the past eight years all cattle were imported from countries with a controlled or negligible BSE risk status under the European Union (EU) standards (EC 999/2001) that comply with Articles 11.4.7. and 11.4.8. of the OIE *Terrestrial Animal Health Code* (*Terrestrial Code*).

  The Group noted that meat-and-bone meal (MBM) in France are categorised under three categories: C1 which includes the carcasses of ruminants and specified risk materials (SRMs), C2 which includes animal by-products not in C1 or C3, and C3 which includes slaughterhouse products which are fit but not intended for human consumption.

  Regarding importations of MBM, greaves and feed containing either, the Group acknowledged that C1 or C2 materials intended for use in feed for terrestrial farmed animals have not been imported since 2000, except for negligible amounts of C2 for the fertilizer sector, and that C3 materials have been imported for use limited to pet food and fertilizers.

  Overall, the Group concluded that the risk that the BSE agent could have entered France during the interval covered by the assessment was considered to be negligible.

- Risk of recycling and amplification of the BSE agent, and appropriate level of control and audit of the feed ban

  The Group noted that France has had a legislation banning the use of animal meals in cattle feed since 1990 which was extended to cover all ruminants in 1994 and all terrestrial farmed animals in 2000.

  The Group took note that the definition, collection and disposal of SRMs followed the EU standards (EC 999/2001) and are compliant with the provisions of the *Terrestrial Code*. The Group noted that C1 materials are disposed of by incineration or co-incineration or used to produced materials that do not enter the food chain. Similar methods are applied for C2 animal by products with the difference that these materials can be recovered for technical use or to produce fertilizers. C3 materials can be processed into animal food applying restrictive conditions when cattle feed is involved.

  The Group regretted that France did not provide a clear description of the rendering industry although the Group acknowledged the information provided on the relevant legislation that governs rendering and the management of animal by-products. Considering the methods described above to disposed C1 materials, the Group considered that any potential BSE infectivity is destroyed and cannot enter the animal feed chain. The Group took note that the inspection frequency of rendering plants is based on risk analysis that assigns a risk to each plant. This ensures that each plant is inspected at least once every four years. The Group took note that no infractions were reported during the interval covered.

  Regarding the feed industry, the Group took note that most feed mills are for mixed species. The Group could not determine whether there are separated lines for feed mills producing feed for ruminants or non-ruminants; however, the Group took note that processing plants that manufacture petfood are exclusively dedicated to this scope. The Group took note that the methods used in France to reduce the BSE infectivity in MBM are in accordance with Article 11.4.19 of the *Terrestrial Code*. The Group took note that facilities that produce feed for farmed animals, including aquaculture animals, are regularly supervised by official inspectors primarily

to check for the absence of MBM and greaves in ruminant feed and more broadly the use of animal proteins in feeding for farm animals. The Group noted that the frequency of inspection of feed mills follows the same approach as for rendering plants and that no infractions were reported during the interval covered.

Also, the Group took note that France inspects the livestock farms regarding implementation of EU rules to prevent TSE risk in cattle and this inspection includes the sampling of raw materials or feed.

Overall, regarding the exposure assessment, the Group concluded that the risk of recycling and amplification of the BSE agent if it was present in France's cattle population during the interval covered by the assessment can be considered negligible.

b. Surveillance according to Articles 11.4.20. - 11.4.22.

The Group noted that the surveillance undertaken over a seven-year period from 2014 to 2020 exceeded the minimum requirements of type B surveillance in accordance with Article 11.4.22. on BSE surveillance of the *Terrestrial Code*. Based on the information provided in the dossier, 965,521 surveillance points were collected from 2014 to 2020, exceeding the minimum requirement of 150,000 for an adult cattle population (i.e., over two years of age) of over 1,000,000 animals.

The Group acknowledged that the age of cattle was determined based on birth records and that in the case of absence of birth records, the body size of the animal and dentition were used. The Group considered that France's definitions of surveillance subpopulations were in accordance with Article 11.4.21 of the *Terrestrial Code*.

The Group took note that France's surveillance programme for BSE targeted all four surveillance subpopulations every year.

c. Other requirements — Article 11.4.2. points 2–4

- Awareness programme

  The Group noted that an awareness program on BSE present since 1990 has been continuously applied. While France reported that the awareness program covered all the country, the Group was unsure whether this was the case as no supportive information was available.

  The Group took note that the veterinarians and relevant officials, cattle farmers, slaughterhouse operators, and personnel in the animal by-product sector were covered by their awareness program although it mainly targeted official veterinarians. The Group was of the opinion that, considering the BSE situation in Europe, France should maintain awareness at all levels.

  The Group acknowledged that France has measures in place for the management of BSE cases should they arise in the country.

- Compulsory notification and investigation

  The Group noted that notification for BSE has been mandatory since 1990 under the relevant Regulation. Upon requesting and receiving additional information, the Group was informed that measures to stimulate notification, penalties for failure to notify BSE suspect cases, and a compensation policy for farmers are in place. The Group concluded that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- Laboratory examination

  The Group noted that BSE diagnosis is conducted in France. The French National Reference Laboratory for BSE in France is the French Agency for Food, Environmental and Occupational

Health & Safety (ANSES) laboratory in Lyon. The Group took note that France has a number of licensed laboratories with French Accreditation Committee accreditation for the diagnosis of TSEs which use mainly ELISA tests. In the case of positive or inconclusive results, the confirmatory testing is performed in the ANSES laboratory by western blot. The Group was also informed that the European Union Reference Laboratory might be consulted for its opinion or further testing when needed.

The Group concluded that the laboratory diagnosis for BSE conducted in France was compliant with Chapter 3.4.5 of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*).

d. BSE history in the country

The Group noted that the first BSE case was detected in France in 1991 with the last case occurring in 2016 in an animal born in 2011. Up to the evaluation of this report, there has been 1,042 cases reported (994 of classical BSE, 20 cases of atypical L-type BSE, and 28 cases of atypical H-type BSE).

At the time of writing this report, the youngest indigenous case of classical BSE was born on 8 April 2011, meaning that all indigenous cases of classical BSE would have been born more than 11 years before the World Assembly in May 2022.

e. Compliance with the questionnaire in Chapter 1.8.

The Group agreed that the dossier submitted was compliant with the format of the questionnaire of Chapter 1.8. of the *Terrestrial Code*.

f. Conclusion

- Recommended status

Considering the information submitted in the dossier and France's answers to follow-up questions raised, the Group concluded that the application was compliant with both the requirements of Article 11.4.3. and the BSE questionnaire in Chapter 1.8. of the *Terrestrial Code*. The Group therefore recommended that France be recognised as 'negligible BSE risk' country.

4. Evaluation of an application from a Member for the official recognition of its controlled BSE risk status

4.1 Russia

In September 2021, Russia submitted a dossier seeking its recognition as a country presenting a controlled BSE risk status. The Group requested additional information and received clarifications from Russia. Points specifically discussed by the Group are summarised below:

a. Section 1: Risk Assessment — Article 11.4.2. point 1

- Risk assessment for entry of the BSE agent

Regarding importation of MBM, greaves or feed ingredients containing either, the Group noted that Russia imported MBM derived from cattle between 2013 and 2017. Based on the information provided in the dossier, the Group took note that a significant proportion (over 90%) of the overall volume of importations between 2013 and 2017 originated from countries with an undetermined BSE risk status. Nevertheless, the Group acknowledged that, since 2019, Russia has officially banned the imports of MBM and greaves from countries with an undetermined BSE risk status.

The Group noted that the majority (96%) of the imports of live cattle into Russia within the past seven years were from countries with a negligible or controlled BSE risk status, while 4% of the cattle imported during that period originated from countries with an undetermined BSE risk

status. From the dossier, the Group was informed that live cattle imported in 2018 and 2019 from countries with an undetermined BSE risk status were immediately slaughtered and their SRM were removed and disposed of. The Group acknowledged that, since 2020, no live cattle from controlled or undetermined risk countries have been imported.

Regarding products of ruminant origin imported within the past seven years, the Group noted that bovine offal including heart, liver, kidneys, tongues, rumens and tendons; and meat including deboned chilled, frozen and bone-in meat were imported. Based on the data available in the dossier, the Group estimated that about 5% of bovine offal and about 30% of bovine meat was imported from countries with and undetermined BSE risk status.

The Group acknowledged the information provided on the veterinary import requirements for cattle and cattle products; nevertheless, the Group regretted that the detailed requirements providing evidence of compliance with the relevant articles of the *Terrestrial Code* were not available nor provided with the additional information requested (i.e. the requirements of the *Terrestrial Code* were broadly referred to in the import model certificates of Russia, but these were not specified in detail as part of the import requirements).

Overall, regarding the entry assessment, the Group concluded that the risk that the BSE risk agent could have entered Russia could be considered negligible since 2019.

- Risk of recycling and amplification of the BSE agent, and appropriate level of control and audit of the feed ban

The Group acknowledged that the definition of SRM was consistent with Article 11.4.14 of the *Terrestrial Code*. The Group asked and received additional information regarding the fate and disposal of fallen stock and SRM. The Group could not determine the scope of the relevant regulations provided. Nevertheless, the Group was of the opinion that Russia has prohibited since 2019, by way of the relevant regulation, the rendering of ruminant carcasses from fallen ruminants and acknowledged that these carcasses were incinerated or buried. In addition, the Group took note, from the information provided by the Russian authorities that SRMs have been categorised as *"highly dangerous hazards"* and these are incinerated; despite this only happening since 2020 when the relevant regulation was issued and put in place in Russia, it was not explicitly clear in the relevant legislation. The Group agreed, based on the information in the dossier and the additional information, that SRMs from healthy animals sent to slaughter have been excluded from further processing into MBM intended for feed since 2019 and probably earlier than 2019 for imported animals. The Group was uncertain about the situation for rendering ruminant material from fallen stock and the potential for SRM to enter the rendering stream prior to 2019. Although the Group acknowledged that Russia interpreted SRM as "highly hazardous materials" and handled them as such; the Group recommended that SRM should be explicitly listed in paragraph 4 of the Ministry of Agriculture Order No. 626 of 26 October 2020.

The Group requested and received additional information regarding the rendering industry in Russia. The Group took note that while the parameters for rendering materials in the countries of the Eurasian Economic Union are 133 degrees Celsius for at least 20 minutes at a pressure of 3 bar, how these measures were monitored, verified and enforced by the competent authorities were not provided. The Group noted that the additional information provided was consistent with Point 1 of Article 11.4.19 of the *Terrestrial Code* on reduction of particle size of raw materials for the reduction of BSE infectivity in MBM; however, the Group regretted that Russia did not provide supportive evidence of the official monitoring and enforcement of the rendering parameters. The Group also noted that a number of rendering facilities process ruminant raw material to produce ruminant MBM, and non-ruminant raw material to produce non-ruminant MBM intended for feed purposes. However, the Group failed to receive detailed information on

the specific measures implemented in these 'mixed' rendering plants to prevent cross contamination between the ruminant and non-ruminant material or MBM.

Regarding the inspections in rendering plants and feed mills, the Group acknowledged the improvements made since 2019 regarding the number of inspections. Despite the questions raised by the Group on the methodology for inspection of rendering plants and feed mills, the Group did not receive information about how these are conducted. While the Group acknowledged that Russia`s methodological guidance for *BSE risk control anti-epidemic measures and surveillance* provides a general overview, the Group highlighted the fact that a document clearly articulating the detail of inspections of rendering plants or feed mills, to ensure that BSE-related risk points are sufficiently assessed was not provided.

The Group acknowledged that the ruminant-to-ruminant feed ban has been in place since 1990. However, the Group was unclear about the nature of the feed ban regarding the use of MBM from various species in non-ruminant feed. In the additional information provided, Russia informed that dedicated feed mills may use ruminant MBM for pet food, pig and poultry feed. These ruminant MBM are sent directly to these establishments under the control of the State Veterinary Service through the issuance of Veterinary Accompanying Documents (VADs). After feed production, the risk of cross contamination of finished feed products is deemed to be insignificant, as their traffic flows do not overlap with ruminant feed during production, transportation and storage. Russia clarified that large livestock establishments are dedicated to a specific animal species and therefore the risk of cross-contamination in the establishments is unlikely. The Group acknowledged the legislations provided by Russia. However, the Group did not receive sufficient evidence demonstrating how the various BSE risk mitigation measures are implemented, enforced and monitored at rendering plants, feed mills and at the establishment level.

Overall, regarding the exposure assessment, the Group concluded that the risk of recycling and amplification of the BSE agent, if it was present in Russia's cattle population, can be considered to have been negligible from 2019 onwards provided that the legislated ordered control measures have been and continue to be correctly and consistently implemented.

b. Surveillance according to Articles 11.4.20. - 11.4.22.

The Group concluded that the level of surveillance over the seven-year period from 2014 to 2020 exceeded the minimum requirements of Type A surveillance in accordance with Article 11.4.22. of the *Terrestrial Code* on BSE surveillance. Based on the information provided in the dossier, 369,269.25 surveillance points were accumulated, compared to a minimal requirement of 300,000 for an adult cattle population over two years of age of over 1 million.

The Group noted that Russia's surveillance programme for BSE targeted all surveillance subpopulations every year and that samples were sufficiently representative of the distribution of the total cattle population in the country. The Group acknowledged that Russia stated that all cattle are individually identified (either by tags, brands, and/or tattoos) and that the age of animals is determined based on the individual number. The Group noted the information on the determination of age by dentition for imported slaughter animals in the Manual for SRM removal. Regarding aging of Russian cattle where they fail to be individually identified by their tags, brands or tattoos, Russia clarified that there is a process to replace lost tags and also to use dentition.

The Group took note that all clinical suspects had been tested and BSE was ruled out. The Group noted that up until 2017, only "nervous pathology" was listed as clinical signs for clinical suspects investigated; however, since 2018 the clinical signs listed for clinical suspects have been more specific (i.e., fearfulness, not recognizing barriers, hypersensitivity, and mobility issues) which is more in line with Article 11.4.21. of the *Terrestrial Code* and subsequent increase in the surveillance of suspected cases. The Group commended Russia for the improvements made in this regard.

c. Other requirements — Article 11.4.2. points 2–4

- Awareness programme

  The Group acknowledged that an awareness programme for BSE had been present since 1999 targeting mainly official veterinarians. Since 2000, seminars and advanced training courses on BSE had been continued. In addition, online training on BSE epidemiology, diagnosis, surveillance, and prevention have been organised annually since 2018. The Group took note that 22 courses have been conducted since 2014 on a variety of topics related to BSE. Nevertheless, the Group was unsure whether the courses were distributed uniformly across the country. In addition, the Group noted that private veterinarians could also participate on the trainings on paid basis, but regretted that no figures were provided on their participation. The Group was of the opinion that private veterinarians play an important role in the control of BSE, and should have free access to the training courses.

  The Group took note that Russia has a contingency plan for the control and eradication of BSE at the Federal level approved in May 2021. At the Regional level, the Group was informed that every Veterinary Department of Russia had developed a BSE contingency plan and an example was provided. Nevertheless, the Group noted that the contingency plan provided appears to have been in place since June 2019. It was unclear to the Group whether Russia had a contingency plan approved by the relevant Veterinary Authority prior to 2019.

- Compulsory notification and investigation

  The Group noted that BSE had been declared a notifiable disease since 1999. The relevant ordinance stipulates that the veterinary specialists working in the regions of Russia shall report animals with BSE clinical signs. The Group was informed that methodological guidelines for the identification of BSE clinical signs are available. The Group took note that penalties for failure to notify BSE suspect cases and a compensation policy are in place. Nevertheless, the Group regretted that Russia did not provide more detailed information on the level of the compensation and penalties imposed for not reporting suspect cases.

  Overall, the Group concluded that, on face value, the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- Laboratory examination

  Regarding BSE diagnosis, the Group noted that BSE diagnosis is carried out in the Russian Reference Laboratory for Rabies and BSE of the Federal Centre for Animal Health (FGBI "ARRIAH"). The Group was informed that this laboratory has been ISO accredited (GOST ISO/IEC 17025-2009) since 2017 and participated in an international inter-laboratory comparison test in the same year. There was no information on participation in inter-laboratory comparison tests for BSE after 2017.

  The Group was informed that screening has been conducted using an ELISA rapid test and that positive tests are sent to the OIE Reference Laboratory for BSE in Italy (Istituto Zooprofilattico Sperimentale del Piemonte Liguria e Valle d'Aosta). The Group noted that the TeSeE test-kits (an ELISA test, Bio-Rad) has been used before 2014, and that since 2014 the HerdCheck BSE-Scrapie Ag Test (an ELISA test, IDEXX Laboratories Inc) has been used for surveillance.

  The Group concluded that the laboratory examination for BSE carried out in Russia was compliant with Chapter 3.4.5 of the *Terrestrial Manual*.

  The Group also recommended that the FGBI "ARRIAH" participate in international inter-laboratory comparison tests on a regular basis.

d. BSE history in the country

The Group acknowledged that BSE had never been reported in Russia.

e. Compliance with the questionnaire in Chapter 1.8.

The Group agreed that the dossier submitted was compliant with the format of the questionnaire of Chapter 1.8. of the *Terrestrial Code*. The Group acknowledged and commended Russia for their effort made to demonstrate improvements in several critical areas since 2019 and encouraged Russia to continue working on them. Nevertheless, the Group noted that they had difficulties evaluating the application due to a lack of clear, detailed information in the dossier and the additional information provided. In addition, the Group pointed out that the submitted dossier and the additional information provided by Russia relied extensively on references to legislative acts and regulations without clear descriptions of the actions carried out to implement them. This led to significant challenges to evaluate this application despite multiple rounds of questions.

f. Conclusion

After multiple rounds of questions and lengthy discussions, a consensus was reached by the Group that Russia had addressed the questions raised, highlighting that evidence of enforcement and monitoring of activities was generally lacking, which made it difficult to conclude how legislation, decrees, and orders are implemented. Therefore, and in order to ensure the appropriate implementation of these activities, the Group recommended that future submissions for annual reconfirmation of Russia's controlled BSE risk status should be comprehensively reviewed by the Scientific Commission for Animal Diseases (Scientific Commission); see section 'Recommended status'.

- Recommended status

  Considering the information submitted in the dossier and the additional information provided by Russia to the questions raised, the Group concluded that the application was compliant with the requirements of Chapter 11.4. of the *Terrestrial Code* and therefore recommended that Russia be recognised as having fulfilled the requirements for a 'controlled BSE risk country'.

  However, the Group advised that Russia should (also detailed in the relevant sections above):

  - Provide supportive evidence of the monitoring of the effective implementation of the BSE-specific technical parameters at rendering plants.
  - Provide supportive information with regard to the appropriate level of control, audit and inspections conducted by official veterinarians at rendering plants and feedmills. Provide official standard operating procedures (SOP)/manual/guideline in which the procedures for inspection in both rendering plants and feedmills are clearly detailed and highlight those procedures that are applicable to BSE control.
  - Provide supportive evidence of the implementation and monitoring mitigation measures for preventing cross-contamination in rendering plants that process material from ruminant and non-ruminant species.
  - Participate in international inter-laboratory comparison tests on a regular basis.

5. Proposal of criteria in determining the starting date when the risk of the BSE agents being recycled within the cattle population has been demonstrated to be negligible

The Group noted that the Point 4c. in Article 1.8.5 of the draft Chapter 1.8. of the *Terrestrial Code* clearly asks Members to indicate the date from which it can be considered that the risk of BSE agents recycling within the cattle population can be considered negligible (the 'starting date'). Therefore, the Group was of the opinion that for Members or zones recognised under the new standards (once adopted), this starting date would be indicated in the relevant OIE reports and used by Members during bi-lateral negotiations. On the other hand, the Group acknowledged that the starting date would not be necessary captured in the relevant OIE reports for Members already recognised as presenting a BSE risk status.

The Group acknowledged the recommendation of the Scientific Commission to the OIE to publish the date of official recognition of BSE risk status on the OIE website (refer to the September 2021 meeting report of the Scientific Commission for more information). The Group concurred that the starting date for i) Members or zones with a negligible BSE risk status would be at least eight years prior to the date of recognition, and ii) Members or zones with a controlled BSE risk status would be at least the date of recognition. For Members or zones that had been recognised as presenting a negligible BSE risk that had their negligible BSE risk status suspended, reinstated as presenting a controlled BSE risk, and eventually recognised as presenting a negligible BSE risk, the Group recommended that the starting date would be eight years prior to the date when the Member or zone was first recognised as presenting a negligible BSE risk, subject to confirmation in and acceptance of an epidemiological report submitted to the OIE.

The Group acknowledged that some Members or zones already recognised either as presenting a negligible or a controlled BSE risk could demonstrate that the starting date could be different to what was proposed above. Nevertheless, the Group was not in favour to develop a simplified criteria to determine the starting date because it considered that a detailed objective evaluation was needed. Therefore, the Group recommended the OIE to invite these Members to submit the necessary evidence to the OIE and to be evaluated by experts, should they wish to pursue evaluation by the OIE. The outcome of these evaluations including the starting date for these Members would be captured in the relevant reports. While the Group acknowledged that the draft Chapter 1.8. of the *Terrestrial Code* contains the necessary guidance for these Members to provide the evidence to determine the starting date, the Group was of the opinion that submission of a complete dossier was unnecessary due to the amount of information to be collected by Members. The Group acknowledged that the starting date could be derived based on the information of the exposure assessment alone; nevertheless, some members of the Group considered that few elements of the entry assessment and consequence assessment could also provide key information to complement the evaluation. In light of this, the Group recommended that the OIE should ask Members to refer to Article 1.8.5 of the draft Chapter 1.8. of the *Terrestrial Code* (once adopted) to use it as a baseline to include the relevant information that applies to their own situation.

6. Adoption of 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 captured the discussions.

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…/Appendices

Appendix I

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

16 to 19 November 2021

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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, 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 to 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 bilateral 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 1.8 and 11.4 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.

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 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).

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Appendix II

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

16 to 19 November 2021

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Agenda

1. Opening
2. Adoption of the agenda and appointment of Chair and Rapporteur
3. Evaluation of an application from a Member for official recognition of negligible BSE risk status
    3.1 France
4. Evaluation of an application from a Member for official recognition of controlled BSE risk status
    4.1 Russia
5. Proposal of criteria in determining the starting date when the risk of the BSE agents being recycled within the cattle population has been demonstrated to be negligible
6. Adoption of the report

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Appendix III

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

16 to 19 November 2021

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List of participants

MEMBERS

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Department of Animal Health
Department of Agriculture, Land Reform and Rural Development
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